July 2025 Board Meeting Handouts

- 5A. Ajumobi Charles Agu
- **5E.** Wells Pharmacy
- 5N/5O. Matthew Okeke
- **5S.** Miguel Vargas-Lagunas
- 18A. Workshop The proposed amendment specifies the requirements for pharmacies and practitioners to be authorized to engage in the sterile or nonsterile compounding of drug products.



BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 22-535-CS-S

Petitioner,

DECLARATION OF JESSETTE PHAYNARIKONE

AJUMOBI CHARLES AGU, MD, Certificate of Registration No. CS21324,

Respondent.

- I, Jessette Phaynarikone, hereby state the following:
- 1. I am the Board Coordinator I and Administrative Assistant to the Nevada State Board of Pharmacy (Board). I have personal knowledge of the matters stated herein and would be competent to testify thereon if called upon to do so.
- I am responsible for filing and serving by mail pleadings and notices related to disciplinary actions before the Board.
- 2. I have examined Exhibits 1 and 2 attached hereto, and make this declaration for the purpose of authenticating Exhibits 1 and 2, each of which is identified and discussed below.
- 3. On April 21, 2025, I served the Order to Show Cause on file herein by certified mail to Respondent at both his business address and his residential address, affixed with a tracking number, in conformance with NRS 639.242 and NAC 639.972. True and correct copies of the Order to Show Cause, the envelopes with tracking numbers, and USPS tracking results are attached hereto as Exhibit 1.
- 4. On June 12, 2025, I served a second Notice of Show Cause Hearing by certified mail to Respondent at both his business address and his residential address, affixed with a tracking number, in conformance with NRS 241.0333. True and correct copies of the Notice of Show Cause Hearing, the envelopes with tracking numbers, and USPS tracking results are attached hereto as Exhibit 2.

I, Jessette Phaynarikone, hereby declare under penalty of perjury that the 5. foregoing is true and correct.

Executed this 14th day of July, 2025.

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

AJUMOBI AGU ORDER TO SHOW CAUSE EXHIBIT 1 22-535-CS-S



BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 22-535-CS-S

Petitioner,

V.

ORDER TO SHOW CAUSE

AJUMOBI CHARLES AGU, MD, Certificate of Registration No. CS21324,

Respondent.

- J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), makes the following that will serve both a notice of intended action under NRS 233B.127(3) and as an order to show cause under NAC 639.965:
- 1. Respondent Ajumobi Charles Agu, MD, revoked Certificate of Registration No. CS21324, is hereby directed to appear before the Board for a hearing to show cause scheduled Wednesday, July 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:

Hilton Garden Inn Las Vegas Strip South 7830 S. Las Vegas Blvd Las Vegas, NV 89123

- 2. On Wednesday, March 6, 2024, the Board entered its Findings of Fact, Conclusions of Law, and Order revoking Certificate of Registration No. CS21324 and imposing discipline on Respondent pursuant to NRS 453.241(1)(b) and NRS 639.255 (Order).
- 3. Respondent has failed to make payment of a fine of One Thousand Dollars (\$5,000.00) pursuant to the Order.
- 4. Respondent has failed to make payment of Four Thousand Sixty-Five Dollars and Fifty-One Cents (\$4,065.51) for reasonable attorney's fees and recoverable costs pursuant to the Order.

5. Respondent is therefore directed to show cause why he should not be subject to further discipline pursuant to NRS Chapters 453 and 639, or otherwise demonstrate that his conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3).

IT IS SO ORDERED.

Entered this 21° day of APRIC 2025.

J. David Wuest, R.Ph., Executive Secretary

Neyada State Board of Pharmacy

Pursuant to NRS 241.033 and 241.034, 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.

CERTIFICATE OF SERVICE

	I certify	that I am an er	nployee of the Nevada State Board of Pharmacy, and that on this
M 22	day of	APRIL	_ 2025, I served a true and correct copy of the foregoing document
by C	ertified U.	S. Mail and Star	ndard U.S. mail to the following:

Ajumobi Charles Agu, MD

Henderson, NV 89074

Ajumobi Charles Agu, MD 2235 East Flamingo, Ste #128 Las Vegas, NV 89119

> JESSETTE PHAYNARIKONE ADMINISTRATIVE ASSISTANT, BOARD COORDINATOR I

FILED

APR 2 1 2025

NEVADA STATE BOARD OF PHARMACY

Aiumobi Charles Agu, MD

Henderson, NV 89074 22-535-CS-S. OSC

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MAILED 4-21-25

certified - \$8.16

Standard - \$ 0.97

FILED

APR 2 1 2025

NEVADA STATE BOARD OF PHARMACY



MAILED 4.21.25

certified -48.16

standard -\$ 0.97

Ajumobi Charles Agu, MD 2235 East Flamingo, Ste #128 Las Vegas, NV 89119 22-535-CS-S. OSC

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FAQs >

Tracking Number:

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Latest Update

Your item was delivered to an individual at the address at 12:46 pm on April 25, 2025 in HENDERSON, NV 89074.

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Delivered, Left with Individual

HENDERSON, NV 89074 April 25, 2025, 12:46 pm

Pre-Shipment, USPS Awaiting Item

April 22, 2025

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

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Return Receipt Electronic	~
USPS Tracking Plus®	~

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Ajumobi Charles Agu, MD 2235 East Flamingo, Ste #128 Las Vegas, NV 89119

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RETURN TO SENDER NOT DELIVERABLE AS ADDRESSED UNABLE TO FORWARD

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AJUMOBI AGU ORDER TO SHOW CAUSE EXHIBIT 2 22-535-CS-S

JOE LOMBARDO Governor

STATE OF NEVADA



DR. KRISTOPHER SANCHEZ
Director

PERRY FAIGIN NIKKI HAAG MARCEL F. SCHAERER Deputy Directors

> J. DAVID WUEST Executive Secretary

DEPARTMENT OF BUSINESS AND INDUSTRY OFFICE OF NEVADA BOARDS, COMMISSIONS AND COUNCILS STANDARDS STATE OF NEVADA BOARD OF PHARMACY

June 12, 2025

Aiumobi Charles Agu

Henderson, NV 89074

Re: Ajumobi Charles Agu and Case No. 22-535-CS-S

Dear Ajumobi Charles Agu,

The hearing for case number 22-535-CS-S has been scheduled for Wednesday, 7/16/2025 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 3039 9848 27

STATE OF NEVADA



DR. KRISTOPHER SANCHEZ

Director

PERRY FAIGIN NIKKI HAAG MARCEL F. SCHAERER Deputy Directors

> J. DAVID WUEST Executive Secretary

DEPARTMENT OF BUSINESS AND INDUSTRY OFFICE OF NEVADA BOARDS, COMMISSIONS AND COUNCILS STANDARDS STATE OF NEVADA BOARD OF PHARMACY

June 12, 2025

Ajumobi Charles Agu 2235 E Flamingo, Ste #128 Las Vegas, NV 89119

Re: Ajumobi Charles Agu and Case No. 22-535-CS-S

Dear Ajumobi Charles Agu,

The hearing for case number 22-535-CS-S has been scheduled for Wednesday, 7/16/2025 at 9:00:00 AM PST or soon thereafter at the following location:

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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

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Feedback

ALERT: TROPICAL STORM CHANTAL, SEVERE WEATHER, AND FLOODING ALONG THE EAST ...

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Tracking Number:

Remove X

9489017898203039984827

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Latest Update

Your item was delivered to an individual at the address at 4:10 pm on June 17, 2025 in HENDERSON, NV 89074.

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Delivered, Left with Individual

HENDERSON, NV 89074 June 17, 2025, 4:10 pm

Departed USPS Regional Facility

LAS VEGAS NV DISTRIBUTION CENTER June 17, 2025, 8:30 am

Arrived at USPS Regional Facility

LAS VEGAS NV DISTRIBUTION CENTER June 16, 2025, 4:34 pm

In Transit to Next Facility

June 15, 2025

Arrived at USPS Regional Facility

RENO NV DISTRIBUTION CENTER June 14, 2025, 12:06 pm Accepted at USPS Origin Facility

RENO, NV 89521 June 14, 2025, 10:51 am

Pre-Shipment, USPS Awaiting Item

June 13, 2025

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USPS Tracking Plus®	~
Product Information	~

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Tracking Number:

Remove X

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Latest Update

Your item has been delivered to the original sender at 1:56 pm on June 23, 2025 in RENO, NV 89521.

