March 2025 Board Meeting Handouts

5C – Rosalina Ross

5E – Jon Siems

5O – Walgreens Pharmacy #7032

5P – Jennifer Englehaupt

5Q – Cathy Quach

5S – Walgreens Pharmacy #03845

5U – Orthopedic Motion, Inc.

5V – Orthopedic Motion, Inc.

5W – Erin Calderon

5X – Safe Chain Solutions

14D – Melissa Heemsath

5C

Rosalina Ross
Exhibit 1
20-075-PT-S

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 13th day of January 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Rosalina Ross, PT
[redacted]
Las Vegas, NV 89147

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
JAN 1 1 2025
NEVADA STATE BOARD
OF PHARMACY

MAILED
1·13·25

certified: $10.99
Standard: $1.77

Rosalina Ross, PT
[redacted]
Las Vegas, NV 89147
20-075-PT-S. NIAA

9171 9690 0935 0314 1242 46

ALERT: WINTER STORMS IN THE MIDWEST THROUGH THE NORTHEAST U.S. MAY DELAY FIN...

USPS Tracking®

FAQs >

Remove ×

Tracking Number:

9171969009350314124246

Copy Add to Informed Delivery (https://informeddelivery.usps.com/)

Latest Update

Your package is moving within the USPS network and is on track to be delivered to its final destination. It is currently in transit to the next facility.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Delivered

Out for Delivery

Preparing for Delivery

Moving Through Network

In Transit to Next Facility
January 19, 2025

Departed USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
January 15, 2025, 8:58 am

Arrived at USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
January 14, 2025, 5:53 pm

Arrived at USPS Regional Facility
RENO NV DISTRIBUTION CENTER

Feedback

20-075-PT-S. NIAA.Exhibit1.Ross003

January 14, 2025, 12:12 am

Hide Tracking History

What Do USPS Tracking Statuses Mean? **(https://faq.usps.com/s/article/Where-is-my-package)**

Text & Email Updates

USPS Tracking Plus®

Product Information

See Less

Track Another Package

Enter tracking or barcode numbers

Need More Help?

Contact USPS Tracking support for further assistance.

FAQs

FILED
JAN 1 1 2025
NEVADA STATE BOARD OF PHARMACY

MAILED
1·28·25

certified: $9.92
standard: $0.97

Rosalina Ross, PT
[redacted]
Las Vegas, NV 89147
20-075-PT-S. NIAA

9171 9690 0935 0314 1246 11

ALERT: WILDFIRES AND EMERGENCY EVENTS IN THE LOS ANGELES METRO AREA U.S. MAY ...

USPS Tracking®

FAQs >

Remove ×

Tracking Number:

9171969009350314124611

Copy Add to Informed Delivery (https://informeddelivery.usps.com/)

Latest Update

Your item was delivered to an individual at the address at 11:34 am on January 31, 2025 in LAS VEGAS, NV 89147.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Feedback

Delivered
Delivered, Left with Individual
LAS VEGAS, NV 89147
January 31, 2025, 11:34 am

Departed USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
January 31, 2025, 8:56 am

Arrived at USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
January 30, 2025, 3:46 pm

Arrived at USPS Regional Facility
RENO NV DISTRIBUTION CENTER
January 30, 2025, 12:32 am

Accepted at USPS Origin Facility
RENO, NV 89521

20-075-PT-S. NIAA.Exhibit1.Ross006

January 29, 2025, 11:17 pm

Pre-Shipment, USPS Awaiting Item
January 29, 2025

Hide Tracking History

What Do USPS Tracking Statuses Mean? (https://faq.usps.com/s/article/Where-is-my-package)

Text & Email Updates

USPS Tracking Plus®

Product Information

See Less

Track Another Package

Enter tracking or barcode numbers

Need More Help?

Contact USPS Tracking support for further assistance.

FAQs

Rosalina Ross
Exhibit 2
20-075-PT-S

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

February 3, 2025

Rosalina Ross
[redacted]
Las Vegas, NV 89147

Re: Rosalina Ross and Case No. 20-075-PT-S

Dear Rosalina Ross

The hearing for case number **20-075-PT-S** has been scheduled for **Wednesday, 3/5/2025** at **9:00:00 AM PST** or soon thereafter at the following location:

Hilton Garden Inn
7830 S Las Vegas Boulevard
Las Vegas, NV 89123

This is an in-person hearing; all respondents, witnesses and counsel must appear in person before the Board.

Pursuant to NRS 241.033, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

If you have any questions, please feel free to contact the board staff.

Sincerely,

Jessette Phaynarikone
Administrative Assistant - Board Coordinator I
Nevada State Board of Pharmacy

9489 0178 9820 3014 0918 09

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

February 12, 2025

Rosalina Ross
[redacted]
Las Vegas, NV 89147

Re: Rosalina Ross and Case No. 20-075-PT-S

Dear Rosalina Ross,

The hearing for case number 20-075-PT-S has been scheduled for **Wednesday, 3/5/2025** at **9:00:00 AM PST** or soon thereafter at the following location:

Hilton Garden Inn
7830 S Las Vegas Boulevard
Las Vegas, NV 89123

This is an in-person hearing; all respondents, witnesses and counsel must appear in person before the Board.

Pursuant to NRS 241.033, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

If you have any questions, please feel free to contact the board staff.

Sincerely,

Jessette Phaynarikone
Administrative Assistant - Board Coordinator I
Nevada State Board of Pharmacy

9489 0178 9820 3028 4350 57

USPS Tracking®

FAQs >

Remove ×

Tracking Number:

9489017898203014091809

Copy Add to Informed Delivery (https://informeddelivery.usps.com/)

Latest Update

Your item arrived at our USPS facility in PORTLAND, OR 97215 on February 23, 2025 at 10:28 am. The item is currently in transit to the destination.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Feedback

Moving Through Network

Arrived at USPS Facility
PORTLAND, OR 97215
February 23, 2025, 10:28 am

In Transit to Next Facility
February 22, 2025

Forwarded
LAS VEGAS, NV
February 18, 2025, 12:02 pm

Departed USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
February 6, 2025, 8:49 am

Arrived at USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
February 5, 2025, 1:02 pm

Arrived at USPS Regional Facility

RENO NV DISTRIBUTION CENTER
February 3, 2025, 11:54 pm

Accepted at USPS Origin Facility
RENO, NV 89521
February 3, 2025, 10:39 pm

Hide Tracking History

What Do USPS Tracking Statuses Mean? (https://faq.usps.com/s/article/Where-is-my-package)

Text & Email Updates

Return Receipt Electronic

USPS Tracking Plus®

Product Information

See Less

Remove ×

Tracking Number:

9489017898203028435057

Copy **Add to Informed Delivery (https://informeddelivery.usps.com/)**

Latest Update

Your package is moving within the USPS network and is on track to be delivered to its final destination. It is currently in transit to the next facility.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Moving Through Network

In Transit to Next Facility
February 22, 2025

Forwarded
LAS VEGAS, NV
February 18, 2025, 11:59 am

Notice Left (No Authorized Recipient Available)
LAS VEGAS, NV 89147
February 18, 2025, 11:49 am

No Access to Delivery Location
LAS VEGAS, NV 89147
February 15, 2025, 10:20 am

Departed USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
February 15, 2025, 8:26 am

Arrived at USPS Regional Origin Facility
LAS VEGAS NV DISTRIBUTION CENTER
February 14, 2025, 2:52 pm

Arrived at USPS Regional Origin Facility
RENO NV DISTRIBUTION CENTER
February 12, 2025, 10:28 pm

USPS picked up item
RENO, NV 89511
February 12, 2025, 6:20 pm

Hide Tracking History

What Do USPS Tracking Statuses Mean? **(https://faq.usps.com/s/article/Where-is-my-package)**

See More

Track Another Package

Enter tracking or barcode numbers

Rosalina Ross
Exhibit 3
20-075-PT-S

From:	Brett Kandt
To:	[redacted]@GMAIL.COM
Cc:	Board Coordination; Laura Tucker
Subject:	Nevada State Board of Pharmacy v. Rosaline Ross, PT - Case No. 20-075-PT-S
Date:	Tuesday, February 25, 2025 7:34:33 AM
Attachments:	Board advisement - Pro Se Respondents at Hearing.pdf 20-075-PT-S. NIAA.Ross.pdf MEMO ATTY FEES AND COSTS - Ross 20-075-PT-S.pdf Outlook-amffp41l

Ms. Ross-

I am prosecuting this administrative case against you on behalf of the State of Nevada. Attached please find a courtesy copy of the charging document and notice of hearing in Case No. 20-075-PT-S; service of these documents was attempted at your address of record with the Nevada Board of Pharmacy. I have also attached information for respondents representing themselves at disciplinary hearings. Please bring 12 copies of any documents you intend to introduce into evidence.

Should you fail to appear at the hearing noticed for March 5, at 9AM, I will proceed to seek a default judgment against you imposing discipline on your Registration No. PT28825. I have also attached a memorandum of attorney's fees and costs that the Board may recover from you pursuant to NRS 622.400 in the event discipline is imposed. You may want to consult an attorney.

Regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

ATTACHMENT A-09

Copy of the statement provided by PTT Ross dated 07/19/2020.

Case # 20-075-S

NSBOP –vs– Rosalina Ross & Meta Pharmacy

Exhibit 4

As per our conversation,

I started volunteering at Meta Pharmacy about four months ago. I had talked to the PIC Sean Barclay about getting my Pharmacy Technician in training license for Meta as soon as I started volunteering at Meta Pharmacy. I filled out the application and was going to mail it in. I was going to go get my checkbook so that I could write a check for the fee, but Sean told me that he would take care of it by paying the fee for me and sending in the application. After I talked to him about sending off my application he had me fill out some other documents to work at the pharmacy.

About a week later I had asked Sean if he had sent in my application for my license. He told me he had not yet sent it in but would by the end of the week. I understood as he is a busy man and I believed that he would follow through. My license from Sunrise Pharmacy was displayed along with the other technicians who worked there just as a precaution and was to be switched later with my new license for Meta when the license came in.

My duties during my time at Meta Pharmacy were mainly clerical; answering phones, ringing up patients and stalking shelves with incoming inventory, etc. My time at Meta was short as I was only there to fulfill the remaining hours needed for my technician license. I worked about 400 hours over the four months that I worked at Meta pharmacy.

I honestly thought that my license was taken care of and that I didn't have anything to worry about. This is a lesson that I have learned from and will take all necessary precautions to ensure nothing like this happen in the future.

Respectfully,

Rosalina Ross

Rosalina M Ross

7/19/20

Nevada State Board Of Pharmacy

(Licensee mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 06/17/2019
Amount:
License #: PT22373

ROSALINA D. HAMMOCK
2560 E SUNSET RD
LAS VEGAS NV 89120

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmaceutical Technician Trainee
Expires:10/31/2020
ROSALINA D. HAMMOCK
2560 E SUNSET RD
LAS VEGAS NV 89120

License #
PT22373
Active

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

NEVADA
STATE BOARD OF PHARMACY
Pharmaceutical Technician Trainee

License Type: Pharmaceutical Technician Trainee
License #: PT22373

Expires: 10/31/2020
STATUS: Active

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

ROSALINA D. HAMMOCK
2560 E SUNSET RD
LAS VEGAS NV 89120

NONTRANSFERABLE

POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

ATTACHMENT A-10

Copy of the statement provided by Pharmacist Sean Barclay dated 08/12/2020.

Case # 20-075-S

NSBOP –vs– Rosalina Ross & Meta Pharmacy

Exhibit 5

Statement regarding Rosalina Ross time at Meta Pharmacy Services.

- The first time Rosa was at the pharmacy she came up to me, another employee, and her dad stating she needed $40 for her technician in training application. It was an awkward statement and after a few moments of uncomfortable silence I asked if she needed cash for it, which her dad responded to saying she did not.
- Rosa's basic training started and was documented on March 14th, 2020 before she had any interactions with actual patients.
- Rosa was not on the payroll of the pharmacy, she was a volunteer so there is not any payroll documentation.
- During the limited time Rosa worked in the pharmacy she did not perform any actual pharmacy technician duties. The initial training is in place for orientation to the pharmacy and then she performed exclusively clerk activities, i.e. working the cash register, setting up shipping and receiving, calling patients when their prescriptions were ready for pickup. Based on these activities she did not yet reach the level of pharmacy technician tasks, thus no additional training logs were documented. The training is based on the individuals specific learning curve and she still required significant time to gain an understanding of the basics on how a pharmacy runs.
- When Rosa decided to stop her time at Meta Pharmacy I took her Pharmacy Technician in Training License which was posted in our pharmacy and submitted her documented hours under that license number. I did not know this license was for another pharmacy and that she did not submit for a new technician in training license for Meta Pharmacy.

8/12/2020

Sean Barclay, PharmD.

Meta Pharmacy Services

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ROSALINA ROSS,** **Certificate of Registration No. PT28825,** **Respondent.**	**CASE NO. 20-075-PT-S** **MEMORANDUM OF ATTORNEY'S FEES AND COSTS**

Pursuant to NRS 622.400, the undersigned hereby submits the following itemized bill of costs and reasonable attorney's fees incurred by the Nevada State Board of Pharmacy in connection with the investigation and prosecution of the above-entitled administrative action.

Investigative Time (Investigator Name)				
Date(s)	Description	Hours	Rate	Amount
			$53.00/hr	
Subtotal (Investigation):				
Attorney Time - Brett Kandt				
Date(s)	Description	Hours	Rate	Amount
12/16/24	Confer with staff and review investigative case file in case 20-075; research and draft Notice of Intended Action and Accusation.	5.50	$104/hr	
1/28/25	Confer with staff regarding potential default and attempted service.	0.25		
2/23/25	Prepare for hearing; confer with staff and witnesses; prepare proposed exhibits and documentation of attorney's fees and costs.	2.75		
2/25//25	Prepare for hearing; notify respondent of pending default and documentation of attorney's fees and costs.	1.50		

Exhibit 6

3/5/25	Hearing in Case 20-075-PT-S.	1.00		
Subtotal (Attorney Time): **11.00 hours x $104/hour = $1,144.00**				
Subtotal (Staff Time)				
Date(s)	Description	Hours	Rate	Amount
1/13/25	Board staff processed and served Notice of Intended Action and Accusation, Statement to the Respondent and Notice of Hearing via certified/regular mail.	0.50	$25.00/hr	$12.50
1/28/25	Board staff re-served Accusation documents via certified/regular mail.	0.50	$25.00/hr	$12.50
2/3/25	Board staff sent Notice of Hearing via certified/regular mail.	0.25	$25.00/hr	$6.25
2/12/25	Board staff resent Notice of Hearing via certified/regular mail.	0.25	$25.00/hr	$6.25
Subtotal (Staff Time): $37.50				
Additional Recoverable Costs: Postage/Mailing Costs: $41.35				
Total Attorney's Fees and Recoverable Costs: ~~$78.85~~ $1,222.85				

I, Brett Kandt, affirm, to the best of my knowledge and belief, that the foregoing is a true and correct statement of reasonable attorney's fees and costs incurred by the Board in the above-entitled action.

DATED this 25th day of February, 2025.

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

5E

Dena M. McClish

From: Sanchez, Estevan <Estevan.Sanchez@dea.gov>
Sent: Tuesday, March 12, 2024 4:01 PM
To: Dena M. McClish
Subject: FW: Controlled Rx / Post-Suspension

FYI

From: Jon Siems <siemslasik@hotmail.com>
Sent: Tuesday, March 12, 2024 3:52 PM
To: Sanchez, Estevan <Estevan.Sanchez@dea.gov>
Subject: [EXTERNAL] Re: Controlled Rx / Post-Suspension

To whom it may concern:

I am writing in response to the letter you forwarded me via email on 03/12/24. As you are already aware of the circumstances surrounding my license suspension, I will not say anything further in regards to this. Board representatives entered my office unannounced in 01/23 and immediately suspended my license. This was executed inappropriately as a 2 week period should have been provided prior to my license suspension. It is in the Board bylaws. The reason for this time is to ensure a proper transition of patient care to another provider. Given the absence of a transition period, chaos ensued. Eventually Dr. Yee was brought on to provide continued care (surgical). Regarding preparation for surgeries, a mild sedative is generally given prior to surgery. Dr. Yee was certainly aware of the need to write for these medications and to place these orders on an Rx pad with his name and info on it. He was aware of my license situation. For reasons unclear to me, he used my Rx pad to provide these medications to patients. At NO time did I ever instruct anyone to ever use my Rx pad for these medications. This was being done without my knowledge. My signature is not on any of the prescriptions in question. This practice apparently continued for a few weeks until my administration became aware of the situation. I was contacted (remember I was spending all of my time in my California home - I was not on the office at all.). We immediately shut down the use of my Rx pads for writing sedating meds or any other meds. To my knowledge, it did not occur again. We have subsequently initiated an electronic submission process for all medications. Each providing doctor writes for his/her own meds.
Regarding the medications written for, they were all for LASIK patients who were having surgery. Minimal amounts (1 pill each) of Valium/Xanax were written for with NO refills provided. There were no inappropriate distributions to non surgical patients. Clearly, a contributing factor to this was the chaos that ensued after being shut down immediately by the board. It was a difficult, stressful time for all. There was never a criminal intent by any party involved.
Regarding my historical practice of writing prescriptions, I did not always personally sign the prescription at the time it was given to the patient. Normal prescriptions for routine doses of the same meds were frequently presigned. If I was out of town etc, it would not be practical for patient care without presigned scripts. Any deviation from the normal required notification. This is standard practice for any office. If presigned scripts were not available, I'm sure there were occasions where a new Rx would have been written by the staff under my direction or directly called in to the pharmacy.
If there are any questions or more information needed, do not hesitate to contact me.
Sent from my iPhone

On Mar 12, 2024, at 11:18 AM, Sanchez, Estevan <Estevan.Sanchez@dea.gov> wrote:

Exhibit A
5E

FYI

From: Sanchez, Estevan
Sent: Wednesday, February 28, 2024 11:38 AM
To: 'siemslasik@hotmail.com' <siemslasik@hotmail.com>
Subject: Controlled Rx / Post-Suspension

Dr. Siems,

See attached Rx issued after your suspension in Dec. 2022.
Some are hard copy w/ signatures.
Others are call-in prescriptions.

Please review and provide a signed statement.
The following should be covered:

Do the prescriptions contain your handwriting?

1. If not, do you know who wrote the Rx?

Do the hard copy Rx contain your signature?

2. If not, do you know who signed the Rx?

Did you authorize the call-in prescriptions?

3. If not, do you know who authorized the Rx?

Did you previously allow staff to sign prescriptions?

When were you made aware of these prescriptions?

Were these legitimate patients receiving LASIK?

4. Which Doctors were providing the surgeries?
5. Include dates of coverage

What steps did you take to ensure the integrity of your DEA#?

6. Contact Police, Nevada Board, Pharmacies, etc.
7. Contact previous staff members
8. Check Nevada PMP data

**

Please forward the signed statement to my e-mail.
You mail also mail it to the DEA Las Vegas office.

9. 550 S. Main Street, Las Vegas, NV 89101

Thanks.

Estevan Sánchez | DEA Investigator
Las Vegas District Office
Cell: 202-674-4257
Estevan.Sanchez@dea.gov

<SIEMS Rx - Albertsons.pdf>

Nevada PRESCRIPTION MONITORING PROGRAM

775-687-5694

Report Prepared: 02/25/2025

Prescriber Activity Report

Date Range: 12/27/2022 - 03/23/2023

Investigation Type:
Case Number:
Primary Drug Category:
Drug Product Name:
Case Notes:
Agency:
Contact: Darla Zarley
Role: Admin
Phone: 7756875694
Email: dzarley@pharmacy.nv.gov

JON SIEMS

8230 W SAHARA AVESTE 111
LAS VEGAS, NV 89117

Report Criteria

DEA Number: [redacted] **Prescriber First Name:** JON, **Prescriber Last Name:** SIEMS

Summary

Prescriptions	70
Patients	38
Pharmacies	22

Prescriber Activity

Last	First	DOB	Fill Date	Written Date	Drug Name	ICD-10	Qty	Supply	Store ID	Rx #	Pymt Type
G[redacted]	D[redacted]	[redacted]	04/25/2023	03/23/2023	ALPRAZOLAM 1 MG TABLET	S0502XA	1.0	1	WALG6549	4969177	Commercial Insurance
G[redacted]	D[redacted]	[redacted]	04/25/2023	03/23/2023	DIAZEPAM 10 MG TABLET	S0502XA	1.0	1	WALG6549	4969175	Commercial Insurance

Exhibit B
5E

Last	First	DOB	Fill Date	Written Date	Drug Name	ICD-10	Qty	Supply	Store ID	Rx #	Pymt Type
[redacted]	[redacted]	[redacted]	03/17/2023	03/16/2023	DIAZEPAM 10 MG TABLET	S0502XA	1.0	1	WAL-5080	4556994	Medicare
			03/16/2023	03/16/2023	DIAZEPAM 10 MG TABLET		1.0	1	WARM4052	1748250	Commercial Insurance
			03/16/2023	03/15/2023	DIAZEPAM 10 MG TABLET		1.0	1	WARM2051	0180061	Commercial Insurance
			03/15/2023	03/15/2023	DIAZEPAM 10 MG TABLET	F05	1.0	1	TRUE3404	183997	Commercial Insurance
			03/15/2023	03/15/2023	ALPRAZOLAM 1 MG TABLET	F05	1.0	1	TRUE3404	183995	Commercial Insurance
			03/15/2023	03/15/2023	ALPRAZOLAM 1 MG TABLET	S0502XA	1.0	1	TRUE3404	183988	Private Pay
			03/09/2023	03/08/2023	ALPRAZOLAM 1 MG TABLET		1.0	1	TRUE3404	183631	Commercial Insurance
			03/09/2023	03/08/2023	DIAZEPAM 10 MG TABLET		1.0	1	TRUE3404	183630	Commercial Insurance
			03/08/2023	03/08/2023	DIAZEPAM 10 MG TABLET	S0502XA	1.0	1	TRUE3404	183533	Commercial Insurance
			03/08/2023	03/08/2023	ALPRAZOLAM 1 MG TABLET	S0502XA	1.0	1	TRUE3404	183535	Commercial Insurance
			03/08/2023	03/08/2023	DIAZEPAM 10 MG TABLET		1.0	1	WAL-7705	4501519	Medicaid
			03/08/2023	03/08/2023	ALPRAZOLAM 1 MG TABLET	S0502XA	1.0	1	TRUE3404	183541	Commercial Insurance
			03/08/2023	03/08/2023	DIAZEPAM 10 MG TABLET	S0502XA	1.0	1	TRUE3404	183539	Commercial Insurance
			03/08/2023	03/08/2023	ALPRAZOLAM 1 MG TABLET		1.0	1	WAL-7705	4501520	Medicaid
			03/08/2023	03/06/2023	DIAZEPAM 10 MG TABLET		1.0	1	WAL-0504	4192509	Private Pay
			03/08/2023	01/11/2023	DIAZEPAM 10 MG TABLET	S0502XA	1.0	1	TRUE3404	183547	Commercial Insurance
			03/07/2023	03/03/2023	ALPRAZOLAM 1 MG TABLET		1.0	1	WALG2642	3999909	Commercial Insurance
			03/06/2023	03/03/2023	DIAZEPAM 10 MG TABLET		1.0	1	WALG2642	3999908	Commercial Insurance
			03/02/2023	03/02/2023	ALPRAZOLAM 1 MG TABLET	S0502XA	1.0	1	TRUE3404	183237	Commercial Insurance
			03/02/2023	03/02/2023	DIAZEPAM 10 MG TABLET	S0502XA	1.0	1	TRUE3404	183236	Commercial Insurance
			03/02/2023	03/02/2023	DIAZEPAM 10 MG TABLET		1.0	1	ALBE7162	4333482	Commercial Insurance
			03/02/2023	03/02/2023	ALPRAZOLAM 1 MG TABLET		1.0	1	ALBE7162	4333483	Commercial Insurance
			02/28/2023	02/28/2023	DIAZEPAM 10 MG TABLET	S0502XA	1.0	1	TRUE3404	183080	Private Pay
			02/28/2023	02/28/2023	ALPRAZOLAM 1 MG TABLET	S0502XA	1.0	1	TRUE3404	183082	Private Pay
			02/27/2023	02/27/2023	ALPRAZOLAM 1 MG TABLET	S0502XA	1.0	1	TRUE3404	183004	Commercial Insurance
			02/27/2023	02/27/2023	DIAZEPAM 10 MG TABLET	S0502XA	1.0	1	TRUE3404	183003	Commercial Insurance
			02/24/2023	01/25/2023	DIAZEPAM 10 MG TABLET	S0502XA	1.0	1	ALBE7225	4622795	Commercial Insurance
			02/24/2023	01/25/2023	ALPRAZOLAM 1 MG TABLET	S0502XA	1.0	1	ALBE7225	4622796	Commercial Insurance
			02/18/2023	01/31/2023	ALPRAZOLAM 1 MG TABLET		1.0	1	NEVA4596	0719576	Commercial Insurance

Last	First	DOB	Fill Date	Written Date	Drug Name	ICD-10	Qty	Supply	Store ID	Rx #	Pymt Type
B[redacted]	R[redacted]	[redacted]	02/18/2023	01/31/2023	DIAZEPAM 10 MG TABLET		1.0	1	NEVA4596	0719575	Commercial Insurance
S[redacted]	D[redacted]		02/15/2023	02/01/2023	ALPRAZOLAM 1 MG TABLET		1.0	1	NEVA7996	1403599	Medicaid
A[redacted]	M[redacted]		02/15/2023	01/27/2023	DIAZEPAM 10 MG TABLET		1.0	1	SMIT2664	4546180	Commercial Insurance
A[redacted]	M[redacted]		02/15/2023	01/27/2023	ALPRAZOLAM 1 MG TABLET		1.0	1	SMIT2664	4546181	Commercial Insurance
S[redacted]	D[redacted]		02/15/2023	02/01/2023	DIAZEPAM 10 MG TABLET		1.0	1	NEVA7996	1403598	Medicaid
U[redacted]	L[redacted]		02/13/2023	02/09/2023	ALPRAZOLAM 1 MG TABLET	S0502XA	2.0	2	TRUE3404	181975	Commercial Insurance
U[redacted]	L[redacted]		02/13/2023	02/09/2023	DIAZEPAM 10 MG TABLET	S0502XA	2.0	2	TRUE3404	181974	Commercial Insurance
C[redacted]	E[redacted]		02/11/2023	01/06/2023	DIAZEPAM 10 MG TABLET	S0502XA	1.0	1	TRUE3404	182169	Commercial Insurance
C[redacted]	E[redacted]		02/11/2023	01/06/2023	ALPRAZOLAM 1 MG TABLET	S0502XA	1.0	1	TRUE3404	182170	Commercial Insurance
[redacted]	D[redacted]		02/10/2023	01/23/2023	ALPRAZOLAM 1 MG TABLET	S0502XA	1.0	1	TRUE3404	182145	Private Pay
[redacted]	D[redacted]		02/10/2023	01/23/2023	DIAZEPAM 10 MG TABLET	S0502XA	1.0	1	TRUE3404	182144	Private Pay
M[redacted]	B[redacted]		02/09/2023	02/08/2023	DIAZEPAM 10 MG TABLET		1.0	1	WALG9636	2847004	Commercial Insurance
P[redacted]	T[redacted]		02/09/2023	01/31/2023	ALPRAZOLAM 1 MG TABLET		1.0	1	WARM4208	1614737	Medicaid
P[redacted]	T[redacted]		02/09/2023	01/31/2023	DIAZEPAM 10 MG TABLET		1.0	1	WARM4208	1614736	Medicaid
M[redacted]	B[redacted]		02/09/2023	02/08/2023	ALPRAZOLAM 1 MG TABLET		1.0	1	WALG9636	2847006	Commercial Insurance
C[redacted]	J[redacted]		02/07/2023	01/04/2023	DIAZEPAM 10 MG TABLET		1.0	1	WAL-5106	4502285	Private Pay
C[redacted]	J[redacted]		02/07/2023	01/04/2023	ALPRAZOLAM 1 MG TABLET		1.0	1	WAL-5106	4502286	Private Pay
S[redacted]	L[redacted]		02/06/2023	01/20/2023	DIAZEPAM 10 MG TABLET		1.0	1	TRUE3404	181701	Private Pay
S[redacted]	L[redacted]		02/06/2023	01/20/2023	ALPRAZOLAM 1 MG TABLET		1.0	1	TRUE3404	181702	Private Pay
F[redacted]	S[redacted]		02/06/2023	02/06/2023	ALPRAZOLAM 1 MG TABLET		1.0	1	WARM4052	1730410	Commercial Insurance
F[redacted]	S[redacted]		02/06/2023	02/06/2023	DIAZEPAM 10 MG TABLET		1.0	1	WARM4052	1730406	Commercial Insurance
P[redacted]	D[redacted]		02/03/2023	02/03/2023	DIAZEPAM 10 MG TABLET		1.0	1	WALG0645	2347526	Commercial Insurance
V[redacted]	L[redacted]		02/03/2023	01/23/2023	ALPRAZOLAM 1 MG TABLET	S0502XA	1.0	1	TRUE3501	246103	Commercial Insurance
V[redacted]	L[redacted]		02/03/2023	01/23/2023	DIAZEPAM 10 MG TABLET	S0502XA	1.0	1	TRUE3501	246102	Commercial Insurance
P[redacted]	D[redacted]		02/03/2023	02/03/2023	ALPRAZOLAM 1 MG TABLET		1.0	1	WALG0645	2347527	Commercial Insurance
C[redacted]	S[redacted]		01/26/2023	01/26/2023	ALPRAZOLAM 1 MG TABLET		1.0	1	WALG3085	895357	Medicare
C[redacted]	S[redacted]		01/26/2023	01/26/2023	DIAZEPAM 10 MG TABLET		1.0	1	WALG3085	895356	Medicare
L[redacted]	J[redacted]		01/24/2023	01/12/2023	ALPRAZOLAM 1 MG TABLET	S0502XA	1.0	1	WALG0055	2578005	Commercial Insurance
H[redacted]	D[redacted]	[redacted]	01/24/2023	01/18/2023	ALPRAZOLAM 1 MG TABLET	S0502XA	1.0	1	TRUE3501	245761	Commercial Insurance

Last	First	DOB	Fill Date	Written Date	Drug Name	ICD-10	Qty	Supply	Store ID	Rx #	Pymt Type
H[redacted]	D[redacted]	[redacted]	01/24/2023	01/18/2023	DIAZEPAM 10 MG TABLET	S0502XA	1.0	1	TRUE3501	245760	Commercial Insurance
R[redacted]	S[redacted]	[redacted]	01/24/2023	01/24/2023	ALPRAZOLAM 1 MG TABLET	S0502XA	1.0	1	TRUE3404	181045	Commercial Insurance
R[redacted]	S[redacted]	[redacted]	01/24/2023	01/24/2023	DIAZEPAM 10 MG TABLET	S0502XA	1.0	1	TRUE3404	181044	Commercial Insurance
L[redacted]	J[redacted]	[redacted]	01/23/2023	01/12/2023	DIAZEPAM 10 MG TABLET	S0502XA	1.0	1	WALG0055	2577185	Commercial Insurance
[redacted]	M[redacted]	[redacted]	01/20/2023	01/20/2023	DIAZEPAM 10 MG TABLET		1.0	1	WALG5026	4184325	Commercial Insurance
[redacted]	M[redacted]	[redacted]	01/20/2023	01/20/2023	ALPRAZOLAM 1 MG TABLET	S0502XA	1.0	1	WALG5026	4184326	Medicare
A[redacted]	A[redacted]	[redacted]	01/17/2023	12/28/2022	DIAZEPAM 10 MG TABLET		1.0	1	NEVA9531	1281912	Commercial Insurance
A[redacted]	A[redacted]	[redacted]	01/17/2023	12/28/2022	ALPRAZOLAM 1 MG TABLET		1.0	1	NEVA9531	1281913	Commercial Insurance
V[redacted]	C[redacted]	[redacted]	12/27/2022	12/27/2022	DIAZEPAM 10 MG TABLET	S0502XA	1.0	1	TRUE3404	179480	Commercial Insurance
V[redacted]	C[redacted]	[redacted]	12/27/2022	12/27/2022	ALPRAZOLAM 1 MG TABLET	S0502XA	1.0	1	TRUE3404	179482	Commercial Insurance

Dispensers

Store ID	Name	Address	City	State	Zip
WARM2051	WARM SPRINGS ROAD CVS, L.L.C.	8750 W CHARLESTON BLVD	LAS VEGAS	NV	89117
SMIT2664	SMITH'S FOOD & DRUG CTRS	1421 N JONES BLVD	LAS VEGAS	NV	89108
WAL-0504	WAL-MART PHARMACY 10-1584	3615 S RAINBOW BLVD	LAS VEGAS	NV	89103
WALG2642	WALGREEN CO.	9415 W DESERT INN RD	LAS VEGAS	NV	89117
WALG9636	WALGREEN CO.	3480 S JONES BLVD	LAS VEGAS	NV	89146
WARM4208	WARM SPRINGS ROAD CVS, L.L.C.	7295 S RAINBOW BLVD	LAS VEGAS	NV	89118
WAL-7705	WAL-MART PHARMACY 10-2884	8060 W TROPICAL PKWY	LAS VEGAS	NV	89149
WALG6549	WALGREEN CO.	7599 W LAKE MEAD BLVD	LAS VEGAS	NV	89128
WALG3085	WALGREEN CO.	5610 CENTENNIAL CENTER BLVD	LAS VEGAS	NV	89149
TRUE3404	TRUE CARE PHARMACY	3525 S FORT APACHE RD	LAS VEGAS	NV	89147
WALG0645	WALGREEN CO.	11001 S EASTERN AVE	HENDERSON	NV	89052
NEVA4596	NEVADA CVS PHARMACY, L.L.C.	8491 FARM RD	LAS VEGAS	NV	89131
WALG5026	WALGREEN CO.	8500 W CHEYENNE AVE	LAS VEGAS	NV	89129
TRUE3501	TRUE CARE PHARMACY 3	2208 S NELLIS BLVD	LAS VEGAS	NV	89104
ALBE7162	ALBERTSON'S LLC	7075 W ANN RD	LAS VEGAS	NV	89130

Store ID	Name	Address	City	State	Zip
NEVA9531	NEVADA CVS PHARMACY, L.L.C.	4800 W CHARLESTON BLVD	LAS VEGAS	NV	89146
WAL-5080	WAL-MART PHARMACY 10-5101	300 SOUTH HWY 160	PAHRUMP	NV	89048
NEVA7996	NEVADA CVS PHARMACY, L.L.C.	1408 W CRAIG RD	NORTH LAS VEGAS	NV	89032
WARM4052	WARM SPRINGS ROAD CVS, L.L.C.	3290 S FORT APACHE RD	LAS VEGAS	NV	89117
WAL-5106	WAL-MART PHARMACY 10-2592	1807 W CRAIG RD	NORTH LAS VEGAS	NV	89032
ALBE7225	ALBERTSON'S LLC	4850 W CRAIG RD	LAS VEGAS	NV	89130
WALG0055	WALGREEN CO.	7755 N DURANGO DR	LAS VEGAS	NV	89131

Therapeutic Class Summary

Therapeutic Class 4	Script Count	Patient Count	Pharmacy Count
BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	70	38	22

Disclaimer:

By proceeding beyond this page and accessing this Prescription Monitoring Program (PMP) system, I certify that I am currently registered and authorized to prescribe or dispense controlled substances, or the duly authorized delegate thereof. I understand that my use of this PMP system is permitted only in connection with providing medical or pharmaceutical care to a patient, which includes evaluating a patient for medical treatment, and only to the extent authorized by law. I understand that my access to or disclosure of any PMP data for any purpose not authorized by law may subject me to disciplinary action, civil penalties, or criminal prosecution. I further understand that I must treat the information in the PMP system as confidential, just as I would any other protected health information. I will protect any PMP information in my possession in accordance with Federal and state laws governing protected health information. I understand that I am responsible for all use of my username and password. I will never share my password with anyone, including my co-workers and staff. If my authentication or password is lost or compromised, I agree to notify the PMP immediately. I understand the PMP will monitor for unusual or potentially unauthorized use of the system.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JON SIEMS, MD,** **Certificate of Registration No. CS09874,** **Respondent.**	**CASE NO. 24-390-CS-S** **MEMORANDUM OF ATTORNEY'S FEES AND COSTS**

Pursuant to NRS 622.400, the undersigned hereby submits the following itemized bill of costs and reasonable attorney's fees incurred by the Nevada State Board of Pharmacy in connection with the investigation and prosecution of the above-entitled administrative action.

Investigative Time (Investigator Name)				
Date(s)	Description	Hours	Rate	Amount
			$53.00/hr	
Subtotal (Investigation):				
Attorney Time - Brett Kandt				
Date(s)	Description	Hours	Rate	Amount
9/25/24	Confer with staff and review investigative case file in case 24-390; research and serve notice of suspension and draft Notice of Intended Action and Accusation.	7.50	$86.50/hr	
10/3/24	Confer with staff regarding attempted service of notice of suspension.	0.25		
10/4/24	Confer with staff and finalize and file Notice of Intended Action and Accusation.	1.00		
10/9/24	Confer with staff regarding attempted service of notice of suspension and Notice of Intended Action and Accusation.	0.25		

Exhibit C

11/11/24	Confer with staff and review investigative case file in case 23-449; research, draft and file First Amended Notice of Intended Action and Accusation consolidating cases.	6.50		
11/19/24	Confer with staff regarding potential default and proposed exhibits.	0.25		
11/25/24	Prepare for hearing; confer with staff and witnesses; prepare proposed exhibits and documentation of attorney's fees and costs.	5.75		
11/26//24	Prepare for hearing; notify respondent of pending default hearing and documentation of attorney's fees and costs.	3.50		
12/10/24	Confer with staff and DEA; review DEA Form-104; research, draft and file Second Amended Notice of Intended Action and Accusation.	1.00	$104/hr	
12/24/24	Confer with staff and respondent on continuance of hearing	0.50		
2//23/25	Prepare for hearing; confer with staff and witnesses; prepare proposed exhibits and documentation of attorney's fees and costs	1.25		
2/25/25	Prepare for hearing; notify respondent of pending default hearing and documentation of attorney's fees and costs.	0.75		
3/5/25	Hearing in Case 24-390-CS-S.	1.00		
Subtotal (Attorney Time): **26.00 hours x $86.50/hour + 4.5 hours x $104/hour = $2,717.00**				
Subtotal (Staff Time)				
Date(s)	Description	Hours	Rate	Amount
9/25/24	Erin Miller served Notice of Suspension for Jon Siems via certified/regular mail and sent courtesy copy via email.	0.50	$25.00/hr	$12.50

10/4/24	Erin Miller served Notice of Intended Action and Accusation via certified/regular mail to Jon Siems via certified/regular mail.	1.0	$25.00/hr	$25.00
10/9/24	Jessette Phaynarikone served Notice of Intended Action and Accusation to an additional address for Jon Siems via certified/regular mail.	0.50	$25.00/hr	$12.50
10/31/24	Jessette Phaynarikone served January Board Meeting Notice of Hearing letter to Jon Siems via certified/regular mail.	0.50	$25.00/hr	$12.50
11/12/24	Erin Miller served First Amended Notice of Intended and Accusation to Jon Siems via certified/regular mail.	1.0	$25.00/hr	$25.00
12/12/24	Darlene Nases served Second Amended Notice of Intended Action and Accusation via certified/regular mail to Jon Siems.	1.0	$25.00/hr	$25.00
2/3/25	Jessette Phaynarikone served March Board Meeting Notice of Hearing letter to Jon Siems via certified/regular mail.	0.50	$25.00/hr	$12.50
Subtotal (Staff Time): $125.00				
Additional Recoverable Costs: Postage/Mailing Costs: $126.64				
Total Attorney's Fees and Recoverable Costs: $2,968.64				

I, Brett Kandt, affirm, to the best of my knowledge and belief, that the foregoing is a true and correct statement of reasonable attorney's fees and costs incurred by the Board in the above-entitled action.

DATED this 25th day of February, 2025.

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #7032, Pharmacy License No. PH01628,** **JENNIFER ENGLEHAUPT, RPH, Certificate of Registration No. 15287, and** **CATHY QUACH, RPH, Certificate of Registration No. 16344,** **Respondents.**	**Case No. 24-083-PH-S** **24-083-RPH-A-S** **24-083-RPH-B-S** **STIPULATION AND ORDER** **(RESPONDENT WALGREENS ONLY)**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through the Board's Senior General Counsel, Gregory L. Zunino, Esq., and Respondent Walgreens Pharmacy #7032 ("Respondent"), by and through counsel, William J. Stilling, Esq., hereby stipulate and agree as follows:

1. The Board has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. The Board and Respondent agreed to delay the date for submitting a Notice of Answer and Defense as the parties pursued settlement negotiations.

4. Respondent acknowledges that its authorized representatives understand the terms of this Stipulation and Proposed Order ("Stipulation"), and they have executed it knowingly and voluntarily.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter

233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

6. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waive the right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

7. Respondent admits that evidence exists, and that the Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in Count One and Count Two of the Accusation.

8. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent shall pay an administrative fine of One Thousand and 00/100 Dollars ($1,000.00) for each of the violations alleged in Count One and Count Two of the accusation for a total fine of **Two Thousand and 00/100 Dollars ($2,000.00).** This sum shall be payable by *cashier's check, certified check, Walgreens company check,* or *money order* written to the **"State of Nevada, Office of the Treasurer."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before May 1, 2025.

B. Respondent shall pay the sum of **Five Hundred and 00/100 Dollars ($500.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check, Walgreens company check,* or *money order* written to the **"Nevada State Board of Pharmacy."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before May 1, 2025.

9. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 24-083-PH-S. Failure by Respondent to comply with the terms stated herein may result in issuance by the

Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in the finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

10. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 5, 2025, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear at the meeting.

11. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 25th **day of February 2025.**

WALGREENS PHARMACY #7032

By: _____

Name: John L. Colaizzi

Title: GVP, Head of Enterprise Pharmacy Practice

Signed this 3rd **day of March 2025.**

_____

Gregory L. Zunino
Senior General Counsel
The Nevada State Board of Pharmacy

Signed this 3rd day of March 2025.

APPROVED AS TO FORM:

William J. Stilling, Esq.
Counsel for Respondent Walgreens #7032

DECISION AND ORDER

As to Respondent Walgreens Pharmacy #7032, in Case No. 24-083-PH-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and orders that its terms be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 5th day of March 2025.

Helen Park, President
Nevada State Board of Pharmacy

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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. WALGREENS PHARMACY #7032, Pharmacy License No. PH01628, JENNIFER ENGLEHAUPT, RPH, Certificate of Registration No. 15287, and CATHY QUACH, RPH, Certificate of Registration No. 16344, Respondents.	Case No. 24-083-PH-S 24-083-RPH-A-S 24-083-RPH-B-S STIPULATION AND ORDER (RESPONDENT ENGLEHAUPT ONLY)

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through the Board's Senior General Counsel, Gregory L. Zunino, Esq., and Respondent Jennifer Englehaupt, RPH ("Respondent"), by and through counsel, William J. Stilling, Esq., hereby stipulate and agree as follows:

1. The Board has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. The Board and Respondent agreed to delay the date for submitting a Notice of Answer and Defense as the parties pursued settlement negotiations.

4. Respondent acknowledges that she understand the terms of this Stipulation and Proposed Order ("Stipulation"), and she has executed it knowingly and voluntarily.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative

procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

6. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waive the right to hearing, reconsideration, appeal, and other rights related to this action as identified above.

7. Respondent admits that evidence exists, and that the Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violation alleged in Count Two of the Accusation. The parties agree that Count One of the Accusation is inapplicable to Respondent.

8. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent shall pay an administrative fine of **Five Hundred and 00/100 Dollars ($500.00)** for the violation alleged in Count Two of the Accusation. This sum shall be payable by *cashier's check, certified check, Walgreens company check,* or *money order* written to the **"State of Nevada, Office of the Treasurer."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before May 1, 2025.

B. Respondent shall pay the sum of **Five Hundred and 00/100 Dollars ($500.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check, Walgreens company check,* or *money order* written to the **"Nevada State Board of Pharmacy."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before May 1, 2025.

9. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 24-083-RPH-A-S. Failure by Respondent to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent

to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in the finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

10. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 5, 2025, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear at the meeting.

11. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all of this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 3 day of March 2025.

Jennifer Englehaupt, RPH
Certificate of Registration No. 15287

Signed this 3rd day of March 2025.

Gregory L. Zuning
Senior General Counsel
The Nevada State Board of Pharmacy

Signed this 3rd day of March 2025.

Approved at to Form:

William J. Stilling, Esq.
Counsel for Respondent Jennifer Englehaupt

DECISION AND ORDER

As to Respondent Jennifer Englehaupt, RPH, Certificate of Registration No. 15287, in Case No. 24-083-RPH-A-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and orders that its terms be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 5th day of March 2025.

Helen Park, President
Nevada State Board of Pharmacy

5Q

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #7032, Pharmacy License No. PH01628,** **JENNIFER ENGLEHAUPT, RPH, Certificate of Registration No. 15287, and** **CATHY QUACH, RPH, Certificate of Registration No. 16344,** **Respondents.**	**Case No. 24-083-PH-S** **24-083-RPH-A-S** **24-083-RPH-B-S** **STIPULATION AND ORDER** **(RESPONDENT QUACH ONLY)**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through the Board's Senior General Counsel, Gregory L. Zunino, Esq., and Respondent Cathy Quach, RPH ("Respondent"), by and through counsel, William J. Stilling, Esq., hereby stipulate and agree as follows:

1. The Board has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. The Board and Respondent agreed to delay the date for submitting a Notice of Answer and Defense as the parties pursued settlement negotiations.

4. Respondent acknowledges that she understands the terms of this Stipulation and Proposed Order ("Stipulation"), and she has executed it knowingly and voluntarily.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative

procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

6. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waive the right to hearing, reconsideration, appeal, and other rights related to this action as identified above.

7. Respondent admits that evidence exists, and that the Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violation alleged in Count One of the Accusation. The parties agree that Count Two of the Accusation is inapplicable to Respondent.

8. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent shall pay an administrative fine of **One Thousand and 00/100 Dollars ($1,000.00)** for the violation alleged in Count One of the Accusation. This sum shall be payable by *cashier's check, certified check, Walgreens company check,* or *money order* written to the **"State of Nevada, Office of the Treasurer."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before May 1, 2025.

B. Respondent shall pay the sum of **Five Hundred and 00/100 Dollars ($500.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check, Walgreens company check,* or *money order* written to the **"Nevada State Board of Pharmacy."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before May 1, 2025.

9. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 24-083-RPH-B-S. Failure by Respondent to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent

issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in the finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

10. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 5, 2025, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear at the meeting.

11. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all of this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 25 day of February 2025.

Cathy Quach, RPH

Signed this 3rd day of February 2025.

Gregory L. Zunino

Certificate of Registration No. 16344

Senior General Counsel
The Nevada State Board of Pharmacy

Approved at to Form:

William J. Stilling, Esq.
Counsel for Respondent Jennifer Englehaupt

DECISION AND ORDER

As to Respondent Cathy Quach, RPH, Certificate of Registration No. 16344, in Case No. 24-083-RPH-B-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and orders that its terms be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 5th day of March 2025.

Helen Park, President
Nevada State Board of Pharmacy

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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS #03845,** **Pharmacy License No. PH01064,** **-and-** **MICHAEL RHODE, PTT,** **Certificate of Registration No. PT28786,** **Respondents.**	**Case Nos. 24-228-PH-S** **24-228-PTT-S** **STIPULATION AND ORDER** **(Respondent Walgreens #03845 Only)**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through counsel, Gregory L. Zunino, Esq., and Respondent Walgreens #03845 ("Respondent"), by and through counsel, William J. Stilling, Esq., hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that its authorized representatives understand the terms of this Stipulation and Proposed Order ("Stipulation"), and that Respondent has executed it knowingly and voluntarily after consulting with counsel.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative

procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent voluntarily waives the right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent does not contest the allegations in Count Two of the Accusation, and further admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violation alleged in Count Two of the Accusation. Upon approval of this Stipulation by the Board, Count One of the Accusation shall be dismissed as it pertains to Respondent. With respect to Count Two of the Accusation, Respondent admits the following:

A. Respondent maintains personally identifiable information pertaining to its patients, including "protected health information" within the meaning of 45 C.F.R. § 160.103.

B. On or about May 20, 2024, while in Respondent's employ, Pharmaceutical Technician Trainee Michael Rhode (PTT Rhode) accessed patient L.G.'s name and personal contact information. PTT Rhode used this information to contact patient L.G. outside of the pharmacy.

C. Patient L.G. was alarmed by PTT Rhode's conduct and expressed concern that PTT Rhode had accessed her protected health information, including prescription drug information.

D. Respondent denies that PTT Rhode accessed patient L.G.'s health information for an improper purpose. However, Respondent acknowledges that PTT Rhode breached a reasonable expectation of patient privacy when he accessed patient L.G.'s name and personal contact information for personal reasons.

E. Respondent immediately terminated PTT Rhode's employment when it became aware that he had breached patient L.G.'s expectation of patient privacy.

F. Respondent acknowledges that PTT Rhode's conduct was deceitful and therefore unprofessional pursuant to NAC 639.945(1)(h).

G. Pursuant to NRS 639.945(3), Respondent is responsible for PTT Rhode's conduct.

7. Now, therefore, to resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agrees to the imposition of the following penalties:

A. Respondent shall pay an administrative fine of **One Thousand and 00/100 Dollars ($1,000.00)**, payable by *cashier's check, certified check, Walgreens company check* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before May 1, 2025.

B. Respondent shall pay the sum of **Five Hundred and 00/100 Dollars ($500.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check, Walgreens company check* or *money order* written to the "**Nevada State Board of Pharmacy.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before May 1, 2025.

8. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 24-228-PH-S. Respondent understands and acknowledges that his failure to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in the finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

9. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 5, 2025, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear for the meeting.

10. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Order.

AGREED:

Signed this 4th **day of March 2025.**

WALGREENS #03845

By_____
Name: John L. Colaizzi
Title: GVP, Head of Enterprise Pharmacy Practice

Signed this ____ day of March 2025.

NEVADA STATE BOARD OF PHARMACY

By_____
GREGORY L. ZUNINO
Senior General Counsel

Signed this ____ day of March 2025.

Approved as to Form and Content:

_____
WILLIAM J. STILLING, ESQ.
Stilling and Harrison
Attorneys for Respondent Walgreens #03845

10. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Order.

AGREED:

Signed this ____ day of March 2025.

WALGREENS #03845

By_____
Name:_____
Title:_____

Signed this 4th day of March 2025.

NEVADA STATE BOARD OF PHARMACY

By_____
GREGORY L. ZUNINO
Senior General Counsel

Signed this 4th day of March 2025.

Approved as to Form and Content:

_____
WILLIAM J. STILLING, ESQ.
Stilling and Harrison
Attorneys for Respondent Walgreens #03845

DECISION AND ORDER

As to Respondent Walgreens #03845, in Case No. 24-228-PH-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and orders that its terms be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 5th day of March 2025.

_____

Helen Park, President
Nevada State Board of Pharmacy

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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. ORTHOPEDIC MOTION, INC., License Nos. MP00026 and MP00772, Respondent.	Case Nos. 24-281-MP-S 24-334-MP-S STIPULATION AND ORDER

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through counsel, Gregory L. Zunino, Esq., and Respondent Orthopedic Motion, Inc. ("Respondent"), by and through counsel, David B. Barney, Esq., hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and the matters alleged in the pleadings on file herein.

2. The Board's staff served Respondent with the Notice of Intended Action and Accusation in Case No. 24-281-MP-S, as well as the Notice of Intended Action and Accusation in Case No. 24-334-MP-S (each an "Accusation" and, collectively, the "Accusations"), together with a Statement to Respondent and Notice of Hearing in connection with each of them.

3. Respondent represents and warrants that it understands the terms of this Stipulation, and that it has executed it knowingly and voluntarily after consulting with counsel. For purposes of construction and enforcement, the parties understand and agree that the terms "medical products," "medical products provider" and "medical products wholesaler" have the meanings ascribed to them in NAC 639.6935, 639.6936 and 639.6937, respectively. The parties further understand and agree that the term "administrator" refers to a person described in NAC 639.694.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusations, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, and NRS Chapter 639, the Nevada Pharmacy Act.

5. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent voluntarily waives the right to a hearing, reconsideration, appeal, and other rights related to the subject actions as identified above.

6. In an effort to avoid the cost and uncertainty of a disciplinary hearing, Respondent has agreed to fully and finally settle and resolve the matters set forth in the Accusations. For purposes of settling such matters, Respondent does not contest the allegations set forth below, which were made in the Accusations, and further admits that evidence exists and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the following violations alleged in the Accusations, to wit:

A. On various occasions between November of 2022 and October of 2024, Respondent sold medical products to one or more of Patients A through G under the circumstances described in the Accusation in Case No. 24-334-MP-S. Respondent failed to maintain an adequate system for resolving complaints by these patients.

B. On or about July 2, 2024, the Board conducted an inspection of Respondent's facility located at 3233 W. Charleston Blvd., Las Vegas, NV 89102. At or around such time, Respondent failed to notify the Board of the departure of its facility administrator within three (3) business days.

7. In mitigation of the offenses referenced above, and for the purpose of resolving the Accusations, Respondent makes the following representations and warranties:

A. Between November of 2022 and early September 2024, Brittany Stryker, OTD ("Dr. Stryker") was the President and Director of Respondent, whereas her husband, Adam Stryker ("Mr. Stryker"), was Respondent's Secretary and Treasurer. Throughout that time, Dr. Stryker handled the clinical aspects of Respondent's business, and Mr. Stryker handled the administrative aspects of the practice.

B. In or around mid-2024, Respondent's business was forced to close due to a series of emergent and unexpected circumstances. In September 2024, Dr. Stryker became the

President, Director, Secretary, and Treasurer of Respondent.

C. Respondent is not currently engaged in business as a medical products provider or a medical products wholesaler, and it has no immediate plans to resume business as a medical products provider, or to commence business as a medical products wholesaler.

8. Now, therefore, to resolve this matter without incurring any further costs or the expenses associated with a hearing, and for no other purpose, the Board and Respondent agree to the following terms, conditions, and penalties:

A. Respondent understands, acknowledges and agrees that license nos. MP00026 and MP00772 have expired under NRS 639.180, and they are of no force or effect. Respondent further agrees that it shall not be eligible to apply for a license to engage in business as a medical products provider or a medical products wholesaler for a period of two (2) years after the effective date of this Stipulation.

B. Respondent agrees that for a period of two (2) years after the effective date of this Stipulation, Respondent shall notify the Board in writing if it becomes aware that any of its current officers, directors, shareholders, partners, or members have applied in an individual or representative capacity for a license to conduct business as a medical products provider or a medical products wholesaler, or to serve as the administrator for a medical products provider or a medical products wholesaler.

C. Respondent accepts this Stipulation as a public reprimand issued pursuant to NRS 639.255(1)(e).

D. To the extent that Respondent has not already reversed applicable credit card charges and/or refunded payments or deposits, Respondent shall do so for the patients described in sections 1a ($1,050), 1b ($2,200), 1c ($1,500), 1d ($1,900) and 1f ($1,500) of the Investigative Report signed on December 24, 2024, by Investigator Dena McClish. Respondent has received a copy of said report and agrees to ensure that such amounts have been refunded or charges reversed by June 30, 2025. Respondent further understands and acknowledges that if the Board's counsel is unable to confirm all applicable refunds have been made, the

matter will be addressed in accordance with paragraph 9 below.

E. In addition to the refund of payments described above, Respondent shall pay an administrative fine of **Five Thousand and 00/100 Dollars ($5,000.00)**, payable by *cashier's check, certified check,* or *money order* written to the **"State of Nevada, Office of the Treasurer."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before August 31, 2025.

F. Respondent shall pay the sum of **One Thousand and 00/100 Dollars ($1,000.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting these matters. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the **"Nevada State Board of Pharmacy."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before August 31, 2025.

9. This Stipulation constitutes a full and final resolution of the Accusations in Case Nos. 24-281-MP-S and 24-334-MP-S, including the underlying factual allegations, legal contentions, and investigations conducted in connection with each of them. Respondent understands and acknowledges that its failure to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in finding that Respondent failed to comply with one or more terms or conditions of this Stipulation, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

10. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 5, 2025, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear for the meeting.

11. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to

the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all of this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusations, at a duly noticed subsequent meeting of the Board, and after providing Respondent with an opportunity to respond and defend itself in accordance with applicable law. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing. Furthermore, this Stipulation shall not be admissible in any other proceeding or action with respect to proof of fact or any other matter, except proceedings brought to enforce this Stipulation.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from or connected with the allegations set forth in the Accusations on file herein, whether known or unknown that might otherwise have been asserted on or before the effective date of this Stipulation.

AGREED:

Signed this 3rd **day of March 2025.**

ORTHOPEDIC MOTION, INC.

By Brittany Stryker
Brittany Stryker, President

Signed this 3rd **day of March 2025.**

NEVADA STATE BOARD OF PHARMACY

By _____
Gregory L. Zunino
Senior General Counsel

Approved as to Form and Content:

_____
David B. Barney, Esq.
Sklar Williams PLLC

Attorneys for Respondent Orthopedic Motion, Inc

DECISION AND ORDER

As to Orthopedic Motion, Inc., in Case Nos. 24-281-MP-S and 24-334-MP-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matters and orders that its terms be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 5th day of March 2025.

Helen Park, President
Nevada State Board of Pharmacy

5V

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. ORTHOPEDIC MOTION, INC., License Nos. MP00026 and MP00772, Respondent.	Case Nos. 24-281-MP-S 24-334-MP-S STIPULATION AND ORDER

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through counsel, Gregory L. Zunino, Esq., and Respondent Orthopedic Motion, Inc. ("Respondent"), by and through counsel, David B. Barney, Esq., hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and the matters alleged in the pleadings on file herein.

2. The Board's staff served Respondent with the Notice of Intended Action and Accusation in Case No. 24-281-MP-S, as well as the Notice of Intended Action and Accusation in Case No. 24-334-MP-S (each an "Accusation" and, collectively, the "Accusations"), together with a Statement to Respondent and Notice of Hearing in connection with each of them.

3. Respondent represents and warrants that it understands the terms of this Stipulation, and that it has executed it knowingly and voluntarily after consulting with counsel. For purposes of construction and enforcement, the parties understand and agree that the terms "medical products," "medical products provider" and "medical products wholesaler" have the meanings ascribed to them in NAC 639.6935, 639.6936 and 639.6937, respectively. The parties further understand and agree that the term "administrator" refers to a person described in NAC 639.694.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusations, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, and NRS Chapter 639, the Nevada Pharmacy Act.

5. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent voluntarily waives the right to a hearing, reconsideration, appeal, and other rights related to the subject actions as identified above.

6. In an effort to avoid the cost and uncertainty of a disciplinary hearing, Respondent has agreed to fully and finally settle and resolve the matters set forth in the Accusations. For purposes of settling such matters, Respondent does not contest the allegations set forth below, which were made in the Accusations, and further admits that evidence exists and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the following violations alleged in the Accusations, to wit:

A. On various occasions between November of 2022 and October of 2024, Respondent sold medical products to one or more of Patients A through G under the circumstances described in the Accusation in Case No. 24-334-MP-S. Respondent failed to maintain an adequate system for resolving complaints by these patients.

B. On or about July 2, 2024, the Board conducted an inspection of Respondent's facility located at 3233 W. Charleston Blvd., Las Vegas, NV 89102. At or around such time, Respondent failed to notify the Board of the departure of its facility administrator within three (3) business days.

7. In mitigation of the offenses referenced above, and for the purpose of resolving the Accusations, Respondent makes the following representations and warranties:

A. Between November of 2022 and early September 2024, Brittany Stryker, OTD ("Dr. Stryker") was the President and Director of Respondent, whereas her husband, Adam Stryker ("Mr. Stryker"), was Respondent's Secretary and Treasurer. Throughout that time, Dr. Stryker handled the clinical aspects of Respondent's business, and Mr. Stryker handled the administrative aspects of the practice.

B. In or around mid-2024, Respondent's business was forced to close due to a series of emergent and unexpected circumstances. In September 2024, Dr. Stryker became the

President, Director, Secretary, and Treasurer of Respondent.

C. Respondent is not currently engaged in business as a medical products provider or a medical products wholesaler, and it has no immediate plans to resume business as a medical products provider, or to commence business as a medical products wholesaler.

8. Now, therefore, to resolve this matter without incurring any further costs or the expenses associated with a hearing, and for no other purpose, the Board and Respondent agree to the following terms, conditions, and penalties:

A. Respondent understands, acknowledges and agrees that license nos. MP00026 and MP00772 have expired under NRS 639.180, and they are of no force or effect. Respondent further agrees that it shall not be eligible to apply for a license to engage in business as a medical products provider or a medical products wholesaler for a period of two (2) years after the effective date of this Stipulation.

B. Respondent agrees that for a period of two (2) years after the effective date of this Stipulation, Respondent shall notify the Board in writing if it becomes aware that any of its current officers, directors, shareholders, partners, or members have applied in an individual or representative capacity for a license to conduct business as a medical products provider or a medical products wholesaler, or to serve as the administrator for a medical products provider or a medical products wholesaler.

C. Respondent accepts this Stipulation as a public reprimand issued pursuant to NRS 639.255(1)(e).

D. To the extent that Respondent has not already reversed applicable credit card charges and/or refunded payments or deposits, Respondent shall do so for the patients described in sections 1a ($1,050), 1b ($2,200), 1c ($1,500), 1d ($1,900) and 1f ($1,500) of the Investigative Report signed on December 24, 2024, by Investigator Dena McClish. Respondent has received a copy of said report and agrees to ensure that such amounts have been refunded or charges reversed by June 30, 2025. Respondent further understands and acknowledges that if the Board's counsel is unable to confirm all applicable refunds have been made, the

matter will be addressed in accordance with paragraph 9 below.

E. In addition to the refund of payments described above, Respondent shall pay an administrative fine of **Five Thousand and 00/100 Dollars ($5,000.00)**, payable by *cashier's check, certified check,* or *money order* written to the **"State of Nevada, Office of the Treasurer."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before August 31, 2025.

F. Respondent shall pay the sum of **One Thousand and 00/100 Dollars ($1,000.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting these matters. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the **"Nevada State Board of Pharmacy."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before August 31, 2025.

9. This Stipulation constitutes a full and final resolution of the Accusations in Case Nos. 24-281-MP-S and 24-334-MP-S, including the underlying factual allegations, legal contentions, and investigations conducted in connection with each of them. Respondent understands and acknowledges that its failure to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in finding that Respondent failed to comply with one or more terms or conditions of this Stipulation, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

10. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 5, 2025, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear for the meeting.

11. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to

the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all of this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusations, at a duly noticed subsequent meeting of the Board, and after providing Respondent with an opportunity to respond and defend itself in accordance with applicable law. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing. Furthermore, this Stipulation shall not be admissible in any other proceeding or action with respect to proof of fact or any other matter, except proceedings brought to enforce this Stipulation.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from or connected with the allegations set forth in the Accusations on file herein, whether known or unknown that might otherwise have been asserted on or before the effective date of this Stipulation.

AGREED:

Signed this 3rd **day of March 2025.**

ORTHOPEDIC MOTION, INC.

By Brittany Stryker
Brittany Stryker, President

Signed this 3rd **day of March 2025.**

NEVADA STATE BOARD OF PHARMACY

By _____
Gregory L. Zunino
Senior General Counsel

Approved as to Form and Content:

_____
David B. Barney, Esq.
Sklar Williams PLLC

Attorneys for Respondent Orthopedic Motion, Inc

DECISION AND ORDER

As to Orthopedic Motion, Inc., in Case Nos. 24-281-MP-S and 24-334-MP-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matters and orders that its terms be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 5th day of March 2025.

Helen Park, President
Nevada State Board of Pharmacy

5W

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

ERIN CALDERON, PT,
Certificate of Registration No. PT18610,

Respondent.

Case No. 24-376-PT-S

ANSWER AND NOTICE OF DEFENSE

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

Accusation 6 isn't entirely correct. I had taken them because there had been a gap in my pain management treatment. My doctor stopped taking my insurance, and it took a bit to find another doctor. It was out of desperation because of the pain I'm normally in and withdrawls.

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

Yes I did take them.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 14 day of February 2025.

ERIN CALDERON, PT

5X

Exhibit A
24-356-WH-O
Safe Chain Solutions, LLC.

Exhibit A

JOE LOMBARDO
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

September 30, 2024

VIA CERTIFIED U.S. MAIL

Charles D. Boyd
Chief Executive Officer
Safe Chain Solutions, LLC
822 Chesapeake Drive
Cambridge, MD 21613-9408

Re: CEASE & DESIST ORDER (Case No. 24-356-WH-O)

Dear Mr. Boyd:

The Nevada State Board of Pharmacy has determined that Safe Chain Solutions, LLC (Safe Chain), Nevada Wholesaler License No. WH02131, has sold and/or distributed counterfeit drugs purportedly manufactured by Gilead Sciences, Inc., for the treatment of HIV-1 patients, including Biktarvy and Descovy, to no fewer than two pharmacies located in Nevada. This constitutes a violation of federal and State law, including, without limitation, 21 U.S.C. 360eee-1, 21 U.S.C. 331(t), NRS 454.351(1), NRS 585.380, NRS 585.410, NRS 585.420, NRS 639.550, NRS 639.555, NAC 639.599, NAC 639.602 and/or NAC 639.603.

Safe Chain is hereby ordered pursuant to NRS 639.2895(1) to immediately CEASE and DESIST engaging in the sale and/or distribution of counterfeit HIV-1 drugs purportedly manufactured by Gilead Sciences, Inc., including Biktarvy and Descovy, into Nevada.

Regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

Tele: 775-850-1440 • Fax: 775-850-1444 • Web: bop.nv.gov
• E-mail: pharmacy@pharmacy.nv.gov

Exhibit B
24-356-WH-O
Safe Chain Solutions, LLC.

Exhibit B

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

GILEAD SCIENCES, INC. and GILEAD SCIENCES IRELAND UC, Plaintiffs, v. SAFE CHAIN SOLUTIONS, LLC; PATRICK BOYD; CHARLES BOYD; WORLDWIDE PHARMA SALES GROUP, INC. d/b/a PHARMASALES.COM; ADAM S. BROSIUS; BOULEVARD 9229 LLC; and ISHBAY SHUKUROV, Defendants.	:	Case No. 21-cv-4106 (AMD) (RER) **FILED UNDER SEAL PURSUANT TO 15 U.S.C. § 1116(d)**

STIPULATION AND [PROPOSED] ORDER ENTERING A PRELIMINARY INJUNCTION, CONFIRMING THE *EX PARTE* SEIZURES, AND RELEASING CERTAIN FUNDS FROM THE ASSET FREEZE AS TO THE SAFE CHAIN DEFENDANTS

WHEREAS, on July 22, 2021, Plaintiffs Gilead Sciences, Inc. and Gilead Sciences Ireland UC (collectively, "Plaintiffs" or "Gilead") filed the above-captioned action against, *inter alia*, Defendants Safe Chain Solutions, LLC, Patrick Boyd, Charles Boyd, Worldwide Pharma Sales Group, Inc. d/b/a Pharmasales.com, and Adam S. Brosius (collectively, the "Safe Chain Defendants"), and sought a temporary restraining order, asset freeze order, and *ex parte* seizure against the Safe Chain Defendants;

WHEREAS, on July 23, 2021, the Honorable Rachel P. Kovner entered a temporary restraining order (Dkt. No. 17), asset freeze order (Dkt. No. 19), sealing order, and *ex parte* seizure order (Dkt. No. 18) against the Safe Chain Defendants;

Exhibit B

WHEREAS, on July 26, 2021, Plaintiffs executed the Court's *ex parte* seizure order at the premises of the Safe Chain Defendants;

WHEREAS, in order to avoid the burden and expense of a preliminary injunction and seizure confirmation hearing, Plaintiffs and the Safe Chain Defendants wish to stipulate to a preliminary injunction without a bond, to modify the Court's asset freeze order, and to confirm the *ex parte* seizures;

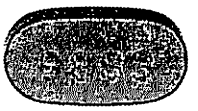
NOW THEREFORE, UPON THE STIPULATION AND AGREEMENT by and between the undersigned counsel for Plaintiffs and counsel for the Safe Chain Defendants, it is hereby ORDERED that:

1. The Safe Chain Defendants and their principals, agents, officers, directors, members, servants, employees, successors, assigns, and all other persons in concert and participation with them pending the final hearing and determination of this action, are preliminarily enjoined from importing, purchasing, selling, distributing, marketing, or otherwise using in commerce in the United States any Gilead Products (as defined below), including authentic products, or assisting, aiding or abetting any other person or business entity in engaging in or performing any of the activities referred to in this paragraph.

2. The "Gilead Products" are defined as all products manufactured by or sold by Gilead or its subsidiaries in the United States, including but not limited to all products bearing anywhere any of the following trademarks (the "Gilead Marks"), whether on the product itself or any of its packaging:

- Gilead's GILEAD trademark, which was registered on the Principal Register of the United States Patent and Trademark Office ("USPTO") on June 12, 2007, as U.S. Registration No. 3251595.

Exhibit B

- Gilead's  trademark, which was registered on the Principal Register of the USPTO on December 3, 2002, as U.S. Registration No. 2656314.
- Gilead's GSI trademark, which was registered on the Principal Register of the USPTO on December 14, 2010, as U.S. Registration No. 3890252.
- Gilead's BIKTARVY trademark, which was registered on the Principal Register of the USPTO on November 28, 2017, as U.S. Registration No. 5344455.
- Gilead's DESCOVY trademark, which was registered on the Principal Register of the USPTO on December 29, 2015, as U.S. Registration No. 4876632.
- Gilead's DESCOVY FOR PREP trademark, which was registered on the Principal Register of the USPTO on November 19, 2019, as U.S. Registration No. 5912591.
- Gilead's 9883 trademark, which was registered on the Principal Register of the USPTO on May 15, 2018, as U.S. Registration No. 5467392.
- Gilead's  trademark, which was registered on the Principal Register of the USPTO on December 25, 2018, as U.S. Registration No. 5636131.
- Gilead's  trademark, which was registered on the Principal Register of the USPTO on November 12, 2019, as U.S. Registration No. 5906177.

3. Plaintiffs and the Safe Chain Defendants agree that, as among them, there are no issues to address at the hearing scheduled for August 5, 2021, with respect to the Order to Show Cause and/or the confirmation of the Seizure Order. The Safe Chain Defendants waive any and all rights they might have to a hearing to contest the issuance of a preliminary injunction and agree to the entry of a preliminary injunction as requested by Plaintiffs without a hearing as memorialized in this Stipulation.

Exhibit B

4. Plaintiffs and their surety U.S. Specialty Insurance Company are released from any and all liability under Bond Number 1001160233 and any liability under or as a result of the seizure order signed by the Court in this case on July 23, 2021, or the execution thereof, and the seizure is hereby confirmed.

5. To the extent they have not done so, the Safe Chain Defendants agree to produce all documents and materials they are required to produce under the Seizure Order and the Temporary Restraining Order by the deadlines set forth in each respective order, including any products bearing any of the Gilead Marks that are or come into the possession of the Safe Chain Defendants. The procedure for reviewing and producing seized documents shall continue as set forth in the Seizure Order.

6. The Court's Asset Freeze Order (Dkt. No. 19) is hereby MODIFIED as follows:

a. Any bank, brokerage house, or financial institution holding frozen assets under the Asset Freeze Order shall continue to hold such assets except as set forth in this Order.

b. Counsel for Plaintiffs or the Safe Chain Defendants may immediately serve this Order upon the banks, brokerage houses, or financial institutions identified in the subparagraphs below.

c. Upon service of this Order upon Univest Bank and Trust Co. ("Univest"), Univest shall create, if it has not already done so, a new, non-interest-bearing account (the "Equitable Trust Account") and shall transfer into the Equitable Trust Account $1,500,000.00 of the frozen assets held in account ending in 9815 (account holder: Univest Bank & Trust Co. F/B/O Safe Chain Solutions,

Exhibit B

LLC). Univest shall hold all funds in Equitable Trust Account in equitable trust, free of all liens and encumbrances, until further order of this Court.

d. Once completed, Univest shall give written confirmation that it has complied with subparagraph c above to counsel for Plaintiffs at gpotter@pbwt.com and CounterfeitHIVMedications@pbwt.com, and to counsel for the Safe Chain Defendants at JDresser@frierlevitt.com and TMizeski@frierlevitt.com. Counsel for Plaintiffs and counsel for the Safe Chain Defendants shall provide to Univest written acknowledgement of receipt of that notification. Once Univest receives such written acknowledgment from counsel for Plaintiffs and counsel for the Safe Chain Defendants, Univest shall unfreeze the accounts ending in 9815 (account holder: Univest Bank & Trust Co. F/B/O Safe Chain Solutions, LLC) and 9807 (account holder: Safe Chain Solutions, LLC).

e. Upon service of this Order upon Bay Vanguard Bank, Bay Vanguard Bank shall immediately unfreeze the accounts ending in 9848, 1765, 8928, and 0961 (account holder: Charles Boyd).

f. Upon service of this Order upon PNC Bank, PNC Bank shall immediately unfreeze the accounts ending in 1135, 3929, 2558, 2566, 2574, and 4459 (account holder: Patrick Boyd).

g. Upon service of this Order upon Seacoast National Bank, Seacoast National Bank shall immediately unfreeze the account ending in 4952 (account holder: Adam Brosius).

h. Except to the extent inconsistent with this Order, the provisions of the Court's Asset Freeze Order shall remain in effect.

Exhibit B

7. Nothing in this stipulation shall constitute or be treated as an admission by any party, including an admission of any liability, wrongdoing, or violation of law. Plaintiffs and the Safe Chain Defendants do not waive and reserve all rights and remedies not specifically addressed herein.

8. Signatures transmitted electronically or by facsimile shall be deemed original.

Dated: July 29, 2021

Respectfully submitted,

GEOFFREY POTTER
AARON FISCHER
TIMOTHY A. WATERS
JOSHUA R. STEIN
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
Tel: (212) 336-2000
Fax: (212) 336-2222
gpotter@pbwt.com
afischer@pbwt.com
twaters@pbwt.com
jstein@pbwt.com

Attorneys for Plaintiffs Gilead Sciences, Inc. and Gilead Sciences Ireland UC

TODD MIZESKI
JESSE DRESSER
LUCAS MORGAN
FRIER LEVITT, LLC
84 Bloomfield Avenue
Pine Brook, NJ 07058
(973) 618-1660
tmizeski@frierlevitt.com
jdresser@frierlevitt.com
lmorgan@frierlevitt.com

Attorneys for Defendants Safe Chain Solutions, LLC, Patrick Boyd, Charles Boyd, Worldwide Pharma Sales Group, Inc. d/b/a Pharmasales.com, and Adam S. Brosius

SO ORDERED

s/Ann M. Donnelly

Hon. Ann M. Donnelly

Exhibit B

CERTIFICATE OF SERVICE

I hereby certify that on July 29, 2021, I served the foregoing upon the following:

Todd Mizeski
Jesse Dresser
Lucas Morgan
FRIER LEVITT, LLC
tmizeski@frierlevitt.com
jdresser@frierlevitt.com
lmorgan@frierlevitt.com

Counsel for Defendants Safe Chain Solutions, LLC, Patrick Boyd, Charles Boyd, Worldwide Pharma Sales Group, Inc. d/b/a Pharmasales.com, and Adam S. Brosius

Boulevard 9229 LLC
92-29 Queens Boulevard, Suite 1i
Rego Park, NY 11374

Ishbay Shukurov
3110 Brighton Seventh Street, Apt 2B
Brooklyn, NY 11235

/s/ Joshua R. Stein

Exhibit C
24-356-WH-O
Safe Chain Solutions, LLC

SETTLEMENT AGREEMENT

This Settlement and Release Agreement (the "Agreement") is entered into and is effective among and between Gilead Sciences, Inc. and Gilead Sciences Ireland UC, and Gilead Sciences, LLC (together "Gilead"), on the one hand, and Defendants Safe Chain Solutions, LLC, Patrick Boyd, and Charles Boyd (collectively, "Safe Chain") on the other. Gilead is referred to herein as "Plaintiffs." Gilead and Safe Chain are each referred to herein as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, on July 22, 2021, Gilead filed an anti-counterfeiting action captioned *Gilead Sciences, Inc., et al. v. Safe Chain Solutions, LLC, et al.*, No. 21-cv-04106-AMD-RER in the United States District Court for the Eastern District of New York (the "Court") against certain defendants ("the Action"), including Safe Chain;

WHEREAS, on July 23, 2021, the Court entered an Asset Freeze Order and Temporary Restraining Order and Order to Show Cause for a Preliminary Injunction against, *inter alia*, Safe Chain (Minute Entry of July 23, 2021, Dkt. No. 19);

WHEREAS, on July 29, 2021, Safe Chain agreed to the entry of a preliminary injunction in connection with the Action and the Court entered the preliminary injunction (Dkt. Nos. 25, 28);

WHEREAS, on March 18, 2022, the Parties mediated in good faith, and at arms-length, under the supervision of then-Magistrate Judge Ramon E. Reyes, Jr.;

WHEREAS, on January 13, 2023, Safe Chain filed counterclaims in the Action against Gilead (Dkt. No. 899);

WHEREAS, on May 3, 2023, Gilead filed its Sixth Amendment Complaint, the currently operative complaint in the Action (Dkt. No. 1056);

WHEREAS, on July 14, 2023, Gilead moved to dismiss Safe Chain's counterclaims against Gilead (Dkt. Nos. 1141-1143);

WHEREAS, the Parties again mediated in good faith, and at arms-length, under the supervision of Magistrate Judge Joseph A. Marutollo;

WHEREAS, Safe Chain denies any liability to Gilead in the Action and has denied, and continues to deny, the claims raised by Gilead in the Action; and

WHEREAS, Gilead denies any liability to Safe Chain relating to Safe Chain's counterclaims and has denied, and continues to deny, the claims raised by Safe Chain in Safe Chain's counterclaims; and

WHEREAS, no Party admits the validity of any claims or defenses in the Action or Safe Chain's counterclaims, the events described therein, or otherwise; and

WHEREAS, Gilead wishes to settle on these terms because it is being paid essentially all of Safe Chain's assets and is obtaining a complete and permanent injunction; and

WHEREAS, Safe Chain wishes to settle and resolve all claims solely in order to avoid the time, expense, inconvenience, and uncertainties of litigation; and

WHEREAS, it is the mutual intention of the Parties to resolve the Action, pursuant to the terms set forth below;

NOW, THEREFORE, the Parties hereby execute this Agreement to reflect and memorialize the terms and conditions of their settlement, and hereby affirm that, in consideration of these promises and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, covenant and agree as follows:

AGREEMENT

1. **Permanent Injunction.** Gilead and Safe Chain agree to execute and be bound by the Consent Judgment and Permanent Injunction attached as Exhibit C, which provides for, *inter alia*, the dismissal of the Action against Safe Chain, including Charles Boyd and Patrick Boyd, with prejudice ("**Consent Judgment and Permanent Injunction**"). Within three (3) business days of the Effective Date of this agreement, Gilead will file and seek entry of the Consent Judgment and Permanent Injunction with the Court. The Parties waive any rights to appeal the entry of the Consent Judgment and Permanent Injunction. The terms of the Consent Judgment and Permanent Injunction are incorporated into this Agreement as if fully set forth herein.

2. **Settlement Payment.**

a. Safe Chain shall pay to Gilead a total sum of two million, seven hundred and thirty thousand, one hundred and eleven dollars and thirty one cents ($2,730,111.31) (the "Settlement Amount") for full resolution of this matter to the attorney trust account of Gilead's attorneys, Patterson Belknap Webb & Tyler ("PBWT") in the manner described in the remaining paragraphs of this Section. This sum is calculated based on the Parties' understanding of the current cash value of the below-described accounts. The payment to Gilead of the current cash value of the below-described accounts, net of any transaction or broker fees associated with liquidating those assets, shall fully resolve this matter between the parties, regardless of whether that value is higher or lower than the dollar value listed above. Gilead shall, however, receive all of the funds in the frozen accounts even if the accounts increase in value.

b. Pursuant to the Consent Judgment and Permanent Injunction (as defined above), Univest Bank and Trust Co., as depository for some of the funds identified on Table 1 of Exhibit A, will immediately be directed to release all funds in the frozen account ending in

4019 (the "Univest Account"), with a current balance of $1,925,160.35, to Gilead in partial satisfaction of the Settlement Amount.

c. In addition, Wells Fargo Advisors, as depository for some of the funds identified on Table 1 of Exhibit A, will immediately be directed to liquidate all holdings and then release all funds in the frozen account ending in 6080 (the "Charles & Christi Boyd Investment Account"), with a current balance of $576,922.66, to Gilead in partial satisfaction of the Settlement Amount.

d. In addition, BayVanguard Bank (alternatively known 1880 Bank), as depository for some of the funds identified on Table 1 of Exhibit A, will immediately be directed to release all funds in the frozen account ending in 4995 (the "Patrick Boyd Checking Account"), with a current balance of $275.16, to Gilead in partial satisfaction of the Settlement Amount.

e. In addition, Queenstown Bank of Maryland, as depository for some of the funds identified on Table 1 of Exhibit A, will immediately be directed to release all funds in the frozen account ending in 3201 (the "Dorchester Holdings LLC Account"), with a current balance of $48,985.41, to Gilead in partial satisfaction of the Settlement Amount.

f. In addition, New York Life Insurance Company will immediately be directed to liquidate life insurance policy Numbers 24 174 858 and 24 174 966, with current net cash values, respectively, of $76,513.84 and $77,358.42, and the policy Number 794414459, with a current net cash value of $24,895.47, and then release the net cash values to Gilead in partial satisfaction of the Settlement Amount.

g. Each bank, brokerage house, financial institution, or life insurance company acting as depositor or holder for the accounts identified on Table 1 of Exhibit A and described in paragraphs (b)-(f) above will release and remit, together, the entire value held in each account, net of any transaction or broker fees associated with liquidating those assets, to Gilead in full satisfaction of the Settlement Amount.

h. All payments required by this Agreement must be made to Gilead via wire, ETF transfer, or check to the escrow account of its attorneys, PBWT (the "**Settlement Account**") pursuant to wire transfer instructions attached as Exhibit B.

i. This Agreement shall be held in escrow until receipt of the above listed funds from all of the transfers described in the foregoing subparagraphs (b)-(f). Within three (3) business days of PBWT's confirming of receipt of the above listed funds, this Agreement shall be released from escrow and given full and binding effect as of the date on which it is released from escrow ("Agreement Escrow Release Date"). The Parties will fully cooperate to secure the release of the funds in each of the accounts to Gilead.

j. The dollar values listed for each account in the foregoing subparagraphs (a) – (f) are for informational purposes only based on the Parties' current understanding of the present cash value of each account described therein. The parties understand that those values may fluctuate from time to time due to market conditions beyond their control.

Thus, for the avoidance of doubt, the Parties agree that Safe Chain shall have fully satisfied its obligation to pay the Settlement Amount pursuant to this paragraph 2 once the entire cash value of the accounts identified in Table 1 of Exhibit A at the time those assets are liquidated, net of any transaction or broker fees associated with liquidating those assets, has been transferred to Gilead pursuant to the foregoing subparagraphs (g) and (h).