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Delivered

Delivered, To Original Sender

RENO, NV 89521 June 23, 2025, 1:56 pm

Arrived at USPS Regional Facility

RENO NV DISTRIBUTION CENTER June 22, 2025, 2:28 pm

In Transit to Next Facility

June 21, 2025

Addressee Unknown

LAS VEGAS, NV 89119 June 17, 2025, 1:42 pm

Departed USPS Regional Facility

LAS VEGAS NV DISTRIBUTION CENTER June 17, 2025, 8:30 am

Arrived at USPS Regional Facility

LAS VEGAS NV DISTRIBUTION CENTER June 16, 2025, 8:19 am

Arrived at USPS Regional Facility

RENO NV DISTRIBUTION CENTER June 14, 2025, 1:44 pm

Accepted at USPS Origin Facility

RENO, NV 89521 June 14, 2025, 12:29 pm

Pre-Shipment, USPS Awaiting Item

June 13, 2025

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Contact USPS Tracking support for further assistance S. OSC. Exhibit2. Agu005

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 23-050-PH-O

Petitioner,

V.

WELLS PHARMACY NETWORK, LLC, Pharmacy License No. PH01589,

Respondent.

EXHIBIT A

1487902	03072022@3/16/2022	60	8/31/2022	PROGESTERONE (OLIVE OIL) 100MG CAPSULE (A)	60	2.4E+09	7919874
1523356	04252022(5/10/2022	60	10/19/2022	PROGESTERONE (OLIVE OIL) 100MG CAPSULE (A)	60	2.4E+09	7867335
1523356	05042022(5/10/2022	60	10/30/2022	PROGESTERONE (OLIVE OIL) 100MG CAPSULE (A)	60	2.4E+09	7867335
1525582	04152022(5/13/2022	60	10/11/2022	PROGESTERONE (OLIVE OIL) 100MG CAPSULE (A)	60	2.4E+09	7976255
1525582	05042022(5/13/2022	60	10/30/2022	PROGESTERONE (OLIVE OIL) 100MG CAPSULE (A)	60	2.4E+09	7976255
1529590	05172022(5/19/2022	60	11/7/2022	PROGESTERONE (OLIVE OIL) 100MG CAPSULE (A)	60	2.4E+09	7982044
1558626	06142022@7/8/2022	60	12/10/2022	PROGESTERONE (OLIVE OIL) 100MG CAPSULE (A)	60	2.4E+09	8026011
1559781	06142022(7/11/2022	60	12/10/2022	PROGESTERONE (OLIVE OIL) 100MG CAPSULE (A)	60	2.4E+09	8027736
1564242	07062022(7/19/2022	60	1/2/2023	PROGESTERONE (OLIVE OIL) 100MG CAPSULE (A)	60	2.4E+09	8035125
1564242	06142022(7/19/2022	60	12/10/2022	PROGESTERONE (OLIVE OIL) 100MG CAPSULE (A)	60	2.4E+09	8035125
1585674	08232022(8/23/2022	60	2/14/2023	PROGESTERONE (OLIVE OIL) 100MG CAPSULE (A)	60	2.4E+09	8070065
1615089	09222022(10/12/2022	60	3/21/2023	PROGESTERONE (OLIVE OIL) 100MG CAPSULE (A)	60	2.4E+09	8118524
1643459	11152022(11/29/2022	60	5/10/2023	PROGESTERONE (OLIVE OIL) 100MG CAPSULE (A)	60	2.4E+09	816463D
1683703	1207202201/25/2023	60	5/31/2023	PROGESTERONE (OLIVE OIL) 100MG CAPSULE (A)	60	2.4E+09	8229746
1688093	01042023(1/31/2023	60	5/31/2023	PROGESTERONE (OLIVE OIL) 100MG CAPSULE (A)	60	2.4E+09	B229746
1462339	11182021(1/28/2022	60	5/15/2022	PROGESTERONE (OLIVE OIL) 125MG CAPSULE (A)	60	2.4E+09	7881791
1462339	12202021(1/28/2022	60	6/14/2022	PROGESTERONE (OLIVE OIL) 125MG CAPSULE (A)	60	2.4E+09	7881791
1504892	03162022(4/12/2022	60	9/10/2022	PROGESTERONE (OLIVE OIL) 125MG CAPSULE (A)	60	2.4E+09	7945920
1556398	0620202267/6/2022	60	12/11/2022	PROGESTERONE (OLIVE OIL) 125MG CAPSULE (A)	60	2.4E+09	B022331
1592416	07122022(9/6/2022	60	1/2/2023	PROGESTERONE (OLIVE OIL) 125MG CAPSULE (A)	60	2.4E+09	8080932
1627429	09092022(11/1/2022	60	3/5/2023	PROGESTERONE (OLIVE OIL) 125MG CAPSULE (A)	60	2.4E+09	8138391
1692418	12132022(2/6/2023	60	5/31/2023	PROGESTERONE (OLIVE OIL) 125MG CAPSULE (A)	60	2.4E+09	8243920
1537703	05202022(6/7/2022	60	11/14/2022	PROGESTERONE (OLIVE OIL) 200MG CAPSULE (A)	60	2.4E+09	7994131
1567951	0715202267/25/2022	60	1/10/2023	PROGESTERONE (OLIVE OIL) 200MG CAPSULE (A)	60	2.4E+09	8041068
1486506	03012022(3/10/2022	60	8/22/2022	PROGESTERONE (OLIVE OIL) 50MG CAPSULE (A)	60	2.4E÷09	7917763
1583168	07182022(8/18/2022	30	1/10/2023	PROGESTERONE (OLIVE OIL) SOMG CAPSULE (A)	30	2.4E+09	8085895
1592652	08182022(9/6/2022	60	2/14/2023	PROGESTERONE (OLIVE OIL) 50MG CAPSULE (A)	60	2.4E+09	8081355
1649278	11182022(12/6/2022	60	5/14/2023	PROGESTERONE (OLIVE OIL) SOMG CAPSULE (A)	60	2.4E+09	8173859

Case#23-050-PH-O. Wells Pharmacy.010

NV	3/16/2022 22:51	Henderson	NV			
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NV	10/12/2022 23:17	LAS VEGAS				***************************************
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NV	11/1/2022 17:20	LAS VEGAS				
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Kenneth C. Scheuber

From:

Sarah Thron @wellsrx.com>

Sent:

Tuesday, February 14, 2023 8:52 AM

To:

Kenneth C. Scheuber

Cc:

regulatoryaffairs@wellsrx.com; Howard Brown; Vinay Bhatt; Christopher Ulbricht;

Danielle Walker

Subject:

Encrypt RE: Case #23-050-PH-O

Attachments:

message.html

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2

Encrypt RE: Case #23-050-PH-O



\$ Reply all | ∨

Today, 8 51 AM

Kenneth C. Scheuber < KSCHEUBER@pharmacy.nv.gov>, regulatoryaffairs@well &

Nevada Dispensing Rep...
443 KB

Greetings Ken,

Wells Pharmacy Network, LLC. in Ocala, FL holds Nevada Non-Resident Pharmacy License PH01589, the Pharmacist in Charge is Howard Brown (Florida Pharmacist License PS61619). The requested dispensing report for Case 23-050-PH-O is attached, feel free to reach out if you have any questions or need additional information. Thank you.

From: Kenneth C. Scheuber < KSCHEUBER@pharmacy.nv.gov>

Sent: Thursday, February 9, 2023 1:33 PM

To: regulatoryaffairs@wellsrx.com

Cc: Kenneth C. Scheuber < KSCHEUBER@pharmacy.nv.gov>

Subject: Case #23-050-PH-O

This message was sent from outside the organization. Please do not click links or open attachments unless you recognize the source of this email and know the content is safe.

The Nevada State Board of Pharmacy has opened an investigation involving Wells Pharmacy Network, LLC regarding the Settlement Agreement from the Missouri Board of Pharmacy. I am requesting the following documents/information be provided to me as soon as possible but no later than 02/16/2023. At this time I am requesting the following:

- 1. A dispensing report for prescriptions sent to Nevada residents from 01/01/2022 through 02/09/2023.
- The name and license number of the pharmacist who is licensed from your pharmacy with the Nevada State Board of Pharmacy.