3. **Payment Default**. If Safe Chain obstructs or otherwise impedes the transfers described above in Section 2 such that the transfers are not timely made and resulting in a default, or if the balances in any of the accounts are less than the balances as listed on Table 1 of Exhibit A, Gilead may send written notice of non-payment to Safe Chain in accordance with paragraph 9 of this Agreement. Safe Chain will have thirty (30) calendar days from the date of such notice to cure the default, time being of the essence. If the default is not timely cured, the entire unpaid portion of the Settlement Amount shall immediately become due and owing and Gilead will be immediately and automatically entitled to a judgment against each of Safe Chain Solutions, LLC, Patrick Boyd, and Charles Boyd, jointly and severally, for violation of this agreement in the entire unpaid portion of the Settlement Amount owed by Safe Chain plus interest of 1% per month, with Safe Chain Solutions, LLC, Patrick Boyd, and Charles Boyd waiving all defenses and objections they may have to Gilead's application for this judgment. Gilead shall be entitled further to its actual attorneys' fees and investigators' fees for obtaining and collecting this portion of the judgment and shall be entitled to an *ex parte* asset freeze in the unpaid amount. This Agreement will remain in full force and effect and continue to be effective notwithstanding that any of Safe Chain Solutions, LLC, Patrick Boyd, or Charles Boyd becomes the subject of any bankruptcy or insolvency proceeding.

4. **Breach**. In addition to the foregoing remedy for nonpayment, in the event of any violation of this Agreement or the terms of the Consent Judgment and Permanent Injunction, Gilead may take any and all actions available under this Agreement or permitted under any applicable law to collect on the joint and several obligations and liabilities of Safe Chain Solutions, LLC, Patrick Boyd, or Charles Boyd, enforce this Agreement, or enforce the Consent Judgment and Permanent Injunction. For the avoidance of doubt, nothing contained in this Agreement requires Gilead to pursue Safe Chain Solutions, LLC before pursuing Charles Boyd or Patrick Boyd, who are jointly and severally liable for the Settlement Amount.

5. **Discovery Rights/Cooperation.** Safe Chain shall use their best efforts to cooperate in good faith with Plaintiffs with respect to the Action, and be truthful at all times with respect to questions asked of them and information sought from them by Plaintiffs in connection with the Action. Without limiting Safe Chain's agreement to cooperate in good faith with reasonable requests by Plaintiffs, the Parties specifically agree:

a. Safe Chain will provide documents reasonably requested by Plaintiffs, to the extent they have not already produced the documents in the Action. To the extent that Safe Chain possess documents that are subject to confidentiality restrictions (other than those imposed by any Protective Order entered in the Action), they will use their best efforts in good faith to obtain relief from said restrictions.

b. During the pendency of the Action, including any appeals, Safe Chain agrees to cooperate with Plaintiffs and Plaintiffs' legal counsel in connection with Plaintiffs' claims

against the remaining defendants in the Action (and any defendants added to the Action in the future) by being truthful in all matters about which they are asked and of which they have knowledge. Safe Chain's cooperation, without limitation, may include (i) responding in a timely fashion to formal and informal requests for documents and information, (ii) participating in telephone calls and meetings to truthfully and completely answer questions, (iii) reviewing documents and information, and (iv) providing sworn testimony in whatever form that Plaintiffs require, including for use in support of court filings, at deposition and/or at trial.

c. Safe Chain shall be entitled to have their own legal counsel represent them in any actions reasonably requested by Plaintiffs pursuant to paragraphs 5a and 5b. The fees of Safe Chain's legal counsel shall be the sole responsibility of Safe Chain.

d. This Agreement is expressly not conditioned upon the substance of any information or testimony Safe Chain may provide, and cannot be construed to require Safe Chain to testify to or otherwise provide information that is not true or that is misleading. Subject to paragraph 12, should Safe Chain provide false or misleading testimony, provide Plaintiffs with information they know to be untrue, or materially breach subsection (a) or (b) of this paragraph 5, Plaintiffs may void this Agreement, and all provisions thereof, including the release granted to Safe Chain in paragraph 8.

e. For the avoidance of doubt, nothing in this Paragraph or in this Agreement requires Safe Chain to waive its Fifth Amendment privilege or attorney-client privilege at any time, or provide any information to Gilead that is subject to any legal privilege, including but not limited to any joint defense/common interest material.

6. **Effective Date.** The "**Effective Date**" of this Agreement is the date on which all Parties have executed this Agreement and the Consent Judgment and Permanent Injunction.

7. **Audit.** Following entry of the Consent Judgment and Permanent Injunction, to ensure Safe Chain's compliance with the Consent Judgment and Permanent Injunction, Gilead shall have the right, upon at least thirty days prior written notice, to have an independent firm audit, at Gilead's expense, Safe Chain's records of purchases and sales of all products purchased or sold by Safe Chain after the date of the Consent Judgment. The independent firm shall not be permitted to provide any information discovered during any such audit to Gilead unless it relates to (a) Gilead-branded products; or (b) Safe Chain's lack of compliance with the Consent Judgment and Permanent Injunction. Gilead's right to demand such an audit shall not be exercised more than once in any twelve-month period.

8. **Mutual Releases.**

a. Upon entry of the Consent Judgment and Permanent Injunction, except for the duties, responsibilities, and obligations which are set forth in this Agreement, Gilead, on behalf of itself and its respective officers, directors, owners, employees, former employees, parent and subsidiary entities, affiliated entities, predecessors, successors, assigns, agents, attorneys, and representatives (collectively, the "Plaintiffs Releasors"), hereby releases Safe Chain and its respective officers, directors, owners, employees, former employees,

parent and subsidiary entities, affiliated entities, predecessors, successors, assigns, agents, and representatives, Charles Boyd, and Patrick Boyd (collectively, the "Safe Chain Releasees") from any and all claims, causes of action, or demands of any nature whatsoever, anticipated or unanticipated, known or unknown at this time or at any time prior to the date hereof, existing from the beginning of the world through the date of this Agreement and arising from or relating to the Action, including but not limited to all claims that are asserted or that could have been asserted in the Action, and any of the Parties' respective rights therein.

b. However, nothing in this Settlement Agreement is intended to or shall be construed to release any other Defendant in the Action or any other person or entity other than the Safe Chain Releasees. For avoidance of doubt, the foregoing release does not release any of Safe Chain's customers, suppliers, trading partners, brokers, or independent sales representatives, nor may any of those individuals and/or entities use this release as a defense against any claim brought by Gilead against them.

c. Upon entry of the Consent Judgment and Permanent Injunction, except for the duties, responsibilities, and obligations which are set forth in this Agreement, the Safe Chain Releasees, on behalf of themselves and their predecessors, successors, assigns, agents, and representatives hereby release the Plaintiffs Releasors and their attorneys from any and all claims, causes of action, or demands of any nature whatsoever, anticipated or unanticipated, known or unknown at this time or at any time prior to the date hereof, existing from the beginning of the world through the date of this Agreement and arising from or relating to the Action, including but not limited to all claims that are asserted or that could have been asserted in the Action, and any of the Parties' respective rights therein.

9. **Notices.** All notices required or permitted to be provided hereunder shall be afforded to the respective Parties to and through their counsel, and shall be transmitted simultaneously by electronic mail (with PDF attachments, as necessary), or internationally recognized overnight courier as follows or to such other addresses or recipients designated by a Party by written notice from time to time:

If to Gilead:

Geoffrey Potter, Esq.
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036
Email: gpotter@pbwt.com *and* CounterfeitGileadMedications@pbwt.com *and* anticounterfeiting@gilead.com

If to Safe Chain or Charles Boyd or Patrick Boyd:

Charles Boyd
Patrick Boyd
Safe Chain Solutions

822 Chesapeake Drive
Cambridge, MD 21613
Email: CharlesB@Safechain.com
PatB@Safechain.com

With a copy to:

August J. Matteis, Jr.
William E. Copley
Matthew S. Krauss
William E. Jacobs
Weisbrod Matteis & Copley PLLC
3000 K Street NW, Suite 275
Washington, DC 20007
Email: amatteis@wmclaw.com
wcopley@wmclaw.com
mkrauss@wmclaw.com
wjacobs@wmclaw.com

10. **Costs.** Each of the Parties shall bear its own costs, attorneys' fees, and other fees incurred in connection with the Action and this Agreement.

11. **Choice of Law.** This Agreement shall be construed and governed by the laws of the State of New York, without regard to conflicts of law principles thereof.

12. **Consent to Jurisdiction.** The Parties consent to the jurisdiction of the United States District Court for the Eastern District of New York for any adjudication, application, action, suit or proceeding necessary to enforce the terms of this Agreement and waive any and all objections they may have in such enforcement proceeding to the laying of venue in such court, that such court is an inconvenient forum for such enforcement proceeding, or that such court does not have personal jurisdiction over them in such enforcement proceeding.

13. **Severability.** The language of this Agreement has been approved by each of the Parties. The language of this Agreement shall be construed as a whole according to its fair meaning. In the event that any provision or portion of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable, or void, the remainder of this Agreement shall be valid and enforceable and continue in full force and effect between the Parties, just as if the provision held to be illegal, unenforceable, or void had never been included in this Agreement, and the provision held to be illegal, unenforceable, or void shall be changed or interpreted so as to best accomplish the objectives of such provision within the limits of applicable law or court decisions.

14. **Entire Agreement.**

a. This Agreement constitutes a single written contract that expresses the entire agreement and understanding concerning the subject matter between the Parties and supersedes and replaces all prior communications, negotiations, understandings, proposed

agreements, or agreements, whether written or oral concerning the Action. All understandings, representations and agreements heretofore had with respect to this Agreement concerning the Action are merged into this Agreement, which alone fully and completely expresses the agreement of the Parties.

b. Each Party acknowledges and warrants that no Party, nor any attorney, agent, or representative of any Party, has made any promise, representation, or warranty whatsoever, expressed or implied, written or oral, not contained herein concerning the subject matter hereof to induce that Party to execute this Agreement.

c. Each Party acknowledges and warrants that he or it has not executed this Agreement in reliance on any promise, representation, or warranty not expressly set out in this Agreement.

15. **No Oral Modification.** This Agreement may only be amended in writing, signed by authorized representatives of the Parties.

16. **Binding Nature of the Agreement.** This Agreement is and shall be binding upon, and shall inure to the benefit of, the predecessors, successors, heirs, and assigns of all Parties to the extent permitted by law.

17. **Headings.** The headings contained in this Agreement are inserted for convenience, identification, and/or reference only, shall not affect the interpretation or meaning of this Agreement or any provision contained herein, and are in no way intended to describe, interpret, define or limit the scope, extent, or intent of this Agreement or any provision contained herein.

18. **Interpretation.** Each party hereto agrees that this Agreement shall not be construed or interpreted for or against any party as the drafter thereof since both Parties have participated in its preparation.

19. **Counterparts.** This Agreement may be executed in counterparts, including electronically, and as of the Effective Date each counterpart shall have the same force and effect as an original and shall constitute an effective, binding agreement on the part of each of the undersigned. This Agreement may be executed on varying dates, and a PDF of the executed Agreement shall have the same force and effect as a hard copy of the original.

20. **Voluntary Execution of Agreement.** This Agreement is executed voluntarily and without any duress or undue influence on the part or behalf of the Parties hereto. The Parties acknowledge that: They have read this Agreement; they have been represented in the preparation, negotiation and execution of this Agreement by legal counsel of their own choice; they understand the terms and consequences of this Agreement and of the releases it contains; and they are fully aware of the legal and binding effect of this Agreement.

21. **Authority.** Each individual executing this Agreement represents and warrants that he/she has the authority to do so and that execution and delivery of this Agreement has been duly and validly authorized by the Party on whose behalf he/she is signing. Each Party releasing claims herein represents and warrants that no other entity has any interest or right in or to such claims.

22. **Waiver.** The failure of a Party to object to, or a waiver by any Party of, one or more breaches or violations of this Agreement shall not constitute a waiver or limitation upon the right of such Party to object to, or operate or be construed as a waiver or estoppel of, any other breach or violation of this Agreement. No waiver by any Party of any breach or of any right under this Agreement shall be valid unless in writing and signed by an authorized representative of such Party.

23. **Final Accord and Satisfaction**. When executed and delivered by all Parties, this Agreement is intended to be final and binding between the Parties hereto and is further to be effective as a full and final accord and satisfaction between the Parties hereto as to any dispute involved in the Action, and each Party expressly relies on the finality of this Agreement as a substantial, material factor inducing the Party's execution of this Agreement.

[*remainder of page intentionally left blank]*

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

GILEAD SCIENCES INC.

Dated: February 16, 2024 | 2:25:51 PM PST

By: DocuSigned by Lori Mayall — Lori Mayall — I approve this document — February 16, 2024 | 2:25:08 PM PST

Name: Lori Mayall

Title: Sr Associate General Counsel, IP/Head of Anti-Counterfeitir

GILEAD SCIENCES IRELAND UC

Dated: February 16, 2024 | 2:25:51 PM PST

By: DocuSigned by Lori Mayall — Lori Mayall — I approve this document — February 16, 2024 | 2:25:15 PM PST — 8029CD41546B459AB1D8F6E415C5B14F

Name: Lori Mayall

Title: Sr Associate General Counsel, IP/Head of Anti-Counterfeitir

GILEAD SCIENCES, LLC.

Dated: February 16, 2024 | 2:25:51 PM PST

By: DocuSigned by Lori Mayall — Lori Mayall — I approve this document — February 16, 2024 | 2:25:19 PM PST

Name: Lori Mayall

Title: Sr Associate General Counsel, IP/Head of Anti-Counterfeitir

SAFE CHAIN SOLUTIONS, LLC

Dated: 2/19/2024 By: 

Name: Charles Boyd

Title: Founder & CEO

PATRICK BOYD

Dated: _____ Signature: _____

CHARLES BOYD

Dated: 2/19/2024 Signature: 

SAFE CHAIN SOLUTIONS, LLC

Dated: _____ By: _____

Name: _____

Title: _____

PATRICK BOYD

Dated: 2/19/24 Signature: 

CHARLES BOYD

Dated: _____ Signature: _____

EXHIBIT A

Table 1: Bank Accounts

Bank Name	Account Title	Account Number Ending In	Balance (Current)
Univest Bank and Trust Co.	Equitable Trust Account	4019	$1,925,160.35
Wells Fargo Advisors	Charles & Christi Boyd Investment Account	6080	$576,922.66
BayVanguard Bank (1880 Bank)	P. Boyd personal checking Account	4995	$275.16
Queenstown Bank of Maryland	Dorchester Holdings LLC Account	3201	$48,985.41
TOTAL			$2,551,343.58

Table 2: Life Insurance Policies

Policy Holder	Insurance Company	Policy Number	Current Cash Surrender Value
Charles Boyd	New York Life Insurance	24174858	$76,513.84
Charles Boyd	New York Life Insurance	794414459	$24,895.47
Patrick Boyd	New York Life Insurance	24174966	$77,358.42
TOTAL			$178,767.73

EXHIBIT B

Bank:	Citibank, N.A. Private Banking Division 153 East 53th Street New York, NY 10022
ABA Routing No.:	021000089
Account No.:	54371288
Swift #:	CITIUS33
Account Title:	Patterson Belknap Webb & Tyler LLP Attorney Trust Account-IOLA
Reference:	Gilead-Safe Chain Settlement

EXHIBIT C

(Consent Judgment and Permanent Injunction)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

GILEAD SCIENCES, INC., *et al.*,	:	
	:	
Plaintiffs,	:	Case No. 21-cv-4106-AMD-JAM
	:	
v.	:	
	:	
SAFE CHAIN SOLUTIONS, LLC, *et al.*,	:	
	:	
Defendants.	:	

CONSENT JUDGMENT AND PERMANENT INJUNCTION
AS TO SAFE CHAIN SOLUTIONS, LLC, PATRICK BOYD, AND CHARLES BOYD

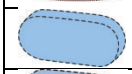
On consent of Plaintiffs Gilead Sciences, Inc., Gilead Sciences Ireland UC, and Gilead Sciences, LLC (together, "Gilead" or "Plaintiffs") and Defendants Safe Chain Solutions, LLC, Patrick Boyd, and Charles Boyd (collectively, "Safe Chain"), and pursuant to Fed. R. Civ. P. 54(b), it is hereby ORDERED, ADJUDGED, and DECREED:

1. Safe Chain, and their predecessors, successors, agents, and assigns, or any other person in active concert and participation with them, is enjoined from importing, purchasing, selling, distributing, marketing, or otherwise using in commerce in the United States any Gilead Products (as defined below), including authentic products, or assisting, aiding or abetting any other person or business entity in engaging in or performing any of the activities referred to in this paragraph.

2. The "Gilead Products" are defined as all products manufactured by or sold by Gilead or its subsidiaries in the United States, including but not limited to all products bearing

anywhere any of the Gilead Marks (as defined below), whether on the product itself or any of its packaging.

3. The "Gilead Marks" include the following:

Trademark	Registration Number	Registration Date
GILEAD	3251595	June 12, 2007
	2656314	December 3, 2002
GSI	3890252	December 14, 2010
BIKTARVY	5344455	November 28, 2017
DESCOVY	4876632	December 29, 2015
DESCOVY FOR PREP	5912591	November 19, 2019
9883	5467392	May 15, 2018
	5636131	December 25, 2018
	5906177	November 12, 2019
	5030567	August 30, 2016
	5154303	March 7, 2017
TRUVADA	2915213	December 28, 2004
GENVOYA	4797730	August 25, 2015
ATRIPLA	3276743	August 7, 2007
RANEXA	3094007	May 16, 2006
VOSEVI	5259592	August 8, 2017
STRIBILD	4263613	December 25, 2012
	6031751	April 14, 2020
SOVALDI	4468665	January 21, 2014
	5018106	August 9, 2016
7977	4585257	August 12, 2014

4. Nothing in this Consent Judgment and Permanent Injunction prohibits Charles Boyd and/or Patrick Boyd from purchasing any Gilead Product, as defined above, for their own personal medical use (not for resale) in accordance with all applicable laws or owning less than 5% of any public company.

5. Safe Chain, on behalf of themselves and their officers, directors, owners, predecessors, successors, assigns, agents, and representatives hereby assign to Plaintiffs any and all claims for damages and restitution against all other Defendants in the Action and/or third

parties, permissive or mandatory, asserted or unasserted, anticipated or unanticipated, known or unknown at this time or at any time prior to the date hereof, existing from the beginning of the world through the effective date of the Settlement Agreement executed between Safe Chain and Gilead (the "Settlement Agreement") and arising from or relating to Safe Chain's purchase or sale of Gilead Products.

6. Following entry of the Consent Judgment and Permanent Injunction, to ensure Safe Chain's compliance with this Consent Judgment and Permanent Injunction, Gilead shall have the right, upon at least thirty days prior written notice, to have an independent firm, at Gilead's expense, audit Safe Chain records of purchases and sales of all products purchased or sold by Safe Chain after the date of this Consent Judgment. The independent firm shall not be permitted to provide any information discovered during any such audit to Gilead unless it relates to (a) Gilead-branded products; or (b) Safe Chain's lack of compliance with this Consent Judgment and Permanent Injunction. Gilead's right to demand such an audit shall not be exercised more than once in any twelve-month period.

7. In addition to other remedies, including damages, for contempt of this Permanent Injunction, in the event of breach or violation of the terms of this Permanent Injunction by Safe Chain, or their predecessors, successors, agents, and assigns, or any other person in active concert and participation with them, Gilead is entitled to a preliminary and permanent injunction against the breaching conduct solely upon a showing of likelihood of success of establishing that such a breach occurred. In addition, Gilead shall be entitled to recover its actual attorneys' fees and investigatory fees for investigating and demonstrating that Safe Chain has violated this Consent Judgment and Permanent Injunction.

8. This Consent Judgment is entered pursuant to Fed. R. Civ. P. 58, and this action is hereby dismissed against Safe Chain Solutions, LLC, Charles Boyd, and Patrick Boyd with prejudice, and Safe Chain's counterclaims against Gilead (*see* Dkt. No. 899) also are dismissed with prejudice, without costs or attorneys' fees, save that this District Court shall retain jurisdiction over this action, including over Safe Chain, for matters relating to implementation of, or disputes arising out of, this Consent Judgment or the settlement of this action.

9. If a court of competent jurisdiction finds that Safe Chain has violated the prohibitions of this Consent Judgment and Permanent Injunction, Gilead is entitled at its election to either liquidated damages of one hundred times (100x) the U.S. Wholesale Acquisition Cost ("WAC") of the authentic Gilead product that Safe Chain sold (individually, or on its behalf by their principals, agents, attorneys, members, servants, employees, directors, officers, parents, successors, heirs, assigns, executors, representatives, and subsidiaries, and all other persons in active concert or participation with them) or Gilead's actual, statutory, and punitive damages as may be permitted by law. In any action, regardless of which measure of damages Gilead selects, Gilead shall be entitled to recover its actual attorneys' fees and investigatory fees for finding and demonstrating that Safe Chain has violated this Consent Judgment and Permanent Injunction.

10. Safe Chain relinquishes all rights to the funds/cash values in the accounts identified below (the "Frozen Settlement Funds"):

Bank Name/Insurance Company	**Account Title/Policy Holder**	**Account Number Ending In**	**Balance/Net Cash Surrender Value (Current)**
Univest Bank and Trust Co.	Equitable Trust Account	4019	$1,925,160.35
Wells Fargo Advisors	Charles & Christi Boyd Investment Account	6080	$576,922.66
BayVanguard Bank (1880 Bank)	P. Boyd personal checking Account	4995	$275.16

Queenstown Bank of Maryland	Dorchester Holdings LLC Account	3201	$48,985.41
New York Life Insurance Company	Charles Boyd	24174858	$76,513.84
New York Life Insurance Company	Charles Boyd	794414459	$24,895.47
New York Life Insurance Company	Patrick Boyd	24174966	$77,358.42
TOTAL			$2,730,111.31

11. The Court's Asset Freeze Order (Dkt. No. 19, as modified by Dkt. Nos. 28, 121, 401) as to Safe Chain Solutions, LLC, Charles Boyd, and Patrick Boyd, is hereby MODIFIED as follows:

a. Counsel for Plaintiffs or Safe Chain may immediately serve this order upon the financial institutions identified or described in Paragraph 10.

b. Upon service of this Order on any of the financial institutions or life insurance companies identified or described in Paragraph 10, such financial institution shall immediately liquidate all holdings in the accounts and then wire all funds (net of any transaction or broker fees associated with liquidating those assets) in the accounts identified or described in Paragraph 10 to a non-interest-bearing escrow account held by counsel for Plaintiffs at Citibank, Private Banking Division, 153 East 53th Street, New York, NY 10022, ABA # 021000089, Swift # CITIUS33, Account # 54371288, Account Name Patterson Belknap Webb & Tyler LLP Attorney Trust Account-IOLA. Confirmation of the date and amount of each wire transfer shall be sent to counsel for Gilead at GPotter@pbwt.com and counterfeitgileadmedications@pbwt.com and counsel for Safe Chain at

amatteis@wmclaw.com, wcopley@wmclaw.com, mkrauss@wmclaw.com, and wjacobs@wmclaw.com.

c. Immediately following the completion of any transfer set forth in Paragraph 11.b above, the financial institution that has completed the transfer shall promptly provide notice to counsel for both Gilead and Safe Chain that the transfer is complete, at the following email addresses: For Gilead, gpotter@pbwt.com and counterfeitGileadmediations@pbwt.com; and for Safe Chain: amatteis@wmclaw.com, wcopley@wmclaw.com, mkrauss@wmclaw.com, and wjacobs@wmclaw.com. Upon receipt of the funds, Gilead's counsel shall promptly confirm by reply email to both the financial institution completing the transfer and Safe Chain's counsel that the transferred funds were received.

12. Consistent with the foregoing, the Court's asset freeze order (Dkt. No. 19, as modified by Dkt. Nos. 28, 121, 401) as to Safe Chain Solutions, LLC, Charles Boyd, and Patrick Boyd only is otherwise hereby DISSOLVED, but—unless and until further order of this Court—otherwise remains in effect as to any other parties to which it applies as of the date of this order.

13. Signatures to this Consent Judgment transmitted electronically or by facsimile shall be deemed original.

[*signatures on following page*]

DATED: February __, 2024

CONSENTED AND AGREED TO BY:

PATTERSON BELKNAP WEBB & TYLER LLP

By: _____
Geoffrey Potter
Timothy A. Waters
Thomas P. Kurland
Gizele Rubeiz
1133 Avenue of the Americas
New York, NY 10036-6710
T: 212-336-2000
F: 212-336-2222
E: gpotter@pbwt.com
twaters@pbwt.com
tkurland@pbwt.com
grubeiz@pbwt.com

Attorneys for Plaintiffs Gilead Sciences, Inc., et al.

WEISBROD MATTEIS & COPLEY PLLC

By: _____
August J. Matteis, Jr.
William E. Copley
Matthew Krauss
William E. Jacobs
3000 K Street NW, Suite 275
Washington, DC 20007
T: 202-499-7910
E: amatteis@wmclaw.com
wcopley@wmclaw.com
mkrauss@wmclaw.com
wjacobs@wmclaw.com

Attorneys for Defendants Safe Chain Solutions, LLC, Patrick Boyd, and Charles Boyd

IT IS SO ORDERED

_____
HON. ANN M. DONNELLY, U.S.D.J.

Dated: _____, 2024

Exhibit D
24-356-WH-O
Safe Chain Solutions, LLC

Exhibit D

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

GILEAD SCIENCES, INC., *et al.*,	:	
	:	
Plaintiffs,	:	Case No. 21-cv-4106-AMD-JAM
	:	
v.	:	
	:	
SAFE CHAIN SOLUTIONS, LLC, *et al.*,	:	
	:	
Defendants.	:	

CONSENT JUDGMENT AND PERMANENT INJUNCTION
AS TO SAFE CHAIN SOLUTIONS, LLC, PATRICK BOYD, AND CHARLES BOYD

On consent of Plaintiffs Gilead Sciences, Inc., Gilead Sciences Ireland UC, and Gilead Sciences, LLC (together, "Gilead" or "Plaintiffs") and Defendants Safe Chain Solutions, LLC, Patrick Boyd, and Charles Boyd (collectively, "Safe Chain"), and pursuant to Fed. R. Civ. P. 54(b), it is hereby ORDERED, ADJUDGED, and DECREED:

1. Safe Chain, and their predecessors, successors, agents, and assigns, or any other person in active concert and participation with them, is enjoined from importing, purchasing, selling, distributing, marketing, or otherwise using in commerce in the United States any Gilead Products (as defined below), including authentic products, or assisting, aiding or abetting any other person or business entity in engaging in or performing any of the activities referred to in this paragraph.

2. The "Gilead Products" are defined as all products manufactured by or sold by Gilead or its subsidiaries in the United States, including but not limited to all products bearing

Exhibit D

anywhere any of the Gilead Marks (as defined below), whether on the product itself or any of its packaging.

3. The "Gilead Marks" include the following:

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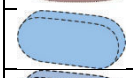	5906177	November 12, 2019
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	5154303	March 7, 2017
TRUVADA	2915213	December 28, 2004
GENVOYA	4797730	August 25, 2015
ATRIPLA	3276743	August 7, 2007
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7977	4585257	August 12, 2014

4. Nothing in this Consent Judgment and Permanent Injunction prohibits Charles Boyd and/or Patrick Boyd from purchasing any Gilead Product, as defined above, for their own personal medical use (not for resale) in accordance with all applicable laws or owning less than 5% of any public company.

5. Safe Chain, on behalf of themselves and their officers, directors, owners, predecessors, successors, assigns, agents, and representatives hereby assign to Plaintiffs any and all claims for damages and restitution against all other Defendants in the Action and/or third

parties, permissive or mandatory, asserted or unasserted, anticipated or unanticipated, known or unknown at this time or at any time prior to the date hereof, existing from the beginning of the world through the effective date of the Settlement Agreement executed between Safe Chain and Gilead (the "Settlement Agreement") and arising from or relating to Safe Chain's purchase or sale of Gilead Products.

6. Following entry of the Consent Judgment and Permanent Injunction, to ensure Safe Chain's compliance with this Consent Judgment and Permanent Injunction, Gilead shall have the right, upon at least thirty days prior written notice, to have an independent firm, at Gilead's expense, audit Safe Chain records of purchases and sales of all products purchased or sold by Safe Chain after the date of this Consent Judgment. The independent firm shall not be permitted to provide any information discovered during any such audit to Gilead unless it relates to (a) Gilead-branded products; or (b) Safe Chain's lack of compliance with this Consent Judgment and Permanent Injunction. Gilead's right to demand such an audit shall not be exercised more than once in any twelve-month period.

7. In addition to other remedies, including damages, for contempt of this Permanent Injunction, in the event of breach or violation of the terms of this Permanent Injunction by Safe Chain, or their predecessors, successors, agents, and assigns, or any other person in active concert and participation with them, Gilead is entitled to a preliminary and permanent injunction against the breaching conduct solely upon a showing of likelihood of success of establishing that such a breach occurred. In addition, Gilead shall be entitled to recover its actual attorneys' fees and investigatory fees for investigating and demonstrating that Safe Chain has violated this Consent Judgment and Permanent Injunction.

Exhibit D

8. This Consent Judgment is entered pursuant to Fed. R. Civ. P. 58, and this action is hereby dismissed against Safe Chain Solutions, LLC, Charles Boyd, and Patrick Boyd with prejudice, and Safe Chain's counterclaims against Gilead (*see* Dkt. No. 899) also are dismissed with prejudice, without costs or attorneys' fees, save that this District Court shall retain jurisdiction over this action, including over Safe Chain, for matters relating to implementation of, or disputes arising out of, this Consent Judgment or the settlement of this action.

9. If a court of competent jurisdiction finds that Safe Chain has violated the prohibitions of this Consent Judgment and Permanent Injunction, Gilead is entitled at its election to either liquidated damages of one hundred times (100x) the U.S. Wholesale Acquisition Cost ("WAC") of the authentic Gilead product that Safe Chain sold (individually, or on its behalf by their principals, agents, attorneys, members, servants, employees, directors, officers, parents, successors, heirs, assigns, executors, representatives, and subsidiaries, and all other persons in active concert or participation with them) or Gilead's actual, statutory, and punitive damages as may be permitted by law. In any action, regardless of which measure of damages Gilead selects, Gilead shall be entitled to recover its actual attorneys' fees and investigatory fees for finding and demonstrating that Safe Chain has violated this Consent Judgment and Permanent Injunction.

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Bank Name/Insurance Company	**Account Title/Policy Holder**	**Account Number Ending In**	**Balance/Net Cash Surrender Value (Current)**
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BayVanguard Bank (1880 Bank)	P. Boyd personal checking Account	4995	$275.16

Exhibit D

Queenstown Bank of Maryland	Dorchester Holdings LLC Account	3201	$48,985.41
New York Life Insurance Company	Charles Boyd	24174858	$76,513.84
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TOTAL			$2,730,111.31

11. The Court's Asset Freeze Order (Dkt. No. 19, as modified by Dkt. Nos. 28, 121, 401) as to Safe Chain Solutions, LLC, Charles Boyd, and Patrick Boyd, is hereby MODIFIED as follows:

a. Counsel for Plaintiffs or Safe Chain may immediately serve this order upon the financial institutions identified or described in Paragraph 10.

b. Upon service of this Order on any of the financial institutions or life insurance companies identified or described in Paragraph 10, such financial institution shall immediately liquidate all holdings in the accounts and then wire all funds (net of any transaction or broker fees associated with liquidating those assets) in the accounts identified or described in Paragraph 10 to a non-interest-bearing escrow account held by counsel for Plaintiffs at Citibank, Private Banking Division, 153 East 53th Street, New York, NY 10022, ABA # 021000089, Swift # CITIUS33, Account # 54371288, Account Name Patterson Belknap Webb & Tyler LLP Attorney Trust Account-IOLA. Confirmation of the date and amount of each wire transfer shall be sent to counsel for Gilead at GPotter@pbwt.com and counterfeitgileadmedications@pbwt.com and counsel for Safe Chain at

amatteis@wmclaw.com, wcopley@wmclaw.com, mkrauss@wmclaw.com, and wjacobs@wmclaw.com.

c. Immediately following the completion of any transfer set forth in Paragraph 11.b above, the financial institution that has completed the transfer shall promptly provide notice to counsel for both Gilead and Safe Chain that the transfer is complete, at the following email addresses: For Gilead, gpotter@pbwt.com and counterfeitGileadmediations@pbwt.com; and for Safe Chain: amatteis@wmclaw.com, wcopley@wmclaw.com, mkrauss@wmclaw.com, and wjacobs@wmclaw.com. Upon receipt of the funds, Gilead's counsel shall promptly confirm by reply email to both the financial institution completing the transfer and Safe Chain's counsel that the transferred funds were received.

12. Consistent with the foregoing, the Court's asset freeze order (Dkt. No. 19, as modified by Dkt. Nos. 28, 121, 401) as to Safe Chain Solutions, LLC, Charles Boyd, and Patrick Boyd only is otherwise hereby DISSOLVED, but—unless and until further order of this Court—otherwise remains in effect as to any other parties to which it applies as of the date of this order.

13. Signatures to this Consent Judgment transmitted electronically or by facsimile shall be deemed original.

[*signatures on following page*]

Exhibit D

DATED: February 19, 2024

CONSENTED AND AGREED TO BY:

PATTERSON BELKNAP WEBB & TYLER LLP

By: _____

Geoffrey Potter
Timothy A. Waters
Thomas P. Kurland
Gizele Rubeiz
1133 Avenue of the Americas
New York, NY 10036-6710
T: 212-336-2000
F: 212-336-2222
E: gpotter@pbwt.com
twaters@pbwt.com
tkurland@pbwt.com
grubeiz@pbwt.com

Attorneys for Plaintiffs Gilead Sciences, Inc., et al.

WEISBROD MATTEIS & COPLEY PLLC

By: */s/ August J. Matteis, Jr.*

August J. Matteis, Jr.
William E. Copley
Matthew Krauss
William E. Jacobs
3000 K Street NW, Suite 275
Washington, DC 20007
T: 202-499-7910
E: amatteis@wmclaw.com
wcopley@wmclaw.com
mkrauss@wmclaw.com
wjacobs@wmclaw.com

Attorneys for Defendants Safe Chain Solutions, LLC, Patrick Boyd, and Charles Boyd

IT IS SO ORDERED

s/Ann M. Donnelly
HON. ANN M. DONNELLY, U.S.D.J.

Dated: 2/29/2024, 2024

CERTIFICATE OF SERVICE

I hereby certify that on November 26, 2024, I caused to be served a true and correct copy of the foregoing **RESPONDENT'S MOTION FOR CONTINUANCE OF THE HEARING FOR CONTESTED CASE** by the method indicated below to:

Brett Kandt
General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy #206,
Reno, NV 895219
Nevada State Board of Pharmacy
(bkandt@pharmacy.nv.gov)

- ☐ U.S. Mail postage prepaid
- ☐ Hand delivery
- ☐ Overnight Mail
- ☐ Facsimile
- ☑ Electronic Mail

David Wuest
Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy #206,
Reno, NV 895219
dwuest@pharmacy.nv.gov

- ☐ U.S. Mail postage prepaid
- ☐ Hand delivery
- ☐ Overnight Mail
- ☐ Facsimile
- ☑ Electronic Mail

Helen Park
President
Nevada State Board of Pharmacy
c/o David Wuest
dwuest@pharmacy.nv.gov

- ☐ U.S. Mail postage prepaid
- ☐ Hand delivery
- ☐ Overnight Mail
- ☐ Facsimile
- ☑ Electronic Mail

Exhibit E
24-356-WH-O
Safe Chain Solutions

SafeChain Solutions

Invoice

Inv Number
01145775
Page: 1

SAFE CHAIN SOLUTIONS, LLC
822 CHESAPEAKE DRIVE
CAMBRIDGE, MD 21613

Tel: 855-437-5727
Fax: 866-930-1128
RS0477617

Remit To:
Safe Chain Solutions, LLC
PO Box 479
Souderton, PA 18964

Tel: 855-437-5727
Fax:

www.safechain.com
accounting@safechain.com

Bill-to: 14-NV0100

AMERICAN SPECIALTY PHARMACY INC
13988 DIPLOMAT DRIVE STE 100
ATTN: ACCTS PAYABLE
FARMERS BRANCH TX 75234

Ship-to: PHAR 001

ASPCARES - LAS VEGAS
501 S RANCHO DRIVE G46
ATTN: KEVIN
LAS VEGAS NV 89106

Invoice Date:	03/29/21	Salesman:	Blackstone
Ship Date:	03/29/21	Ship Via:	UPS Ground
Our Order No:	01S41266001	Customer Order #:	343035
		Terms:	NET 30
License	PHN03347 Exp: 10/31/22	DEA #	FA5224530 Exp:06/30/21 LicExp:10/31/22
Special Instructions:			

Line	Item Number / Description	Ordered	UM	Shipped	UM	B/O Qty	Unit Price	UM	Extension
1	49702-0231-13 TRIUMEQ NDC#: 49702-0231-13 Prod Strength: 600-50-300 MG Prod Size: 30 EA Lot #: GS5E Expiration Date: 10/31/22	5	EA	5 5	EA	0	2990.97*	EA	14,954.85
	SUB TOTAL								**14,954.85**
	INVOICE TOTAL								**$14,954.85**
	CARTON TRACKING NUMBERS: CTN#1 1Z7156794294224880 Additional License Information State License for MD - Origin D03211 Exp 05/31/21 State License for NV - Destination PHN03347 Exp 10/31/22								
	PLEASE NOTE OUR NEW REMIT TO ADDRESS								

Cartons: 1 | Weight: 0.9

* Non-Taxable

SafeChain Solutions

Invoice

Inv Number
01145767
Page: 1

SAFE CHAIN SOLUTIONS, LLC
822 CHESAPEAKE DRIVE
CAMBRIDGE, MD 21613

Tel: 855-437-5727
Fax: 866-930-1128
RS0477617

Remit To:
Safe Chain Solutions, LLC
PO Box 479
Souderton, PA 18964

Tel: 855-437-5727
Fax:

www.safechain.com
accounting@safechain.com

Bill-to: 14-NV0100

AMERICAN SPECIALTY PHARMACY INC
13988 DIPLOMAT DRIVE STE 100
ATTN: ACCTS PAYABLE
FARMERS BRANCH TX 75234

Ship-to: PHAR 001 MGO

ASPCARES - LAS VEGAS
501 S RANCHO DRIVE G46
ATTN: KEVIN
LAS VEGAS NV 89106

Invoice Date:	03/29/21	Salesman:	Blackstone
Ship Date:	03/29/21	Ship Via:	UPS Ground
Our Order No:	01S40700002	Customer Order #:	339012
		Terms:	NET 30
License	PHN03347 Exp: 10/31/22	DEA #	FA5224530 Exp:06/30/21 LicExp:10/31/22
Special Instructions:			

Line	Item Number / Description	Ordered	UM	Shipped	UM	B/O Qty	Unit Price	UM	Extension
1	61958-2501-01 BIKTARVY 30CT NDC#: 61958-2501-01 Prod Strength: 50-200-25 MG Prod Size: 30 EA	10	EA	10	EA	0	3190.13*	EA	31,901.30
	Lot #: 6341501A			1					
	Expiration Date: 06/30/22								
	Lot #: 6341502A			1					
	Expiration Date: 06/30/22								
	Lot #: CDFXYA			1					
	Expiration Date: 08/31/22								
	Lot #: 6400503A			1					
	Expiration Date: 09/30/22								
	Lot #: 6400504A			1					
	Expiration Date: 09/30/22								
	Lot #: 6400505A			1					
	Expiration Date: 09/30/22								
	Lot #: CDFYDA			1					
	Expiration Date: 09/30/22								
	Lot #: CDGWYA			1					
	Expiration Date: 09/30/22								
	Lot #: 6400501A			2					
	Expiration Date: 09/30/22								
	SUB TOTAL								**31,901.30**
	INVOICE TOTAL								**$31,901.30**
	CARTON TRACKING NUMBERS: CTN#1 1Z7156794292607916 Additional License Information State License for MD - Origin								
	Multiple Page Invoice Page: 1								CONTINUED

Cartons: 1 | Weight: 1.8

* Non-Taxable

SafeChain Solutions

Invoice

Inv Number
01I44678
Page: 1

SAFE CHAIN SOLUTIONS, LLC
822 CHESAPEAKE DRIVE
CAMBRIDGE, MD 21613

Tel: 855-437-5727
Fax: 866-930-1128
RS0477617

Remit To:
Safe Chain Solutions, LLC
PO Box 479
Souderton, PA 18964

Tel: 855-437-5727
Fax:

www.safechain.com
accounting@safechain.com

Bill-to: 14-NV0100

AMERICAN SPECIALTY PHARMACY INC
13988 DIPLOMAT DRIVE STE 100
ATTN: ACCTS PAYABLE
FARMERS BRANCH TX 75234

Ship-to: PHAR 001 MGO

ASPCARES - LAS VEGAS
501 S RANCHO DRIVE G46
ATTN: KEVIN
LAS VEGAS NV 89106

Invoice Date:	03/11/21	Salesman:	Blackstone
Ship Date:	03/11/21	Ship Via:	UPS Ground
Our Order No:	01S40079007	Customer Order #:	334149
		Terms:	NET 30
License	PHN03347 Exp: 10/31/22	DEA #	FA5224530 Exp:06/30/21 LicExp:10/31/22
Special Instructions:			

Line	Item Number / Description	Ordered	UM	Shipped	UM	B/O Qty	Unit Price	UM	Extension
1	61958-2501-01 BIKTARVY 30CT NDC#: 61958-2501-01 Prod Strength: 50-200-25 MG Prod Size: 30 EA Lot #: 023253 Expiration Date: 02/28/23 Lot #: 020733 Expiration Date: 02/28/23	10	EA	10 2 8	EA	0	3190.13*	EA	31,901.30
	SUB TOTAL								**31,901.30**
	INVOICE TOTAL								**$31,901.30**
	CARTON TRACKING NUMBERS: CTN#1 1Z7156794295130783 Additional License Information State License for MD - Origin D03211 Exp 05/31/21 State License for NV - Destination PHN03347 Exp 10/31/22 **PLEASE NOTE OUR NEW REMIT TO ADDRESS**								

Cartons: 1 | Weight: 1.3

* Non-Taxable

SafeChain Solutions

Invoice

Inv Number
01143594
Page: 1

SAFE CHAIN SOLUTIONS, LLC
822 CHESAPEAKE DRIVE
CAMBRIDGE, MD 21613

Tel: 855-437-5727
Fax: 866-930-1128
RS0477617

Remit To:
Safe Chain Solutions, LLC
PO Box 479
Souderton, PA 18964

Tel: 855-437-5727
Fax:

www.safechain.com
accounting@safechain.com

Bill-to: 14-NV0100
AMERICAN SPECIALTY PHARMACY INC
13988 DIPLOMAT DRIVE STE 100
ATTN: ACCTS PAYABLE
FARMERS BRANCH TX 75234

Ship-to: PHAR 001 KF
ASPCARES - LAS VEGAS
501 S RANCHO DRIVE G46
ATTN: KEVIN
LAS VEGAS NV 89106

Invoice Date:	02/23/21	Salesman:	Blackstone
Ship Date:	02/23/21	Ship Via:	UPS Ground
Our Order No:	01S39548002	Customer Order #:	330010
		Terms:	NET 30
License	PHN03347 Exp: 10/31/22	DEA #	FA5224530 Exp:06/30/21 LicExp:10/31/22
Special Instructions:			

Line	Item Number / Description	Ordered	UM	Shipped	UM	B/O Qty	Unit Price	UM	Extension
1	00006-5007-01 DELSTRIGO 100/300/300MG 30TAB NDC#: 00006-5007-01 Prod Strength: 100-300-300 MG Prod Size: 30 EA Lot #: T018775 Expiration Date: 08/04/22	2	EA	2 2	EA	0	2176.19*	EA	4,352.38
	SUB TOTAL								**4,352.38**
	INVOICE TOTAL								**$4,352.38**
	CARTON TRACKING NUMBERS: CTN#1 1Z7156794292759557 Additional License Information State License for MD - Origin D03211 Exp 05/31/21 State License for NV - Destination PHN03347 Exp 10/31/22								
	PLEASE NOTE OUR NEW REMIT TO ADDRESS								

Cartons: 1 | Weight: 0.5

* Non-Taxable

SafeChain Solutions

Invoice

Inv Number
01143600
Page: 1

SAFE CHAIN SOLUTIONS, LLC
822 CHESAPEAKE DRIVE
CAMBRIDGE, MD 21613

Tel: 855-437-5727
Fax: 866-930-1128
RS0477617

Remit To:
Safe Chain Solutions, LLC
PO Box 479
Souderton, PA 18964

Tel: 855-437-5727
Fax:

www.safechain.com
accounting@safechain.com

Bill-to: 14-NV0100

AMERICAN SPECIALTY PHARMACY INC
13988 DIPLOMAT DRIVE STE 100
ATTN: ACCTS PAYABLE
FARMERS BRANCH TX 75234

Ship-to: PHAR 001

ASPCARES - LAS VEGAS
501 S RANCHO DRIVE G46
ATTN: KEVIN
LAS VEGAS NV 89106

Invoice Date:	02/23/21	Salesman:	Blackstone
Ship Date:	02/23/21	Ship Via:	UPS Ground
Our Order No:	01S38653004	Customer Order #:	323170
		Terms:	NET 30
License	PHN03347	DEA #	FA5224530 Exp:06/30/21 LicExp:10/31/22
Special Instructions:			

Line	Item Number / Description	Ordered	UM	Shipped	UM	B/O Qty	Unit Price	UM	Extension
1	61958-2501-01 BIKTARVY 30CT NDC#: 61958-2501-01 Prod Strength: 50-200-25 MG Prod Size: 30 EA	20	EA	20	EA	0	3224.06*	EA	64,481.20
	Lot #: CDMGSA			3					
	Expiration Date: 10/31/22								
	Lot #: 022054			2					
	Expiration Date: 11/30/22								
	Lot #: CDMHBA			2					
	Expiration Date: 11/30/22								
	Lot #: CDMHCA			2					
	Expiration Date: 11/30/22								
	Lot #: CDSDYA			3					
	Expiration Date: 11/30/22								
	Lot #: 022058			1					
	Expiration Date: 12/31/22								
	Lot #: CDSDZA			1					
	Expiration Date: 12/31/22								
	Lot #: 022053			2					
	Expiration Date: 12/31/22								
	Lot #: 022055			2					
	Expiration Date: 12/31/22								
	Lot #: 022057			2					
	Expiration Date: 12/31/22								
2	61958-1901-01 GENVOYA TAB 30CT NDC#: 61958-1901-01 Prod Strength: 150-150-200-10 MG Prod Size: 30 EA	5	EA	5	EA	0	3224.06*	EA	16,120.30
	Lot #: 020478			1					
	Expiration Date: 12/31/22								

CONTINUED

Cartons: 1 | Weight: 4.5

* Non-Taxable

SafeChain Solutions

Invoice

Inv Number
01143600
Page: 2

SAFE CHAIN SOLUTIONS, LLC
822 CHESAPEAKE DRIVE
CAMBRIDGE, MD 21613

Tel: 855-437-5727
Fax: 866-930-1128
RS0477617

Remit To:
Safe Chain Solutions, LLC
PO Box 479
Souderton, PA 18964

Tel: 855-437-5727
Fax:

www.safechain.com
accounting@safechain.com

Bill-to: 14-NV0100

AMERICAN SPECIALTY PHARMACY INC
13988 DIPLOMAT DRIVE STE 100
ATTN: ACCTS PAYABLE
FARMERS BRANCH TX 75234

Ship-to: PHAR 001

ASPCARES - LAS VEGAS
501 S RANCHO DRIVE G46
ATTN: KEVIN
LAS VEGAS NV 89106

Invoice Date:	02/23/21	Salesman:	Blackstone
Ship Date:	02/23/21	Ship Via:	UPS Ground
Our Order No:	01S38653004	Customer Order #:	323170
		Terms:	NET 30
License	PHN03347 Exp: 10/31/22	DEA #	FA5224530 Exp:06/30/21 LicExp:10/31/22
Special Instructions:			

Line	Item Number / Description	Ordered	UM	Shipped	UM	B/O Qty	Unit Price	UM	Extension
	Lot #: 020716 Expiration Date: 12/31/22			1					
	Lot #: 021357 Expiration Date: 01/31/23			3					
	SUB TOTAL								**80,601.50**
	INVOICE TOTAL								**$80,601.50**
	CARTON TRACKING NUMBERS: CTN#1 1Z7156794295616482 Additional License Information State License for MD - Origin D03211 Exp 05/31/21 State License for NV - Destination PHN03347 Exp 10/31/22								
	PLEASE NOTE OUR NEW REMIT TO ADDRESS								

Multiple Page Invoice Page: 2

Cartons: 1 | Weight: 4.5

* Non-Taxable

SafeChain Solutions

Invoice

Inv Number
01143602
Page: 1

SAFE CHAIN SOLUTIONS, LLC
822 CHESAPEAKE DRIVE
CAMBRIDGE, MD 21613

Tel: 855-437-5727
Fax: 866-930-1128
RS0477617

Remit To:
Safe Chain Solutions, LLC
PO Box 479
Souderton, PA 18964

Tel: 855-437-5727
Fax:

www.safechain.com
accounting@safechain.com

Bill-to: 14-NV0100

AMERICAN SPECIALTY PHARMACY INC
13988 DIPLOMAT DRIVE STE 100
ATTN: ACCTS PAYABLE
FARMERS BRANCH TX 75234

Ship-to: PHAR 001

ASPCARES - LAS VEGAS
501 S RANCHO DRIVE G46
ATTN: KEVIN
LAS VEGAS NV 89106

Invoice Date:	02/23/21	Salesman:	Blackstone
Ship Date:	02/23/21	Ship Via:	UPS Ground
Our Order No:	01S38653002	Customer Order #:	323170
		Terms:	NET 30
License	PHN03347 Exp: 10/31/22	DEA #	FA5224530 Exp:06/30/21 LicExp:10/31/22
Special Instructions:			

Line	Item Number / Description	Ordered	UM	Shipped	UM	B/O Qty	Unit Price	UM	Extension
1	49702-0231-13 TRIUMEQ NDC#: 49702-0231-13 Prod Strength: 600-50-300 MG Prod Size: 30 EA	5	EA	5	EA	0	3022.79*	EA	15,113.95
	Lot #: 7N9K			1					
	Expiration Date: 08/31/22								
	Lot #: 7N9J			3					
	Expiration Date: 08/31/22								
	Lot #: 2T4G			1					
	Expiration Date: 08/31/22								
	SUB TOTAL								**15,113.95**
	INVOICE TOTAL								**$15,113.95**
	CARTON TRACKING NUMBERS: CTN#1 1Z7156794297316516 Additional License Information State License for MD - Origin D03211 Exp 05/31/21 State License for NV - Destination PHN03347 Exp 10/31/22								
	PLEASE NOTE OUR NEW REMIT TO ADDRESS								

Cartons: 1 | Weight: 0.9

* Non-Taxable

SafeChain Solutions

Invoice

Inv Number
01143603
Page: 1

SAFE CHAIN SOLUTIONS, LLC
822 CHESAPEAKE DRIVE
CAMBRIDGE, MD 21613

Tel: 855-437-5727
Fax: 866-930-1128
RS0477617

Remit To:
Safe Chain Solutions, LLC
PO Box 479
Souderton, PA 18964

Tel: 855-437-5727
Fax:

www.safechain.com
accounting@safechain.com

Bill-to: 14-NV0100
AMERICAN SPECIALTY PHARMACY INC
13988 DIPLOMAT DRIVE STE 100
ATTN: ACCTS PAYABLE
FARMERS BRANCH TX 75234

Ship-to: PHAR 001
ASPCARES - LAS VEGAS
501 S RANCHO DRIVE G46
ATTN: KEVIN
LAS VEGAS NV 89106

Invoice Date:	02/23/21	Salesman:	Blackstone
Ship Date:	02/23/21	Ship Via:	UPS Ground
Our Order No:	01S38653003	Customer Order #:	323170
		Terms:	NET 30
License	PHN03347 Exp: 10/31/22	DEA #	FA5224530 Exp:06/30/21 LicExp:10/31/22
Special Instructions:			

Line	Item Number / Description	Ordered	UM	Shipped	UM	B/O Qty	Unit Price	UM	Extension
1	49702-0228-13 TIVICAY 50MG TAB 30CT NDC#: 49702-0228-13 Prod Strength: 50 MG Prod Size: 30 EA Lot #: 8N2W Expiration Date: 10/31/24 Lot #: HC6L Expiration Date: 01/31/25	2	EA	2 1 1	EA	0	1820.87*	EA	3,641.74
	SUB TOTAL								**3,641.74**
	INVOICE TOTAL								**$3,641.74**
	CARTON TRACKING NUMBERS: CTN#1 1Z7156794295816122 Additional License Information State License for MD - Origin D03211 Exp 05/31/21 State License for NV - Destination PHN03347 Exp 10/31/22								
	PLEASE NOTE OUR NEW REMIT TO ADDRESS								

Cartons: 1 | Weight: 0.2

* Non-Taxable

SafeChain Solutions

Invoice

Inv Number
01143613
Page: 1

SAFE CHAIN SOLUTIONS, LLC
822 CHESAPEAKE DRIVE
CAMBRIDGE, MD 21613

Tel: 855-437-5727
Fax: 866-930-1128
RS0477617

Remit To:
Safe Chain Solutions, LLC
PO Box 479
Souderton, PA 18964

Tel: 855-437-5727
Fax:

www.safechain.com
accounting@safechain.com

Bill-to: 14-NV0100

AMERICAN SPECIALTY PHARMACY INC
13988 DIPLOMAT DRIVE STE 100
ATTN: ACCTS PAYABLE
FARMERS BRANCH TX 75234

Ship-to: PHAR 001

ASPCARES - LAS VEGAS
501 S RANCHO DRIVE G46
ATTN: KEVIN
LAS VEGAS NV 89106

Invoice Date:	02/23/21	Salesman:	Blackstone
Ship Date:	02/23/21	Ship Via:	UPS Ground
Our Order No:	01S38653005	Customer Order #:	323170
		Terms:	NET 30
License	PHN03347 Exp: 10/31/22	DEA #	FA5224530 Exp:06/30/21 LicExp:10/31/22
Special Instructions:			

Line	Item Number / Description	Ordered	UM	Shipped	UM	B/O Qty	Unit Price	UM	Extension
1	61958-2002-01 DESCOVY TAB 30CT NDC#: 61958-2002-01 Prod Strength: 200-25 MG Prod Size: 30 EA	5	EA	5	EA	0	1834.17*	EA	9,170.85
	Lot #: 022033			2					
	Expiration Date: 03/31/23								
	Lot #: 019695			1					
	Expiration Date: 04/30/23								
	Lot #: 019696			1					
	Expiration Date: 04/30/23								
	Lot #: 019699			1					
	Expiration Date: 04/30/23								
	SUB TOTAL								**9,170.85**
	INVOICE TOTAL								**$9,170.85**
	Additional License Information State License for MD - Origin D03211 Exp 05/31/21 State License for NV - Destination PHN03347 Exp 10/31/22								
	PLEASE NOTE OUR NEW REMIT TO ADDRESS								

Cartons: 0 | Weight: 0.0

* Non-Taxable

Invoice

SAFE CHAIN SOLUTIONS, LLC
322 CHESAPEAKE DRIVE
CAMBRIDGE, MD 21613

Tel: 855-437-5727
Fax: 866-930-1128
RS0477617

Remit To:
Safe Chain Solutions, LLC
PO Box 479
Souderton, PA 18964

Tel: 855-437-5727
Fax:

www.safechain.com
accounting@safechain.com

Page

Bill-to: 14-NV0100

AMERICAN SPECIALTY PHARMACY INC
13988 DIPLOMAT DRIVE STE 100
ATTN: ACCTS PAYABLE
FARMERS BRANCH TX 75234

Ship-to: PHAR 001

ASPCARES - LAS VEGAS
501 S RANCHO DRIVE G46
ATTN: KEVIN
LAS VEGAS NV 89106

Invoice Date:	02/22/21	Salesman:	Blackstone
Ship Date:	02/22/21	Ship Via:	UPS Ground
Our Order No:	01S39548001	Customer Order #:	330010
		Terms:	NET 30

License: PHN03347 Exp: 10/31/22 DEA # FA5224530 Exp: 06/30/21 LicExp: 3[illegible]22

Qty / Description	Ordered	UM	Shipped	UM	B/O Qty	Unit Price	UM	
14-0[illegible]20								
TRULANCE 3MG TAB 30CT BP	2	EA	2	EA	0	433.29	EA	866.58
NDC#: 70194-0003-30								
Prod Strength: 3 MG								
Prod Size: 30 EA								
Lot #: 1627708			1					
Expiration Date: 02/28/22								
Lot #: 1659417			1					
Expiration Date: 06/30/22								
SUB TOTAL								866.58
INVOICE TOTAL								$866.58
CARTON TRACKING NUMBERS:								
CTN#1 1Z715679429450909[illegible]								
Additional License Information								
State License for MD - Origin								
D03211 Exp 05/31/21								
State License for NV - Destination								
PHN03347 Exp 10/31/22								
[illegible]								
[illegible] NEW PERMIT TO ADDRESS								
[illegible]								
[illegible]								

RECEIVED
MAR 01 2021

Cartons: 1 Weight: 0.9

* Non-Taxable

Exhibit F
24-356-WH-O
Safe Chain Solutions

WARNING LETTER

Safe Chain Solutions, LLC

MARCS-CMS 636044 — JUNE 08, 2023

Delivery Method:

Via Email

Product:

Drugs

Recipient:

Mr. Charles D. Boyd

Founder and Chief Executive Officer

Safe Chain Solutions, LLC

822 Chesapeake Drive

Cambridge, MD 21613-9408

United States

Issuing Office:

Division of Pharmaceutical Quality Operations I

United States

Warning Letter #636044

June 08, 2023

Dear Mr. Boyd:

The U.S. Food and Drug Administration (FDA) inspected your wholesale drug distribution facility, Safe Chain Solutions, LLC (Safe Chain), FEI 3009729473, at 822 Chesapeake Drive, Cambridge, Maryland from April 11 to May 11, 2022.

The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54), enacted by Congress on November 27, 2013, added Section 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 582 of the FD&C Act (21 U.S.C. 360eee-1) states the requirements that certain entities in the pharmaceutical distribution supply chain (including wholesale drug distributors) must follow related to product tracing, verification, and authorized trading partners. This warning letter summarizes significant violations of the requirements found in section 582(c) of the FD&C Act. These requirements are intended to help preserve the security of the supply chain for certain prescription drug products, thereby protecting patients from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful.

FDA issued a Form FDA 483 to Safe Chain at its Cambridge, MD headquarters on May 10, 2022. FDA reviewed your firm's response, dated June 1, 2022.

FDA has observed that Safe Chain did not have adequate verification systems in place in violation of section 582(c)(4)(A) & (B) of the FD&C Act. FDA observed that Safe Chain failed to maintain records regarding suspect product investigations in violation of section 582(c)(4)(A)(iii) of the FD&C Act, and failed to respond to a notification of illegitimate product in violation of section 582(c)(4)(B)(iii) of the FD&C Act. In addition, Safe Chain engaged in transactions with unauthorized trading partners in violation of section 582(c)(3) of the FD&C Act. Failure to comply with any of the requirements under section 582 of the FD&C Act is a prohibited act under section 301(t) of the FD&C Act (21 U.S.C. 331(t)).

DSCSA Violations

During FDA's inspection, our investigators observed that your firm failed to comply with various requirements of the DSCSA. Specific violations include, but may not be limited to, the following:

1. Your firm failed to have systems in place to enable compliance with the verification requirements of the DSCSA (FD&C Act Section 582(c)(4)(A) & (B)).

Under section 582(c)(4)(A) & (B) of the FD&C Act, wholesale drug distributors must have systems in place to enable the wholesale distributor to comply with the verification requirements of the DSCSA.

Your firm was not able to demonstrate systems that would enable Safe Chain to comply with a number of verification requirements required by the DSCSA. For example, your document, "Standard Operating Procedure for Suspect & Illegitimate Product" (Suspect & Illegitimate Product SOP) (re-issue date 3/15/21) lacked sufficient detail or instruction to enable Safe Chain to adequately:

o Identify suspect product,[1]
o Conduct an investigation (including validating any applicable transaction history and transaction information) to determine whether a suspect product is an illegitimate product in coordination with trading partners,
o Handle an illegitimate product notification,
o Handle a request for verification of a suspect product from FDA,
o Make notifications of cleared product, and
o Maintain adequate records relating to the investigation of suspect product or the disposition of illegitimate product.

Your firm's failure to establish and implement systems to enable your compliance with these DSCSA requirements may have resulted in suspect product entering the supply chain rather than the product being quarantined as required by section 582(c)(4)(A)(i)(I) of the FD&C Act. For example, an email from February 6, 2021 from the California Board of Pharmacy to Safe Chain, explains that Safe Chain distributed Gentek lot CCXKVA (discussed in more detail in section 2 below) to White Cross Pharmacy and that this lot lacked the required **(b)(4)** and the original induction seal had been removed and replaced with a non-genuine seal.[2] A physical examination of the product may have prevented the lot from being distributed.

Your firm's Suspect & Illegitimate Product SOP also contained information inconsistent with the DSCSA. Specifically, the SOP stated that if "SCS [Safe Chain Solutions] receives confirmation the product is illegitimate or potentially fraudulent an FDA form 3911 will be filed. Disposition of the product will depend on guidance received from the FDA." As written, this SOP indicated that the firm is expecting guidance from FDA upon submission of a 3911, and disposition of the product depends on such guidance. However, disposition of illegitimate product is your responsibility and is not dependent on FDA's response to a FDA Form 3911. (FD&C Act section 582(c)(4)(B)).

In addition, your document "Standard Operating Procedures for Vendor and Transaction History Authentication" (re-issue date 4/1/21) contained information inconsistent with the DSCSA. The document indicated that in case of "**(b)(4)**," your firm should contact the Maryland Board of Pharmacy and the FDA within 3 days. However, the DSCSA requires a trading

partner that determines a product in its possession or control is an illegitimate product to notify the FDA within 24 hours of making such a determination. (FD&C Act section 582(c)(4)(B)(ii)). (FDA understands **"(b)(4).**

Your lack of sufficient written procedures, or other systems related to compliance with the verification requirements of the DSCSA, rendered your firm unable to demonstrate compliance with the verification requirements of the section 582(c)(4) of the FD&C Act.

2. Your firm conducted transactions with trading partners that were not authorized (FD&C Act Section 582(c)(3)).

The DSCSA requires that trading partners of wholesale distributors meet the applicable requirements for being *authorized* trading partners. (FD&C Act Section 582(c)(3)). To be authorized, a wholesale drug distributor must have a valid license under State law or section 583 of the FD&C Act, in accordance with section 582(a)(6) of the FD&C Act, and comply with the licensure reporting requirements in section 503(e) of the FD&C Act. (FD&C Act Section 581(2)(B)). Under section 503(e)(2)(A) of the FD&C Act, wholesale distributors must report to FDA, on an annual basis, "each State by which the person is licensed and the appropriate identification number of each such license; the name, address, and contact information of each facility at which, and all trade names under which, the person conducts business;" and "any significant disciplinary actions."

Your firm has a written procedure to verify a trading partner's status, "Standard Operating Procedures for Trading Partner Validation" (re-issue date of 3/15/21) (Trading Partner Validation SOP). This procedure recognizes that **(b)(4)** as defined by the DSCSA. Your Trading Partner Validation SOP even goes so far as to provide the link to FDA's publicly accessible database of WDDs and 3PLs that have reported their state licensure status to FDA: https://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/index.cfm. Your firm, however, did not adhere to this SOP and failed to verify that all of your trading partners reported licensure information to FDA.

Between July, 2020 and March, 2021, your firm purchased drug products from wholesale drug distributors that were not authorized trading partners according to sections 581(2) and 503(e) of the FD&C Act. For example, your firm purchased prescription drug products from wholesale distributors Gentek and Boulevard 9229 LLC. However, FDA has no record of Gentek or Boulevard 9229 LLC ever submitting the required annual reports to FDA regarding state licensure as required by section 503(e) of the FD&C Act. In addition, Boulevard 9229 LLC provided your firm with a fraudulent license. Therefore, Boulevard 9229 LLC not only failed to report to FDA, but it was also never appropriately licensed as required by section 503(e)(1)(A) and 582(a)(6) of the FD&C Act.

The importance of the requirement that trading partners of wholesale distributors be authorized is highlighted by the fact that, on multiple occasions, your firm was notified that it had received prescription drug products containing different medication than was purported to be present based on the product labeling, making those products suspect product and unfit for distribution. For example, on multiple occasions your firm was notified by trading partners that patients reported receiving bottles of a product labeled as Biktarvy (bictegravir, emtricitabine and tenofovir alafenamide) that in fact contained different tablets instead of the Biktarvy tablets.

- Your firm purchased Biktarvy (lot CCXKVA) from Gentek on July 28, 2020. Subsequently, on July 29, 2020, your firm sold bottles from this lot to pharmacy trading partner White Cross. On November 23, 2020, Gilead Sciences, Inc., the manufacturer of Biktarvy, notified your firm that a bottle from lot CCXKVA that was dispensed by White Cross to a patient contained different tablets instead of Biktarvy tablets.
- On September 30, 2020, your firm purchased Biktarvy from Gentek (lot CDFYCA) and subsequently sold it to Medicine Shoppe Pharmacy #1802. On October 14, 2020, your firm was notified through an email from World Wide Pharma Sales that a patient returned a bottle of Biktarvy (lot CDFYCA) to the pharmacy because it contained a different medication than was purported to be present based on the product labeling. Furthermore, in another email from World Wide Pharma Sales, from November 24, 2020, you were notified of yet another patient complaint

concerning lot CDFYCA. A second patient had retuned a bottle of Biktarvy (lot CDFYCA) to the same pharmacy because it also contained a different medication than was purported to be present based on the product labeling.

- On January 7, 2021, your firm purchased Biktarvy from Gentek for a third time (lot CCZCFA), having already been informed that two prior lots purchased from this firm contained bottles of a medication that was different than what was purported to be present based on the product labeling. Safe Chain subsequently sold the product to Medicine Shoppe Pharmacy #1802. Safe Chain discovered that the drug product purchased in this third lot also contained multiple tablets of a different product than should have been present based on the product's label. A letter from Safe Chain to Gilead indicates that your firm knew of the issue with this third lot by February 12, 2021.
- On March 1, 2021, your firm purchased Biktarvy (lot CDSFFA) from Boulevard 9229 LLC. In a letter to your customer, dated March 27, 2021, Safe Chain reported a quality complaint regarding this product. The drug product purchased contained multiple tablets of a different product than should have been present based on the product's label.

These instances are especially concerning from a public health perspective given that Biktarvy is indicated to treat a serious health condition, HIV-1 infection, and the recommended dosage for adult and pediatric patients is one pill daily. As explained in the Patient Counseling Information section of the Prescribing Information for Biktarvy, "it is important to take BIKTARVY on a regular dosing schedule with or without food and to avoid missing doses as it can result in development of resistance." Patients who receive the wrong drug product from the pharmacy may not be able to take the prescribed dose in a timely manner which can cause serious adverse health consequences. In addition, FDA-approved Biktarvy bears a boxed warning, commonly referred to as a "black box warning," which is the strongest warning FDA requires, indicating that the drug carries a significant risk of serious and even life-threatening adverse effects. The boxed warning addresses risks including post treatment acute exacerbation of Hepatitis B.

Your firm continued to purchase product from the same unauthorized trading partners, which resulted in acquiring more suspect product from those entities after they had previously sold you suspect product. This is extremely concerning from a public health perspective given the serious health condition Biktarvy is indicated for. In FDA's 2016 final guidance *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification*, FDA warns trading partners that purchasing from a source that a trading partner knows or has reason to believe has engaged in questionable business practices could significantly increase the chance of suspect product entering the pharmaceutical distribution supply chain.

3. Your firm failed to maintain records of suspect product investigations (FD&C Act Section 582(c)(4)(A)(iii)).

The DSCSA requires that wholesale distributors maintain records of investigations of suspect product for not less than 6 years. (FD&C Act section 582(c)(4)(A)(iii)). Your firm was both unable to provide any written documentation of what products were held in or released from quarantine, and unable to provide records explaining how suspect product was quarantined. In addition, while you were able to produce some correspondence pertaining to the various lots of suspect product, you were unable to provide records about when and how investigations took place to determine whether suspect product was illegitimate.

For example, in a letter from Safe Chain's outside counsel to Gilead, dated February 12, 2021, you indicate that you would quarantine Biktarvy lot CCZCFA when it was returned to you by the dispenser. The letter explains that Safe Chain notified your immediate trading partner, but does not clarify whether you were referring to a dispenser trading partner or your supplier, Gentek. Your letter also explains that Gentek advised you to destroy the product. However, you were not able to produce records demonstrating that you quarantined the product, any notice you shared about the suspect product with Gentek or other immediate trading partners, or records of the disposition of the product.

Also, your firm could not produce adequate records pertaining to three other suspect product investigations for which Safe Chain made notifications of illegitimate product to the FDA using Form FDA 3911. These Form FDA 3911s were submitted on March 25, 2021 (lots CCXKVA and CDFYCA), March 27, 2021 (lot CDSFFA), and April 7, 2021 (Lot CCZCFA was

included on the March 25, 2021 Form FDA 3911 as well.) While these FDA Form 3911s provide some insight into actions Safe Chain claims to have taken, you were not able to provide documentation supporting these actions. As a result, FDA is unable to determine if, or at what point, the drugs referred to in the FDA Form 3911s were appropriately quarantined, as required by section 582(c)(4)(A)(i)(I) of the FD&C Act, and whether investigations were conducted in coordination with trading partners, as required by section 582(c)(4)(A)(i)(II) of the FD&C Act.

4. Your firm failed to respond to a notification of illegitimate product (FD&C Act Section 582(c)(4)(B)(iii)).

Upon receiving a notification of illegitimate product, a wholesale distributor must identify all illegitimate product subject to such notification in its possession or control, including any product that is subsequently received. (FD&C Act section 582(c)(4)(B)(iii)). You are also required to quarantine such product within your possession or control from product intended for distribution (FD&C Act sections 582(c)(4)(A)(i)(I) and 582(c)(4)(B)(i)(I)) and investigate the product as suspect product (FD&C Act sections 582(c)(4)(A)(i)(II) and 582(c)(4)(B)(iii)). You were not able to provide evidence that you appropriately responded to notifications of illegitimate product.

For example, you emailed Gilead regarding Biktarvy Lot CDGXKA in October 2020. You were informed in an email response from Gilead to Safe Chain dated October 9, 2020, that the transaction history in your records was inconstant with Gilead's records and that Gilead considers the product to be illegitimate product. You were not able to provide any further information about Lot CDGXKA and whether your firm investigated or quarantined the product.

Your Response to the FDA Form 483

FDA has reviewed your June 1, 2022 response to our Form FDA 483 in detail and your response is inadequate for the following reasons:

- FDA understands that your firm hired a third-party consulting firm after FDA's inspection to assist in reviewing and enhancing all the company's SOPs. However, your firm's new SOP, "Handling and Reporting Suspect and/or Illegitimate Products" (effective 5/5/22) contains information not consistent with the DSCSA. For example, the SOP indicates that immediate trading partners be notified **(b)(4)** after Safe Chain makes a determination that product in its possession or control is illegitimate product. FDA reiterates that the DSCSA requires immediate trading partners to be notified within 24 hours of an illegitimate product determination. (FD&C Act section 582(c)(4)(B)(ii)). FDA notes that the revised SOP you provided, "Vendor and Transaction History Authentication" (effective 5/9/15) is updated with the correct time-frame. However, the inconsistency between the two SOPs creates the potential for significant confusion and untimely notification.
- In your response you state that you have: "...NEVER knowingly purchased illegitimate products from any of our Vendors..." (emphasis in original). You explain that you continued to purchase products from Gentek, and did not cease sales of the product, even after becoming aware of issues with product received from the firm because the products were part of an ongoing investigation and you believed the issue was at the retailer/pharmacy level.

Your response is inadequate because you failed to provide any documentation demonstrating the rationale for your belief that the issue was at the retailer/pharmacy level. If your firm had conducted the required investigations, which would have included your firm's knowledge of reported issues with the drug, you may have recognized the inherent risk of these Gentek products to the supply chain. Furthermore, your response appears to acknowledge that your efforts to look into the problematic product was limited to Safe Chain and Safe Chain's attorneys. If this is the case, this is inadequate because the DSCSA requires that investigations of suspect product take place in coordination with trading partners. (FD&C Act section 582(c)(4)(A)(i)(II)).

DSCSA Resources

As explained above, your firm has failed to comply with a number of DSCSA provisions. Please see the FDA guidance documents listed below for additional information about the DSCSA requirements noted above:[3]

- Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification, Final Guidance, June 2021, https://www.fda.gov/media/88790/download
- Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act, Final Guidance for Industry, March 2023, https://www.fda.gov/media/111468/download.
- Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs, Draft Guidance for Industry, March 2022, https://www.fda.gov/media/117950/download.
- Identifying Trading Partners Under the Drug Supply Chain Security Act, Draft Guidance for Industry, July 2022, https://www.fda.gov/media/159621/download.

Conclusion

Safe Chain's response to FDA Form 483 does not indicate that sufficient remediation efforts have been taken. FDA is sending this compliance letter to Safe Chain because of the inherent risk to the supply chain when firms do not comply with the provisions of the DSCSA.

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist at your facility. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations.

Correct any violations promptly. Failure to promptly and adequately address these violations may result in regulatory or legal action without further notice, including seizure and injunction.

This letter notifies you of our findings and provides you an opportunity to address the above deficiencies. After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done to address any violations and to prevent their recurrence. In response to this letter, you may provide additional information for our consideration as we continue to assess your activities and practices. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Please send your electronic reply to ORAPHARM1_Responses@FDA.HHS.GOV and "cc" Compliance Officer, Emmanuel Ramos (Emmanuel.Ramos@fda.hhs.gov). Your written notification should refer to the Warning Letter #636044 and include FEI number 3009729473.

If you have questions regarding the contents of this letter, please contact Emmanuel Ramos, Compliance Officer, via email at Emmanuel.Ramos@fda.hhs.gov or by telephone at 240-507-7119.

Sincerely,
/S/

Lisa Harlan
Program Division Director
Office of Pharmaceutical Quality Operations, Division I
U.S. Food & Drug Administration

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1 "Suspect product" and "illegitimate product" are defined in sections 581(21) and (8) of the FD&C Act, respectively.

2 Trading partners should be mindful of product that is missing required information or security features, as that may indicate the product should be considered suspect. See FDA's 2016 final *guidance Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification*.

3 Draft guidances, when finalized, will represent the agency's current thinking on the topic.

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAFE CHAIN SOLUTIONS, LLC, Wholesaler License No. WH02131,** **Respondent.**	**CASE NO. 24-356-WH-O** **MEMORANDUM OF ATTORNEY'S FEES AND COSTS**

Pursuant to NRS 622.400, the undersigned hereby submits the following itemized bill of costs and reasonable attorney's fees incurred by the Nevada State Board of Pharmacy in connection with the investigation and prosecution of the above-entitled administrative action.

Investigative Time - Dena McClish				
Date(s)	Description	Hours	Rate	Amount
08/22/24	Research, court case review	1.75	$53.00/hr	$92.75
8/29/24	Report writing	1.00	$53.00/hr	$53.00
9/11/24	Review & submit	0.75	$53.00/hr	$39.75
Subtotal (Investigation): $185.50				
Attorney Time - Brett Kandt				
Date(s)	Description	Hours	Rate	Amount
9/27/24	Confer with staff and review investigative case file in case 24-356-WH-O; research, draft and serve cease-and-desist order.	4.25	$86.50/hr	$367.62
9/30/24	Confer with staff and finalize and serve cease-and-desist order.	1.50	$86.50/hr	$129.75

Exhibit G

10/1/24	Confer with staff; research and draft Notice of Intended Action and Accusation.	5.00	$86.50/hr	$432.50
10/2/24	Confer with staff; research and finalize Notice of Intended Action and Accusation for filing and service.	2.50	$86.50/hr	$216.25
11/6/24	Confer with counsel for respondent and grant extension to file Answer and Notice of Defense.	0.50	$86.50/hr	$43.25
11/10/24	Confer with counsel for respondent re: merits of case and request for continuance.	0.25	$86.50/hr	$21.62
11/12/18	Confer with staff and counsel for respondent re: discovery request.	0.25	$86.50/hr	$21.62
11/18/24	Confer with staff and counsel for respondent re: discovery production.	1.25	$86.50/hr	$108.12
11/20/24	Confer with staff and counsel for respondent re: hearing date and request for continuance.	0.50	$86.50/hr	$43.25
11/26/24	Confer with staff and counsel for respondent re: motion for continuance; research and draft/file response to motion.	4.50	$86.50/hr	$389.25
11/27/24	Review Answer and Notice of Defense.	1.50	$86.50/hr	$129.75

12/2/24	Review reply on motion for continuance; confer with staff on invoices, review prep for hearing.	2.75	$104.00/hr	$286.00
12/3/24	Confer with staff and counsel for respondent on hearing and exhibits.	1.00	$104.00/hr	$104.00
12/4/24	Confer with staff and counsel for respondent; stipulate to continuance of hearing.	1.00	$104.00/hr	$104.00
12/17/24	Proposal to counsel on exhibits.	0.25	$104.00/hr	$26.00
12/30/24	Review Amended Answer and Notice of Defense	0.50	$104.00/hr	$52.00
1/4/25	Confer with staff and counsel for respondent on Amended Answer and potential stipulated facts and exhibits for hearing.	1.75	$104.00/hr	$182.00
1/6/25	Confer with staff and counsel for respondent on hearing and exhibits.	0.50	$104.00/hr	$52.00
1/7/25	Confer with staff and counsel for respondent on exhibits; prep for hearing.	2.50	$104.00/hr	$260.00
1/9/25	Confer with staff; prepare memorandum of attorney's fees and costs; submit to respondent; draft proposed findings of fact, conclusions of law and order.	2.25	$104.00/hr	$234.00
1/15/25	Hearing in case 24-356-WH-O; finalize order.	1.00	$104.00/hr	$104.00
Subtotal (Attorney Time): $3,306.98				

Staff Time				
Date(s)	Description	Hours	Rate	Amount
9/30/24	Jessette Phaynarikone served Cease & Desist Order via certified mail.	0.25	$25.00/hr	$6.25
10/9/24	Darlene Nases served Accusation via certified/regular mail.	0.50	$25.00/hr	$12.50
10/31/24	Jessette Phaynarikone served Notice of Hearing for December 4, 2025.	0.50	$25.00/hr	$12.50
0.9811/18/24	Jessette Phaynarikone compiled discovery file.	0.30	$25.00/hr	$7.50
12/24/24	Jessette Phaynarikone served Notice of Hearing for January 15, 2025.	0.50	$25.00/hr	$12.50
Subtotal (Staff Time): $38.75				
Additional Recoverable Costs: Postage/Mailing Costs: $52.87				
Total Attorney's Fees and Recoverable Costs: $3,584.10				

I, Brett Kandt, affirm, to the best of my knowledge and belief, that the foregoing is a true and correct statement of reasonable attorney's fees and recoverable costs incurred by the Board in the above-entitled action.

DATED this 9th day of January, 2025.

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

Roles and Responsibilities for Chief Operating Officer

The Chief Operating Officer (COO) is a senior executive responsible for managing the day-to-day operations of a company. The COO is responsible for working closely with other executives and consultants to develop and implement strategies that enhance efficiency, drive growth, and ensure the company's long-term success. Roles are as follows (but not limited to):

1. **Operational Management**
    - Oversee daily operations of the company, ensuring efficient and effective business processes.
    - Implement operational strategies, plans, and procedures to improve productivity and performance.
    - Monitor key performance indicators (KPIs) to assess the effectiveness of business operations.
2. **Strategic Planning**
    - Collaborate with the executive team to develop long-term business strategies.
    - Translate strategic goals into actionable plans for departments and teams.
    - Lead the execution of the company's business strategies to achieve growth and profitability.
3. **Team Leadership and Development**
    - Manage and mentor department heads and senior managers to foster a high-performance culture.
    - Drive the recruitment, training, and retention of talent to build a skilled and motivated workforce.
    - Ensure alignment of departmental goals with the overall company objectives.
4. **Financial Oversight**
    - Work closely with the financial consultants to develop budgets, forecast financial needs, and monitor financial performance.
    - Identify cost-saving opportunities and ensure efficient allocation of resources.
    - Manage operational costs to maximize profitability while maintaining high service standards.
5. **Process Improvement and Innovation**
    - Identify areas for process improvement and drive initiatives to enhance efficiency and effectiveness.
    - Implement new technologies and systems to streamline operations and support business growth.
    - Lead change management efforts to adapt to market dynamics and internal process shifts.
6. **Risk Management and Compliance**
    - Ensure that all business operations comply with relevant laws, regulations, and standards.
    - Identify potential risks to the business and develop strategies to mitigate them.
    - Establish and enforce company policies and procedures.
    - Work closely with Compliance Officer to ensure adherence to all pharmaceutical laws and regulations and to maintain an ongoing evaluation of all existing policies and procedures.
    - Work closely with all compliance consultants and counsel, and Compliance Officer to monitor and manage ongoing changes in pharmaceutical distribution requirements with licensing authorities.
7. **Customer Experience Management**
    - Enhance the customer experience by ensuring consistent delivery of high-quality products or services.
    - Collaborate with sales, marketing, and customer service teams to meet customer expectations.

- Address customer complaints or operational issues that impact customer satisfaction.

8. **Stakeholder Communication**
   - Act as a key liaison between the executive team and other stakeholders.
   - Present operational performance updates to invested parties.
   - Foster strong relationships with external partners, suppliers, and vendors.
9. **Performance Monitoring and Reporting**
   - Develop and track performance metrics to evaluate operational effectiveness.
   - Implement corrective actions when performance does not meet established goals.
10. **Scaling and Expansion**
    - Support the company's growth initiatives, including market expansion, acquisitions, and new product launches.
    - Develop and implement scalable operational strategies to support business expansion.
    - Ensure that operational capacity meets current and future business demands.

SafeChain Solutions

Roles and Responsibilities for Senior Compliance Officer

The Senior Compliance Officer plays a critical role in ensuring that the company adheres to all regulatory requirements, industry standards, and internal policies. This role is vital in maintaining the integrity of the organization's operations, safeguarding public health, and minimizing legal and financial risks. Below are the roles and responsibilities of the Senior Compliance Officer (but not limited to):

Roles and Responsibilities the Senior Compliance Officer

1. **Regulatory Compliance Management**
    - Ensure compliance with relevant laws, regulations, and guidelines, including FDA, DEA, Local Boards of Pharmacy, and other applicable standards.
    - Monitor and interpret changes in federal, state, and local laws affecting the pharmaceutical industry. Work directly with legal counsel for formal interpretations and feedback on any changes to laws.
    - Develop and maintain a compliance calendar to ensure timely submission of reports, renewals, and regulatory filings.
    - Work closely with external consultants and counsel to ensure all company policies and procedures comply with federal, state and local laws.
2. **Policy and Procedure Development**
    - Develop, implement, and update company policies and procedures to ensure compliance with regulatory requirements.
    - Ensure that all policies and procedures are accessible, understood, and followed by employees.
    - Conduct regular reviews and updates of compliance manuals and documentation.
3. **Training and Education**
    - Design and deliver training programs for employees on compliance-related topics, such as good distribution practices, anti-bribery, and regulatory updates.
    - Ensure that staff is adequately trained in regulatory requirements and internal compliance standards.
    - Track and document employee training sessions to ensure compliance with mandatory training requirements.
4. **Auditing and Monitoring**
    - Conduct regular internal audits of operations, including inventory management, distribution practices, and record-keeping, to ensure compliance with regulations.
    - Monitor daily operations to detect potential compliance issues and ensure adherence to established policies.
    - Implement corrective actions for identified non-compliance and ensure follow-up to verify resolution.
5. **Licensing and Permits**
    - Ensure that the company and its facilities maintain all necessary licenses and permits to operate legally.
    - Manage the application, renewal, and maintenance of licenses, including state and federal controlled substances registrations.
    - Ensure compliance with state licensing requirements for all operating jurisdictions.