Please contact me with any questions.

Thank you,

Ken

Venneth Scheither Investigator



Message Encryption by Microsoft Office 365

Kenneth C. Scheuber

From:

Kenneth C. Scheuber

Sent:

Thursday, February 9, 2023 10:33 AM

To:

RegulatoryAffairs@WellsRx.com

Cc: Subject: Kenneth C. Scheuber Case #23-050-PH-O

The Nevada State Board of Pharmacy has opened an investigation involving Wells Pharmacy Network, LLC regarding the Settlement Agreement from the Missouri Board of Pharmacy. I am requesting the following documents/information be provided to me as soon as possible but no later than 02/16/2023. At this time I am requesting the following:

1. A dispensing report for prescriptions sent to Nevada residents from 01/01/2022 through 02/09/2023.

2. The name and license number of the pharmacist who is licensed from your pharmacy with the Nevada State Board of Pharmacy.

Please contact me with any questions.

Thank you, Ken

Kenneth Scheuber, Investigator

Nevada State Board of Pharmacy 1140 N Town Center Dr Ste 300 Las Vegas, NV, 89144

Office: 702.486.6420 ext 153

Cell: 702.683.4785 Fax: 702.486.7903

E-mail: kscheubena pharmacy.nv.gov

Web Page: www.bop.nv.gov



CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission. Thank you.

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 23-050-PH-O

Petitioner,

V.

WELLS PHARMACY NETWORK, LLC, Pharmacy License No. PH01589,

Respondent.

EXHIBIT B

Kenneth C. Scheuber

From: Kenneth C. Scheuber

Sent: Saturday, February 25, 2023 6:38 PM

To: Sarah Thron

Cc: regulatoryaffairs@wellsrx.com; Howard Brown; Vinay Bhatt; Christopher Ulbricht;

Kenneth C. Scheuber

Subject: RE: Case #23-050-PH-O

Ms. Sarah Thron.

Thank you for the information you provided me however, I need additional documentation that was not included in what I received.

The FDA enforces the Drug Quality and Security Act which states that compounding pharmacies may not make "Essential Copies" of commercially available drug products unless the Prescriber has requested a change to the formulation that will make a "Clinical Difference" for that individual patient. Under this provision, certain prescriptions of compounded medicines must have a "Clinical Difference Statement" notated on the prescription.

I need copies of the prescriptions for the patients I sent back to you regarding compounding Progesterone with Olive Oil. These compounded medicines must have a "Clinical Difference Statement" notated on the prescription.

Respectfully.

Kenneth Scheuber, Investigator

Nevada State Board of Pharmacy 1140 N Town Center Dr Ste 300 Las Vegas, NV, 89144

Office: 702.486.6420 ext 153

Fax: 702.486.7903

E-mail: kscheuberapharmacy.nv.gov

Web Page: www.bop.nv.gov

igator irmacy e 300

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From: Sarah Thron @wellsrx.com> Sent: Friday, February 17, 2023 12:03 PM

To: Kenneth C. Scheuber < KSCHEUBER@pharmacy.nv.gov>

Cc: regulatoryaffairs@wellsrx.com; Howard Brown < @wellsrx.com>; Vinay Bhatt

Christopher Ulbricht • @wellsrx.com>

Subject: RE: Case #23-050-PH-O

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Mr. Ken Scheuber,

Please see attached documentation as requested regarding the clinical benefits of utilizing an olive oil formulation to provide significant improvement in absorption of the medication and therefore additional clinical benefits to the patient. According to the American Heart Association, olive oil has been shown to lower blood pressure and contains compounds that offer anti-inflammatory and antioxidant benefits. Moreover, the retail formula of the oil-based Progesterone utilizes oil derived from peanuts which is an allergen and presents great risk to the consumer.

Regards.





Document Control Manager
Wells Pharmacy Network, LLC

E: <u>Owellsrx com</u>

1210 SW 33rd Avenue Ocala, FL 34474 www.wellsrx.com

Follow us on LinkedIn









Help us preserve patient access to compounded hormones. Learn more at <u>compounding.com</u>

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From: Kenneth C. Scheuber < KSCHEUBER@pharmacy.nv.gov>

Sent: Wednesday, February 15, 2023 7:28 PM

To: Sarah Thron

Cc: Kenneth C. Scheuber < KSCHEUBER@pharmacy.nv.gov>

Subject: Case #23-050-PH-O

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Ms. Sarah Thron,

Please provide the documentation as to why the Progesterone was compounded with Olive Oil for the attached patients.

Please contact me with any questions,

Thank you,

Ken

Kenneth Scheuber, Investigator

Nevada State Board of Pharmacy 1140 N Town Center Dr Ste 300 Las Vegas, NV, 89144

Office: 702.486.6420 ext 153

Cell: Fax: 702.486.7903

E-mail: kscheuber@pharmacy.nv.gov

Web Page: www.bop.nv.gov



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Encrypted Message

Encrypted Message

Kenneth Scheuber

Sign Out

RE: Encrypt RE: Case #23-050-PH-O

ST

Sarah Thron @wellsrx.com> Yesterday, 9:58 AM

夢 Reply all | マ

Kenneth C. Scheuber <KSCHEUBER@pharmacy.nv.gov>; regulatoryaffairs@welli ≥

Progesterone was comp...

Prometrium Product Inf...

¥ Show all 2 attachments (250 KB)

Mr. Scheuber,

Applogies, this email has been stuck in my Outbox since February 28th and I just realized it. The file size was too large so I am sending the Prometrium product information separately in this second email. Please let me know if there is anything else I may be of assistance with. Thank you.

From: Sarah Thron

Sent: Monday, March 13, 2023 12:52 PM

To: 'Kenneth C. Scheuber' < KSCHEUBER@pharmacy.nv.gov>

Cc: regulatoryaffairs@wellsrx.com; Howard Brown @wellsrx.com>; Vinay Bhatt < Christopher Ulbrich

@wellsnx.com> Subject: Encrypt RE: Case #23-050-PH-O

Mr. Ken Scheuber,

Per your request, please see attached prescriptions. In addition the Prometrium Product Information sheet is attached. Wells Pharmacy Network's compounded formulation does not infringe upon the commercially available product (Prometrium).

The inactive ingredients for PROMETRIUM Capsules 100 mg include: peanut oil NF, gelatin NF, glycerin USP, lecithin NF, titanium dioxide USP, D&C Yellow No. 10, and FD&C Red No. 40.

The inactive ingredients for PROMETRIUM Capsules 200 mg include: peanut oil NF, gelatin NF, glycerin USP, lecithin NF, titanium dioxide USP, D&C Yellow No. 10, and FD&C Yellow No. 6.

The inactive ingredients for Wells Pharmacy Network Progesterone in Olive Oil Capsules 50 mg, 100 mg, 125 mg, and 200 mg; polyethylene glycol 1450 MW NF, olive oil NF

- 200 mg Capsule Clear
- 125 mg Light Blue/White Capsule
- 100 mg Dye Free Clear Capsule
- 100 mg White Opaque Capsule
- 50 mg Pink Opaque Capsule

Message Encryption by Microsoft Office 365

Sign Out

?



Hide email



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Ms. Sarah Thron.

Please provide the documentation as to why the Progesterone was compounded with Olive Oil for the attached patients.

Please contact me with any questions,

Thank you,

Ken

Kenneth Scheuber, Investigator

Nevada State Board of Pharmacy 1140 N Town Center Dr Ste 300 Las Vegas, NV. 89144

Office: 702.486.6420 ext 153

Cell:

Fax: 702.486.7903

E-mail: kscheuberapharmacy.nv.gov

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Message Encryption by Microsoft Office 365

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 23-050-PH-O

Petitioner,

V

WELLS PHARMACY NETWORK, LLC, Pharmacy License No. PH01589,

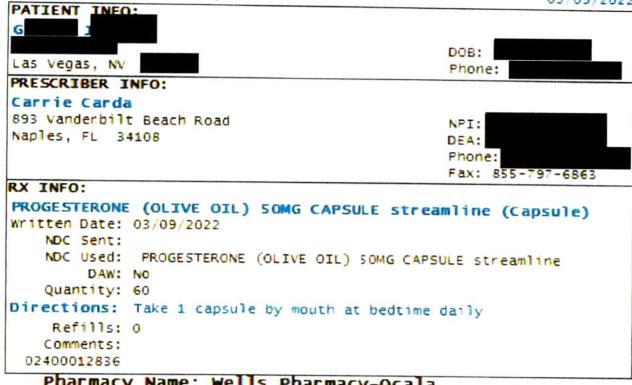
Respondent.