6. **Risk Assessment and Mitigation**
    - Identify compliance risks and develop strategies to mitigate potential regulatory, operational, and reputational risks.
    - Conduct risk assessments to evaluate the company's exposure to compliance risks.
    - Develop and implement action plans to address identified risks and prevent future occurrences.
7. **Incident Management and Reporting**
    - Investigate compliance-related incidents, such as product recalls, distribution errors, or regulatory violations.
    - Report significant compliance issues to senior management and regulatory authorities as required.
    - Maintain records of incidents, corrective actions, and communications with regulatory agencies.
8. **Documentation and Record Keeping**
    - Maintain accurate and up-to-date records of all compliance-related activities, including audit findings, corrective actions, and training records.
    - Ensure that documentation is readily available for regulatory inspections and audits.
    - Establish document retention policies in line with regulatory requirements.
9. **Regulatory Inspections and Responses**
    - Prepare the organization for regulatory inspections, audits, and site visits by external agencies.
    - Act as the primary point of contact during inspections and provide requested information to regulators.
    - Develop and manage responses to inspection findings, including corrective and preventive action plans.
10. **Collaboration with Other Departments**
    - Work closely with other departments, such as Operations, Processing/Purchasing, Legal, and IT, to ensure company-wide compliance.
    - Advise on compliance implications of new business initiatives, changes in processes, and product launches.
    - Collaborate with supply chain partners to ensure compliance across the distribution network.
11. **Ethics and Code of Conduct Enforcement**
    - Promote a culture of compliance and ethical conduct within the organization.
    - Investigate and address any breaches of the company's code of conduct or compliance policies.
12. **Performance Metrics and Reporting**
    - Develop compliance metrics and KPIs to measure the effectiveness of the compliance program.
    - Regularly report on compliance performance to senior management.
    - Use data analysis to identify trends, areas for improvement, and opportunities for enhancing the compliance program.

Title:	Standard Operating Procedures for **Drug Disposal**
Issue Date:	**05/2/2015**
Last Revised Date:	**09/17/2024**

Purpose:

To establish guidelines for the Compliance Department, VP of Operations and Warehouse Associates to refer to when completing drug disposal at Safe Chain Solutions.

Scope:

Safe Chain Solutions has an established relationship with Return Solutions, a licensed reverse distributor. Return Solutions is utilized at least once a quarter to dispose of or return expired, damaged and/or suspect or illegitimate inventory.

Responsibilities:

Warehouse Associate(s)	• Assist Return Solutions • Oversees all activities of Return Solutions. • Ensure all products on the receipt of goods are present.
VP of Operations	• Reviews and complete final paperwork with Return Solutions • Coordinate Freight pick up for returned products
Compliance Department	• Receive and complete the DEA 222 form for all controlled Schedule II products.

Procedures:

1. On the first of every month the Warehouse associates will collect all expired products from the prior month.
    a. All expired items will be removed from the sellable products shelves and quarantined in a separate location located inside the warehouse
2. The warehouse associates will organize all expired products.
3. The VP of Operations will coordinate with Return Solutions to ship products to Return Solutions.
4. In the case where a Return Solutions employee is **on site** at the SCS Warehouse, they will be supervised by a Safe Chain warehouse employee while working in the warehouse.
    a. Return Solutions employee organizes all expired products.
    b. For any controlled CII products, a 222 form must be filled out by Return Solutions.
        i. A copy must be provided to the Compliance Department for completion.

Exhibit 3

   c. Products are then boxed and sealed by the Warehouse Supervisor and a shipping label will be created from Return Solutions and shipped to Safe Chain Solutions.
   d. Once the shipping label is printed and affixed to the packaging, a pickup is scheduled.
      i. Packaged inventory scheduled for return will remain within the secure warehouse until it is picked up by freight.
   e. Upon completion of the return, DEA 222 forms are supplied to the compliance manager, and bill of lading is supplied to the warehouse manager.
5. If Return Solutions will **not be on site** at the SCS Warehouse, The VP of Operations will coordinate with Return Solutions for the RMA, Shipping labels, DEA 222 form (if required) and an inventory list to be dispositioned. Safe Chain employees are responsible for preforming the following steps:
   a. The warehouse associate will organize all expired products.
      i. Double checks will be performed by another warehouse associate to confirm the product Name, NDC, Lot number, and Expiration Date.
   b. For any controlled CII products, a 222 form must be filled out by Return Solutions.
      i. This is mailed by Return Solutions and received ahead of time
         1. The DEA 222 form will be completed by the Compliance Department by filling in the quantity shipped and the date the products were shipped.
   c. Products are then boxed and sealed by the warehouse associates and a shipping label will be printed.
   d. Once the shipping label is printed and affixed to the packaging, a pickup is scheduled.
      i. Packaged inventory scheduled for return will remain within the secure warehouse until it is picked up by freight.
   e. Upon completion of the return, DEA forms are filed within the compliance department, and bill of lading is supplied to the VP of Operations.
6. Access to current and past reports for view or print can be accessed at any time online.
   a. www.drugreturns.com
      i. Safe Chain keeps electronic records stored for up to 6 years, after that time, information is auto archived.
      ii. Records of disposal and credit can be found within our electronic records maintained by Return Solutions and accessible by our customer log-in.
7. For suspect and/or illegitimate products placed in quarantine, disposition of the product(s) in question will not take place until a thorough investigation has been completed.
   a. After completion of the investigation, the Compliance manager will initiate a request for termination of the 3911 forms via the CDER NextGen platform on the FDA website.
      i. Please note that the FDA considers a request to terminate the notification by a trading partner as a request for consultation, The FDA may request additional information to complete the consultation.
   b. Once completed, the Compliance manager will notify the VP of Operations to schedule disposition of the product, if the product is to be disposed of.

Exhibit 3

c. For full details surrounding suspect and/or illegitimate products concerning investigations, handling, and FDA form 3911 (initiation and completion), please refer to the SOP named *"Handling & Reporting Suspect and/or Illegitimate Products"*

d. The warehouse associate will organize the suspect and/or illegitimate products.
    i. Double checks will be performed by another warehouse associate to confirm the product Name, NDC, Lot number, and Expiration Date.
e. If applicable, controlled CII products will require a 222 form and must be filled out by Return Solutions.
    i. This is mailed by Return Solutions and received ahead of time
        1. The DEA 222 form will be completed by the Compliance Department by filling in the quantity shipped and the date the products were shipped.
f. Products are then boxed and sealed by the warehouse associates and a shipping label will be printed.
g. Once the shipping label is printed and affixed to the packaging, a pickup is scheduled.
    i. Packaged inventory scheduled for return will remain within the secure warehouse until it is picked up by freight.
h. Upon completion of the return, if applicable, the DEA 222 form is filed within the compliance department, and bill of lading is supplied to the VP of Operations.

Version Number	Description of Revision	Person Authorizing Revision	Date
2	Document implementation	Dakota Flowers	06.22.2022
3	Updated Formatting; Revised to add, Suspect and/or illegitimate products to Purpose and Procedures. Added VP of Operations to replace Warehouse Supervisor	Dakota Flowers	9.17.2024

Exhibit 3

Title:	Standard Operating Procedures for **Handling & Reporting Suspect and/or Illegitimate Products**
Issue Date:	**05/05/2022**
Last Revised Date:	**09/17/2024**

Purpose:

This policy was implemented to ensure Safe Chain Solutions (SCS) is handling suspect and/or illegitimate products according to federal regulations and Current Good Distribution Practices (CGDP) in a manner that is consistent with the public's interest.

Scope:

All prescription drug orders will be evaluated by SCS according to this SOP to mitigate the risk of suspect or illegitimate product being passed through SCS's facility to a downstream trading partner. Furthermore, any identified suspect/illegitimate products will be reported to the FDA, State Board of Pharmacy, and trading partners as required.

Responsibilities:

Warehouse Associate	• Responsible for evaluating inbound products. If a suspect/illegitimate product is identified these parties will be responsible for quarantining the product and notifying the Compliance Department, Purchasing Department and upper management.
Compliance Manager	• Responsible for proper investigation, notification and reporting to the appropriate regulations and trading partners as required.

Procedures:

1. **Handling Suspect Product**
   A. Identification of Potential Suspect Product through inspection of Rx Products and packaging
      i. Rx Products and packaging will be inspected for any of the following:
         • Signs that the product packaging has been compromised (opened, broken seal, damaged, repaired, or otherwise altered).

Exhibit 3

- Examination of the outer appearance to see if the shrink wrap has unexpected markings, or a seal that is broken, torn, or repaired.
- Differences in products contained in shipments from vendors. A comparison will be made of the current shipment to the last shipment of the same product type to identify any irregularities or differences in product packaging or overall product appearance (or any other notable differences)
- Product inserts missing and/or do not correspond to the product.
- Shipping addresses, postmarks, or other materials indicating that the product came from an unexpected foreign entity or source.
- Lot numbers and expiration dates on product that do not match the lot numbers and expiration dates of its outer container.
- Inspection of labels on the package and the individual retail unit, to look for any missing information. (Lot number, other lot identification, NDC, or strength of the drug)
- Altered product information, such as smudged print, illegible print, misspelled words, bubbling in the surface of a label and lack of an "Rx only" symbol.
- Foreign language with little or no English provided, and/ or foreign language that is used to describe the lot number.
- Product name that differs from the FDA-approved drug label or labeling.
- Product name that is the product name for a foreign version of the drug.
- Review of general labeling or product labeling to identify any instances of varying fonts or other inconsistencies.

B. When suspect product is identified, the warehouse associate will immediately place the suspect product into the physical quarantine area of our warehouse where it will remain until the product is dispositioned (cleared, approved for return, or approved for destruction).

i. Product will be physically moved from its current location to the quarantine location which is far removed (and out of the general operations area) from saleable/active product locations. The product will be marked as "suspect product" by affixing a label indicating such to the product bin. This will prevent the product from inadvertently be sent back to the manufacturer, the wholesale distributor, or destroyed (with other products in quarantine, such as expired products) before it is cleared or dispositioned by the Compliance Manager.

ii. The Compliance Manager will immediately review and start the verification process on the authenticity of the Transaction Data information. This process includes validating the transaction information (TI) and all entities listed in the transaction history (TH). Validation is performed by contacting each entity, either by telephone or email, starting with the manufacturer of the product and moving down the Transaction

History, to verify the transaction is legitimate and can be confirmed by each entity in the Transaction History. Documentation of interactions with each entity will be recorded (date, name, vendor/customer name, findings, etc.) and saved (see below for document retention policies).

iii. The Compliance Manager will utilize additional resources to make an accurate assessment of the status of a drug as a suspect product. Those additional resources include, but are not limited to, contact with regulatory authorities, law enforcement, or other available resources to aid in that determination when additional expertise is required. Once these resources have been exhausted, the Compliance Manager will make a final decision on the identified products. Any low-risk products will be put back into "saleable inventory". Medium to high-risk products will be quarantined according to the process below. Low risk would indicate that verification through the supply chain can be made, and the legitimacy of this product is confirmed. Medium risk would indicate that are one or more factors that have been identified and there are discrepancies existing in the supply chain investigation. High-risk would indicate that the initial investigation of the product and the follow up investigation have confirmed deficiencies in the product or product documentation.

iv. SCS will retain all documentation pertaining to the suspect product and the investigation for a minimum of 6 years. Documents will be stored on the Safe Chain Solutions Microsoft 365 One Drive platform, which is stored in the cloud and backed up via Axcient in snapshot 3x-4x times daily. The daily backups are stored in AWS Data Storage. In addition, documentation for any product investigations will be stored in the current ERP and affixed to appropriate customer, vendor, product, or order records.

v. If the product is approved for *destruction*, the Compliance Manager will coordinate with the VP of operations and warehouse associates to schedule a drug return with Return Solutions, a licensed reverse distributor. The product will remain in Quarantine until its date of return. Please see the SOP named "Drug Disposal" for complete disposition procedures.

2. Handling of Illegitimate Product

A. Following an SCS Investigation, if it is determined illegitimate product passed through or into the facility, SCS will take following additional steps:

i. The Warehouse Associates will quarantine the product until the

product is dispositioned (see detailed steps above) and the Warehouse Associates will take all reasonable steps to assist the manufacturer or vendor in the disposition of any illegitimate product not in possession of SCS.

ii. SCS will retain a sample of the product for further physical examination by the manufacturer, FDA, or other governmental agency upon request. This sample will remain in quarantine.

iii. SCS will maintain all records of the investigation and disposition of the product for a minimum of 6 years (see document retention details in B, iv)

iv. The Compliance Manager will notify the FDA within **24 hours** of SCS's determination that the product is illegitimate by submitting FDA Form 3911 (additional guidance is contained in *FDA's June 2014 Draft Guidance for Industry, entitled "Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification"*) via the CDER NextGen platform on the FDA website (https://cdernextgenportal.fda.gov/Login_CDER?ec=302&startURL=%2Fs%2F);

v. Furthermore, the Compliance Manager will notify the Maryland State Board of Pharmacy and any other required entity within **24 hours** of SCS's determination that the product is illegitimate.

vi. The Compliance Manager will notify all immediate Trading Partners within **24 hours** of SCS's determination that the product it received from such vendor is believed to be illegitimate.

B. In the event Safe Chain receives a **Request for Verification** of a product from a trading partner (i.e. manufacturer, wholesale distributor or customer), and/or the FDA, Safe Chain will take the following steps:

i. The Compliance Manager will notify the Warehouse Associate(s) to identify and quarantine all the illegitimate product identified in the notice that is in SCS's possession or is in the process of receipt and will perform the activities described for suspect product determinations above.

ii. The Compliance Manager will promptly conduct an investigation, in coordination with other trading partners, into whether a suspect product is an illegitimate product. Investigations will include but not be limited to the following:

- Communication and coordination between the manufacturer, repackager and/or additional trading partners.
- Analysis of how the product came to be in possession and process to take place to prevent a similar situation in the future.
- Coordination with the manufacturer if testing of the product is necessary.
- Verifying the product identifier of the product at the package level.

iii. The Compliance Manager will respond to all requests from trading partners and/or the FDA for verification of product within **24 hours**.

iv. If, after investigating a suspect product that is *the subject of an FDA request for verification* of the product identifier, and the Compliance Manager determines that the product is not an illegitimate product, he/she will promptly submit a cleared product notification to FDA documenting its determination. (Please note: Only the trading partner to whom FDA made its request for verification need submit a cleared product notification.)

- The cleared product notification should be submitted via the FDA's electronic DSCSA Portal (https://cdernextgenportal.fda.gov/s/)
- SCS will retain all documentation pertaining to the suspect product investigation for a minimum of 6 years. Documents will be stored on the Safe Chain Solutions Microsoft 365 One Drive platform, which is stored in the cloud and backed up via Axcient in snapshot 3-4x times daily. The daily backups are stored in AWS Data Storage. In addition, documentation for any product investigations will be stored in the current ERP and affixed to appropriate customer, vendor, product, or order records.

C. If the Compliance Manager, in conjunction with the investigation results, determines that an illegitimate product notification is no longer necessary:

i. The Compliance Manager will terminate the illegitimate product notification using FDA Form 3911 via the CDER NextGen platform on the FDA website. (additional guidance is found in *FDA's June 2014 Draft Guidance for Industry, entitled "Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification" & FDA's December 2016 Draft entitled "Guidance for Industry Drug Supply Chain Security Act (DSCSA) Implementation: Identification of Suspect Product and Notification*")

- The FDA considers a request to terminate the notification by

a trading partner as a request for consultation, as required in section 582 of the Federal Food Drug and Cosmetic Act. The FDA may request additional information to complete the consultation.

ii. Once the Compliance Manager receives notification from the FDA that the Form 3911 is concluded, the Compliance Manager will promptly notify the manufacturer, vendors, and/or additional trading partners to which SCS sent an illegitimate product notice that the notice has been terminated.

INSTRUCTIONS FOR COMPLETING AN FDA FORM 3911 CAN BE ACCESSED HERE:

https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-notifications-frequently-asked-questions

FDA FORM 3911 CAN BE ACCESSED HERE:

https://www.fda.gov/media/99185/download

Note: If the file will not download, proceed to save it on your desktop and attempt to re-open. The fillable PDF FDA Form 3911 should open without issue once saved.

Version Number	Description of Revision	Person Authorizing Revision	Date
2	Implementation of formal "Suspect and/or Illegitimate Product Handling & Reporting" SOP	Dakota Flowers	05.05.2022
3	Updated Handling of Illegitimate Product, section vi. To 24 hours	Dakota Flowers	06.09.2023

4	Updated Sections: Responsibilities, Handling Suspect Product, and Handling of Illegitimate Product	Dakota Flowers	06.12.2023
5	Updated Section Handling Suspect Product, adding under section B. v. -more direct disposition procedures if drug if approved for disposition.	Dakota Flowers	09.10.2024
6	Updated and added Handling of Illegitimate Product; Section C; ii & iii	Dakota Flowers	09.17.2024

Title:	Standard Operating Procedures for **Inventory Controls**
Issue Date:	**05/02/2015**
Last Revised Date:	**09/17/2024**

Purpose:

To ensure all personnel are familiar with the policies in place to prevent diversion and that all inventory is properly stored.

Scope:

Each employee should be aware of the policies in place to prevent diversion and suspicious products from Safe Chain inventory.

Responsibilities:

Warehouse Associate(s)	• Initiates inventory counts. • Ensures the warehouse area is secure. • Thoroughly inspects products for legitimacy. • Responsible for leading inventory counts and adjusting inventory discrepancies as needed. • Reports any thefts, losses or suspected illegitimate product to the Compliance Department.
Purchasing/Processing Department	• Handles communication with vendors • Initiates and handles all communication for investigations between Safe Chain and Common Carriers (i.e. FedEx, UPS)
Compliance Department	• Responsible for verifying product and transaction history legitimacy. • Handles all reporting needs to the Maryland Board of Pharmacy, FDA and DEA. • Identifies suspicious orders and initiates virtual inspections for Safe Chain customers.

Procedures:

1. Suspicious Orders
    a. Compliance is responsible for identifying and reporting suspicious orders to the Drug Enforcement Administration (DEA) Baltimore Field Office within **24 hours.**
    b. An order is considered suspicious when one or more of the following occur:
        i. Any order that is submitted for the full allowance of one class of drug. (Appendix A)
        ii. An inactive customer resumes purchasing at a higher volume.
        iii. A customer's orders are flagged by NavigateSOM.
        iv. A customer's-controlled substance orders has substantially increased.
    c. Once a suspicious order is pended and reported, a 90-day drug usage report (DUR) will be requested and filed with the customers' information.
    d. If necessary, the Compliance Department will initiate a virtual inspection of the pharmacy that placed the order. The areas that will be reviewed and inspected include:
        i. Prescription validation process.
        ii. Reporting to prescription drug monitoring program.
        iii. Most recent board of pharmacy inspection report.
        iv. Appropriate security for controlled substances. (i.e. cameras, alarm system)
        v. Employees with access to controlled substances.
        vi. Percentage of prescriptions that are self-pay versus insurance/3rd party.
        vii. Top four fast moving drugs.
        viii. Top four prescribing physicians and their DEA numbers.
        ix. Compliance will review the results from the virtual inspection to evaluate and determine if any action or corrective action is required. (i.e. terminate or freeze account, discontinue controlled substance sales, resume sales or schedule a repeat inspection)
    e. A pended order will be released if there is sufficient evidence that shows the pharmacy is submitting larger orders for legitimate purposes such as:
        i. Nearby pharmacy closed and patients from the closed pharmacy now use the pharmacy.
        ii. Medical facility has opened or expanded nearby.
        iii. Recent reported burglary or theft. (With police report and DEA form 106)
        iv. Recent natural disaster that destroyed inventory or rendered it unfit for use. (Hurricane, flooding, earthquake, fire, etc.)

2. Identifying Theft or Loss
    a. At the beginning of each business day, the Warehouse Associate(s) will conduct an inventory of all controlled substances.
        i. If any discrepancies are found, the Warehouse Associate(s) will perform an audit of the drug with the discrepancy to determine if there is an error in the system or an inaccurate order from the previous day.
        ii. If the cause of the discrepancy is determined to be a receipt, shipment, or system error, the appropriate steps will be taken to remedy the discrepancy. Examples of these types of errors may include:
            1. Wrong lot number picked and sent to the customer (an updated invoice and

packing slip will be sent to the customer.)
2. An order was shorted product. (the remaining balance will be shipped to the customer with the shortage)
3. An order was shipped with an overage. (The customer will be notified and asked to submit an order and DEA 222 form if applicable if they wish to keep the drug OR return the overage using an overnight shipping label provided by Safe Chain.)
4. Product was moved to quarantine physically. But not moved in the virtual inventory
5. Examples of system errors would include:
    a. An order was shipped correctly; however, the system didn't "confirm" the shipment. The Warehouse Associate or Order Analyst can simply confirm the shipment to resolve the issue
6. If the above causes are not believed to be the reason for a discrepancy, an internal investigation will be launched to determine if a theft has taken place. Investigations include:
    a. Security camera review
    b. Employee interviews
    c. Searches of employee lockers
    d. Review of employees' technology use

iii. If the above listed causes determine a theft has taken place, law enforcement will be engaged to pursue criminal charges against the responsible individual(s). The employee will be immediately terminated.

b. Each week the warehouse does a cycle count on the applicable sections of racks (cycle counts are done weekly to count each rack in the warehouse at least once per month.

i. If any discrepancies are found, the warehouse manager will notify the Compliance Depart and/or Purchasing Department and an audit of the drug with the discrepancy will be conducted.

ii. Once the cause of the discrepancy is determined, the inventory will be adjusted. Causes that will warrant adjustment with approval from the Director of Compliance and VP of Operations are:

1. Wrong lot number picked and sent to the customer (an updated invoice and packing slip will be sent to the customer.)
2. An order was shorted product. (the remaining balance will be shipped to the customer with the shortage)
3. An order was shipped with an overage. (The customer will be notified and asked to submit an order if they wish to keep the drug OR return the overage using an overnight shipping label provided by Safe Chain.)
4. Product was moved to quarantine physically but not moved in virtual inventory.
5. If the above causes are not believed to be the reason for a discrepancy an internal investigation will be launched to determine if a theft has taken place. Investigations include:
    a. Security camera review
    b. Employee interviews
    c. Searches of employee lockers (if applicable)

d. Review of employees' technology use

iii. If the above listed causes determine a theft has taken place, law enforcement will be engaged to pursue criminal charges against the responsible individual(s). The employee will be immediately terminated.

3. Suspected Theft or Loss with Common Carrier
   a. Thefts and losses with common carriers are recorded and trended. After a recorded trend has been identified use of that common carrier should be terminated. Examples of trends are:
      - Lost in transit reported frequently for one specific geographical area.
      - Common carrier internal investigations are repeatedly inconclusive.

4. Theft or Loss Recording for Controlled Substances
   a. The Compliance Department is responsible for reporting thefts or losses to the DEA using form 106 and if necessary, contacting law enforcement.
   b. Controlled substances lost in transit will immediately be reported by the Compliance Department using the DEA form 106 if the shipment was not received by the customer. The Purchasing Department will contact the common carrier used to ship the product. The Common carrier will be asked to conduct an internal investigation and that the findings be submitted to the Purchasing Department, as well as forwarded to the Compliance Manager for record keeping. The information will be stored in the DEA Binder that is in the compliance office for 6 years. After the 6-year period, it will be filed with DEA related documents from the year the report was filed and placed in on site storage.
      i. If the shipment that was believed to be lost in transit is delivered to the customer, the DEA form 106 will be amended to reflect the resolution.
   c. If the shipment was received by the customer, the Compliance Department will advise the customer to submit DEA form 106 and aid as necessary.
   d. In the event of a theft from the Safe Chain warehouse, a DEA form 106 will immediately be submitted and local law enforcement will be requested to file a police report and investigate the theft. Safe Chain will press criminal charges against the individual(s) responsible for the theft.

   If necessary, an internal investigation will be launched if employee theft is suspected to be the cause of a discrepancy. All computers are password protected and will require the user to log in to use any programs that would require the adjustment of inventory.
   Safe Chain will also record any patterns regarding in transit losses or suspected thefts and will report any incidents to the appropriate representative of the courier services.

5. Illegitimate Products
   a. Any products that are suspected of being illegitimate should immediately be in quarantine by the warehouse team.
   b. The warehouse associate(s) will provide the Compliance Department with all the documentation that accompanied the shipment.
   c. The Compliance Department will review and verify the transaction histories.
   d. The information will be compiled and sent to the FDA, Maryland Board of Pharmacy and DEA (if applicable) within **24 hours**.

Version Number	Description of Revision	Person Authorizing Revision	Date
2	Document Revision	Abigail Divilio	12.20.2021
3	Document implementation	Dakota Flowers	06.22.2022
4	Updated Formatting, Updated Purchasing responsibilities, updated from third party inspections to virtual inspections	Dakota Flowers	09.17.2024

Title:	Standard Operating Procedures for **Personnel**
Issue Date:	**5/2/2015**
Last Revised Date:	**09/17/2024**

Purpose:

To ensure that SCS follow federal and state requirements in hiring personnel in the future and existing personnel involved in the distribution of prescription drugs from this facility.

Scope:

The Designated Representative is required to be at the facility during working hours. Background and financial checks and education of key personnel, management and owners/officers are required. A requirement to sign the "DEA Cage Access Agreement" is required for all employees who handle or regulate controlled substances. (i.e. Warehouse associate(s), order analyst, Compliance Department and VP of Operations) All employees, new or current, will have continuous on-the-job training specified for their department.

Responsibilities:

Dakota Flowers	• Designated Representative of Safe Chain Solutions • Oversees all activities of Return Solutions. • Ensure all products on the receipt of goods are present.
Amanda Biggart	• In the absence of the Designated Representative, they will assume all responsibility of the designated representative, in

Procedures:

1. Designated Representative
    a. Dakota Flowers is the Designated Representative.
        i. The Designated Representative is responsible for all policies and procedures at this facility.
        ii. The Designated Representative is required to be at the facility, along with documentation of such person's title, duties, and qualifications.
    b. Dakota Flowers has not been enjoined, disciplined, fined, punished or the like for violating any federal or state laws regulating prescription Drugs or Devices.
    c. Dakota Flowers has **not** been found guilty, pled guilty, or plead nolo contendere to any criminal offense.
    d. Dakota Flowers experience and qualifications:
        i. She has over 4 years of verifiable experience within the wholesale pharmaceutical industry where his responsibilities included but were not limited to recordkeeping,

storage and shipment of drugs
   ii. She serves only at Safe Chain Solutions, LLC as the Designated Representative.
   iii. She is actively involved in and aware of the actual daily operations of Safe Chain Solutions, LLC.
   iv. She is physically present at Safe Chain Solutions, LLC during normal business hours except for periods when absent due to illness, family illness or death, scheduled vacations or authorized absence.
   v. She is aware of and knowledgeable about all policies and procedures pertaining to the operations of Safe Chain Solutions.
e. During Dakota Flowers pre-approved absence, Amanda Biggart will assume all responsibility of the designated representative.

2. New Personnel
   a. Background and financial checks and education of key personnel, management and owners/officers are required.
   b. Before an employee is allowed access to the secure warehouse area, they will be required to sign the "DEA Cage Access Agreement" This is required for all employees who handle or regulate controlled substances. (i.e. Warehouse associate(s), order analyst, Compliance Department and VP of Operations)
   c. All initial training is done by the department manager or lead. All future employees will have criminal background checks as well as drug testing prior to employment and on-going during their time of employment.

3. Current Personnel
   a. Background and financial checks and education of key personnel, management and owners/officers are required.
   b. Before an employee is allowed access to the secure warehouse area, they will be required to sign the "DEA Cage Access Agreement" This is required for all employees who handle or regulate controlled substances. (i.e. Warehouse associate(s), order analyst, Compliance Department and VP of Operations)
   c. All current personnel have been found to be of good moral character, drug free and no criminal background.
   d. All employees have completed and have continuous on-the-job training for their department.

4. Job Descriptions:
   a. <u>Warehouse Associate (may include but not limited to):</u>
      i. Receives products from vendors and processes receiving paperwork.
      ii. Packs products for shipment to customers and processes invoices.
      iii. Places products in physical inventory shelf/refrigerator
      iv. Orders packaging supplies
      v. Conducts physical inventories.
      vi. Conducts physical inventory counts
      vii. Reports to the Warehouse Manager

b. Warehouse Manager (may include but not limited to):
   i. Can perform the functions of all the duties of the Logistics Coordinators as well as:
   ii. Responsible for maintenance inside and outside of the facility
   iii. Oversees the performances and compliance of the Coordinators and the Logistics Manager.
   iv. Responsible for the product inventory and will report to the VP of Operation.

c. VP of Operations (may include but not limited to):
   i. Can perform all the duties of the Warehouse Managers and Logistics Coordinators as well as:
   ii. System maintenance and troubleshooting
   iii. Creating and maintaining SOPs and best practices surrounding warehouse operations
   iv. Takes lead on DSCSA serialization requirements and implementation.

d. Accounting Specialist (may include but not limited to):
   i. Verify, process, and record transactions and payments.
   ii. Maintain accurate and relevant records of incoming and outgoing payments, such as journals, invoices, receipts, etc.
   iii. Maintain receipts and supply and inventory information.
   iv. Assist in daily, monthly, and annual financial activities, such as financial reports, budgets, and taxes.
   v. Communicate with vendors and suppliers to ensure payments are processed and received on time.
   vi. Handle payroll functions if required.
   vii. Review and update financial information and documents.
   viii. Manage general ledger bookkeeping.
   ix. Manage clients' accounts and their payment schedules.
   x. Identify and resolve accounting irregularities or errors.
   xi. Prepare and submit documentation regularly in the accounting system.
   xii. Follow all procedures to maintain the company's financial security.

e. Accounting Manager (may include but not limited to):
   i. Can perform all the duties of the Accounting Specialist as well as:
   ii. Financial strategies, this includes planning, implementing, and overseeing the company's financial strategy.
   iii. Creating financial reports, including financial statements, investment activity reports, and cash flow forecasts.
   iv. Analyzing financial data to identify trends, risks, and opportunities.
   v. Establishing and enforcing internal controls to prevent fraud and errors.
   vi. Ensuring accordance with financial laws and regulations, including tax laws and financial reporting standards.
   vii. Managing the company's annual audit with external auditors and contributing to timely and accurate monthly closes.
   viii. Reconciling with financial institutions to detect errors and discrepancies.

f. Chief Operating Officer, COO (may include but not limited to):
   i. Operational Management; Oversee daily operations of the company, ensuring efficient and effective business processes. Implement operational strategies, plans, and procedures to improve productivity and performance.
   ii. Strategic Planning: Collaborate with the executive team to develop long-term business strategies and translate strategic goals into actionable plans for departments and teams. Lead the execution of the company's business strategies to achieve growth and profitability.
   iii. Team Leadership and Development: Manage and mentor department heads and senior managers and drive the recruitment, training, and retention to build a skilled and motivated workforce. Ensure alignment of departmental goals with the overall company objectives.
   iv. Financial Oversight: Work closely with the financial consultants to develop budgets, forecast financial needs, and monitor financial performance. Identify cost-saving opportunities and ensure efficient allocation of resources and manage operational costs.
   v. Process Improvement and Innovation: Identify areas for process improvement and drive initiatives. Implement new technologies and systems to streamline operations and support business growth.
   vi. Risk Management and Compliance: Ensure that all business operations comply with relevant laws, regulations, and standards. Identify potential risks to the business and develop strategies to mitigate them. Establish and enforce company policies and procedures. Work closely with the Senior Compliance Officer to ensure adherence to all pharmaceutical laws and regulations and to maintain an ongoing evaluation of all existing policies and procedures.
   vii. Customer Experience Management: Enhance the customer experience by ensuring consistent delivery of high-quality products or services. Collaborate with sales, marketing, and customer service teams to meet customer expectations. Address customer complaints or operational issues that impact customer satisfaction.
   viii. Stakeholder Communication: Act as a key liaison between the executive team and other stakeholders. Present operational performance updates to invested parties. Foster strong relationships with external partners, suppliers, and vendors.
   ix. Performance Monitoring and Reporting: Develop and track performance metrics to evaluate operational effectiveness. Implement corrective actions when performance does not meet established goals.
   x. Scaling and Expansion: Support the company's growth initiatives, including market expansion, acquisitions, and new product launches. Develop and implement scalable operational strategies to support business expansion. Ensure that operational capacity meets current and future business demands.

g. Senior Compliance Specialist (may include but not limited to):
   i. Regulatory Compliance Management; Ensure compliance with relevant laws, regulations, and guidelines, including FDA, DEA, Local Boards of Pharmacy, and other applicable standards.
   ii. Monitor and interpret changes in federal, state, and local laws affecting the pharmaceutical industry. Work directly with legal counsel for formal interpretations

and feedback on any changes to laws.

iii. Develop and maintain a process to ensure timely submission of reports, renewals, and regulatory filings.

iv. Develop, implement, and update company policies and procedures to ensure compliance with regulatory requirements. Ensure that all policies and procedures are accessible, understood, and followed by employees.

v. Design and deliver training programs for employees on compliance-related topics, such as good distribution practices, anti-bribery, and regulatory updates.

vi. Ensure that staff are adequately trained in regulatory requirements and internal compliance standards. Track and document employee training sessions.

vii. Conduct regular internal audits of operations, including inventory management, distribution practices, and record-keeping, to ensure compliance with regulations.

viii. Monitor daily operations to detect potential compliance issues and ensure adherence to established policies. Implement corrective actions for identified non-compliance and ensure follow-up to verify resolution.

ix. Ensure that the company and its facilities maintain all necessary licenses and permits to operate legally.

x. Manage the application, renewal, and maintenance of licenses, including state and federal controlled substances registrations.

xi. Ensure compliance with state licensing requirements for all operating jurisdictions.

xii. Identify compliance risks and develop strategies to mitigate potential regulatory, operational, and reputational risks. Conduct risk assessments to evaluate the company's exposure to compliance risks and develop and implement action plans to address identified risks and prevent future occurrences.

xiii. Investigate compliance-related incidents, such as product recalls, distribution errors, or regulatory violations and report significant compliance issues to regulatory authorities as required. Maintain records of incidents, corrective actions, and communications with regulatory agencies.

xiv. Maintain accurate and up-to-date records of all compliance-related activities, including audit findings, corrective actions, and training records. Ensure that documentation is readily available for regulatory inspections and audits and establish document retention policies in line with regulatory requirements.

xv. Prepare the organization for regulatory inspections, audits, and site visits by external agencies and act as the primary point of contact during inspections and provide requested information to regulators.

xvi. Develop and manage responses to inspection findings, including corrective and preventive action plans.

xvii. Work closely with other departments, such as Operations, Processing/Purchasing, Legal, and IT, to ensure company-wide compliance.

xviii. Advise on compliance implications of new business initiatives, changes in processes, and product launches.

xix. Collaborate with supply chain partners to ensure compliance across the distribution network.

xx. Regularly report on compliance performance to senior management.

h. Purchasing Specialist (may include but not limited to):
   i. Initiate, track, and facilitate purchase orders in accordance with company policies
   ii. Build and maintain relationships with suppliers to ensure timely deliveries, favorable terms, and issue resolution.
   iii. Evaluate suppliers and products to find the best quality, price, delivery, and service options.
   iv. Negotiate contracts to secure the best pricing, terms, and delivery options for products and services.
   v. Monitor inventory levels and place orders to prevent shortages.
   vi. Determine the total cost of ownership of items, including purchase prices, transportation fees, and storage expenses.
   vii. Ensure compliance with company policies, procedures, and external regulations.
   viii. Communicate with vendors and suppliers to ensure timely delivery and high-quality products.
   ix. Track and analyze purchasing trends to develop strategies for future purchases

i. Order Analyst (may include but not limited to):
   i. Order Processing and Management: Review and analyze incoming orders for accuracy, completeness, and compliance with company policies. Verify pricing, quantities, discounts, and terms of sale on each order before processing.
   ii. Ensure orders are processed promptly and accurately in the system to meet customer expectations.
   iii. Monitor inventory levels to ensure adequate stock is available to fulfill orders.
   iv. Place purchase orders with suppliers on an as-needed basis and communicate with the inventory and warehouse teams to resolve any stock discrepancies or backorders.
   v. Communicate with customers to confirm order details, resolve order discrepancies, and provide updates on order status. Handle customer inquiries regarding order issues, delivery timelines, and product availability.
   vi. Analyze order data to identify trends, patterns, and areas for improvement in the order management process and generate regular reports on order accuracy, processing times, and fulfillment rates.
   vii. Collaborate with the sales, warehouse, and finance teams to ensure a seamless order-to-delivery process. Work closely with the warehouse team to confirm delivery schedules and resolve any logistics issues.
   viii. Use ERP software to manage and track orders and identify system inefficiencies and recommend improvements or automation to streamline order processing.
   ix. Conduct quality checks on processed orders to minimize errors and reduce returns or complaints and implement and maintain standard operating procedures (SOPs) related to order processing and management.
   x. Investigate and resolve issues related to order discrepancies, delivery problems, and customer complaints. Manage order cancellations, returns, and exchanges in coordination with relevant departments.
   xi. Monitor order processing times and work to reduce delays or bottlenecks in the workflow.
   xii. Track order fulfillment accuracy and work with the team to achieve performance targets and develop metrics to assess the efficiency and effectiveness of the order

management process.

xiii. Maintain accurate records of orders, changes, cancellations, and customer communications.
    1. Ensure all order data is documented correctly in the system for auditing and reporting purposes and keep detailed records of order discrepancies and corrective actions taken.

xiv. Assist the sales team by analyzing order trends and customer buying patterns to support sales strategies.

xv. Provide input on promotions and campaigns by reviewing historical order data and forecasting demand.

xvi. Identify opportunities to enhance the order management process, including reducing manual tasks and improving accuracy.

xvii. Participate in continuous improvement projects aimed at enhancing customer satisfaction and operational efficiency.

xviii. Stay updated on industry trends and best practices in order management and fulfillment.

DEA Cage Access Agreement

Safe Chain Solutions is a DEA compliant facility that stores both controlled and non- controlled substances. Access to the DEA cage is restricted to authorized employees of Safe Chain Solutions that have signed this DEA Cage Access Agreement and have been approved by management.

By signing this agreement, the approved Safe Chain employee acknowledges the following:

- Random drug tests may be conducted at any time without notice.
- They have not ever been convicted of a felony.
- The access codes to the DEA cage are strictly confidential.
- No unauthorized employee shall be allowed in the DEA cage.
- Any discrepancies in inventory are to be immediately reported to management.

Anyone not following the Standard Operating Procedure for handling-controlled substances will immediately be terminated and if necessary, will be prosecuted to the highest extent allowed by law.

Employee Signature_____Date_____

Printed Name_____Title_____

Version Number	Description of Revision	Person Authorizing Revision	Date
2	Document Revision	Dakota Flowers	03.15.2021
3	Document implementation	Dakota Flowers	06.22.2022
4	Updated Formatting, updated to include all active positions, updated DR to Dakota flowers, removed Patrick Boyd	Dakota Flowers	09.17.2024

Title:	Standard Operating Procedures for **Product Inventory**
Issue Date:	**5/2/2015**
Last Revised Date:	**09/17/2024**

Purpose:

To ensure the correct actions and information are taken with the inventory of all products within the Safe Chain Solutions (SCS), Cambridge, Maryland office/warehouse space, as required by the most stringent law or regulation and in compliance with the U.S. FDA reference number 21CFR§205.50.

Scope:

Each Warehouse associate(s) will be aware of the following procedures in place to receive product into Safe Chain's inventory.

Responsibilities:

Warehouse Associate(s)	• Initiates receiving product. • Performs double checks on all products received and shipped. • Document received and shipped product thoroughly.
Compliance Department	• Handles all reporting needs to the Maryland Board of Pharmacy, FDA and DEA.

Procedures:

1. When receiving products from a vendor, a complete inventory will be conducted of the product received.
   a) On the invoice or packing slip, record the NDC; LOT; expiration date; and quantity. If neither of those documents came with the order, on a printed purchase order, record the same information.

   b) The following is an example of how it will be written:

NDC 00000-0000-00
LOT OO000000-OO \ QTY
EXP MM/DD/YY

Exhibit 3

c) The person recording this information will then get a co-worker to double check this information and initial under the QTY that everything is correct.
d) Stamp the receiving paperwork to reflect the common carrier (i.e. Ups, FedEx) used to ship the received products
e) This paper with the above information will be given to the person inputting all the data into the computer that day.

2. Putting product into stock requires an inventory completed of the product going into stock. Product name, Strength & Size, NDC, LOT, quantity, expiration date, purchase order number, vendor, purchase order quantity and the date received.

3. An inventory will be conducted prior to sending the product to a client.
   a) Upon receipt of a pick slip, an individual assigned to pack, will check the information on the pick slip and remove the product from either off the stock shelves or the receiving table.
   b) The packer will ensure that all the information (Product, NDC, and QTY) is correct and move the product over to the packing table.
   c) The packer will then get a co-worker to double check that the product pulled for shipment and the pick slip match, and the co-worker will then initial the pick slip retained for record.
   d) The packer will then pack the product correctly and initial the pick slip retained for record directly underneath the co-workers' initials.

4. A weekly inventory of all products in stock is performed every Tuesday and Thursday. Procedure of conducting a physical inventory is:
   a) The Warehouse Associate will print an inventory report, and the items in the report will be compared to the stock product on the shelves.
   b) A check will be placed next to each item found on the report
   c) Any discrepancies found will be noted in the inventory report and reported to the Logistics Manager.
   d) The Warehouse Associate will make on-hand inventory corrections in the computer system.
   e) This facility has a zero (0) threshold for discretions in inventory, therefore all shortages will be diligently researched until the status of the missing product is known.
   f) All non-resolved shortages and losses and possible thefts will be documented and reported to the Compliance Department who will then report the theft or loss to the Maryland Board of Pharmacy, the Food and Drug Administration (FDA) and/or the Drug Enforcement Agency (DEA) within **24 hours**.
5. On the last working day of the month a complete inventory will be conducted. The procedures listed in #4 above will be followed.
6. On the last working day of the year a complete inventory will be conducted. The procedures listed in #4 above will be followed.
7. A complete inventory will be conducted whenever SCS management calls one. The procedures listed in #4 above will be followed.

Exhibit 3

Version Number	Description of Revision	Person Authorizing Revision	Date
2	Document Revision	Dakota Flowers	03.15.2021
3	Document implementation	Dakota Flowers	06.22.2022
4	Updated Formatting, updated reporting requirements	Dakota Flowers	09.17.2024

Exhibit 3

Title:	Standard Operating Procedures for **Product Recalls**
Issue Date:	**5/2/2015**
Last Revised Date:	**09/17/2024**

Purpose:

To ensure all personnel in the warehouse, purchasing and compliance department are familiar with what steps should be taken once notified of a drug recall or withdraw as required by the most stringent law or regulation and in compliance with the U.S. FDA reference number 21CFR§205.50.

Scope:

This procedure applies to the warehouse, purchasing and compliance processes for handling product recalls.

Responsibilities:

Compliance Manager	• Notifies the Purchasing Department and warehouse Associate(s) of a recall if needed. • Identifies and notifies customers who may be in possession of recalled drugs.
Purchasing Manager	• Initiates recall procedures. • Removes recalled products from virtual inventory. • Arranges disposition of recalled products to vendors. • Coordinates with the Accounting Department to issue credits to customers who return recalled products to Safe Chain. • Identifies and notifies customers who may be in possession of recalled drugs.
Warehouse Associate(s)	• Removes recalled product from physical inventory and moves to quarantine. • Receives recalled returns from customers and moves to quarantine until disposition. • Ships recalled drugs to vendors or their authorized reverse distributor.

Exhibit 3

Procedures:

1. Upon being notified of a recall the Compliance department will coordinate with the purchasing department to:
   a) Take any action initiated at the request of the Food and Drug Administration or other Federal, State, or local law enforcement or other government agency.
   b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or
   c) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

2. The purchasing department will search inventory records to identify if Safe Chain has received any of the recalled products.
   a) If inventory is found the compliance department and purchasing department will coordinate to notify the Warehouse Associate.
      i.) The Warehouse Associate will physically remove the product from Safe Chain inventory and place in quarantine until disposition.
      ii.) The Purchasing Department will virtually remove the product from Safe Chain inventory and arrange for disposition of the product with the vendor the product was purchased from.

   b) If Safe Chain has sold and shipped any of the recalled products to customers, the Compliance Department and/or Purchasing Department will notify the customer in writing of the recall and follow up with a phone call to the pharmaceutical buyer.
      i.) If the customer is still in possession of any of the recalled product a return merchandise authorization will be provided to the customer with a shipping label and the customer will be issued a credit for the product returned.
      ii.) If the customer no longer possesses the recalled product, no further action is required.

   c) Any returned, recalled product will be placed in quarantine by warehouse personnel and the return merchandise authorization will be given to the purchasing manager to issue credits to the customer.
   d) Once all expected recalled products are received by the Warehouse Associate and disposition has been arranged, the recalled product will be removed from inventory and shipped to the vendor, or a reverse distributor authorized by the vendor.

Version Number	Description of Revision	Person Authorizing Revision	Date
2	Document Revision	Dakota Flowers	03.15.2021
3	Document implementation	Dakota Flowers	06.22.2022
4	Updated Formatting, Updated responsibilities	Dakota Flowers	09.17.2024

Exhibit 3

Title:	Standard Operating Procedures for **Receiving**
Issue Date:	**5/2/2015**
Last Revised Date:	**09/17/2024**

Purpose:

To ensure Safe Chain Solutions receives products and inspects them to validate legitimacy and suitability for distribution.

Scope:

The Warehouse Associate(s) follows the below procedures to ensure that the pharmaceutical products received at Safe Chain Solutions are accurately received and stored according to drug schedule or temperature requirements. Safe Chain Solutions Warehouse Associate(s) is adequately trained to ensure all products received are in acceptable condition as defined below.

Responsibilities:

Warehouse Associate(s)	• Initiate receiving procedures • Sort and organize received products. • Ensure all products on the receipt of goods are present • Secures controlled substances immediately after performing second check. • Reports any issues (damages, overages, or shortages) with the shipment to the purchasing department.

Procedures:

1. Upon receipt, an SCS employee will visually examine each container that products are shipped in for damage or tampering. If damage or evidence of tampering is found, the sender will be notified, and a return authorization will be requested. The products will be placed in quarantine until disposition.
    a. Evidence of damage includes but is not limited to dented or crushed packaging, leaking liquids or broken glass.
    b. Evidence of tampering includes but is not limited to resealed outer shipping containers, broken safety seals and any cuts or punctures to the plastic wrap that seals the products.

2. When receiving products, the SCS employee will verify each expiration date and lot number match the shipping information included in the package. If there are any discrepancies, the product will be moved to quarantine until sender is notified and clarification or a resolution is met.

Exhibit 3

3. In the event a controlled substance is received, an SCS employee will follow the same protocol as listed above. The receiving SCS employee will remain with the controlled substances until a second employee can double check the product and verify the first employee has received and noted all products. The employees will immediately transport the controlled substances to the storage area and secure them in the safe or cage.

4. When receiving temperature-controlled products, SCS employees should note any indicators on the box that would alert them to prioritize receiving process. The employee will examine the packaging to ensure proper precautions were taken when shipping the product. Proper packaging includes foam coolers, cooler bags, and ice packs. The employee will verify storage requirements for the product and immediately transport it to the refrigerator or freezer.
    a. If it is found that packaging for temperature-controlled products was inadequate, the product will be quarantined, and the vendor will be informed, and disposition will be arranged.

5. If there are any overages or shortages when receiving in product, warehouse personnel will inform the purchasing team. The purchasing team will then report the discrepancy to the vendor and arrangements will be made to return any overages to the vendor or have any shortages shipped to Safe Chain if possible. If Safe Chain has been shorted and the product is no longer available, the purchasing team will adjust the purchase order.

6. After a product has been physically received, the warehouse manager or supervisor will update the inventory management system with the day's receipts and turn in all hard copies of receipt of goods to the purchasing team for filing.

Procedures for Lot Corrections:

1. For items still in stock
    a. In Acumatica, correct the remaining Lot Number's in stock.
        i. This will ensure that all remaining inventory will reflect the corrected lot number.

2. For items that have already sold
    a. In Acumatica, on the original invoice receipt, add a note in the ERP, listing the product NDC, incorrect Lot Number and corrected lot number.
        i. Example: Product 47781-0265-01, LOT 000050300 is missing a 0, it should be 0000503000
    b. On the same screen, select "FILES" in the top right corner of the ERP screen and add a PDF and/or screen shot of the original receiving paperwork. This will reflect the correct Lot number.
    c. On the Customer Invoices/shipments add a note stating the following information: product NDC, incorrect Lot Number, corrected lot number and statement "Revised invoice attached as a file."
        i. Example: "47781-0265-01 LOT 000050300 is missing a 0, Lot number should be 0000503000. Revised invoice attached as a file."
    d. Save the original invoice with the correct Lot number listed as a PDF in the Acumatica ERP pages on the Sales Order, Shipment, and Invoice. PDF of the original invoice with the "0" added. Save it with the original invoice number ending with "-REVISED."
        i. (Example: IN123456-REVISED) This would serve as the new amended invoice.

3. Correcting the T3 transactions
    a. The RFXCEL team will be notified of the Lot error and the steps listed above.
    b. The RFXCEL team will ensure that the correct lot number is listed on the products T3 documentation.
    c. Supporting documentation can/will be sent to the RFXCEL team if needed for T3 documentation.

Version Number	Description of Revision	Person Authorizing Revision	Date
2	Document Revision	Dakota Flowers	03.15.2021
3	Document implementation	Dakota Flowers	06.22.2022
4	Revision to include updated procedures for Lot Corrections	Dakota Flowers	08.09.2023
5	Updated Formatting, updated responsibilities	Dakota Flowers	09.17.2027

Title:	**Standard Operating Procedures for Recordkeeping**
Issue Date:	**5/2/2015**
Last Revised Date:	**09/17/2024**

Purpose:

This policy will establish a guideline for storing records relating to the wholesale distribution business.

Scope:

The Compliance Department will understand the proper procedures for proper record storage to include both electronic and paper records. As well as documentation related to trading partners, both upstream and downstream, and product investigations.

Responsibilities:

Compliance Department	• Maintain all regulatory records • Handles Storage of the following: i. disposition records ii. transaction histories iii. investigation records iv. trading partner records

Procedures:

1. Product Recordkeeping
    a. Business Records
        i. Any document relating to the business that does not involve prescription drugs will be stored onsite for 5 years. The documents will be sorted by month & year and alphabetically.
    b. Storage of Records
        i. Electronic Storage
            1. All documents will be stored on the Safe Chain network and filed by date and document type by the department manager it pertains to. All documents will be stored for a minimum of 6 years.
                a. Example: invoices will be stored by accounting, pedigrees/T3s will be stored by compliance, receipt of goods stored by warehouse.
        ii. Hard Copy/Paper Storage
            1. All hard copies of documents will be stored on site in the Safe Chain warehouse until they are due for destruction. The documents will be sorted by date and department.

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c. Product Records
    i. Trading Partners
        1. All trading partners are required to submit a valid hard copy of their license to compliance to be verified online. Once verified the trading partner may conduct business with Safe Chain.
        2. T3s from vendors are stored electronically via rfxcel portal for a minimum of 6 years. The portal is maintained by rfxcel. Customers have access to the portal and can retrieve their own T3 records.
    ii. Product Investigation
        1. Records of suspect product investigations will be stored in electronic format. The records will be maintained by the compliance department and updated as needed.
        2. Product Investigations
            a. Any records of investigations of products by any federal or state official will be stored for at least 6 years by the compliance department. These records include disposition records, returned product after recalls and saleable returned product.

Version Number	Description of Revision	Person Authorizing Revision	Date
2	Document Revision	Dakota Flowers	03.15.2021
3	Document implementation	Dakota Flowers	06.22.2022
6	Updated formatting. Updated Scope and Responsibilities	Dakota Flowers	09.17.2024

Title:	Standard Operating Procedures for **Records Retention and Reporting to Agencies**
Issue Date:	**05/02/2015**
Last Revised Date:	**09/17/2024**

Purpose:

This policy will establish a guideline for properly stored records of Safe Chain Solutions and the authorized distribution of copies to authorized Federal, State, or local law enforcement agencies. Documents will be readily accessible via hard copy or electronic copy.

Scope:

Safe Chain Solutions records are stored either electronically and/or hard copies for a minimum of six (6) years. All records stored on site will be made available for inspection within two (2) working days of a request by an authorized official of a Federal, State, or local law enforcement agency.

Responsibilities:

Compliance Department	• Maintain all regulatory records. • Retrieve and respond to all records requests. • Responsible for proper investigation, notification and reporting to the appropriate regulations within 24 hours.

➢ **PROCEDURES:**

1. Inventories and records shall be made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of six (6) years after the date of their creation.
2. Records that are kept at this office that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period.
    a. Records kept at the SCS Cambridge, MD office and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a Federal, State, or local law enforcement agency.
3. All unneeded hard copies of records will be shredded.
4. If a product is questionable, counterfeit or suspect, then this will be documented and reported to the Board of Pharmacy and the Food and Drug Administration (FDA) and/or Drug Enforcement Agency (DEA) within **24 hours**.
    a. The drug will be held in the quarantine area until a thorough investigation has been

completed. Please see Safe Chain Solutions SOP's named *"SOP Handling & Reporting Suspect Products"* and *"Drug Disposal"* for completed investigation and disposition details concerning Suspect and/or Illegitimate Products.

Version Number	Description of Revision	Person Authorizing Revision	Date
2	Document Revision	Dakota Flowers	03.15.2021
3	Document implementation	Dakota Flowers	06.22.2022
4	Updated Formatting and updated Section 4a	Dakota Flowers	09.17.2024

Title:	Standard Operating Procedures for **Sales & Marketing Code of Conduct**
Issue Date:	**11/01/2024**
Last Revised Date:	

Purpose:

In interacting within the Healthcare community, Safe Chain Solutions is committed to following the highest ethical standards as well as all legal requirements. Ensuring that our interactions with health care professionals are not perceived as inappropriate by patients or the public at large. This SOP is to reinforce Safe Chain Solutions interactions with health care professionals are professional and designed to benefit the healthcare industry. The following SOP is created using the most recent versions of "The Code on Interactions with Healthcare Professionals" developed by the Pharmaceutical Research and Manufacturers of America (PhRMA) as well as the "PhAMA Code of Pharmaceutical Marketing Practices" by The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

Scope:

To set standards for the ethical promotion of pharmaceutical products to healthcare professionals to ensure that Safe Chain Solutions' Sales Representatives interactions with healthcare professionals, patient organizations and medical institutions are appropriate.

Responsibilities:

Sales Representatives	• Responsible for understanding and practicing the SOP. • Reports to the Compliance Manager of any non-compliance of the outlined procedures.
Compliance Manager	• Responsible for proper investigations of complaints and non-compliance. • Responsible for developing, operating and monitoring the procedures outlined.

Procedures:

1. **General**
    a. The Healthcare and Well-Being of Patients are priority for Safe Chain Solutions.
    b. Methods of promotion or marketing must never discredit or reduce confidence in the pharmaceutical industry.
    c. Safe Chain Solutions relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare

professionals about products.

d. No financial benefit or benefit-in-kind (including grants, sponsorships, gifts, scholarships, subsidies, support, consulting contracts or educational or practice related items) may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on a healthcare professional's prescribing practices.

e. All promotions should never be disguised. Materials relating to pharmaceutical products and their uses, whether promotion in nature or not, which is sponsored by a company should clearly indicate by whom it has been sponsored.

f. Pharmaceutical companies will respect the privacy and personal information of patients**.**

2. Promotional Materials

a. Promotional materials provided to health care professionals by or on behalf of Safe Chain Solutions should:

i. be accurate and not misleading
ii. make claims about a product only when properly substantiated
iii. reflect the balance between risks and benefits
iv. be consistent with all other Food and Drug Administration (FDA) requirements governing such communications.

3. Presentations by Safe Chain Representatives & Accompanying Meals

a. Informational presentations and discussions by Safe Chain representatives and others speaking on behalf of a company provide health care providers with valuable scientific and clinical information about medicines that may lead to improved patient care.

b. In order to provide important scientific information and to respect health care professionals' abilities to manage their schedules and provide patient care, company representatives may take the opportunity to present information during health care professionals' working day, including mealtimes. In connection with such presentations or discussions, it is appropriate for occasional, incidental meals to be offered as a business courtesy to the health care professionals, as well as members of their staff attending presentations, so long as the presentation provides scientific or educational value, and the meal provided is:

i. modest as judged by local standards
ii. not part of an entertainment or recreational event
iii. provided in a manner conducive to informational communication.

c. Any such incidental meals offered in connection with informational presentations made by sales representatives, or their immediate managers should also be limited to in-office or in-hospital settings. Inclusion of an attendee's significant other or guest in a meal accompanying an informational presentation made by or on behalf of a company is not appropriate. Incidental meals can be provided only where there is a reasonable expectation, and reasonable steps are taken to confirm that each attendee has a substantive interaction or discussion with the company representative. Offering "grab-and-go" meals is not appropriate.

4. Prohibition on Entertainment and Recreation

a. Company interactions with health care professionals are professional in nature and are intended to facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on education and informational exchange and to avoid the appearance of impropriety, companies should not provide any entertainment or recreational

items, such as tickets to the theater/sporting events, sporting equipment, leisure or vacation trips, to any health care professional who is not a salaried employee of the company.

b. Such entertainment or recreational benefits should not be offered, regardless of the following:
    i. The value of the items
    ii. Whether the company engages the health care professional as a speaker or consultant
    iii. Whether entertainment or recreation is secondary to an educational purpose.
c. Occasional meals that are modest by local standards are permitted if they are offered in the appropriate circumstances and venues as described Section 3 of this SOP.

5. **Pharmaceutical Company Support for Third Party Educational or Professional Meetings**
    a. Third-party scientific and educational conferences or professional meetings can contribute to the improvement of patient care, and therefore, financial support from companies is appropriate.
    b. A conference or meeting is any activity, held virtually or at a physical location where:
        i. The event is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the event)
        ii. The main incentive for bringing attendees together is to further their knowledge of the topic(s) being presented.
    c. Since the giving of any subsidy directly to a health care professional by a company may be viewed as an inappropriate cash gift, any financial support should be given to the conference's sponsor, which, in turn, can use the money to reduce the overall conference registration fee for all attendees. When companies underwrite medical conferences or meetings other than their own, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue or digital platform belongs to the organizers of the conferences or meetings in accordance with their guidelines.
    d. Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty health care professionals attending the conferences or professional meetings, either directly to the individuals attending the conference or indirectly to the conference's sponsor. Additionally, funding should not be offered to compensate for the time spent by health care professionals attending conferences or meetings. This Section applies to in-person and virtual meetings.

6. Consultants
    a. Consulting arrangements with health care professionals allow companies to obtain information or advice from medical experts on such topics as the marketplace, products, therapeutic areas, and the needs of patients. Safe Chain will use this advice to ensure that the products they market are meeting the needs of patients. Decisions regarding the selection or retention of health care professionals as consultants should be made based on defined criteria such as general medical expertise and reputation, or knowledge and experience regarding a particular therapeutic area. Safe Chain will ensure that consultant agreements are neither incentives nor rewards for prescribing or recommending a particular medicine.
    b. It is appropriate for consultants who provide advisory services to be offered reasonable compensation for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services if applicable. Any compensation or reimbursement made in conjunction with a consulting arrangement

should be reasonable and based on fair market value and should not take into account the volume or value of past business that may have been or potential future business that could be generated for the company. Token consulting or advisory arrangements should not be used to justify compensating health care professionals for their time or their travel, lodging, and other out-of-pocket expenses. The following factors support the existence of a bona fide consulting arrangement:

i. A written contract specifies the nature of the consulting services to be provided and the basis for payment of those services
ii. A legitimate need for the consulting services has been clearly identified in advance of requesting the services and entering arrangements with the prospective consultants
iii. The criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the health care professionals meet those criteria
iv. The number of health care professionals retained is not greater than the number reasonably necessary to achieve the identified purpose
v. The retaining company maintains records concerning and makes appropriate use of the services provided by consultants
vi. The venue and circumstances of any meeting with consultants are conducive to the consulting services, and activities related to the services are the primary focus of the meeting; luxury resorts, high-end restaurants, and entertainment, sporting, or other recreational venues or events are not appropriate.

c. While receptions or meals that are modest by local standards may be appropriate during company-sponsored meetings with health care professional commercial consultants, companies should not provide recreational or entertainment events in conjunction with these meetings. It is not appropriate to pay travel or lodging expenses to non-faculty and non-consultant health care professional attendees at company-sponsored meetings, including attendees who participate in interactive sessions.

7. Prohibition of Non-Educational and Practice Related Items

a. Providing items for health care professionals' use that do not advance disease or treatment education — even if they are practice-related items of minimal value (such as pens, note pads, mugs, and similar "reminder" items with company or product logos) — may foster misperceptions that company interactions with health care professionals are not based on informing them about medical and scientific issues. Such non-educational items should not be offered to health care professionals or members of their staff, even if they are accompanied by patient or physician educational materials.
b. Items intended for the personal benefit of health care professionals (such as floral arrangements, artwork, or tickets to a sporting event) likewise should not be offered.
c. Payments in cash or cash equivalents (such as gift cards/certificates) should not be offered to health care professionals either directly or indirectly, except as compensation for bona fide services (as described in Sections 6 and 7). Cash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest. It is appropriate to provide product samples for patient use in accordance with the Prescription Drug Marketing Act.

8. Prescriber Data

a. Safe Chain can use non-patient identified prescriber data to facilitate information to and from health care professionals. Such prescriber data, which does not identify individual patients, enabling to:
   i. reveal important safety and risk information to prescribers of a particular drug
   ii. conduct research
   iii. comply with FDA-mandated risk management plans that require drug companies to identify and interact with physicians who prescribe certain drugs
   iv. track adverse events of marketed prescription drugs
   v. focus marketing activities on health care professionals who would most likely benefit from information about a particular drug.

b. Choosing to use non-patient identified prescriber data to facilitate communications with health care professionals should use this data responsibly by:
   i. respect the confidential nature of prescriber data
   ii. develop policies regarding the use of the data
   iii. educate employees about those policies
   iv. maintain a contact person to handle inquiries regarding the use of the data
   v. identify appropriate disciplinary actions for misuse of this data.

c. In addition, Safe Chain will respect and abide by the wishes of any health care professional who asks that their prescriber data not be made available to company sales representatives.

9. Independence & Decision Making

a. No grants, scholarships, subsidies, support, consulting contracts, or educational or practice-related items should be provided or offered to a health care professional in exchange for prescribing products or for a commitment to continue prescribing products. **Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a health care professional's prescribing practices.**

10. Training and Conduct of Company Representatives

a. Safe Chain Sales Representatives play an important role in delivering accurate, up-to-date information to health care professionals about pharmaceutical products. Sales Representatives serve as the primary point of contact between the Safe Chain and the health care professionals. As such, all Safe Chain representatives must act with the highest degree of professionalism and integrity.

b. Safe Chain Solutions ensures that all representatives who are employed by or acting on behalf of the company receive training about the applicable laws, regulations, and industry codes of practice, that govern the representatives' interactions with health care professionals.

c. Safe Chain will provide updated or additional training in all these areas as needed for the representatives who visit health care professionals.

d. Safe Chain will periodically check to ensure that representatives comply with the relevant policies and standards, acting when representatives fail to comply.

11. Quid Pro Quo
    a. Quid pro quo means “something for something” or “this for that.” It describes a situation where someone expects to receive a benefit or favor in return for what they provide.
        i. Bribery
            1. Where a person offers money, gifts, or favors to influence the actions of a Sales Representative or other person. This quid pro quo arrangement seeks to gain an unfair advantage through illegal means, directly challenging the integrity and trust of public service organizations.
        ii. Illegal Kickbacks
            1. Kickbacks involve a person or entity receiving a return on a referral or transaction. For instance, a healthcare provider might receive money from a pharmaceutical company for prescribing its drugs to patients. This quid pro quo arrangement compromises the integrity of professional decisions and patient safety, prioritizing personal gain over the welfare of others.
        iii. Legal Penalties for Quid Pro Quo Arrangements
            1. Unlawful quid pro quo arrangements can result in serious legal penalties, such as:
                a. Fines: Courts often impose fines on those found guilty of engaging in illegal quid pro quo arrangements. These fines aim to punish the wrongdoer and serve as a deterrent to others.
                b. Prison Time: Serious quid pro quo offenses, such as bribery or extortion, can lead to prison sentences. The length of imprisonment can vary depending on the severity of the crime.
                c. Probation: In some cases, the court might sentence an individual to probation instead of, or in addition to, other penalties. During probation, the person must follow certain conditions set by the court, such as regular check-ins with a probation officer and avoiding legal trouble.
                d. Community Service: Courts sometimes require offenders to complete community service hours as a way for them to give back to the community as reparation for their actions.
                e. Restitution: Restitution involves offenders compensating the victims of their unlawful actions. For example, if a quid pro quo arrangement led to financial loss for a victim, the court might order the offender to pay back the lost money.

Exhibit 3

SC 0046

Version Number	Description of Revision	Person Authorizing Revision	Date
6	Created SOP	Dakota Flowers	11.01.2024

Exhibit 3

Title:	Standard Operating Procedures for **Security**
Issue Date:	**5/2/2015**
Last Revised Date:	**09/17/2024**

Purpose:

To ensure the facility remains secure and in compliance with the U.S. FDA reference number 21CFR§205.50.

Scope:

Safe Chain Solutions will ensure the facility is secured by overseeing the following procedures: Security system (includes alarm and motion sensors), visitors, drug storage security, drug diversion and IT services.

Responsibilities:

VP of Operations	• Responds to any alarm calls after hours as needed. • Ensures drug storage area is secured. • Enforces policies directly relating to the drug storage area.
IT Services	• Ensure all computers and technology related to Safe Chain are up to date and secure. • Responsible for researching possible upgrades to security systems.
Holly Dodson	• Responds to any alarm calls after hours in the event the VP of Operations is unavailable.
SafeHouse	• SafeHouse has been established as an Observint Technologies authorized re-seller partner and a reliable security company for Delaware & Maryland.

Procedures:

1. Security System
    a. Security Cameras
        i. Safe Chain is equipped with 15 motion detecting security cameras. The COO and VP of Operations have access to security footage. Video is maintained for a minimum of 75 days.

Exhibit 3

b. Motion Sensors
    i. Motion sensors are installed and cover both sides of the warehouse, all doors and windows. If the motion sensors are triggered while the alarm is activated, the alarm will sound, and the security monitoring company (SafeHouse) will call the office during normal business hours or call the afterhours contact list to notify. Anytime the alarm is triggered local law enforcement will be requested to investigate and a Safe Chain employee will go to the facility to secure the building.
    ii. The call list in order is: Main Line, VP of Operations and Holly Dodson.
c. Alarm System
    i. The alarm system at Safe Chain has contacts on all doors. If any door is opened the alarm will be triggered after 30 seconds if the correct code has not been entered. The safes that store schedule II products each have contacts on them, if the safe door is opened prior to entering the alarm system being deactivated the alarm will immediately sound.

2. Visitors
    a. Safe Chain visitors or vendors will be required to sign in and be issued an ID badge by the employee who grants the visitor entry.
    b. A Safe Chain employee will escort all visitors, including regulatory and/or licensing agencies representatives at all times. For visitors who will be on site for an extended period and may need to be left without an escort, they should be guided to the conference room and asked to use the phone to reach an employee who will then escort the visitor where they need to go in the building.
    c. Any visitor who identifies themselves as representative from the Maryland Board of Pharmacy, Maryland Department of Health, Drug Enforcement Administration, NABP, or Food and Drug Administration will be asked to show their credentials. Once credentials are verified, visitor badges will be issued to each representative. If no credentials are provided, the compliance manager or general manager will reach out to the local field office or main office to verify the person(s) are part of their agency. If the agency is unable to verify the individuals, they will be asked to leave and law enforcement will be contacted.
3. Drug Storage Area Security
    a. Controlled Substance Storage
        i. Access to the controlled substance storage area is limited to warehouse personnel, VP of Operations, Holly Dodson (Order Analyst) and the compliance manager.
        ii. All employees with controlled substance access, must have a signed DEA Cage Access Agreement (See attached) that is signed and dates. These documents are stored within the Compliance Department.
        iii. Visitors or vendors who need access to the controlled substance storage area shall be granted entry only with an escort at all times.
    b. Non-Controlled Drug Storage Area
        i. The drug storage area is accessible to all Safe Chain Solutions personnel, however there is a clear pathway that non warehouse personnel will use to navigate the warehouse.
4. Diversion Prevention

a. Employee Diversion
    i. Employees are not permitted to bring any food, drink or personal items into the drug storage and processing area aside from clear water bottles. Personal items include but are not limited to:
        1. Coats
        2. Purses
        3. Lunch boxes
        4. Cell phones
        5. Gym bags.
b. Diversion via trash is prevented by not using trash bags. Trash receptacles are made of hard plastic and dumped into a larger trash receptacle every evening by the Warehouse Associate. The warehouse associate will then dispose of the garbage in a locking dumpster.

5. Co-located Businesses
    a. Safe Chain Solutions is the sole occupant of the building located at 822 Chesapeake Drive Cambridge, MD. No other business will be permitted to use the building.
6. IT Security
    a. All computers are accessed only by credentials issued by IT services. The user will be required to sign in after the computer or program has been idle for 5 minutes. Passwords must be changed every 180 days and each user's password must be kept confidential.
    b. User Logon Ids
        i. Individual users shall have unique logon IDs and passwords. An access control system shall identify each user and prevent unauthorized users from entering or using information resources. Security requirements for user identification include:
        ii. Each user shall be assigned a unique identifier.
        iii. Users shall be responsible for the use and misuse of their individual logon ID.
        iv. All user login IDs are audited annually, and all inactive logon IDs are revoked. The SCS Human Resources Department notifies the IT Department upon the departure of all employees and contractors, at which time login IDs are revoked.
        v. The logon ID is locked or revoked after a maximum of three (3) unsuccessful logon attempts which then require the passwords to be reset by the appropriate Administrator.
        vi. Users who desire to obtain access to SCS systems or networks must have a completed and signed Network Access Form. This form must be signed by the supervisor or department head of each user requesting access.
    c. Firewalls
        i. Authority from the Privacy Officer or appropriate personnel must be received before any employee or contractor is granted access to an SCS router or firewall.
    d. Timeouts
        i. Unattended Computers - Unattended computers should be locked by the user when leaving the work area. This feature is discussed with all employees during yearly security training. SCS policy states that all computers will have the automatic screen lock function

set to automatically activate upon fifteen (15) minutes of inactivity. Employees are not allowed to take any action which would override this setting.

e. Passwords
   i. User Account Passwords- User IDs and passwords are required to gain access to all SCS networks and workstations. All passwords are restricted by a corporate-wide password policy to be of a "Strong" nature. This means that all passwords must conform to restrictions and limitations that are designed to make the password difficult to guess. Users are required to select a password to obtain access to any electronic information both at the server level and at the workstation level. When passwords are reset, the user will be automatically prompted to manually change that assigned password.
   ii. Password Length – Passwords are required to be a minimum of eight characters.
   iii. Content Requirements - Passwords must contain a combination of upper- and lower-case alphabetic characters, numeric characters, and special characters.
   iv. Change Frequency – Passwords must be changed every 180 days. Compromised passwords shall be changed immediately.
   v. Reuse - The previous twelve passwords cannot be reused.
   vi. Restrictions on Sharing Passwords - Passwords shall not be shared, written down on paper, or stored within a file or database on a workstation and must be kept confidential.
   vii. Restrictions on Recording Passwords - Passwords are masked or suppressed on all online screens and are never printed or included in reports or logs. Passwords are stored in an encrypted format.

Version Number	Description of Revision	Person Authorizing Revision	Date
2	Document Revision	Dakota Flowers	03.15.2021
3	Document implementation	Dakota Flowers	06.22.2022
4	Document Revision-Bay Country/Safe House	Dakota Flowers	01.01.2023
5	Updated Formatting, updated responsibilities	Dakota Flowers	09.17.2024

ATTACHMENTS:
DEA Cage Access Agreement

DEA Cage Access Agreement

Safe Chain Solutions is a DEA compliant facility that stores both controlled and non- controlled substances. Access to the DEA cage is restricted to authorized employees of Safe Chain Solutions that have signed this DEA Cage Access Agreement and have been approved by management.

By signing this agreement, the approved Safe Chain employee acknowledges the following:

- Random drug tests may be conducted at any time without notice.
- They have not ever been convicted of a felony.
- The access codes to the DEA cage are strictly confidential.
- No unauthorized employee shall be allowed in the DEA cage.
- Any discrepancies in inventory are to be immediately reported to management.

Anyone not following the Standard Operating Procedure for handling-controlled substances will immediately be terminated and if necessary, will be prosecuted to the highest extent allowed by law.

Employee Signature_____Date_____

Printed Name_____Title_____

Title:	Standard Operating Procedures for **Shipping**
Issue Date:	**05/02/2015**
Last Revised Date:	**09/17/2024**

Purpose:

This policy will serve a guideline for shipping procedures at Safe Chain Solutions.

Scope:

Safe Chain Solutions warehouse associate(s), using the following procedures will be able to pick, pack, and ship orders accurately and proficiently.

Responsibilities:

Warehouse Associate(s)	• Primary check to ensure all products picked match what is on the packing slip of the order. • Double Check the picked shipment to ensure the primary check is accurate. • Pick orders. • Packs orders after checking them for accuracy. • Ships orders in shipping system

Procedures:

1. Packing slips are automatically generated in the ERP system (Acumatica) and must be printed by the warehouse associate(s). The ERP system will only generate a packing slip after an order is placed and has gone through all necessary Accounting and Compliance Checks. Once received, a Warehouse Associate will be assigned to the order and pick the items.
2. The packing slip will note which lot numbers and expiration dates are to be used. The products that will be on the packing slip will be the product that has been in inventory the longest OR has the shortest expiration date. This is consistent with first in/first out requirements (FIFO)
3. The Warehouse Associate will pick the order by locating which section of the warehouse the product is in and finding the NDC, lot number and expiration date that have been invoiced on the order. Each product on the item is individually picked and marked off on the packing slip. The process will be repeated for each product until the order has been fulfilled.
4. Once the order has been picked, another Warehouse Associate will double check the order to ensure the products match the packing slip and the products have not been damaged or improperly stored (i.e., in room temperature storage rather than refrigerator.).

Exhibit 3

a. The quantity, NDC, lot number and expiration date of the product should all match what is on the packing slip.

5. When shipping temperature-controlled products, the Warehouse Associate will follow the steps below.
   a. Once an order is placed for the product to go out, it is packed in a cooler with the appropriate ice packs, and bags as needed.
   b. A "WarmMark" indicator is then pulled and placed in an environment at least 5c (9 F) below the WarmMark activation threshold temperature for a minimum of 30 minutes.
   c. The activated indicator is then placed inside the cooler along with the product.
   d. Each customer that orders a temperature-controlled product with a "WarmMark" indicator will be sent a packing slip which includes the instructions of use. The "WarmMark" indicator also comes with self-explanatory reader that shows exposure time to temperatures above 8*C/46*F.
6. When shipping controlled substances, the Warehouse Associate will follow the steps below.
   a. Another Warehouse Associate will check the order for accuracy. (Completed in Procedure 4.)
   b. Controlled substances will be packaged in grey, self-seal tamper evident bags.
7. The order will then be packed and shipped via FedEx, UPS or DHL.

Version Number	Description of Revision	Person Authorizing Revision	Date
2	Document Revision	Dakota Flowers	03.15.2021
3	Document implementation	Dakota Flowers	06.22.2022
4	Updated Formatting, Updated Responsibilities and procedure 1.	Dakota Flowers	09.17.2024

Title:	Standard Operating Procedures for **Suspicious Order Monitoring (SOMS) & Diversion Prevention**
Issue Date:	**12/15/2018**
Last Revised Date:	**09/17/2024**

Purpose:

This process is to ensure Safe Chain Solutions is monitoring all controlled substance orders to be sure they are not suspicious per DEA regulations.

Scope:

All orders placed for controlled substance will be analyzed electronically via our SOMS program.

Responsibilities:

Compliance Team	• Responsible for order entry into the SOMS Software. • Responsible for reviewing SOMS system and identifying potential red flags

Definitions:

1. Drug Utilization Report (DUR)
    a. DUR must include a date range or be specified in the correspondence when providing the requested DUR to the Compliance Department.
    b. The requested DUR will be accepted in Microsoft Excel format only. Required data parameters included in DUR are as follows: date dispensed, drug name dispensed, NDC dispensed, quantity dispensed, and dosage units dispensed.
    c. Data will provide the Compliance Department with the requested date range (30, 60 or 90-day) data spread of both Controlled and Non-Controlled products dispensed from the pharmacy.

2. DEA Automation of Reports and Consolidated Orders System (ARCOS) Retail Buyer Statistics Data
    a. ARCOS reports are generated online courtesy of the DEA for CII and CIII narcotics.
    b. Data is separated by drug class family and broken into Dosage Units by number of Suppliers
    c. Reports are a rolling 6-month view showing dosage units by family class. See example below.

3. NavigateSOM
    a. Third party software that uses artificial intelligence-powered algorithms to calculate flagged orders based on DEA requirements.
    b. The data is downloaded from the ERP system and uploaded to NavigateSOM.
    c. Customizable and usage of 12 intuitive algorithms that programmatically review order data.

4. Controlled Substance Solutions (CS Solutions)
    a. A third-party vendor that screens the pharmacy dispensing data and maintains compliance with HIPAA/PA regulations and requirements to protect patient and dispensing data. While deidentifying all HIPAA-related data outside of where it originated, without compromising the integrity of the data that Safe Chain needs to manage their compliance program.

Procedures:

1. All controlled substance orders are screened by the NavigateSOM system.
    a. Specific roles and permissions are given to each NavigateSOM user.

2. Customer Verification
    a. Customer distribution information is either provided by our third-party data gathering company, CS Solutions, or by self-reported drug utilization reports
    b. CS Solutions screening is required for those customers seeking to purchase CII's and narcotics
    c. Drug Utilization Reports are required for those seeking CIII- CV, non-narcotic drugs.
    d. DEA ARCOS purchasing data is also used for determination of control limits

3. Compliance reviews customer orders to check for the "9 Red Flags"
    a. The 9 Red Flags are described below:
        1. Ordering ratio of Highly Diverted Controlled Substances to noncontrolled Substances
        2. Ordering ratio of Highly Diverted Controlled Substance base codes or drug families to non-Controlled Substances
        3. Excessive ordering growth of Controlled Substances
        4. Unusual formulation ordering
        5. Out-of-area patients
        6. Cash prescriptions
        7. Prescriber activity of Customers
        8. Public regulatory actions against Customers
        9. Customer termination data

4. SOM algorithms are developed by NavigateSOM and customized per Safe Chain Solutions requirements. Algorithms implemented are below:
    a. Algorithm 1b: NDC over quantity average
    b. Algorithm 3: NDC frequency over tolerance level
    c. Algorithm 4b: NDC over customer's family average

d. Algorithm 5b: NDC over customer's quantity average
e. Algorithm 6b: NDC over customer's monthly trade average
f. Algorithm 9: Algorithm to flag line items with already existing suspicious or NDC flags.

5. If an algorithm is triggered, an order is flagged by the NavigateSOM program.
    a. Once the order has been flagged, compliance staff must review the order
    b. Compliance will reach out to the customer to review the details of the order to determine if the order is in fact suspicious.
    c. If there is a reasonable explanation for the order, compliance staff will document the explanation on NavigateSOM system and continue processing the order. Red flag's will be kept electronically on the NavigateSOM website.
        i. If there is no reasonable explanation, the order will not be processed and a SORS report/transaction will be reported to the DEA via the electronic SORS reporting function on the DEA webpage. The following information will be provided to the DEA:
            1. DEA registration number of the entity seeking to purchase the controlled substances.
            2. The date the order was received.
            3. DEA registration number of the reporter
            4. The National Drug Code number and the quantity of the controlled substance ordered.
            5. For schedule II:
                a. the order form number (DEA Form 222)

6. Copies of all SOMS reports, and due diligence will be kept electronically in the compliance records.

7. If the order is considered suspicious and a SOMS report has been submitted online to the DEA, the account will have to be reviewed to determine if Safe Chain Solutions will continue to supply controlled substances to the customer.
    a. Compliance may request CS Solutions.
    b. CS Solutions report results will be reviewed by compliance staff and upper management to come to a consensus about the customer status
    c. If Safe Chain is to discontinue to supply controlled substances, the customer and sales representative will be notified via email.
    d. If it is determined that we will no longer supply controlled substances, the customer may still be approved to purchase over the counter items and non-controlled substances.

8. Shipping controlled substances will be done in a 3:1 ratio
    a. Each controlled substance order placed is reviewed for satisfaction of a 3:1 ratio. For more details, please reference the SOP named *"Ratio Requirements for Controlled Substance Ordering"*

Version Number	Description of Revision	Person Authorizing Revision	Date
2	Document implementation	Dakota Flowers	04.01.2021
3	Document implementation	Dakota Flowers	05.20.2022
4	Update Ratio and added algorithm's	Dakota Flowers	11.7.22
5	Added 9 Red Flags	Dakota Flowers	12.29.22
6	Updated Formatting, Updated CS Solutions and added Algorithm 9.	Dakota Flowers	9.17.2024

Title:	Standard Operating Procedures for **Pedigree (T3) Documentation**
Issue Date:	**03.01.2023**
Last Revised Date:	**09.17.2024**

Purpose:

This policy will establish a guideline for proper Pedigree (T3) Documentation. Ensuring to comply with the FDA's DSCSA policies and procedures.

Scope:

Working together, the Safe Chain Compliance Department, Purchasing Department and BizTranSights will ensure proper Documentation and receiving on pedigree data and documentation.

Responsibilities:

Compliance Department	• Collection of any initial missing T3 documentation from vendors and/or Authorized Distributors (AD) Morningstar other than Morning Star and Crivitz to Sameer's team • Communication with Vendors for discrepancies regarding lot number, transaction date and expiration date. • Communication with Customers regarding Rfxcel login initial set up, password help, assistance with navigation of Rfxcel website, as well as sources T3 documents at request of customer.
Purchasing Department	• Sending BTS invoices from Morning Star Pharmacy and Crivitz Pharmacy the Purchasing Department received through AD accounts • Communication with Vendors prior to submitting Receipt of Goods (ROG) for discrepancies of NDC and Quantity.
BizTranSights (BTS)	• Responsible for all data integrations.