EXHIBIT C

```
PATIENT INFO:
5
                                                  DOB:
Las Vegas, NV
                                                  Phone:
PRESCRIBER INFO:
Richard Martinez
                                                  NPI:
838 SW Federal Hwy
stuart, FL
           34994
                                                  DEA:
                                                  Phone:
                                                  Fax: 772-264-2925
RX INFO:
PROGESTERONE (OLIVE OIL) 125MG CAPSULE (Capsule)
Written Date: 01/27/2022
    NDC Sent:
    NDC Used:
               PROGESTERONE (OLIVE OIL) 125MG CAPSULE
         DAW: No
    Quantity: 60
Directions: Take one capsule by mouth daily before bed
     Refills: 0
    Comments:
 02400008864
```

```
RMM SURESCRIPTS DATA

Message ID= [6a871d628a6d46959fdafa1a4539c3aa]
Coordination of Benefits Bin Location Number= [618014]
Coordination of Benefits Gardholder Id= [186655742]
Coordination of Benefits Group Id= [PX580801784981]
Coordination of Benefits Forup Id= [PX580801784981]
Coordination of Benefits Hutually Defined= [32835488]
Coordination of Benefits Hutually Defined= [32835488]
Patient Roman Roman
```



```
RAW SURESCRIPTS DATA
 Message ID= [bd6a8042de274751b027380adceac64e]
Coordination of Benefits Bin Location Number= [004336]
Coordination of Benefits Cardholder Id= [W46132773501]
Coordination of Benefits Group Id= [RX7434]
Coordination of Benefits Mutually Defined= [702734271]
Coordination of Benefits Pauer Name= [CUSICAREMARK]
 Coordination of Benefit
Patient Address Line
Patient Address Line
Patient Birth Date
Patient City= [Las ver-
Patient First Name= [G
Patient Last Name= [J
Patient Postal=
Patient Postal=
  Patient
Patient
 Patient Primary Phone=
Patient Primary Phone=
Patient State= [NV]
Patient State= [NU]

Pharmacy Agency Address Line 1= [1210 SW 33RD AVE]

Pharmacy Agency City= [OCALA]

Pharmacy Agency Postal= [34474]

Pharmacy Agency State= [FL]

Pharmacy Fax= [8774016(FC)]

Pharmacy Fax= [8774016(FC)]

Pharmacy Postal

Pharmacy NCPDescription

Pharmacy NPI

Pharmacy Party Name= [WELLS PHARMACY]

Pharmacy Primary Phone= [3526222913]

Prescribed Drug DAW= [No]

Prescribed Drug Daw= [No]

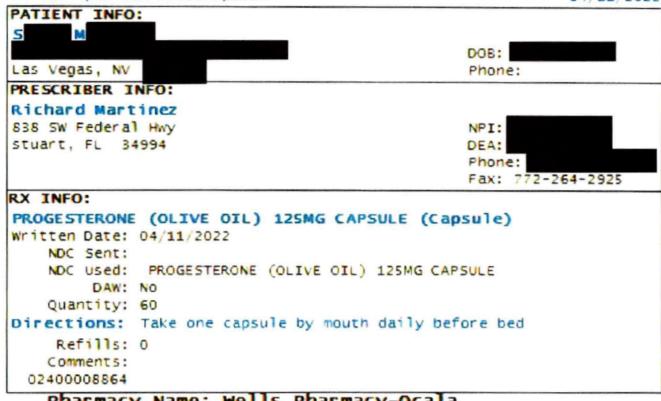
Prescribed Drug Instructions= [Take 1 capsule by mouth at bedtime daily]

Prescribed Drug Instructions= [PROGESTERONE (OLIVE OIL) 50MG CAPSULE streamline]
 prescribed Drug
streamline]
Prescribed Drug
Prescribed Drug
                                                   Drug Notes= [02400012836]
Drug Potency Unit= [Capsule]
Drug Quantity= [60]
Drug Refills= [0]
Drug Refills= [0]
Drug Written Date= [20220309]
Agency Address Line 1= [893 Vanderbilt Beach Road]
Agency City= [Naples]
Agency Postal= [34108]
Agency State
DEA Number=
   Prescribed
  Prescribed
 Prescribed
Prescriber
Prescriber
Prescriber
Prescriber
Prescriber
Prescriber
                                                     Fax=
   Prescriber
Prescriber NPI=
Prescriber Party Name= IStreamline Medical Group]
Prescriber Primary Phone:
Prescriber Provider First Name= [Comparison Prescriber Provider Last Name= [Comparison Prescriber Provider Name Suffix= [MD]
Prescriber State License Number= [130703]
                                                                                                                                                                                                                                                         Case#23-050-PH-O. Wells Pharmacy.017
```

```
PATIENT INFO:
                                                  DOB:
henderson, NV
                                                  Phon
PRESCRIBER INFO:
Carrie Carda
893 Vanderbilt Beach Road
                                                  NPI:
Naples, FL
           34108
                                                  DEA:
                                                  Phon
                                                  Fax: 855-797-6863
RX INFO:
PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE (Capsule)
Written Date: 03/12/2022
    NDC Sent:
    NDC Used:
               PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE
         DAW: NO
    Quantity: 60
Directions: Take 1 capsule by mouth at bedtime daily.
     Refills: 0
    Comments:
  02400010478 Bill to streamline medical group. See account notes
  for shipping method
```

```
RAW SURESCRIPTS DATA

Message ID= [9e4a950536534b7099ed4063667ff9d2]
Coordination of Benefitz Mutually Defined- [793561607]
Patient Address Line
Patient Birth Date=
Patient First Name= ID=
Patient First Name= ID=
Patient First Name= ID=
Patient Last Name= ID=
Patient Primary Prone=
Patient Primary Prone=
Patient Primary Prone=
Patient Primary Prone=
Patient State= [NU]
Pharmacy Agency City= [0CALA]
Pharmacy Agency City= [0CALA]
Pharmacy Agency State= [FL]
Pharmacy Agency State= [FL]
Pharmacy Agency State= [FL]
Pharmacy Pay= 127404E660]
Pharmacy Primary Phone= [3526222913]
Prescribed Drug DAW= [No]
Prescribed Drug DAW= [No]
Prescribed Drug DAW= [No]
Prescribed Drug DaW= [No]
Prescribed Drug Instructions= [Take 1 capsule by mouth at bedtime daily.]
Prescribed Drug Notes= [0240010478 Bill to streamline medical group. See account notes for shipping method]
Prescribed Drug Notes= [0240010478 Bill to streamline medical group. See account notes for shipping method]
Prescribed Drug Moitter Date= [20220312]
Prescribed Drug Refills= [0]
Prescribed Drug Refills= [0]
Prescribed Drug Refills= [0]
Prescribed Prescriber Agency Address Line != [893 Vanderbilt Beach Road]
Prescriber Agency Postal= [34108]
Prescriber Regency Postal= [34108]
Prescriber Regency Postal= [34108]
Prescriber Patien Phase=
Prescriber Patien Phase=
Prescriber Primary Phone= [2393259645]
Prescriber Provider First Name= [0]
Prescriber Provider First Name= [0]
Prescriber Provider First Name= [0]
Prescriber Provider Last Name= [0]
Prescriber Provider Last Name= [0]
Prescriber Provider Last Name= [0]
Prescriber Provider Hame Suffix= [11]
Prescriber Provider Last Name= [0]
Prescriber Provider Hame Suffix= [11]
Prescriber State License Number= [130703]
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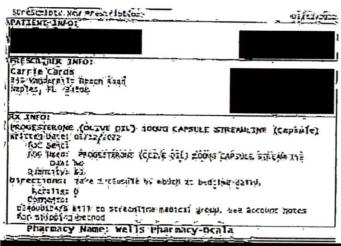
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RAW SURESCRIPTS DATA

Message ID= [5a7eb96c5f9941a49e6eddd486c4deb6]
Coordination of Benefits Bin Location Number= [001553]
Coordination of Benefits Cardholder Id= [00002578313]
Coordination of Benefits Group Id= [MUND]
Coordination of Benefits Mutually Defined= [431721361]
Patient Birth Date= [4818]
Patient Birth Date= [4818]
Patient First Hame= [4818]
Patient Bender= [4818]
Patient Postal= [4818]
Patient Bender= [4818]
Pharmacy Regency Postal= [4818]
Pharmacy Primary Phone= [48260008864]
Prescribed Drug Guantity= [681]
Prescribed Drug Guantity= [681]
Prescribed Drug Guantity= [681]
Prescribed Drug Maritten Date= [20220411]
Prescribed Drug Maritten Date= [20220411]
Prescribed Program Marity= [4818]
Prescriber Regency Postal= [34994]
Prescriber Postal Rumber= [4818]
Prescriber Postal Ru
```

```
PATIENT INFO:
                                                  DOB:
                                                  Phone:
henderson, NV
PRESCRIBER INFO:
Carrie Carda
893 Vanderbilt Beach Road
                                                  NPI:
Naples, FL 34108
                                                  DEA:
                                                  Phone:
                                                  Fax: 855-797-6863
RX INFO:
PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE (Capsule)
Written Date: 05/12/2022
    NDC Sent:
    NDC Used: 02400-0104-78 PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE
         DAW: NO
    Quantity: 60
Directions: Take 1 capsule by mouth at bedtime daily.
     Refills: 0
    Comments:
  02400010478 Bill to streamline medical group. See account notes for
  shipping method
```

```
RAM SURESCRIPTS DATA

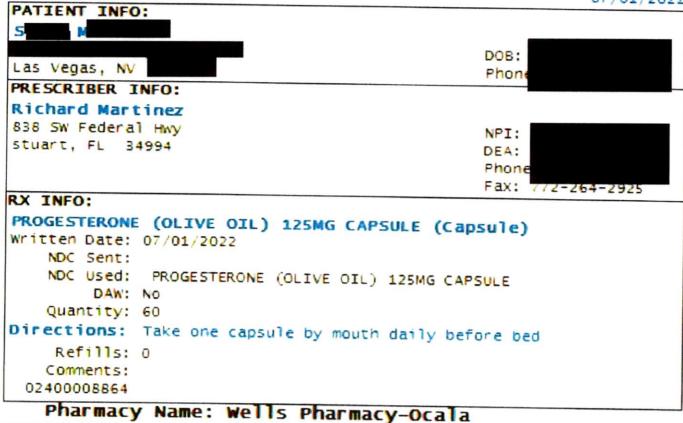
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Coordination of Benefits Mutually Defined= [518591219]
Coordination of Benefits Mutually Defined= [518591219]
Patient First Mare 1
Patient Birth Date= [197as120]
Patient Birth Date= [197as120]
Patient Birth Date= [197as120]
Patient Gender=
Patient Address Line I=
Patient City= [henderson
Patient First Mone= [7252076024]
Patient Postal
Patient Postal
Patient Postal
Patient Postal
Patient Postal
Pharmacy Party Hame= [UELLS PHERMRCY]
Pharmacy Party Hame= [UELLS PHERMRCY]
Pharmacy Party Hame= [UCALH]
Pharmacy Agency State= [FL]
Pharmacy Agency State= [FL]
Pharmacy HPI=
Pharmacy HPI=
Pharmacy HPI=
Pharmacy HPI=
Pharmacy HPI=
Pharmacy HPI=
Prescribed Drug Item Description= [PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE)
Prescribed Drug Ountity= [60]
Prescribed Drug Instructions= [Take I capsule by mouth at bedtime daily.]
Prescribed Drug Instructions= [Take I capsule by mouth at bedtime daily.]
Prescribed Drug Mirtuten Date= [20220512]
Prescriber Drug Mirtuten Date= [20220512]
Prescriber Provider Market Mirtuten Mirtuten Medical group. See account notes for shipping method 02408010478 Biil to streamline medical group. See
```





```
PATIENT INFO:
         R
                                                  DOB:
Las Vegas, NV
                                                  Phone:
PRESCRIBER INFO:
Thomas Alfreda
2779 W. Horizon Ridge Pkwy., Suite
                                                  NPI:
Henderson, NV 89052
                                                  DEA:
                                                  Phone
                                                  Fax:
                                                       702-666-0401
RX INFO:
PROGESTERONE (OLIVE OIL) 200MG CAPSULE (Capsule)
Written Date: 06/01/2022
    NDC Sent:
    NDC Used:
               PROGESTERONE (OLIVE OIL) 200MG CAPSULE
         DAW: NO
    Quantity: 60
Directions: Please take one capsule each day.
     Refills: 0
    Comments:
 MAIL TO PATIENT ADDRESS - DO NOT INCLUDE INVOICE - BILL DOCTORS
 OFFICE - SHIP 2ND DAY! 02400012852
```

```
Message ID= Loci8d3c5450845b39969b4c62ec6dac3]
Coordination of Benefits Mutually Defined= [043942514]
Patient Right Date= [15]
Patient Birth Date= [15]
Patient First Name= [15]
Patient First Name= [15]
Patient Gender= LFemale]
Patient Hast Name= [16]
Patient Postal= [16]
Patient State= [17]
Patient State= [17]
Patient State= [17]
Pharmacy Regency Rddress Line 1= [1210 SW 33RD AVE]
Pharmacy Regency City= [105RLA]
Pharmacy Regency State= [16]
Pharmacy Regency State= [17]
Pharmacy Regency State= [17]
Pharmacy Regency State= [17]
Pharmacy Patient Name= [WELLS PHARMACY]
Pharmacy NCPDP
Pharmacy NCPDP
Pharmacy Patient Name= [WELLS PHARMACY]
Pharmacy Patient Name= [18]
Patient State= [18]
Pharmacy Patient Name= [18]
Prescribed Drug Days Supply= [60]
Prescribed Drug Instructions= [Please take one capsule each day.]
Prescribed Drug Instructions= [Please take one capsule each day.]
Prescribed Drug Instructions= [Please take one capsule each day.]
Prescribed Drug Instructions= [Please take one capsule each day.]
Prescribed Drug Instructions= [Please take one capsule each day.]
Prescribed Drug Instructions= [Please take one capsule each day.]
Prescribed Drug Instructions= [Please take one capsule each day.]
Prescribed Drug Instructions= [Please take one capsule each day.]
Prescribed Drug Instructions= [Please take one capsule each day.]
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Prescribed Drug Instructions= [Please take one capsule each day.]
Prescribed Drug Instructions= [Please take one capsule each day.]
Prescribed Drug Instructions= [Please take one capsule each day.]
Prescribed Drug Instructions= [Please take one capsule each day.]
Prescribed Drug Instructions= [Please take one capsule each day.]
Prescribed Drug Instructions= [Please take one capsule each day.]
Prescribed Drug Instructions= [P
```