Definitions:

1. BizTranSights (BTS): integration services and custom integration from reliable data transfer to application workflow optimization.
2. FDA's DSCSA: outlines steps to achieve interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States.
3. AD: Authorized Distributor
4. Rfxcel: Traceability cloud-based platform

Procedures:

1. BTS team reviews all transaction receipts generated from Acumatica.
2. BTS team has full access to Safe Chain Solutions pedigree inbox to email/organize invoices, backup paperwork and PDF's.
3. BTS team will store invoices, backup paperwork and PDF's in SCS OneDrive folder labeled with the Purchase Order number.
4. Upload the FTP receipt file formatted for Acumatica into Rfxcel.
5. If the Vendor Invoice and T3 PDF Found:
    a. Verify the Lot and NDC on the Vendor PDF before uploading.
    b. Attach the Vendor PDF to the transaction receipt into Rfxcel.
    c. BTS team will continuously update the Daily T3 master document with the status of complete.
    d. Upload shipments into Rfxcel file for Acumatica.
6. If the Vendor Invoice and T3 PDF is NOT Found:
    a. Using the Safe Chain Pedigrees outlook (pedigrees@safechain.com), email Safe Chain Compliance and Purchasing Department for each missing vendor T3 with the subject line shown with PO number and vendor name.
    b. One email per vendor per day will be issued.
        i. BTS Team will update the Daily T3 Master Document with the status of documents and date of the sent email.
        ii. Upload documentation into Rfxcel file for Acumatica without Receipt PDF.
    c. The Safe Chain Compliance Department will contact the vendor to get the required missing documents.
    d. Upon receiving the missing T3 documents, the Compliance Department will send the documents to the Safe Chain pedigrees inbox for the BTS team to complete the following:
        i. Attach the PDF to past receipt in Rfxcel.
        ii. Find all shipments for that receipt and VOID the shipments manually in Rfxcel.
        iii. Re-submit the same shipments again in Rfxcel, updating the PDF.
7. 7. BTS team will update any Rfxcel errors in the Daily T3 Master Document.

8. BTS team will email any pending or unresolved Vendor T3's to the Compliance and Purchasing department weekly.

Version Number	Description of Revision	Person Authorizing Revision	Date
2	Document Creation	Dakota Flowers	03.01.2023
3	Document implementation	Dakota Flowers	03.30.2023
4	Updated Formatting	Dakota Flowers	09.17.2024

Title:	Standard Operating Procedures for **Customer Trading Partner Validation**
Issue Date:	**05.02.2015**
Last Revised Date:	**09.17.2024**

Purpose:

To ensure Safe Chain Solutions is conducting business with authorized licensed healthcare facilities and businesses.

Scope:

All validations will be approved by compliance first and then Accounting.

Responsibilities:

Compliance Team	• Responsible for all trading partner validation and research • Validating which drugs will be purchased/sold to trading partner
Accounting Department	• Determine the terms and conditions of sales/remittance to trading partner

➢ **PROCEDURES:**

1) Initial Customer Authentication and Validation
   a) New customer applications are initiated by the sales team via DocuSign. Customer Applications may also be submitted via the Safechain.com website without a sales Representative.
   b) Retail Pharmacy Customers will complete the DocuSign application labeled "Pharmacy" which includes:
      i) Completed agreement(s) (Account Terms and Conditions, Resale Tax Certificate, Signed Payment Authorization, and Credit application, if applicable)
      ii) Copy of resident state License
      iii) Copy of DEA license (if applicable)
      iv) Photographs of the pharmacy to include the following:
         (1) Pharmaceutical storage area (behind the counter, counter area, OTC section)
         (2) Outside of building (including signage)
         (3) Controlled Substance storage (safe, locked cabinet)
      v) 90 days DUR (if applicable)
      vi) Controlled Substance SOP
      vii) Acknowledgement of CS Solutions; third-party data gathering company (if applicable)

Exhibit 3

2) General Trading Partner Requirements
   a) Potential trading partners *may* be denied for the following reasons:
      i) Disciplinary actions against pharmacy license and/or a Suspended or Revoked PIC and/or Pharmacy License
      ii) Shipping address does not match license address.
      iii) Anti-diversion methods are deemed inadequate.
      iv) Large Discrepancies on the application compared to the DUR, CS Solutions, or any information discovered while vetting the customer.
      v) Dishonest or Forging Documents on their Application
      vi) Pharmacy and/or PIC is under investigation (Depending on the nature of the case)
      vii) Review of the Trading Partners DUR and seeing over 30% of prescriptions are controls (For Control customers)

3) On-Going Trading Partner Requirements
   a) After initial approval, all customer licenses will be reviewed at least annually. Any expired licenses will be verified online via the governing body's webpage (i.e. State Board of Pharmacy).
   b) Annual 'Know Your Customer' update.
   c) Re-submission of CS Solutions Report as needed for up-to-date data.

Version Number	Description of Revision	Person Authorizing Revision	Date
2	Document Revision	Dakota Flowers	03.15.2021
3	Document implementation	Dakota Flowers	06.22.2022
4	Document Revision, Customer SOP, removed Vendor	Dakota Flowers	06.16.2023
4	Document Revision, Add CS Solutions, Remove Pro Compliance	Dakota Flowers	09.01.2023
5	Updated Formatting	Dakota Flowers	09.17.2024

Exhibit 3

Title:	**Standard Operating Procedures for Vendor Trading Partner Validation**
Issue Date:	**05.02.2015**
Last Revised Date:	**09.17.2024**

Purpose:

To ensure Safe Chain Solutions is conducting business with authorized licensed facilities and healthcare businesses.

Policies:

All validations will be approved by compliance first and then Accounting.

Responsibilities:

Compliance Team	• Responsible for all trading partner validation and research • Validating which drugs will be purchased to trading partner
Accounting Department	• Determine the terms and conditions of sales/remittance to trading partner

Procedures:

1. Initial Vendor Authentication and Validation
   a) Vendor validations will be conducted upon opening a new account with a vendor.
   b) The Compliance Team will verify all paperwork/licenses from prospective manufacturers/vendors and/or their 3PL company, if utilized. Requirements include, but are not limited to:
      i) Completed agreement.
      ii) Confirming that the vendor has a physical place of business.
      iii) Copy of current wholesaler license.
      iv) Copy of current domicile license, if different.
      v) In the case of DEA Registration, current DEA Registration.
      vi) In the case of VAWD accreditation, current VAWD accreditation certificate.
      vii) Verification of compliance with licensure reporting requirements to the FDA (under DQSA section 503(e) for wholesale distributors and under section 584(b) for 3PL companies).
      viii) Review the Vendor Intake Application for completeness and references
2) General Trading Partner Requirements
   a) At no time will the product be accepted if there is a provider on the Transaction History.
   b) Trading partners will be asked to provide information to verify they are compliant with section 582 of

Exhibit 3

the DSCSA as deemed appropriate.

3) On-Going Trading Partner Requirements
   a) Vendor licenses are validated at least annually, and scanned copies of new licenses are requested at this time.
   b) Annual 'Know Your Customer' update
   c) All entities must be "authorized" per Title II of the Drug Quality Security Act, as follows:
      i) in the case of a manufacturer or re-packager, having a valid registration in accordance with section 510 by searching http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm
      ii) in the case of a wholesale distributor, having a valid license under State law or section 583, in accordance with section 582(a)(6) by searching http://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/index.cfm
      iii) in the case of a third-party logistics provider, having a valid license under State law or section 584(a)(1), in accordance with section 582(a)(7) by searching http://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/index.cfm

Version Number	Description of Revision	Person Authorizing Revision	Date
2	Document Revision	Dakota Flowers	03.15.2021
3	Document implementation	Dakota Flowers	06.22.2022
4	Document Revision, Vendor only, removed customer	Dakota Flowers	06.13.2023
5	Updated Formatting	Dakota Flowers	09.17.2024

Title:	Standard Operating Procedures for **Vendor and Transaction History Authentication**
Issue Date	**5/2/2015**
Last Revised Date:	**09/17/2024**

Purpose:

To ensure the correct actions are taken with Transaction Histories of all products shipped to and from Safe Chain Solutions (SCS) and when appropriate, vendor authentication is performed as required by the most stringent law or regulation and in compliance with the Code of Federal Regulations Sections 21CFR§203.3, 21CFR§203.50, 21CFR§203.60.

Policies:

All validations will be approved by compliance first and then Accounting.

Responsibilities:

Compliance Team	• Responsible for evaluating inbound Transaction History

Guidelines:

1. All products received at a SCS distribution center from wholesale distributors shall include a Transaction History.
2. A cause for Authentication shall be conducted if:
   (a) there is any reason to believe that the drugs purchased from another wholesale distributor are counterfeit, suspect of counterfeit, misbranded, or adulterated. (See Procedures)
   (b) A cause for Authentication shall be conducted if there is any reason to believe that the drugs were previously distributed to a pharmacy or via a special pricing contract, in violation of VAWD standards.
3. Notify your manager right away if product cannot be verified.
4. Products that cannot be verified will be treated as suspect or illegitimate products.
5. Proper authorities to contact in case of suspected counterfeit product that cannot be verified are Maryland Board of Pharmacy and the Food and Drug Administration within **24 hours**.
6. A Transaction History shall be created for all prescription drugs distributed by SCS.
7. Transaction Histories shall be available for inspection and photocopying by authorized Federal, State or local law enforcement agency officials for a period of six (6) years after the date of their creation (the "Retention Period").

Exhibit 3

8. Transaction History records (both electronic and hard copy versions) will be kept at this office and shall be readily available for authorized inspection during the retention period. Records that are not electronically retrievable at the time of request by an authorized official shall be made available for inspection within two (2) working days of the request.

All vendors SCS does business with shall be authenticated by verifying their wholesale distribution license for their state and SCS shall maintain a list of all vendors and their license numbers as well as a hard copy or online verification of their license which shall be updated annually.

Procedures:

A. When the product is received, verify there is a Transaction History for the product. If no Transaction History is included with the product, contact the vendor. Once you have the Transaction History, verify the product information on the Transaction History matches the actual product received.
B. If there is any reason to believe that the product is counterfeit, suspect of counterfeit, misbranded or adulterated, conduct a For Cause Authentication by verifying the following information for ALL of the owners of the product back to the manufacturer:
    a. The date of purchase
    b. Lot number
    c. Sales invoice number and
    d. Contact information including name, address, telephone number and email address for all wholesalers up to the purchase from the manufacturer.
    e. Notify your manager right away if product cannot be verified.
C. When Transaction History is completed, it will be saved and stored in the purchase order Transaction History file.
D. Once product ships, corresponding Transaction History will be available to the recipient via an online portal.
E. If a product is returned from the customer, Transaction History will be corrected to reflect additional locations until disposed of or distributed again. In the case of the product being resold by SCS client, another additional location will be added.
F. <u>Establishing the Legitimacy of Prescription Drugs and/or Devices</u>
    a. <u>It is the policy of SCS to only purchase product directly from manufacturers or a distributor that purchases directly from the manufacturer.</u>
    b. <u>Establishing the Legitimacy of Prescription Drugs and/or Devices purchased directly from a manufacturer source:</u>
        i. <u>The T3 must reflect that the product came directly from the manufacturer.</u>
        ii. <u>SCS will verify that Transaction Information exactly matches those products received.</u>
        iii. <u>SCS shall make every reasonable effort to verify authenticity of merchandise received and in conjunction, make every reasonable effort to comply with T3 analysis and supplier licensing to verify the authenticity of received merchandise.</u>

Exhibit 3

iv. If unable to authenticate a T3, notification will be made to the Board of Pharmacy and Food and Drug Administration within **24 hours**.

c. Establishing the Legitimacy of Prescription Drugs and/or Devices purchased directly from a distributor that purchases directly from a manufacturer:
   i. The T3 must reflect that there are only two entities listed on the T3, the manufacturer and the distributor.
   ii. SCS will verify that Transaction Information exactly matches those products received.
   iii. SCS shall make every reasonable effort to verify authenticity of merchandise received and in conjunction, make every reasonable effort to comply with T3 analysis and supplier licensing to verify the authenticity of received merchandise.
   iv. If unable to authenticate a T3, notification will be made to the Board of Pharmacy and Food and Drug Administration within **24 hours.**

G. FDA Guidelines on Suspect Product
   a. Trading Partners and Product Sourcing
      i. Be alert for offers of product for sale at a very low price or one that is "too good to be true."
      ii. Purchasing from a source new to the trading partner.
      iii. Receiving an unsolicited sales offer from an unknown source. Trading partners might receive unsolicited offers or advertisements through an email, a fax, a telephone call, or an in-person sales call from a person or entity with whom they do not have an established business relationship.
      iv. Purchasing on the Internet from an unknown source. Trading partners might be searching for a better price on the Internet or for a product that they cannot obtain from their usual source and might be tempted to turn to a person or entity with whom they do not have an established business relationship.
      v. Purchasing from a source that a trading partner knows or has reason to believe has transacted business involving suspect products, such as:
         1. A trading partner that has been involved in business transactions where they sold or delivered suspect or illegitimate product.
         2. A trading partner that has a history of problematic or potentially false transaction histories or pedigrees, such as those that contain misspelled words or incomplete information.
         3. A trading partner that is reluctant to provide a transaction history or pedigree associated with the product being purchased or does not do so in a timely manner.
         4. Transaction information, a transaction statement, and/or transaction history that appears to be incomplete or suspicious
   b. Supply, Demand, History, and Value of the Product
      i. Product that is generally in high demand in the U.S. market.
      ii. Product that is in higher demand because of its potential or perceived relationship 166 to a public health or other emergency (e.g., antiviral drugs).

Exhibit 3

iii. Product that has a high sales volume or price in the United States.
iv. Product that has been previously or is currently being counterfeited or diverted (e.g., HIV, antipsychotic, or cancer drugs).
v. Product that has been previously or is currently the subject of a drug shortage
vi. Product that has been or is the subject of an illegitimate product notification under the DSCSA or other alert or announcement related to drug quality.
vii. Product that has been or is the subject of an FDA counterfeit or cargo theft alert

c. Appearance of the Product
   i. Appearance of a package or a container used for transport (e.g., case or tote) that seems suspicious (e.g., it has a label that contains misspellings or appears different from the standard label for that product in color, font, images, or otherwise).
   ii. Package that uses foreign terms, such as a different drug identification number rather than the National Drug Code (NDC).
   iii. Package that is missing information, such as the lot number or other lot identification, or the expiration date.
   iv. Package that is missing anti-counterfeiting technologies normally featured on the FDA-approved product that are easily visible to the eye, such as holograms, color shifting inks, or watermarks.
   v. Finished dosage form that seems suspicious (e.g., it has a different shape or color from the FDA-approved product, a different or unusual imprint, an unusual odor, or there are signs of poor quality like chips or cracks in tablet coatings or smeared or unclear ink imprints
   vi. Closely examine the package and the transport container (such as the case or tote):
      1. To look for signs that it has been compromised (e.g., opened, broken seal, damaged, repaired, or altered).
      2. To see if it has changed since it was last received for an unexplained reason (e.g., a notification about the change from the manufacturer has not been received).
      3. To see if product inserts are missing or do not correspond to the product.
      4. For shipping addresses, postmarks, or other materials indicating that the product came from an unexpected foreign entity or source.
   vii. Closely examine the label on the package, or the label on the individual retail unit, if applicable, for:
      1. Any missing information, such as the lot number or other lot identification, NDC, or strength of the drug.
      2. Any altered product information, such as smudged print or print that is very difficult to read.
      3. Misspelled words.
      4. Bubbling in the surface of a label.
      5. Lack of an Rx symbol.
      6. Foreign language with little or no English provided.
      7. Foreign language that is used to describe the lot number.

Exhibit 3

8. A product name that differs from the name of the FDA-approved drug.
9. A product name that is the product name for a foreign version of the drug.
10. A product that is transported in a case or tote, when not expected under the circumstances.

H. Lot numbers and expiration dates on product that do not match the lot numbers and expiration dates of its outer container.

REVISION HISTORY

Version Number	Description of Revision	Person Authorizing Revision	Date
1	Format Update	Dakota Flowers	03.15.2021
2	Implementation of formal "Vendor and Transaction History Authentication" SOP	Dakota Flowers	05.05.2022
3	Added Guideline "Products that cannot be verified will be treated as suspect or illegitimate products.	Dakota Flowers	06.12.2023
4	Updated Formatting,	Dakota Flowers	09.17.2024

LSPedia

ONESCAN

Global Traceability & Supply Chain Solutions

FOOD MANUFACTURING 3PL WHOLESALE HEALTHCARE PHARMACY

Exhibit 4

SC 0071

About LSPedia

A global leader in turnkey compliance, serialization, traceability, business intelligence, and supply chain solutions to the pharmaceutical, healthcare, and food industries. Manufacturers, wholesale distributors, 3PLs, and dispensers rely on LSPedia to ensure compliance, secure the supply chain, manage operations, make smarter business decisions, and improve supply chain efficiencies.

Global Network

Serialization

Verification

Exceptions Management

Warehouse Solutions

Big Data

Rx Lifecycle Management

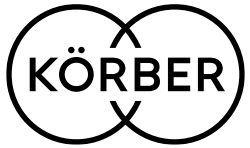
ATP License Management

Suspect Order Monitoring

Exhibit 4

... and thousands more

Exhibit 4



... and many more!

Exhibit 4

Global Traceability Solutions

Comprehensive regulatory compliance and supply chain solutions, ensuring companies engaged in international business achieve seamless adherence to diverse regulations and efficient supply chain management across global operations.

Exhibit 4

SC 0075

U.S. DSCSA Requirements

Product Tracing and Interoperability

Pharmacies must be interoperable to receive and maintain serialized EPCIS product information for every prescription drug.

Authorized Trading Partners (ATP)

Products must be purchased from authorized trading partners with valid licenses.

Enhanced Drug Distribution Security (EDDS)

Match/verify the product identifiers (PI) and the data (EPCIS) upon receiving. Notify suppliers of any errors and discrepancies.

DSCSA Standard Operating Procedures (SOPs)

Trading partners are required to have DSCSA standard operating procedures (SOPs) to establish and document the processes that ensure compliance.

Data Retention and Reporting

Keep all tracing documentation for at least six (6) years and provide to authorities within 48 hours of a request.

Product Identifiers

Ensure all products contain the correct product identifiers that allows the product to be traced. (serial number, GTIN, lot, expiration)

Product Verification

Verify the authenticity of suspect or illegitimate products with the manufacturer. Promptly notify trading partners of any suspect or illegitimate products.

FDA 3911

Immediately report illegitimate products to the FDA via form 3911.

Exhibit 4

EPCIS
Interoperability and Serialized Receiving

Serialized unit-level tracing using EPCIS (Electronic Product Code Information Services) is replacing lot-level tracing entirely. Under the Drug Supply Chain Security Act (DSCSA), EPCIS must be used to capture and share information, such as the product identifier, serial number, and transaction history, of each individual unit of product.

OneScan is the industry's leading platform for serialization and EPCIS data interoperability. EPCIS is where serialized unit-level events are created, updated, and stored. OneScan enables serial generation, encoding, commissioning, reworking, and decommissioning.

Key Features

Efficient Shipping/Receiving

Our system revolutionizes the shipping/receiving process, enabling manufacturers and distributors to complete the entire workflow in a matter of minutes. Manufacturers can provide EPCIS data through direct AS2 connections

Seamless Data Integration

Harmonious integration with your Enterprise Resource Planning (ERP) & Warehouse Management Systems (WMS), provides a streamlined and cohesive solution for warehouse management. This integration enhances operational efficiency, allowing for accurate, real-time tracking.

Streamlined Compliance

EPCIS facilitates DSCSA compliance by providing a standardized and traceable framework for documenting the entire pharmaceutical supply chain, ensuring accurate and transparent product information exchange.

Interoperability

OneScan facilitates seamless interoperability by connecting (via AS2) with your trading partners.

Each (Unit) Serialization

Carton Serialization

Case Serialization

Pallet Serialization

Benefits

- Accurate EPCIS/Serialization
- 6+ Years of Data Storage
- Aggregation
- DSCSA Compliance Guarantee
- Seamless Data Integration with ERP & WMS systems

Exhibit 4

VRS Verification Router Service

LSPedia's Verification Router Service for EPCIS provides a secure and efficient way for companies to manage their product data in compliance with DSCSA regulations. By routing and verifying product information in real-time through the network, directly with the manufacturer's lookup directory, our service helps companies ensure that their supply chain operations are always compliant, efficient, and secure.

Key Features

Product Verification

Verifier initiates a verification by scanning a 2D barcode from an integrated warehouse system or from LSPedia's Verifier module. Verifier routes the verification to the manufacturer's serial data repository and retrieves the corresponding response.

Verification History

Verifier keeps the complete history of each verification transaction. The history can be searched, researched, and audited for any specific transaction. Verifier sorts and groups all transaction history data and can export that data to other business systems for analytics and audits.

Look-Up Directory (LD)

Verifier consolidates all LD records on the VRS network with all the GTIN and GTIN Connection Information. The LD is synchronized daily in real-time to keep the connection information up to date so that all requests can be routed to the correct data repository.

Real-Time Collaboration

Portal and messaging capabilities within the VRS network and outside of it ensure that any issues with data are routed to contributing parties for awareness and resolution, all within the VRS platform.

Benefits

- Manufacturer Authentication
- 24/7/365 Access
- Responses in Less Than 1 Second
- Updated LD

Complimentary Modules

- EPCIS
- EDGE Warehouse Solution
- Investigator

EDGE Warehouse Management

LSPedia's Edge module enables Scan In (receive) and Scan Out (pick/pack/ship) of packages utilizing the 1D UPC barcode and the 2D data matrix barcode. It also enables aggregation for serialized packages. Edge can be used as a stand-alone or integrated with your ERP/WMS to generate and exchange data files across the supply chain.

Key Features

WMS Integrations

Process efficiency to meet regulatory requirements without the introduction of additional steps.

Uninterrupted Flow

Keep product out of quarantine and en route to end users with efficient receiving and EPCIS matching.

Mobile Scanning

Scanning technology on the go to support pick, pack, and ship everywhere it takes place across your operation. Works on any device; iOS, Android, mobile scanners, smart phones and tablets.

Benefits

- 1D/2D Data Collection
- Aggregation and Labeling
- Receiving Matches ASN/EPCIS
- Pick/Pack/Ship and Scan Once
- Integrated ASN/EPCIS
- Partial Shipment

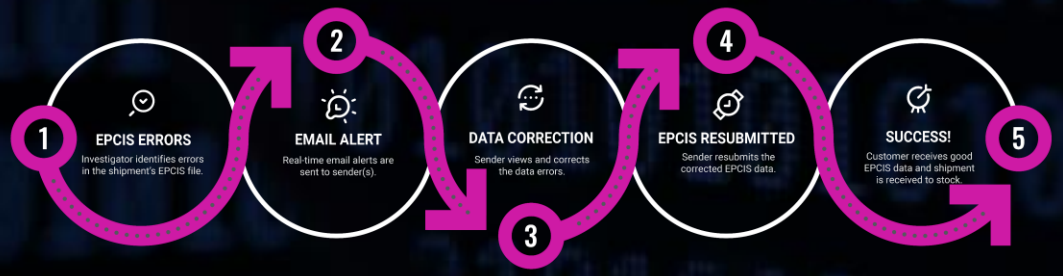
Complimentary Modules

- Verification Router Service (VRS)
- EPCIS
- CONNECTOR (APIs)
- Customer Portal

Exhibit 4

INVESTIGATOR
Exceptions Management

Seamlessly collaborate with trading partners to resolve errors and exceptions quickly. Investigator is the go-to exceptions management solution for the FDA's Enhanced Supply Chain Security requirement, a 2023 mandate under the Drug Supply Chain Security Act (DSCSA). It manages the EPCIS and VRS errors and exceptions that arise from data transactions.



Key Features

AI Data Validation
Investigator validates data following DSCSA, GS1, and configurable business rules. The AI detects EPCIS errors and displays details of all errors.

Speed
The notification email contains a live hyperlink that enables trading partners to easily view, edit, and apply fixes within a few minutes. The result is a successful EPCIS data file exchange that keeps the supply chain moving.

Security
Secure and encrypted file exchange delivers data to the right parties, and only the right parties.

Automation & Collaboration
Investigator automatically emails the responsible point of contact (PoC) in real-time. A speedy resolution is vital as the products must be quarantined until the errors are resolved. FDA DSCSA provides suppliers 72 hours to resolve the data errors.

Benefits

- AI Data Validation
- Automated Error Notifications
- Quick Error Resolutions

Complimentary Modules

- Customer Portal
- Investigator EPCIS
- Investigator VRS
- Investigator Logistics
- Supply Chain Big Data Analytics

Exhibitt 4

ATP Authorized Trading Partners

LSPedia's ATP Module is your comprehensive solution for achieving seamless compliance with licensing requirements mandated by the DEA and FDA's Drug Supply Chain Security Act (DSCSA). Engineered to ensure that your business only engages with authorized trading partners, the ATP Module revolutionizes license management, authentication, and validation. By streamlining the validation process, this module empowers businesses to overcome operational bottlenecks, enhance compliance, and foster sustainable growth.

NABP National Association of Boards of Pharmacy

MedPro SYSTEMS

Key Features

Risk Mitigation

Doing business with authorized trading partners is a Federal and state regulatory requirement. ATP ensures that you trade with suppliers and customers with valid regulatory standing, and you are not penalized for their license laps.

Automated Workflow

Don't limit your business speed to someone checking data in multiple websites. ATP eliminates these manual tasks with a single platform, saving time and reducing clerical workload for buyers.

Velocity Acceleration

You can now focus on taking orders instead of checking license. Switch to ATP for real-time validation through NABP Pulse and/or MedPro. It reduces time, labor, and risk associated with verifying the trading partner for every order.

Streamlined Compliance

Compliance does not need to be complicated. ATP simplifies the process of managing, authenticating, and validating licenses.

Benefits

- License Management
- Communication Tools
- File Attachment
- Real-Time License Validation available via NABP Pulse & Medpro
- OCI Integration
- GLN Cross Reference

Complimentary Modules

- Suspect Order Monitoring (SOM)
- Investigator
- Policies and SOPs

Exhibit 4

CONNECTOR
API Integration

LSPedia's API Integration module offers 24+ standard RESTful APIs for easy integration to your business systems. Connector enables master data, serialized product data, and order data to flow seamlessly in real-time or in batches between connected systems. No more scanning into multiple systems or risking human (data entry) errors!

Key Features

Efficiency Through Automation
By unlocking LSPedia's APIs, the Connector module enables automated data flow between systems, reducing the need for repetitive scanning into multiple platforms and enhancing operational efficiency.

Streamlined Operations
Connector facilitates seamless integration with various systems such as ERP, WMS, PMS, EHR, and more, eliminating manual data entry errors and significantly streamlining overall operations.

Error Prevention
OneScan functionality ensures accurate and error-free data transmission, preventing discrepancies that may arise from manual input and promoting data integrity across integrated systems.

Holistic Data Accessibility
With the Connector module, a single scan initiates a comprehensive data flow, allowing users to effortlessly access and update information across various systems, enhancing overall connectivity and information accessibility.

Benefits

- Eliminate Multiple Scans
- Sync Data Across All Systems
- Increased Operational Efficiencies

Complimentary Modules

- EPCIS
- EDGE Warehouse Management
- VRS Connector

Exhibit 4

CUSTOMER PORTAL

The Customer Portal module provides downstream customers with 24/7/365 access to their ASN and EPCIS transaction data, meeting DSCSA requirements and fostering transparency. By offering a centralized and user-friendly platform, the module enhances operational efficiency by enabling customers to independently retrieve and download their data, minimizing the need for manual communication and allowing your staff to focus on higher-value tasks. This self-service portal not only ensures compliance but also promotes proactive customer engagement and a streamlined business workflow.

Key Features

Customer Access to Transaction Data

The Customer Portal module ensures compliance with DSCSA requirements by offering downstream customers a dedicated portal for 24/7/365 access to their EPCIS transaction data, promoting transparency and accessibility.

Efficient Data Retrieval

By providing a centralized portal for dispenser customers to retrieve their data without the need for direct AS2 connections, LSPedia enhances operational efficiency, reducing the reliance on manual communication methods and enabling streamlined data retrieval processes.

Proactive Customer Engagement

The Customer Portal empowers dispenser customers to independently access and download their transaction data, fostering proactive engagement and reducing the need for them to contact LSPedia staff, resulting in a more efficient and customer-centric business model.

Enhanced Business Workflow

With the portal's self-service functionality, LSPedia not only ensures compliance but also optimizes business workflows, allowing staff to focus on higher-value tasks rather than responding to routine data requests, ultimately contributing to increased overall operational efficiency.

Benefits

- 24/7 Customer Data Access
- DSCSA Compliance
- User-Friendly Interface
- Operational Efficiency

Complimentary Modules

- TRACK (ASN)
- EPCIS

Exhibit 4

SOM Suspicious Order Monitoring

LSPedia's robust Big Data module introduces powerful Suspicious Order Monitoring (SOM) capabilities, enabling manufacturers, wholesalers, and pharmacies to meticulously track potentially suspicious ordering activities related to controlled substances. This essential report facilitates compliance with regulatory mandates from the Drug Enforcement Agency (DEA) pertaining to the shipment of controlled substances. SOM streamlines reporting by analyzing customer ordering patterns based on aggregated quantities and ordering behaviors.

Key Features

Streamlined Compliance

Simplify the tracking of suspicious activities and ordering patterns, enabling quick reporting to the DEA for compliance.

Regulatory Adherence

Ensure all stakeholders in the supply chain meet their regulatory obligations, fostering transparency and security in the pharmaceutical industry.

Faster and Safer

With real-time order analysis, SOM reduces the time, labor, and risk associated with managing numerous customer trading partners.

Automated Workflow

Buyers are relieved from performing clerical tasks by consolidating tracking of suspicious ordering activities into a single, efficient system.

Benefits

- Ingredient Level Analysis
- Look Back Horizon
- Drill Down Capabilities
- Advanced Filtering
- Data Export

Complimentary Modules

- Customer Portal
- Investigator EPCIS
- Investigator VRS
- Investigator Logistics

Exhibit 4

BIG DATA

In the fast-paced world of pharmaceuticals, the right tools can make all the difference. Imagine a pharmaceutical company grappling with the challenges of managing a complex network of suppliers, intricate customer interactions, ever-present compliance pressure, and constant operational bottlenecks. This is where LSPedia's transformative Big Data module, comes into play.

Key Features

Empowered Decision-Making

You can now focus on taking orders instead of checking license. Switch to ATP for real-time validation. It reduces time, labor, and risk associated with verifying the trading partner for every order.

Efficiency Redefined

Streamlined data analysis, efficient onboarding, and real-time tracking redefine operational efficiency, ensuring that deadlines and commitments are met with ease.

Unmatched Visibility

GS1 standards provide an unparalleled view of the pharmaceutical supply chain, making complex trading partner networks effortless to navigate.

Customer-Centric Approach

By incorporating Customer Intelligence, LSPedia personalizes your customer interactions, enhancing compliance, and elevating your service delivery, resulting in improved customer satisfaction.

Proven Success

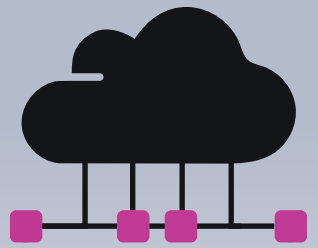
Learn from the industry leaders who have embraced a transformative approach to pharmaceutical supply chain management, leading to a more efficiently compliant, proactive, and customer-focused organization.

Benefits

- Supplier Intelligence
- Customer Intelligence
- Compliance Intelligence
- Scorecard Integration

Complimentary Modules

- Customer Portal
- Investigator EPCIS
- Investigator VRS
- Investigator Logistics



Cloud-Based and Device Agnostic

OneScan is a cloud-based solution, providing accessibility across all devices and operating systems, ensuring convenient and flexible usage for streamlined processes.

Dashboard and Reporting

OneScan provides a user-friendly dashboard and robust reporting functionality, granting comprehensive visibility into your supply chain, products, and operations for informed decision-making and enhanced efficiency.

Exhibit 4

FDA 3911 Reporting

Easy FDA 3911 reporting with auto-fill. With just the click of a button, OneScan will generate a complete 3911 form auto-populated with all the correct data, ready to send, saving time and eliminating human errors from manual data entry.

Multi-Level Users

OneScan is built to scale and provides unmatched visibility into your orders and business operations from a national, regional, district, and local level. Users have clear visibility to all of the locations they manage.

Exhibit 4

Precision Scanning

OneScan excels in 1D and 2D scanning capabilities, enabling users to swiftly scan, match, and verify products, effectively eliminating human errors; its seamless compatibility with 2D scanners enhances operational efficiency.

Complete Recall Management

A fully automated, precise, and expedited recall and decommissioning process that saves you time, and money while dramatically improving efficiency.

Exhibit 4

Matt Sample, Cencora

"OneScan allows us to work smarter, manage technical issues and negative verifications better, and not find it necessary to hire FTEs and throw other resources at the problem. OneScan is the only solution that solves the management of anticipated volumes of negative verifications. In addition, it gives us the ability to manage suspect/illegitimate products and file FDA 3911 notifications in one place and do trading partner notifications when required."

Bill Carney, Genetco

"LSPedia is so easy to work with and responsive, it's been a home run. The testing went well, integration is seamless, and the software runs smoothly . Working with the team has been easy, and they really know what they're doing."

Ken Riester, KOWA Pharmaceuticals

"LSPedia's cost was in-line, it's user-friendly, but most of all it was the support and trust we have in LSPedia beyond almost anything. We have just had a really positive relationship for approximately eight years."

Frank Juliano, St. Mary's

"LSPedia was the most appealing in software strength and value. The software, hardware, support, and services are bundled in a fixed annual payment. There are no hidden fees or unexpected charges. LSPedia's solution is now ingrained in our daily operations. We repackage 500+ serialized drug products and distribute to more than 450 clinics. I absolutely recommend LSPedia."

Kelly Lacy, Cencora

"OneScan is efficient, effective, and accurate. It's accurate because the system communicates the data. There are no typos, no human intervention, no human has to type anything with their eyes getting crossed as they count the zeros in the serial numbers. Investigator is really a great system for exceptions management."

Exhibit 4

David Scott, Pharmsource

"Working with LSPedia has been a pleasure since the first day. Their best-in-class team demonstrates incredible industry knowledge and has always supported our requirements. I look forward to our continued partnership through the changing landscape of DSCSA regulation."

Jeff Herman, Pharmsource

"If you want to ensure full DSCSA compliance in your organization, LSPedia is the way to go. They outperform all other solutions with their robust features, ease of use, and affordability."

Benjamin Jolley, Jolley's Pharma

"LSPedia's cost was in-line, it's user-friendly, but most of all it was the support and trust we have in LSPedia beyond almost anything. We have just had a really positive relationship for approximately eight years."

Jeff Falardeau, Cardinal Health

"We feel the pain when EPCIS files are late or error out. Shipments get set aside and pile up at receiving. With our volume, it's impossible for us to check and catch errors manually. This needs to be addressed with automation and, Investigator is, in my mind, the best product out there to help with exceptions management."

Jay Madden, ACI Healthcare

"There are challenges out there and one of the challenges is our CMOs. We rely on our CMOs and most of them are abroad. LSPedia has been instrumental in managing CMOs and getting the EPCIS data. My CEO and I place our trust into LSPedia. I am just happy that LSPedia is in our corner because I don't have time to check EPCIS for errors. We are a small company. I wear a lot of hats. LSPedia took a lot of burden away from us which gives me more time to generate revenue."

Exhibit 4

Contact

National Enterprise Sales Manager

Matt Vincent

CALL

(248) 212-0845

EMAIL

mtvincent@lspedia.com

Exhibit 4

LSPedia

Product Traceability • Regulatory Compliance • Supply Chain Solutions

FOOD MANUFACTURING 3PL WHOLESALE HEALTHCARE PHARMACY

Exhibit 4

SC 0092

DSCSA Compliance Statement

The Drug Supply Chain Security Act (DSCSA) and its predicate rules require product traceability at the serialized package level starting November 27, 2023. To that end, trading partners must implement systems to govern the trade of serialized prescription products including exchange interoperable Electronic Product Code Information Services (EPCIS) data, and request or respond to product verification.

LSPedia's OneScan solution provides native functionalities that meet FDA's DSCSA requirements, HDA's VRS industry governance, and GS1's EPCIS standards. OneScan supports customers' implementation of:

- Authorized Trading Partners (ATP)
- Labeling and packaging products with unique Product Identifier at the package level
- Interoperable data exchange of Transaction Information and Transaction Statement with ATPs in GS1 EPCIS standard.
- Product Verification using Verification Router Service that authenticates directly with manufacturers.
- Enhanced Supply Chain Security with exceptions notification and resolution for errors and discrepancies.

I certify that customers in Live OneScan environment are serialization ready for EPCIS data exchange for all DSCSA-eligible products. OneScan facilitates the EPCIS data exchange via LSPedia's secure electronic AS2 connections. LSPedia maintains DSCSA transaction records for six years from the transaction date.

This letter certifies OneScan's DSCSA Compliance and Customers readiness for serialization.

X

Riya Cao
CEO

4/10/2023

February 13, 2025

Amanda Biggart, Chief Operating Officer
Safe Chain Solutions, LLC
822 Chesapeake Dr, Cambridge, MD, 21613-9408
Tel: 855-437-5727 x 1016
Email: AmandaB@SafeChain.com

and

Dakota Flowers, Compliance Manager
Safe Chain Solutions, LLC
822 Chesapeake Dr, Cambridge, MD, 21613-9408
Tel: 855-437-5727 x 1017
Email: DakotaF@SafeChain.com

Dear Ms. Biggart and Ms. Flowers,

The U.S. Food and Drug Administration (FDA) inspected your wholesale drug distribution facility, Safe Chain Solutions, LLC, FEI 3009729473, at 822 Chesapeake Dr, Cambridge, MD 21613-9408, from April 11 to May 10, 2022, and from September 9 to September 11, 2024. FDA has determined that the inspection classification of this facility for the follow-up inspection in 2024 is "no action indicated" (NAI). [1] Based on the 2024 follow-up inspection, this facility is considered to be in an acceptable state of compliance with regards to the Drug Supply Chain Security Act (DSCSA).

FDA has concluded that this inspection is "closed" under 21 CFR 20.64(d)(3), and we are enclosing a copy of the narrative portion of the Establishment Inspection Report (EIR) from each of the above-mentioned inspections. It may reflect redactions made by FDA in accordance with the Freedom of Information Act (FOIA) and 21 CFR part 20. This, however, does not preclude you from requesting additional information under FOIA.

This letter is not intended as an endorsement or certification of the facility, and it does not address or reflect FDA's decision making with respect to any potential non-DSCSA compliance issues. This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The Agency expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

[1] See Inspection Classification Definitions, at https://www.fda.gov/ICECI/Inspections/ucm223231.htm.

If you have any questions regarding this letter, you may contact DSCSAInspections@fda.hhs.gov.

Sincerely,

Tia Harper-Velazquez, Director
Division of Supply Chain Integrity
Office of Drug Security, Integrity and Response
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food & Drug Administration

Enclosure: Two (2) Establishment Inspection Reports

TABLE OF CONTENTS

SUMMARY

(Written by ARR)

This Warning Letter follow-up inspection of Safe Chain Solutions, LLC, a wholesale drug distributor, was initiated under eNSpect Operation ID: 286100 and pursuant to an inspection memorandum dated June 11, 2024 (**Attachment 03)** from the Office of Drug Security, Integrity, and Response (ODSIR). The inspection was conducted in accordance with Section 582 of the FD&C Act to assess the firm's compliance with the Drug Supply Chain Security Act (DSCSA) and to follow up on corrective actions since the previous inspection.

The previous inspection conducted from 04/11/2022-05/10/2022 was the firm's first FDA inspection and provided CGMP coverage of the firm's facilities and equipment, material storage and handling, and assessed the firm's compliance with section 582 of the FD&C Act. The inspection concluded with the issuance of a 5-item Form FDA 483, Inspectional Observations, for the following summarized deficiencies:

1. There are no systems in place to enable compliance with the requirements of the Food, Drug and Cosmetic Act section 582(c)(4)(A) and (B).
2. Conducting transactions with trading partners who are not authorized.
3. Failure to notify FDA within twenty-four hours after determining that a product in your firm's possession or control was illegitimate.
4. Records regarding suspect product investigations and disposition of illegitimate product were not kept.
5. Routine calibration of mechanical and electronic equipment is not performed according to a written program designed to assure proper performance and ensure that storage and handling conditions do not adversely affect drug product.

A Warning Letter was issued to the firm on June 08, 2023; voluntary corrections completed since the 2022 FDA inspection were reviewed during the current inspection.

The current inspection, conducted from 09/09/2024-09/11/2024, provided coverage of the firm's corrective actions to the previous Inspectional Observations and to the Warning Letter and assessment of whether the firm is in compliance with the DSCSA. No Form FDA 483, Inspectional Observations, was issued at the close out of the inspection on 09/11/2024; four items were verbally discussed with the firm management. The discussion items included inadequate procedure for the disposition of the illegitimate product; insufficient detail on the disposition and assisting of trading partners in the disposition of illegitimate product; the procedure for *Handling and Reporting Suspect and/or Illegitimate Products* does not include steps to verify the product identifier at the package level and to verify the product identifier with the manufacturer, and inadequate temperature mapping study for the warehouse used to store pharmaceutical products. A handout titled "Electronic Submission of FDA-483 Response" was provided to Mr. Jesse Hammett, Vice President of Operations, and Ms. Dakota Flowers, Compliance Manager, with details on how to submit an electronic response to the Agency for the discussion items. Mr. Hammett and Ms. Flowers acknowledged the verbal discussion items and stated that a written response will be submitted to the Agency within fifteen (15) business days.

No refusals were encountered, and no samples were collected.

ADMINISTRATIVE DATA

Inspected Firm:	Safe Chain Solutions, LLC
Location:	822 Chesapeake Dr, Cambridge, MD, 21613-9408
Phone:	855-437-5727
Mailing address:	822 Chesapeake Dr, Cambridge, MD, 21613-9408
Dates of inspection:	09/09/2024-09/11/2024
Days in the facility:	3
Participants:	**Annet R. Rajan, Investigator**
	Christina Picard, Regulatory Counsel

(*Written by ARR*)

On 09/09/2024, we, Investigator Annet R. Rajan and Regulatory Counsel, Christina Picard, presented our credentials and issued a Form FDA 482, Notice of Inspection (**Attachment 01**) to Ms. Dakota Flowers, Compliance Manager, in the absence of Ms. Amanda Biggart, Chief Operating Officer (COO). During the opening meeting, Ms. Holly Dodson, Order Analyst, was also present as a scribe. I, Investigator Rajan, explained the purpose of our visit was to conduct a follow up inspection to the Warning Letter dated Jun 8, 2023, to review voluntary corrections, and determine if the firm is in compliance with the requirements of the Drug Supply Chain Security Act. A second Form FDA 482 was issued on 09/09/2024 to Ms. Amanda Biggart (**Attachment 02**) upon her arrival to the firm, who identified herself as the most responsible person of the firm.