RAW SURESCRIPTS DATA Message ID= [84c8f0405deb4d64b48bfaa985a02b03] Coordination of Benefits Mutually Defined= [790918376] Patient Address Line 1-Birth Date= City= [Las Veg First Name= [S Patient Patient Patient Patient Gender= Pharmacy Agency Address Line 1= [1210 SW 33RD AUE] Pharmacy Agency City= [OCALA] Pharmacy Agency Postal= [34474] Pharmacy Agency State= [FL] Pharmacy Fax= [9274015652] Pharmacy NCPDP Pharmacy NPI= Pharmacy NCPDP Pharmacy NPI= Pharmacy NPI= Pharmacy Party Name= [WELLS PHARMACY] Pharmacy Party Name= [S526222913] Pharmacy Primary Phone= [3526222913] Prescribed Drug DAW= [No] Prescribed Drug Drug Coverage Status Code= [Compound] Prescribed Drug Instructions= [Take one capsule by mouth daily before bed] Prescribed Drug Item Description= [PROGESTERONE (OLIVE OIL) 125MG CAPSULE] Prescribed Drug Notes= [02400008864] Prescribed Drug Potency Unit= [Capsule] Prescribed Drug Quantity= [60] Prescribed Drug Refills= [0] Prescribed Drug Written Date= [20220701] Drug Written Date= [20220701] Agency Address Line 1= [838 SW Federal Hwy] Agency City= [stwart] Prescribed Prescriber Prescriber Postal= State= Prescriber Agency [34994] [FL] Agency Stat DEA Number= Prescriber Prescriber Prescriber Fax= Prescriber Fax= Prescriber NPI= Prescriber Party Name= [Stuart ProPerformance] Prescriber Primary Phone= [7726317266] Prescriber Provider First Name= [Richard] Prescriber Provider Last Name= [Martinez] Prescriber Provider Name Suffix= [MD] Prescriber State License Number= [ME129112] Prescriber Prescriber Prescriber Case#23-050-PH-O. Wells Pharmacy.023

```
PATIENT INFO:
                                                  DOB:
henderson, NV
                                                  Phon
PRESCRIBER INFO:
Carrie Carda
                                                  NPI:
893 Vanderbilt Beach Road
Naples, FL
           34108
                                                  DEA:
                                                  Phon
                                                  Fax: 855-797-6863
RX INFO:
PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE (Capsule)
Written Date: 07/07/2022
    NDC Sent:
               PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE
    NDC Used:
         DAW: NO
    Quantity: 60
Directions:
             Take 1 capsule by mouth at bedtime daily.
     Refills: 0
    Comments:
  02400010478 Bill to streamline medical group. See account notes
  for shipping method
```

```
RMM SURESCRIPTS DETA

Message ID = [8] cc55675a5b45e8a3bf034f5c104227]
Coordination of Benefits Mutually Defined [93694744]
Patient Rddress Line
Patient Birth Date=
Patient City= [hendersath
Patient First Name= [1]
Patient First Name= [1]
Patient First Name= [1]
Patient Fostal=
Patient Postal=
Patient Primary Phone=
Patient Primary Phone=
Patient State= [NU]
Pharmacy Agency Address Line = [1210 SW 33RD AUE]
Pharmacy Agency Rostal= [34474]
Pharmacy Agency State= [61]
Pharmacy Agency Postal= [3526222913]
Pharmacy Agency Postal= [3526222913]
Pharmacy Primary Phone= [3526222913]
Pharmacy Primary Phone= [3526222913]
Pharmacy Primary Phone= [3526222913]
Prescribed Drug DAW= [No]
Prescribed Drug DAW= [No]
Prescribed Drug Instructions= [Take 1 capsule by mouth at bedtime daily.]
Prescribed Drug Instructions= [Take 1 capsule by mouth at bedtime daily.]
Prescribed Drug Notes= [02400010478 Bill to streamline medical group. See account notes for shipping method]
Prescribed Drug Potency Unit= [Capsule]
Prescribed Drug Quantity= [60]
Prescribed Drug Gentless Line 1= [893 Vanderbilt Beach Road]
Prescriber Agency Address Line 1= [893 Vanderbilt Beach Road]
Prescriber Agency Postal= [34108]
Prescriber Agency Postal= [34108]
Prescriber Agency First Name= [1884]
Prescriber Agency First Name= [1884]
Prescriber Patient Primary Phone= [299259645]
Prescriber Patient Primary Phone= [299259645]
Prescriber Patient Primary Phone= [299259645]
Prescriber Provider First Name= [Carrie]
Prescriber Provider Last Name= [Carrie]
Prescriber Pro
```

```
PATIENT INFO:
                                                 DOB:
las vegas, NV
                                                 Phone
PRESCRIBER INFO:
Carrie Carda
893 Vanderbilt Beach Road
                                                 NPI:
Naples, FL 34108
                                                 DEA:
                                                 Phor
                                                 Fax: 855-797-6863
RX INFO:
PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE (Capsule)
Written Date: 07/09/2022
    NDC Sent:
    NDC Used:
              PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE
        DAW: No
   Quantity: 60
Directions: Take 1 capsule by mouth at bedtime daily.
    Refills: 0
   Comments:
 02400010478 Bill to streamline medical group. See account notes
 for shipping method
   Pharmacy Name: Wells Pharmacy-Ocala
```

```
RAW SURESCRIPTS DATA

Message ID= [leb6e4b5df564f7fb5279ebfc2eb4665]
Coordination of Benefits Mutually Defined F000778115]
Patient Address Line |=
Patient Birth Date=
Patient First Name= [Left]
Patient First Name= [Left]
Patient Gender=
Patient First Name= [Left]
Patient Formary
Phone
Patient Primary
Phone
Pharmacy Reency Postal= [354474]
Pharmacy Patient Phone
Pharmacy Patient Phone
Pharmacy Patient
Pharmacy
Pharmac
```

```
PATIENT INFO:
         P
                                                  DOB:
Las Vegas, NV
                                                  Phon
PRESCRIBER INFO:
Carrie Carda
893 Vanderbilt Beach Road
                                                  NPI:
Naples, FL 34108
                                                  DEA:
                                                  Phone
                                                  Fax:
                                                       000-19/-0005
RX INFO:
PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE (Capsule)
Written Date: 07/18/2022
    NDC Sent:
    NDC Used:
              PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE
         DAW: NO
    Quantity: 60
Directions: Take 1 capsule by mouth at bedtime daily.
     Refills: 0
    Comments:
 02400010478 Bill to streamline medical group. See account notes
 for shipping method
```

```
RAW SURESCRIPTS DATA
  RAW SURESCRIPTS DATA

Message ID= [07af453beea7457a9e79af59e3d1f951]
Coordination of Benefits Mutually Defined= [25131954]
Patient Address Line 1=
Patient Address Line 1=
Patient Birth Date=
Patient City= [Las Use | Patient First Name= [1]
Patient Gender= | Patient Last Name | Patient Last Name | Patient Primary Phone=
Patient Primary Phone=
Patient Primary Phone=
Patient State= [NU]
Pharmacy Agency Address Line 1= [1210 SW 33RD BUF1]
                                              Agency
Agency
Agency
Agency
Agency
Fax=
NCPDF
    Pharmacy
                                                                                   Address Line 1= [1210 SW 33RD AVE]
City= [OCALA]
Postal= [34474]
State= [FL]
    Pharmacy
    Pharmacy
    Pharmacy
    Pharmacy
    Pharmacy
Pharmacy NPI=
Pharmacy Party Name= [WELLS PHARMACY]
Pharmacy Party Name= [3526222913]
Prescribed Drug DAW= [No]
Prescribed Drug Drug Coverage Status Code= [Compound]
Prescribed Drug Instructions= [Take 1 capsule by mouth at bedtime daily.]
Prescribed Drug Instructions= [PROGESTERONE (OLIVE OIL) 100MG CAPSULE
STREAMLINE]
Prescribed Drug Notes= [02400010478 Bill to streamline medical group. See account notes for shipping method]
Prescribed Drug Potency Unit= [Capsule]
Prescribed Drug Quantity= [60]
Prescribed Drug Refills= [0]
Prescribed Drug Refills= [0]
Prescribed Drug Written Date= [20220718]
Prescriber Agency Address Line 1= [893 Vanderbilt Beach Road]
Prescriber Agency City= [Naples]
Prescriber Agency Postal= [34108]
Prescriber Agency State= [FI]
Prescriber DEA Number=
Prescriber DEA Number=
Prescriber DEA Number=
                                                 NPI=
    Pharmacu
  Prescriber
Prescriber
Prescriber
Prescriber
                                                          Fax=
NPI=
Prescriber Name | Streamline Medical Group]
Prescriber Party Name | [Streamline Medical Group]
Prescriber Primary Phone | [2393259645]
Prescriber Provider First Name | [Carrie]
Prescriber Provider Last Name | [Carda]
Prescriber Provider Name Suffix | [MD]
Prescriber State License Number | [130703]
                                                                                                                                                                                                                                                                           Case#23-050-PH-O. Wells Pharmacy.026
```

```
PATIENT INFO:
                                                 DOB:
Las Vegas, NV
                                                 Phone:
PRESCRIBER INFO:
Thomas Alfreda
2779 W. Horizon Ridge Pkwy., Suite
                                                 NPI:
Henderson, NV
              89052
                                                 DEA:
                                                 Phone
                                                 Fax: 702-666-0401
RX INFO:
PROGESTERONE (OLIVE OIL) 200MG CAPSULE (Capsule)
Written Date: 07/22/2022
    NDC Sent:
    NDC Used:
              PROGESTERONE (OLIVE OIL) 200MG CAPSULE
        DAW: NO
    Quantity: 60
Directions: Please take one capsule each day.
    Refills: 0
   Comments:
 MAIL TO PATIENT ADDRESS - DO NOT INCLUDE INVOICE - BILL DOCTORS
 OFFICE - SHIP 2ND DAY! 02400012852
   Pharmacy Name: Wells Pharmacy-Ocala
```

RAW SURESCRIPTS DATA Message ID= [e347c7fcbedc4fe4a07b33c9e0f4e378] Coordination of Benefits Mutually Defined= [35 Patient Address Line 1= Patient Birth Date= Patient City= [Las Jegs Patient First Name= [6] [356223790] Patient Gender= Patient Last Name= Postal= State= [NU] Patient Patient Pharmacy NPI= Pharmacy Party Name= [WELLS PHARMACY] Pharmacy Party Name= [3526222913] Prescribed Drug DAW= [No] Prescribed Drug Days Supply= [60] Prescribed Drug Drug Coverage Status Code= [Compound] Prescribed Drug Instructions= [Please take one capsule each day.] Prescribed Drug Item Description= [PROGESTERONE (OLIVE OIL) 200MG CAPSULE] Prescribed Drug Item Description= [PROGESTERONE (OLIVE OIL) 200MG CAPSULE] Prescribed Drug Notes= [MAIL TO PATIENT ADDRESS - DO NOT INCLUDE INVOICE - BILL DOCTORS OFFICE - SHIP 2ND DAY! 02400012852] Prescribed Drug Potency Unit= [Capsule] Prescribed Drug Potency Unit= [Capsule] Prescribed Drug Quantity= [60] Prescribed Drug Refills= [0] Prescribed Drug Written Date= [20220722] Prescriber Agency Address Line 1= [2779 W. Horizon Ridge Pkwy., Suite] Prescriber Agency City= [Henderson] Prescriber Agency Postal= [89052] Prescriber Agency State= [NU] Prescriber DEA Number= Agency State= [NU] DEA Number= Fax= NPI= Part Primary Phone= [7026668645] Provider First Name= [Thomas] Provider Last Name= [Alfreda] Provider Name Suffix= [DO] Prescriber Prescriber Prescriber Prescriber Prescriber Prescriber Prescriber Case#23-050-PH-O. Wells Pharmacy.027 Prescriber Provider Name Suffix= [DO]

```
PATIENT INFO:
                                                  DOB:
Las Vegas, NV
                                                  Phone
PRESCRIBER INFO:
Carrie Carda
893 Vanderbilt Beach Road
                                                  NPI:
Naples, FL 34108
                                                  DEA:
                                                  Phon
                                                  Fax: 855-797-6863
RX INFO:
PROGESTERONE (OLIVE OIL) SOMG CAPSULE Streamline (Capsule)
Written Date: 08/18/2022
    NDC Sent:
    NDC Used:
              PROGESTERONE (OLIVE OIL) 50MG CAPSULE streamline
    Quantity: 30
Directions: Take 1 capsule by mouth at bedtime daily
     Refills: 0
    Comments:
 02400012836
```

```
RAW SURESCRIPTS DATA
     Message ID= [34d94c502ca74d61ab1a4aa04a754675]
    The stage ID= 13407405b2Car40bIaDIa4aab4ar540r5]
Coordination of Benefits Bin Location Number= [004336]
Coordination of Benefits Cardholder Id= [W46132773501]
Coordination of Benefits Group Id= [RX7434]
Coordination of Benefits Mutually Defined= [073452119]
Coordination of Benefits Payer Name= [CUS:CAREMARK]
Patient Oddress Line 1-
   Patient Address Line 1=
Patient Address Line 2=
Patient Birth Date=
Patient City= [Las Vegas
Patient First Name= [G
    Patient
                                           Gender=
                                          Last Name L.K
Postal=
Primary Phone=
    Patient
    Patient
  Patient Primary Phone=
Patient Primary Phone=
Patient State= [NV]
Patient Primary Phone=
Patient State= [NU]
Pharmacy Agency Address Line 1= [1210 SW 33RD AVE]
Pharmacy Agency City= [OCALA]
Pharmacy Agency Postal= [34474]
Pharmacy Agency Postal= [FL]
Pharmacy Agency State= [FL]
Pharmacy Fax= [PL]
Pharmacy Pare Pharmacy Primary Phone= [3526222913]
Pharmacy Primary Phone= [3526222913]
Prescribed Drug DAW= [No]
Prescribed Drug DaW= [No]
Prescribed Drug Unstructions= [Take 1 capsule by mouth at bedtime daily]
Prescribed Drug Item Description= [PROGESTERONE (OLIVE OIL) 50MG CAPSULE streamline]
Prescribed Drug Notes= [02400012836]
Prescribed Drug Potency Unit= [Capsule]
Prescribed Drug Quantity= [30]
Prescribed Drug Refills= [0]
Prescribed Drug Refills= [0]
Prescribed Drug Written Date= [20220818]
Prescriber Agency Address Line 1= [893 Vanderbilt Beach Road]
 streamline]
Prescribed Drug Notes= [02400012836]
Prescribed Drug Potency Unit= [Capsule]
Prescribed Drug Quantity= [30]
Prescribed Drug Refills= [0]
Prescribed Drug Refills= [0]
Prescribed Drug Written Date= [20220818]
Prescriber Agency Address Line 1= [893 Vanderbilt Beach Road]
Prescriber Agency City= [Naples]
Prescriber Agency Postal= [34108]
Prescriber Agency State= [FL]
Prescriber DEA Mumber-
Prescriber DEA Mumber-
 Prescriber
Prescriber
Prescriber
Prescriber
Prescriber
Prescriber
                                                       Fax=
NPI=
Prescriber MPI=
Prescriber Party Name= [Streamline Medical Group]
Prescriber Primary Phone= [2393259645]
Prescriber Provider First Name= [Carrie]
Prescriber Provider Last Name= [Carda]
Prescriber Provider Name Suffix= [MD]
Prescriber State License Number= [130703]
                                                                                                                                                                                                                                                                       Case#23-050-PH-O. Wells Pharmacy.028
```

```
PATIENT INFO:
                                                  DOB:
las vegas, NV
                                                  Phone
PRESCRIBER INFO:
Carrie Carda
893 Vanderbilt Beach Road
                                                  NPI:
Naples, FL
           34108
                                                  DEA:
                                                  Phon
                                                  Fax:
                                                       855-797-6863
RX INFO:
PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE (Capsule)
Written Date: 08/23/2022
    NDC Sent:
               PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE
    NDC Used:
         DAW: No
    Quantity: 60
Directions: Take 1 capsule by mouth at bedtime daily.
    Refills: 0
    Comments:
 02400010478 Bill to streamline medical group. See account notes
 for shipping method
```

```
RAW SURESCRIPTS DATA
   Message ID= [b8aeaae79ded4968b250329ff4f080e6]
Coordination of Benefits Mutually Defined= [195749926]
Patient Address Line
                               Address Line
Birth Date=
City= [las v
First Name=
   Patient
   Patient
   Patient
Patient
                                Gender=
                                Last Nam
Postal=
   Patient
   Patient
   Patient Primary Pho
Patient State= [NU]
                                                             Address Line 1= [1210 SW 33RD AVE]
City= [OCALA]
Postal= [34474]
State= [FL]
                                   Agency
Agency
Agency
   Pharmacy
   Pharmacy
   Pharmacy
Pharmacy Agency 3740156531
Pharmacy Fax= 187740156531
Pharmacy NCPDP
Pharmacy NPI=
Pharmacy NPI=
Pharmacy Party Name= [WELLS PHARMACY]
Pharmacy Primary Phone= [3526222913]
Prescribed Drug DAW= [No]
Prescribed Drug Daw= [No]
Prescribed Drug Coverage Status Code= [Compound]
Prescribed Drug Instructions= [Take 1 capsule by mouth at bedtime daily.]
Prescribed Drug Instructions= [PROGESTERONE (OLIVE OIL) 100MG CAPSULE
Prescribed Drug Item Description= [PROGESTERONE (OLIVE OIL) 100MG CAPSULE
 STREAMLINE]
Prescribed Drug Notes= [02400010478 Bill to streamline medical group. See account notes for shipping method]
Prescribed Drug Potency Unit= [Capsule]
Prescribed Drug Quantity= [60]
Prescribed Drug Refills= [0]
Prescribed Drug Refills= [0]
Prescribed Drug Written Date= [20220823]
Prescriber Agency Address Line 1= [893 Vanderbilt Beach Road]
Prescriber Agency City= [Naples]
Prescriber Agency Postal= [34108]
Prescriber Agency State= [61]
Prescriber DEA
                                         Agency
Agency
Agency
Agency
DEA
Fax=
Prescriber Fax:
Prescriber Fax:
Prescriber Fax:
Prescriber Party Name: [Streamline Medical Group]
Prescriber Primary Phone: [2393259645]
Prescriber Provider First Name: [Carrie]
Prescriber Provider Last Name: [Carda]
Prescriber Provider Name Suffix: [MD]
Prescriber State License Number: [130703]
                                                                                                                                                                                             Case#23-050-PH-O. Wells Pharmacy.029
```