Investigator Rajan and Regulatory Counsel Picard were present on all days of the inspection.

This inspectional report was collectively written by Investigator Rajan and Regulatory Counsel Picard. “We”, “Our”, and “Us” refers to Investigator Rajan and Regulatory Counsel Picard; “I” refers to the individual that is identified as writing the applicable section of this report. Written contributions and exhibits for this report are identified with the following initials: Annet. R. Rajan (ARR), Christina Picard (CP). References made within this report to the “firm”, or “Safe Chain” refers to the inspected facility Safe Chain Solutions, LLC.

All post-inspectional FDA correspondence to be addressed to:
Amanda Biggart, Chief Operating Officer
Safe Chain Solutions, LLC
822 Chesapeake Dr, Cambridge, MD, 21613-9408
Tel: 855-437-5727 x 1016
Email: AmandaB@SafeChain.com

and

Dakota Flowers, Compliance Manager
Safe Chain Solutions, LLC
822 Chesapeake Dr, Cambridge, MD, 21613-9408
Tel: 855-437-5727 x 1017
Email: DakotaF@SafeChain.com

HISTORY
(Written by ARR)

Safe Chain Solutions, LLC continues to be a wholesale distributor of human prescription drug products. The firm maintains a sister site in Utah located at 1812 West Sunset Blvd, Suite 34, St. George, 84770; per Ms. Dakota Flowers, Compliance Manager, the site in Utah is owned by Safe Chain but is separately licensed as a business and does business as “SC Wholesale”. The firm’s operation hours are Monday to Friday from 8:00 A.M. to 5:30 P.M. and currently employs ~12 employees. Safe Chain occupies one building encompassing ~ 15,780 sq. ft; a facility diagram is included as **Exhibit 1**. Per Ms. Flowers, the firm’s annual revenue for finished prescription human drug products for 2023 and 2024 was ~$13.5 M and ~$12M, respectively.

Since July 2021, the firm has removed the sales of some prescription human drug products from its offering, including but not limited to, BIKTARVY, DESCOVY and PREZISTA pursuant to a formal complaint filed by Gilead Sciences and a Seizure Order (Refer to memo provided by Ms. Amanda Biggart, COO, included as **Exhibit 2**). Additionally, on 08/11/2024, Mr. Charles Boyd (Founder and CEO) and Mr. Partick Boyd (Managing Partner) took a temporary leave of absence from the firm to comply with a court order and named Ms. Amanda Biggart as the COO of the firm (Refer to memo included as **Exhibit 3**).

INTERSTATE (I.S.) COMMERCE AND JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)
(Written by ARR)

The firm continues to operate nationwide as a wholesale distributor. The firm is licensed for distribution in 45 states and the District of Columbia (Refer to **Exhibit 4** for distribution licenses). According to Ms. Dakota Flowers, Compliance Manager, ~ 99.7% of the firm's distributed products enter into interstate commerce. Per Ms. Holly Dodson, Order Analyst, incoming shipments are received through UPS, FedEx, by freight or air, and outgoing shipments are primarily handled through UPS and occasionally through FedEx. A list of suppliers/vendors/trading partners from who the firm purchases drug products for sale and distribution is included as **Exhibit 5**. A list of products sold and distributed by the firm from September 2023 to September 2024 is included as **Exhibit 6**.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED
(*Written by ARR*)

A copy of the firm's Organization Chart is included as **Exhibit 7**. Refer to **Page 1** of **Exhibit 7** for the organization chart prior to 08/11/2024 with Mr. Charles Boyd (Founder and CEO) as the most responsible person; refer to **Page 2** for the current organization chart with Ms. Amanda Biggart, COO, as the most responsible person. The following personnel participated in the inspection, facilitated discussions, and provided documents as requested:

Amanda Biggart, COO is the most responsible person at the firm as of 08/11/2024 following Mr. Charles Boyd (Founder and CEO) and Mr. Patrick Boyd's (Manager Partner) temporary leave of absence from the firm. Prior to that, Ms. Biggart served as the Corporate Vice President of Finance. As COO, Ms. Biggart is in the official capacity to run Safe Chain and make all decisions on behalf of the owners and is responsible for overseeing daily operations of the firm, has financial oversight and is responsible for developing budgets, and ensuring that all business operations comply with relevant laws and regulations. A second Form FDA 482, Notice of Inspection, was issued to Ms. Biggart on 09/09/2024 when she arrived at the firm; Ms. Biggart was present briefly on day 1, 09/09/2024, to accept the FDA 482 and during the close out meeting on 09/11/2024 via Team's call.

Jesse Hammett, VP of Operations has been with the firm since November 2014 and reports directly to Ms. Biggart. Mr. Hammett's responsibilities include management of the purchasing and processing department, facilitating working relationships between sales, compliance, warehouse and accounting, warehouse management, ERP System management, and working with the Compliance Manager and COO to support decision making. Mr. Hammett was present on 09/10/2024-09/11/2024 and provided information and documentation related to warehouse temperature mapping.

Dakota Flowers, Compliance Manager/Senior Compliance Officer, has been with the firm since June 2020 and has been in the Compliance Manager position since February 2022. Per Ms. Flowers, since 08/11/2024, she reports directly to both, Ms. Biggart and Mr. Hammett. Ms. Flowers' responsibilities include ensuring that the firm adheres to all regulatory requirements and internal policies, monitor, and interpret changes in federal, state, and local laws affecting the pharmaceutical industry, develop, implement, and update company policies and procedures to ensure compliance with regulatory requirements and monitor daily operations to detect potential compliance issues. The initial Form FDA 482, Notice of Inspection, was issued to Ms. Flowers on 09/09/2024 in the absence of Ms. Biggart. Ms. Flowers was present on all days of inspection and was the primary source of documentation and information provided during the inspection.

FIRM'S TRAINING PROGRAM
(Written by ARR)

The firm has an annual training program; Ms. Dakota Flowers, Compliance Manager, performs training on sales, orders, compliance process, day to day license verification, applications, and time frame for applications. Warehouse personnel receive yearly training on day to day activities; training is performed on the job and is conducted under the supervision of Mr. Jesse Hammett, VP of Operations. I reviewed the training records for the yearly training on day to day activities conducted for Warehouse personnel Ms. Tracy Taylor and Ms. Jenna Willey; the training provided instructions on checking packages for leaks/damages, performing inspection of each shipment of suspect products, reviewing the packing slip and invoices, checking the inventory matches the invoices/packing slip, and reporting discrepancies to the Manager and/or Purchasing department. No deficiencies were noted.

MANUFACTURING/DESIGN OPERATIONS
(Written by ARR)

Standard Operating Procedures (SOPs)

The firm's procedure "*Handling and Reporting Suspect and/or Illegitimate Products*", Issue Date: 05/05/2022, Effective Date: 05/05/2022, Re-issue date: 06/12/2023, governs the handling of suspect and/or illegitimate products, quarantine of the subject product, notification to the FDA if product is determined to be illegitimate, handling of notification from the FDA, manufacturer, or wholesale distributor about an illegitimate product and responding to a request to notification for verification of product. Upon receipt of each shipment, the warehouse management is responsible for evaluating the inbound items for suspect or illegitimate products. The SOP includes directions to quarantine the suspect and/or illegitimate product by physically moving the products to the quarantine location in the warehouse, affixing a label marking it as "suspect product" and for the warehouse management to notify the Compliance department. Additionally, the procedure states that the "Warehouse manager will quarantine the product until the product is dispositioned" but does not provide additional details on how to disposition of illegitimate product; per Ms. Dakota Flowers, Compliance Manager, once the investigation and validation of T3 (Transaction History, Transaction Information, and Transaction Statement) is completed, the firm would send the

products to "Return Solutions", a drug return company for disposition, however, this is not outlined in the SOP. Ms. Flowers provided a copy of the firm's procedure "Standard Operating Procedures for Drug Disposal" which includes a reference to "Return Solutions", but I noted to her that the SOP applies to expired and damaged inventory/drug products only. We stated to Ms. Flowers that the firm's procedures should include sufficient detail on the disposition and assisting of trading partners in the disposition of illegitimate product (Refer to **Item# 2** in the "**GENERAL DISCUSSION WITH MANAGEMENT**" Section).

Per SOP for *Handling and Reporting Suspect and/or Illegitimate Products*, upon notification of illegitimate product, the Compliance Manager should begin the process of verification of the authenticity of the transaction data, including a validation of the transaction information and all entities listed in the transaction history and initiate a thorough investigation. Regarding illegitimate products, the SOP includes directions to notify the Maryland State Board of Pharmacy and immediate trading partners within 24 hours of Safe Chain's determination that the product is illegitimate as well as to notify the FDA by submitting an FDA Form 3911 within 24 hours. The SOP also includes directions to retain a sample of the illegitimate product for further physical examination if requested by the manufacturer, FDA, or other governmental agency and to maintain all records of investigation and dispositions for a minimum of 6 years. If an illegitimate product notification is no longer necessary, the SOP includes directions to terminate the illegitimate product notification using the FDA Form 3911 and notify the manufacturer and other vendors that the notice has been terminated. During the review of the illegitimate product investigation handling steps, we observed that the SOP does not include steps to verify the product identifier at the package level and to verify the product identifier with the manufacturer to determine if the product identifier on the package corresponds with that affixed by the manufacturer (Refer to **Item #3** in the "**GENERAL DISCUSSION WITH MANAGEMENT**" Section).

The firm's procedures "*Standard Operating Procedures for Vendor Trading Partner Validation*", "*Standard Operating Procedure for Customer Trading Partner Validation*" and "*Standard Operating Procedures for Vendor and Transaction History Authentication*", govern conducting business with authorized trading partners, authorized licensed healthcare facilities and business, and conducting vendor authentication, respectively. During initial vendor authentication and validation, the SOP for Vendor Trading Partner Validation includes directions to verify the compliance of each vendor with the licensure reporting requirements to the FDA under the Drug Quality and Security Act section 503(e) for wholesale distributors; the SOP also includes directions that products from trading partners will not be accepted without a Transaction History and that vendor licenses will be validated at least annually. Per the SOP for Vendor and Transaction History Authentication, all products received at Safe Chain from a wholesale distributor should include a Transaction History and that it is Safe Chain's policy to only purchase product directly from the manufacturer or a distributor that purchases directly from the manufacturer. The SOP also included directions that if the firm is unable to authenticate a T3 (Transaction History, Transaction Information and Transaction Statement), a notification will be made to the Board of Pharmacy and the FDA within 24 hours.

Procedures "*Standard Operating Procedures for Records Retention and Reporting to Agencies*" and "*Standard Operating Procedures for Recordkeeping*" govern the storage of records. The

firm's procedure for Recordkeeping states that any records of investigations and disposition of products will be stored for at least six years. Additionally, T3 (Transaction History, Transaction Information and Transaction Statement) records will be stored electronically via the online portal for a minimum of six years. During our review of the firm's SOP for "Records Retention and Reporting to Agencies", we observed that Step 4.a states that "the drug will be held in quarantine area until the drug's disposition is authorized by the Board of Pharmacy and or the FDA"; we stated to Ms. Dakota Flowers, Compliance Manager, that the disposition of the illegitimate product is the firm's responsibility and that the FDA does not advise on the disposition of the products. Ms. Flowers acknowledged the comments and stated that the SOP may not have been updated to remove the specific verbiage (Refer to **Item #1** in the **GENERAL DISCUSSION WITH MANAGEMENT**" Section).

Suspect and Illegitimate Products

Since the previous inspection, the firm has not identified any suspect product in its possession or control. During the inspection, I reviewed the firm's standard operating procedure to quarantine suspect product until such product is cleared or dispositioned and no significant deficiencies were identified. During the facility walkthrough on 09/10/2024, I observed products placed in the quarantine location in the warehouse; however, none of the products were identified as suspect or illegitimate. To determine if the firm has procedures in place to prevent the inadvertent distribution of quarantined product, I reviewed the status and location of select products that were placed in quarantine within the ERP Management System. For the products selected, I verified that the locations of the product in the ERP inventory system was listed as "Quarantine" and also verified that the products were not available in the "Sales" inventory which prevented personnel in the Sales department from viewing the item, preventing the inadvertent sale of quarantined product.

On 09/15/2022, the firm submitted a Form FDA 3911 to notify the FDA of illegitimate product regarding Xylocaine (Lidocaine and Epinephrine), 10 mg per ml, Injectable, Lot# 6127399 and deemed the product unfit for distribution. Per Ms. Dakota Flowers, Compliance Manager, the firm received notification from the dispensing practice on 09/14/2022 that the drug product was not working, that the patient was still bleeding a lot, and the Doctor stated that she believes it's a "bad lot". I asked Ms. Flowers if the complaint from the dispensing practice met the firm's definition of "illegitimate product" or if this was a complaint about lack of efficacy; Ms. Flowers stated that the firm reported the product as illegitimate in an abundance of caution and that the report was not as egregious as a counterfeit product and selected "unfit for distribution" as the best fit on the Form FDA 3911. During the inspection, we reviewed the firm's investigation into this specific complaint; we observed that the firm received the complaint on 09/14/2022 and the firm submitted the form FDA 3911 on 09/15/2022, within 24 hours. When asked if the firm quarantined any of the subject product, Ms. Flowers stated that at the time of complaint receipt, the firm did not have any of the lots of product on hand and did not quarantine any product. Although the firm did not have a formal investigation report, we reviewed the firm's e-mail correspondences with the manufacturer and doctor's office, as well as reviewed the transaction information and history provided along with the documents. Ms. Flowers stated that the doctor's office and the manufacturer have not responded to requests for additional information; when asked if the firm will be submitting a termination of illegitimate product notification to the Agency, Ms. Flowers

stated that she would like to follow up with the manufacturer before terminating the notification. No significant deficiencies were identified with the firm's handling of the investigation.

Since the previous inspection, the firm has not received notification of illegitimate product by a trading partner or received a request for verification of suspect or illegitimate product from FDA or an authorized trading partner. Per Ms. Dakota Flowers, Compliance Manager, the firm has not been notified about counterfeit Prezista or diverted Triumeq tablets by any of their trading partners or other entities. Ms. Flowers stated that the firm has seized distribution of Prezista and Triumeq drug products pursuant to a Seizure Order. When asked if the firm has been notified (by the FDA or a trading partner) of a product with a high risk of illegitimacy in its possession or control or if the firm has made a determination that a product in its possession or control was at a high risk of illegitimacy, Ms. Flowers stated that the firm has received notifications about GLP-1 receptor agonist, active pharmaceutical ingredients, but has not received any for prescription drug products.

Authorized Trading Partners

Per Ms. Flowers, since the previous inspection, the firm has not identified any questionable information from a trading partner or discovered that the firm conducted business with an unauthorized trading partner. During the inspection, we reviewed copies of licenses of select Wholesale Drug Distributors who are authorized trading partners of Safe Chain; we verified the status of licensures with the respective State Board of Pharmacies and verified licensure reporting requirements. We reviewed select purchasing invoices and verified that purchases were made from partners who are authorized; no significant deficiencies were observed.

COMPLAINTS

(Written by ARR)

The firm does not have a formal complaint procedure; per Ms. Dakota Flowers, the firm has a Customer Complaint receipt form that is used to intake and record customer complaints. The firm received one complaint from a dispensing practice on 09/14/2022 for which the firm submitted a Form FDA 3911 for illegitimate product notification.

RECALLS

(Written by ARR)

The firm's procedure "Standard Operating Procedure for Product Recalls", Effective Date: 01/08/2018 governs recall handling; per Ms. Flowers, the firm does not initiate its own recalls but assists manufacturers and other customers with their recall strategy. Per the firm's procedure, the Compliance Manager initiates the recall procedure and notifies the Purchasing and Warehouse Manager if a recall is needed and identifies and notifies customers who may be in possession of recalled drugs. The recalled products are pulled from physical inventory and moved to quarantine and the Compliance Manager will notify the customer in writing of the recall or follow up with a phone call.

GENERAL DISCUSSION WITH MANAGEMENT
(*Written by ARR*)

On 09/11/2024, we, Investigator Rajan, and Regulatory Counsel Picard, held a close out meeting with the firm's management which included Mr. Jesse Hammett, VP of Operations and Ms. Dakota Flowers, Compliance Manager; Ms. Amanda Biggart, COO was present via Teams Call. No Form FDA 483, Inspectional Observations, was issued. The following items were discussed verbally with firm management.

1. The SOP for Records Retention and Reporting to Agencies states that the drug will be held in quarantine area until the drug's disposition is authorized by the Board of Pharmacy and or the FDA; we clarified that the disposition of the illegitimate product is the firm's responsibility.
2. No clear instructions or procedure on the disposition of illegitimate products; the "Standard Operating Procedures for Drug Disposal" procedure only applies to expired or damaged products.
3. The SOP for Handling and Reporting Suspect and/or Illegitimate Products lacks instructions to include a verification of the product identifier at the package level and a verification with the manufacturer during the investigation phase.
   Note: During the close out meeting, Mr. Jesse Hammett asked for clarification on what the product identifier is; we guided Mr. Hammett and Ms. Flowers to the "*Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers Guidance for Industry*" and "*Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs- Guidance for Industry*" documents for additional information on product identifiers and components of a robust investigation.
4. The temperature mapping of the warehouse and the cold storage where drug products are stored was inadequately conducted (Refer to the "**VOLUNTARY CORRECTIONS**" to previous Inspectional **Observation #5** for additional information).

I provided Ms. Hammett and Ms. Flowers with a handout titled "Electronic Submission of FDA-483 Response" and requested that the firm to provide a response with their corrective actions to the discussion items to the Agency using the email address listed on the handout; Mr. Hammett and Ms. Flowers acknowledged the discussion items and stated that a written response would be provided to the inbox.

VOLUNTARY CORRECTIONS
The previous inspection, conducted from 04/11/2022-05/10/2022, was classified as "Official Action Indicated" and closed with a five item Form FDA 483, Inspectional Observations, and resulted in the issuance of an FDA Warning Letter, dated June 08, 2023 (**Attachment 04**). During the current inspection, we reviewed corrections implemented since the previous inspection, a summary of which is listed below:

Corrective Actions to Warning Letter

(Written by CP)

Warning Letter Cite 1 Summary:

Your firm failed to have systems in place to enable compliance with the verification requirements of the DSCSA (FD&C Act Section 582(c)(4)(A) & (B)). Specifically,

The firm's Suspect & Illegitimate Product SOP was lacking in several areas pertaining to the verification requirements. Additionally, the Suspect & Illegitimate Product SOP contained information inconsistent with the DSCSA. For example, the SOP stated that if "SCS [Safe Chain Solutions] receives confirmation the product is illegitimate or potentially fraudulent an FDA form 3911 will be filed. Disposition of the product will depend on guidance received from the FDA." As written, this SOP indicated that the firm is expecting guidance from FDA upon submission of a 3911, and disposition of the product depends on such guidance. However, disposition of illegitimate product is the firm's responsibility and is not dependent on FDA's response to a FDA Form 3911. In addition, the document "Standard Operating Procedures for Vendor and Transaction History Authentication" (re-issue date 4/1/21) contained information inconsistent with the DSCSA. The document indicated that in case of "suspected counterfeit product that cannot be verified," the firm should contact the Maryland Board of Pharmacy and the FDA within 3 days. However, the DSCSA requires a trading partner that determines a product in its possession or control is an illegitimate product to notify the FDA within 24 hours of making such a determination. (FD&C Act section 582(c)(4)(B)(ii)).

Corrective Actions to Warning Letter Cite 1:

Follow up to corrective actions included the review of, but not limited to, the following SOPs:

- "Handling and Reporting Suspect and/or Illegitimate Products". The SOP now covers how to:
    - Identify suspect product
    - Conduct an investigation (including validating any applicable transaction history and transaction information) to determine whether a suspect product is an illegitimate product in coordination with trading partners
    - Handle an illegitimate product notification
    - Handle a request for verification of a suspect product from FDA
    - Make notifications of cleared product
    - Maintain adequate records relating to the investigation of suspect product or the disposition of illegitimate product.

Additionally, the SOP now reads, in part "The Warehouse Manager or the Compliance Manager will notify the FDA within 24 hours of SCS's determination that the product is illegitimate by submitting FDA Form 3911…". The statement that "Disposition of the product will depend on guidance received from the FDA" has been removed from the SOP.

(ARR) However, during review of the SOP for Records Retention and Reporting to Agencies, we observed that step 4.a states that the drug will be held in quarantine area until the drug's disposition

is authorized by the Board of Pharmacy and or the FDA (Refer to **Item #1** in the **GENERAL DISCUSSION WITH MANAGEMENT** Section).

- *(CP)* "Standard Operating Procedures for Vendor and Transaction History Authentication". The SOP was re-issued 6/12/23; The statement indicating that in case of "suspected counterfeit product that cannot be verified, your firm should contact the Maryland Board of Pharmacy and the FDA within 3 days," has been removed. The SOP now reads, "Proper authorities to contact in case of suspected counterfeit product that cannot be verified are Maryland Board of Pharmacy and the Food and Drug Administration within 24 hours."

Warning Letter Cite 2 Summary:

Your firm conducted transactions with trading partners that were not authorized (FD&C Act Section 582(c)(3)). Specifically,

At the time of the initial FDA inspection of Safe Chain the firm had a written procedure to verify a trading partner's status, "Standard Operating Procedures for Trading Partner Validation" (re-issue date of 3/15/21) (Trading Partner Validation SOP). The procedure recognized that all entities must be authorized as defined by the DSCSA. The firm, however, did not adhere to this SOP and failed to verify that all of their trading partners reported licensure information to FDA.

Corrective Actions to Warning Letter Cite 2:

Follow up to corrective actions included the review of, but not limited to, the following:

(ARR) The firm implemented procedure "*Standard Operating Procedures for Vendor Trading Partner Validation*" (on 06/13/2023) which includes directions to, during the initial vendor authentication and validation, verify the compliance of each vendor with the licensure reporting requirements to the FDA under the Drug Quality and Security Act section 503(e) for wholesale distributors; the SOP also includes directions that products from trading partners will not be accepted without a Transaction History and that vendor licenses will be validated at least annually.

(CP) A copy of the firm's vendor list was reviewed and several entities on the list were checked individually during the inspection and found to be authorized in that they met the applicable DSCSA requirements under FD&C Act Section 582(c)(3). To be authorized, a wholesale drug distributor must have a valid license under State law or section 583 of the FD&C Act, in accordance with section 582(a)(6) of the FD&C Act and comply with the licensure reporting requirements in section 503(e) of the FD&C Act (FD&C Act Section 581(2)(B)). Under section 503(e)(2)(A) of the FD&C Act, wholesale distributors must report to FDA, on an annual basis, "each State by which the person is licensed and the appropriate identification number of each such license; the name, address, and contact information of each facility at which, and all trade names under which, the person conducts business;" and "any significant disciplinary actions." We reviewed the status of the trading partners the firm had purchased from since 08/09/2024. The following trading partners were verified during the inspection and found to be authorized:

- Genetco, Inc.
- Independent Pharmacy Distributor
- Richie Pharmacal Co.
- Quagen Pharmaceuticals
- Top RX
- Direct RX
- Terrain Pharmaceuticals
- Major Pharmaceuticals
- Safeway Distributors, Inc.
- Alexso Inc.
- Wilshire Pharmaceuticals, Inc.
- Paramed

Warning Letter Cite 3 Summary:

Your firm failed to maintain records of suspect product investigations (FD&C Act Section 582(c)(4)(A)(iii)). Specifically,

The DSCSA requires that wholesale distributors maintain records of investigations of suspect product for not less than 6 years (FD&C Act section 582(c)(4)(A)(iii)). During the initial inspection, the firm was, both, unable to provide any written documentation of what products were held in or released from quarantine, and unable to provide records explaining how suspect product was quarantined. In addition, the firm was unable to provide records about when and how investigations took place to determine whether suspect product was illegitimate.

Corrective Actions to Warning Letter Cite 3:

Follow up to corrective actions included the review of, but not limited to, the firm's documentation relating to their filing of an FDA Form 3911 on 09/15/2022 for Xylocaine.

We discussed the circumstances surrounding the firm's filing of an FDA Form 3911 on 09/15/2022 for Xylocaine. The firm shared copies of emails demonstrating how they reached out to various parties, such as the practitioner's office and the manufacturer. Additionally, the firm was able to provide transaction documents related to the purchase of the product; no significant deficiencies were noted during the review of the firm's investigation.

(ARR) Additionally, we reviewed the firm's quarantine procedure and documentation; we reviewed the firm's ERP Management System and verified that products placed in quarantine are designated as such with the System. I also verified that the products are not available in the "Sales" inventory which prevented the inadvertent sale of quarantined products.

Warning Letter Cite 4 Summary:

Your firm failed to respond to a notification of illegitimate product (FD&C Act Section 582(c)(4)(B)(iii)). Specifically,

(*ARR*) The firm failed to respond to notification of illegitimate product from the manufacturer and demonstrate that product in possession was quarantined and an investigation was conducted.

Corrective Actions to Warning Letter Cite 4:

(*ARR*) Since the previous inspection, the firm has not received any notification of illegitimate product; however, we reviewed the firm's procedures governing notification of illegitimate products, quarantine, and investigation; no significant deficiencies were noted.

Corrective Actions to Previous Form FDA 483 Observations

(Written by ARR)

Observation 1 Summary

There are no systems in place to enable compliance with the requirements of the Food, Drug and Cosmetic section 582(C)(4)(A) and (B). Firm does not have adequate verification systems required by the Drug Supply Chain Security Act (DSCSA). This lack of systems results in insufficient procedures to enable the firm, as a wholesale distributor, to conduct thorough and documented investigations of a suspect/and or illegitimate product.

Corrective Actions to Observation 1

Refer to corrective actions related to Warning Letter Cite 1.

Observation 2 Summary

Firm conducted transactions with trading partners who are not authorized (582(c)(3)).

Corrective Actions to Observation 2

Refer to corrective actions related to Warning Letter Cite 2.

Observation 3 Summary

Firm did not notify FDA within twenty-four hours after determining that a product in its possession or control was illegitimate [582 (c)(4)(B)(ii)] and did not submit a notification to FDA within 24 hours of determination that a product is illegitimate.

Corrective Actions to Observation 3

Refer to corrective actions related to Warning Letter Cite 1 and 4.

Observation 4 Summary

Records regarding suspect product investigations and disposition of illegitimate product were not kept [582(c)(4)(A)(iii) and 582(c)(4)(B)(v)].

Corrective Actions to Observation 4
Refer to corrective actions related to Warning Letter Cite 3.

Observation 5 Summary
Routine calibration of mechanical and electronic equipment is not performed according to a written program designed to assure proper performance and ensure that storage and handling conditions do not adversely affect drug product; no temperature mapping studies of warehouse and cold storage performed.

Corrective Actions to Observation 5
The firm implemented temperature mapping, calibration and maintenance schedules of all mechanical and electronic equipment located in the Drug Storage Areas. Per the "Temperature Calibration SOP", Effective Date: 05/04/2022 **(Exhibit 8, Page 2**), temperature sensors are to be calibrated on an annual basis on or near June 1st. Per the "Temperature Mapping SOP" (**Exhibit 8, Page 1**), Effective Date: 05/20/2022, temperature mapping will be conducted on an annual basis in May of each year. During my review of the temperature mapping SOP, I observed that the SOP does not include directions such as measuring the temperature over a defined period of time. I reviewed the temperature mapping completed on 05/20/2022 and 05/24/2022 (**Exhibit 9**) with Mr. Jesse Hammett, VP of Operations. Mr. Hammett stated that the firm placed a thermometer for a period of 30 seconds to 1 minute at each location to perform the temperature mapping; I stated to Mr. Hammett temperature mapping involves measuring and recording multiple data points at various locations over a specified duration of time to identify temperature variations and fluctuations over that time period and that the firm's temperature mapping procedure is deficient. I also stated to Mr. Hammett that the firm is using a thermometer which provides data for just that snapshot of time and that the firm should use an equipment that can track the data over the period of the temperature mapping; Mr. Hammett acknowledged the comments. I reviewed the temperature log for the warehouse and the cold storage from May to September 2024; no significant excursion for lengthy durations of time were observed. Refer to **Item #4** in the **GENERAL DISCUSSION WITH MANAGEMENT** Section.

ADDITIONAL INFORMATION
Exhibits referenced in this report were sourced from hard copies and electronic documents from Hard drives provided by the firm. The firm provided two identical hard drives containing electronic documents. One drive containing electronic documents received from the firm is enclosed in a sealed FDA 525 (**Exhibit 10**). The officially sealed original copy of the drive and unsealed working copy of the drive containing electronic documents and the unlabeled hard copy exhibits received during the inspection are filed with the hard copy attachments.

EXHIBITS COLLECTED

#	Exhibit Title	Total Pages
1	Facility Layout	1
2	SCS Letterhead - List of products removed from sale	2
3	SCS Letterhead - AB appointment as COO	1

4	Distribution Licenses	2
5	Vendor Detail	1
6	SCS Sales History	51
7	Organization Chart	2
8	Temperature Mapping and Calibration SOPS	2
9	Temperature Mapping 05242022	2
10	Hard drive enclosed in FDA 525	1

ATTACHMENTS

#	**Attachment Title**	**Total Pages**
01	FDA 482 Notice of Inspection, Issued to Ms. Flowers	3
02	FDA 482 Notice of Inspection, Issued to Ms. Biggart	3
03	Inspection Memorandum, Dated Jun 11 2024	6
04	Warning Letter, dated June 08, 2023	8

Annet Rajan -S Digitally signed by Annet Rajan -S Date: 2024.10.03 09:57:42 -04'00'

Annet R. Rajan
Investigator

Christina M. Picard -S Digitally signed by Christina M. Picard -S Date: 2024.10.07 12:29:18 -04'00'

Christina Picard
Regulatory Counsel

14D

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

APPLICATION FOR ADVANCED PRACTICE REGISTERED NURSE TO PRESCRIBE

Rev (01/05/2023)

What types of drug(s) will you be prescribing?

☐ Dangerous Drugs ONLY (Non-Refundable $80 Fee) (PR)

☐ Dangerous Drugs AND Controlled Substances (CS) I, II, III, IV and/or V (Non-Refundable $200 Fee) (CS)
Select the Controlled Substance Schedules you are applying to prescribe

☐ Schedule I ☒ Schedule II ☒ Schedule III ☒ Schedule IV ☒ Schedule V

Section 1: Personal Information (NAC 639.850)

First: Melissa Middle: Last: Heemsath

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Home Address: [redacted]

City: Carson City State: NV Zip Code: 89701

Telephone: [redacted] Email: [redacted]@gmail.com

APRN License #: 863933 Specialty:

(A current license and active-PRESCRIBING status with the Nevada State Board of Nursing is required to apply for and maintain a Prescribe or a CS Registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name: Saint Mary's Urgent Care

Practice Address: 6255 Sharlands Ave Suite #:

City: Reno State: NV Zip: 89523

Telephone: 775-770-7664 Fax: 775-770-7369 Email: SMMG-Credentialing@primehealthcare.com

Section 3: NRS 632.237 (Complete this section if you are applying to also prescribe SCHEDULED II CS).

An advanced practice registered nurse may apply to prescribe CS listed in schedule II if they meet one of the following qualifications (please mark that apply):

☐ I have at least 2 years or 2,000 hours of clinical experience; OR

☒ The CS will be prescribed pursuant to a protocol approved by a collaborating physician. (If you marked this answer, provide the information as requested below per NAC 639.850.)

Collaborating Physician Name: Bayo Curry-Winchell, MD

Collaborating Physician Practice Address: 6255 Sharlands Ave Suite #:

City: Reno State: NV Zip: 89523

Telephone: 775-770-7664 Fax: 775-770-7369 Email: BCurry-Winchell@primehealthcare.com

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
June 21, 2011	July 27, 2011	Florida	Jacksonville	Duval
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2011-10613		State of Florida Department of Health		
Reason/Charge				
Possession of a Controlled Substance				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
FL Department of Health vs. Melissa Heemsath				
Name of Business/Industry/Entity				

Provide explanation below:

4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?

As stated in explanations provided for questions two and three, The Florida Department of Health issued discipline against Registered Nurse license #9268827. On Thursday, December 5, 2019, I presented to the FL Board of Nursing Licensure Hearing. As a result of the testimony I provided, the State of Florida Board of Nursing voted to vacate the Notice of Intent to Deny. The Board voted to approve me for a Florida single state Registered Nurse license following completion of a Board approved remedial course. Following completion of all Board requirements for licensure, The Florida Department of Health issued me license number RN9551751 on December 10, 2020. This license is currently Null and Void, as I have moved out of state and do not currently plan to apply to activate the RN license in Florida. Registered Nurse license number 95287966 in the State of California is currently in the process of renewal. Registered Nurse license number 863933 in the State of Nevada was issued on July 13, 2023 and is active. Advanced Practice license APRN-CNP 863933 in the State of Nevada was issued on May 3, 2024, is active with prescribing privileges and no discipline.

Please see documents provided:
-Florida Department of Health License #RN9268827 printed details
-Florida Department of Health Notice of Hearing
-The Florida Board of Nursing December 2019 Meeting Minutes
-State of Florida Board of Nursing Order Vacating Notice of Intent to Deny and Application Approval with Contingency
-Florida Department of Health License #RN9551751 printed details
-California Board of Nursing RN license renewal application for License #95287966 printed details
-Nevada State Board of Nursing License verification printed details for license #RN863933 and APRN-CNP 863933

Melissa Heemsath
Original Signature (electronic, copies or stamps not accepted)

2/27/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Melissa Heemseth

Applicant Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/26/2025

Date

COLLABORATING PHYSICIAN's name and signature per Section 3 of the application (if applicable):

Bayo Curry-Winchell

Collaborating Physician's Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/26/25

Date

Board Use Only: Date Processed: _____ Amount: _____

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Melissa Heemsath
Applicant Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/20/2025
Date

COLLABORATING PHYSICIAN's name and signature per Section 3 of the application (if applicable):

Baya Curry-Winchell
Collaborating Physician's Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/26/25
Date

Board Use Only: Date Processed: _____ Amount: _____

NOTIFICATION TO NEVADA STATE BOARD OF MEDICAL EXAMINERS OF COLLABORATION WITH ADVANCED PRACTICE REGISTERED NURSE

STATE OF NEVADA)
) ss.
COUNTY OF Washoe)

NOTE: NO FEE REQUIRED

COMES NOW Bayo Curry Winchell, M.D., being first duly sworn, who deposes and says that: I, the undersigned physician, am duly licensed to practice medicine in the state of Nevada by the Nevada State Board of Medical Examiners, possess an active license to practice medicine in the state of Nevada, License Number 15915, and am in good standing with the Nevada State Board of Medical Examiners. I am engaged in the practice of medicine in the state of Nevada, am current on all my required CME and am not aware of any disciplinary action, formal or informal, pending against me by the Nevada State Board of Medical Examiners or any other jurisdiction's medical licensing entity. I have checked with the Nevada State Board of Nursing and determined that the advanced practice registered nurse with whom I am going to collaborate has never been formally disciplined by the Nevada State Board of Nursing.

I have read and am aware of the provisions of Chapter 630 of the Nevada Revised Statutes concerning the duties of a supervising physician, as well as Chapter 630 of the Nevada Administrative Code, which are the regulations adopted by the Nevada State Board of Medical Examiners concerning a physician's relationship with a physician assistant and/or advanced practice registered nurse. I have read and am aware of the regulation of the Nevada State Board of Medical Examiners under Chapter 630 of the Nevada Administrative Code that precludes a physician from simultaneously supervising more than three physician assistants or collaborating with more than three advanced practice registered nurses, or with a combination of more than three physician assistants and advanced practice registered nurses, without first filing a petition with the Board for approval to supervise more, and the requirement that I prove to the satisfaction of the Board that the circumstances of my practice necessitate more and that I will be able to supervise/collaborate with the greater number in a satisfactory manner.

I hereby certify that this relationship does not violate the limitation cited above concerning the total number of physician assistants or advanced practice registered nurses with whom I may simultaneously supervise or collaborate. An advanced practice registered nurse may perform the practice of nursing by using equipment that transfers information concerning the medical condition of a patient in this state electronically, telephonically or by fiber optics from within or outside this State or the United States. Further, this relationship will not begin until I am in receipt of a file-stamped copy of this Notification bearing the receipt stamp of the Nevada State Board of Medical Examiners thereon. Upon receipt of same, I will be collaborating with the following named advanced practice registered nurse at the following practice location(s):

Melissa Heemsath, APRN
Name of Advanced Practice Registered Nurse

Email: mmheemsath@gmail.com

6255 Sharlands Ave, Reno, NV 89523
280 Vista Knoll Pkwy Suite 110, Reno, NV 89511
775-770-7682
Practice Location(s) AND Telephone No. (use extra page if necessary)

I am aware that the original copy of this Notification will be placed in my licensing file at the offices of the Nevada State Board of Medical Examiners, and that I must immediately notify the board, in writing, of the termination of this relationship.

WHEREFORE, I set my hand this 26 day of February, 2025.

Bayo Curry-Winchell, MD
Collaborating Physician's Name (Print or Type)

Collaborating Physician's Signature

COMES NOW Melissa Heemsath, APRN, being first duly sworn, who deposes and says that: I, the undersigned advanced practice registered nurse, am duly licensed as an advanced practice registered nurse in the state of Nevada, and in good standing with the Nevada State Board of Nursing, have never been formally disciplined by the Nevada State Board of Nursing for a violation of the Nursing Practice Act of the state of Nevada. That I have read and am aware of the provisions of Chapter 630 of the Nevada Revised Statutes and the Nevada Administrative Code as those laws apply to advanced practice registered nurses. I am aware of the requirements of the Nevada State Board of Medical Examiners that my collaborating physician notify that Board of the termination of this agreement.

WHEREFORE, I set my hand this 26 day of February, 2025.

Melissa Heemsath, APRN
Advanced Practice Registered Nurse's Name (Print or Type)

Advanced Practice Registered Nurse's Signature

The above-named Bayo Curry-Winchell, MD
Physician's Name (Print)
being first duly sworn, appeared before me on the 26 day of February, 2025, and in my presence, executed this document consisting of one (1) page.

Notary Public

CRYSTAL LOPEZ
Notary Public - State of Nevada
Appointment No. 11-3952-3
My Appointment Expires November 3, 2028

The above-named Melissa Heemsath, APRN
Advanced Practice Registered Nurse's Name (Print)
being first duly sworn, appeared before me on the 26 day of February, 2025, and in my presence, executed this document consisting one (1) page.

Notary Public

CRYSTAL LOPEZ
Notary Public - State of Nevada
Appointment No. 11-3952-3
My Appointment Expires November 3, 2028

Completed original form is to be mailed directly to:
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, NV 89521

PROTOCOL FOR PRESCRIPTION OF SCHEDULE II CONTROLLED SUBSTANCE DRUGS

Date: February 26, 2025

Re: Protocol for Prescription of Schedule II Controlled Substance Drugs

Dear Board:

Per NRS 632.237 Subsection 2(b)-3(b): "An advanced practice registered nurse may:

(b) If authorized pursuant to NRS 639.2351 and subject to the limitations set forth in subsection 3, prescribe controlled substances, poisons, dangerous drugs and devices.

3. An advanced practice registered nurse who is authorized to prescribe controlled substances, poisons, dangerous drugs and devices pursuant to NRS 639.2351 shall not prescribe a controlled substance listed in schedule II unless:

(a) The advanced practice registered nurse has at least 2 years or 2,000 hours of clinical experience; or

(b) The controlled substance is prescribed pursuant to a protocol approved by a collaborating physician."

Please be advised that APRN, Melissa (APRN First Name) Heemsath (APRN Last Name), 863933 (Nevada APRN License Number)

will begin collaboration on 2/26/2025 (Date) with Bayo (Physician First Name) Curry-Winchell (Physician Last Name),

15918 (Physician License Number) at Saint Mary's Urgent Care (Facility Name)

6255 Sharlands Ave (Facility Street Address) Reno (Facility City) NV (Facility State) 89523 (Facility Zip Code).

Dr. Bayo Curry-Winchell (Physician Name) is a Family Practice (Family Practice, etc MD/DO/DPM etc...)

and has agreed to be the collaborating physician for prescribing Schedule II Controlled Substance Drugs for the APRN per NRS 639.2351 and the following protocol.

The signatures below affirm that:

- Prior to prescribing Schedule II Controlled Substances, the advanced practice registered nurse (APRN) shall obtain a Controlled Substance Registration Certification through the U.S. Drug Enforcement Agency and be approved by the Nevada State Board of Pharmacy.
- The parties agree that the APRN will have full authority to prescribe any medication in the Class II category.

PROTOCOL FOR PRESCRIPTION OF SCHEDULE II CONTROLLED SUBSTANCE DRUGS

- The parties further agree that the APRN will consult with the physician in a manner and on a schedule determined by the parties.
- The parties agree that meaningful consultation will best be conducted face-to-face or via telephone. Consultations may occur spontaneously, as needed, in addition to scheduled interactions.
- Either party may rescind this agreement at any time.
- The Nevada State Board will be notified within twenty-four (24) hours of any changes to this protocol/agreement.
- The APRN will not practice outside the scope of the APRN's role or population of focus issued by the Nevada State Board of Nursing.

APRN Signature — Date: 2/26/2025

Physician Signature — Date: 2/26/25

Return to the Nevada State Board of Nursing via upload in the message center in your Nevada Nurse Portal Account or email to nursingboard@nsbn.state.nv.us