Surescripts Message 96374fd10fb24899b639fade7318	21eh
--	------

		lessage '96374fd10fb24899b638fade73182feb'
Segment	Field Name	Value
Patient		
	Last Name	Market 1
	First Name	S
	Birth Date	
	Gender	
	Address Line 1	
	City	Las Vegas
	State	NV
	Zip	
	Country	
	Primary Phone	
Prescriber	•	
	Last Name	Martinez
	First Name	Richard
	Suffix	MD
	Address Line 1	838 SW Federal Hwy
	City	shari
	State	FL.
	Zip	34994
	Country	US
	Primary Phone	7726317266
	Fax Phone	7722642925
	Siate License	
	DEA	
	NPI	
	Practice Name	Situari ProPerformance
Pharmacy		
	Pharmacy Name	WELLS PHARMACY
	Address Line 1	1210 SW 33RD AVE
	City	OCALA
	State	FL.
	<i>Z</i> ip	34474
	Country	US
	Primary Phone	3526222913
	Fax Phone	8774915653
	NCPDP	
	NPI	
Prescribed Drug		
	Drug Description	PROGESTERONE (OLIVE OIL) 125MG CAPSULE
	Quantity	60
•	Potency Unit	Capsule
	DEA Schedule	3
	Written Date	20220901
	DAW	No
	Refills	0
	Noie Sie Teur	02400008864
O	Sig Text	Take one capsule by mouth daily before bed
Coordination of B		
	Mutually Defined	547160168
	IIN Number	810279
	Payer Name	OPTUMRX GOMMERCIAL
		Page 1 of 2

Case#23-050-PH-O. Wells Pharmacy.030

Surescripts Message '98374id10fb24699b639iade731821eb'

Segment	Field Name	Value	
	Cardholder ID Group ID	22009107600 UNEVADA	



** Include Initials and Date on All Notes! **

Order Log

Prescription	o Origin: Fax	Order Number:
Billing to:	Doctor Account	Patient
Special Note Instructions:		
Types of Da (Order Dela		
Call Log:		

** Include Initials and Date on All Notes! **

Email: OcalaCS1@wellsrx.com Call: Toll Free (800) 622-4510 Fax: Toll Free (877) 401-5653



```
PATIENT INFO:
                                                  DOB:
Las Vegas, NV
                                                  Phone:
PRESCRIBER INFO:
Carrie Carda
893 Vanderbilt Beach Road
                                                  NPI:
Naples, FL 34108
                                                  DEA:
                                                  Phon
                                                  Fax: 855-797-6863
RX INFO:
PROGESTERONE (OLIVE OIL) 50MG CAPSULE streamline (Capsule)
Written Date: 09/06/2022
    NDC Sent:
    NDC used:
              PROGESTERONE (OLIVE OIL) SOMG CAPSULE streamline
        DAW: NO
    Quantity: 60
Directions: Take 1 capsule by mouth at bedtime daily
    Refills: 0
   Comments:
 02400012836
```

```
RAW SURESCRIPTS DATA

Message ID= [332]3ff36d3f426cb3d2a59e676db3c5]
Coordination of Benefits Mutually Defined= [538876111]
Coordination of Benefits IIN Number= [610279]
Coordination of Benefits Fayer Name= [0PTUHRX COMMERCIAL]
Coordination of Benefits Cardholder ID= [16088233400]
Patient Last Name= [Mame= [Mame= Mame= Mam
```

```
PATIENT INFO:
         P
                                                  DOB:
Las Vegas, NV
                                                  Phone
PRESCRIBER INFO:
Carrie Carda
893 Vanderbilt Beach Road
                                                  NPI:
Naples, FL
           34108
                                                  DEA:
                                                  Phon
                                                  Fax: 855-797-6863
RX INFO:
PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE (Capsule)
Written Date: 10/12/2022
    NDC Sent:
    NDC Used:
               PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE
    Quantity: 60
Directions: Take 1 capsule by mouth at bedtime daily.
    Refills: 0
    Comments:
 02400010478 Bill to streamline medical group. See account notes
 for shipping method
```

```
PATIENT INFO:
S
      M
                                                  DOB:
Las Vegas, NV
                                                  Phon
PRESCRIBER INFO:
Richard Martinez
838 SW Federal Hwy
                                                  NPI:
stuart, FL 34994
                                                  DEA:
                                                  Phone
                                                  Fax: 772-264-2925
RX INFO:
PROGESTERONE (OLIVE OIL) 125MG CAPSULE (Capsule)
Written Date: 11/01/2022
    NDC Sent:
    NDC Used:
              PROGESTERONE (OLIVE OIL) 125MG CAPSULE
    Quantity: 60
Directions: Take one capsule by mouth daily before bed
     Refills: 0
    Comments:
 02400008864
```

```
RAW SURESCRIPTS DATA

Message ID= [47b172e7f3e5450e8bfd72fd647lob18]
Coordination of Benefits Mutually Defined= [272606416]
Coordination of Benefits IIN Number: [610279]
Coordination of Benefits IIN Number: [610279]
Coordination of Benefits Cardholder ID= [220606187600]
Coordination of Benefits Cardholder ID= [07UMRX COMMERCIAL]
Coordination of Benefits Group ID= [UNEUADA]
Patient Last Name: [IS]
Patient Birth Date= [IS]
Patient First Name: [IS]
Patient Rith Date= [IS]
Patient City= [Las Uegas]
Patient Address Line I= [IS]
Patient Country= [US]
Patient Primary Phone= [WELLS PHARMACY]
Pharmacy Pharmacy Name= [WELLS PHARMACY]
Pharmacy Pharmacy Name= [WELLS PHARMACY]
Pharmacy Pharmacy III [IS]
Pharmacy State= [I]
Pharmacy State= [I]
Pharmacy State= [I]
Pharmacy Fax Phone= [3526222913]
Pharmacy NoPDP
Pharmacy
                        RAW SURESCRIPTS DATA
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          Case#23-050-PH-O. Wells Pharmacy.035
         Prescriber Practice Name= [Stuart ProPerformance]
```

```
PATIENT INFO:
                                                 DOB:
Las Vegas, NV
                                                 Phon
PRESCRIBER INFO:
Carrie Carda
893 Vanderbilt Beach Road
                                                 NPI:
Naples, FL
           34108
                                                 DEA:
                                                 Phon
                                                 Fax: 855-797-6863
RX INFO:
PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE (Capsule)
Written Date: 11/28/2022
    NDC Sent:
    NDC Used:
              PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE
    Quantity: 60
Directions: Take 1 capsule by mouth at bedtime daily.
    Refills: 0
    Comments:
 02400010478 Bill to streamline medical group. See account notes
 for shipping method
    Pharmacy Name: Wells Pharmacy-ocala
```

```
RAW SURESCRIPTS DATA

Hessage ID= [28f74269c3dd45358c300f7e11976718]
Coordination of Benefits Mutually Defined= [023309402]
Patient Last Name= [0]
Patient First Name= [0]
Patient First Name= [0]
Patient Birth Date= [0]
Patient Ronder= [0]
Patient Ronder= [0]
Patient Rodress Line 1= [0]
Patient Rodress Line 2= [0]
Patient City= [Las Vegas]
Patient City= [Las Vegas]
Patient Country= [US]
Patient Country= [US]
Patient Country= [US]
Patient Primary Phone
Patient Patient
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```
PATIENT INFO:
        N
                                                  DOB:
Las Vegas, NV
                                                  Phone:
PRESCRIBER INFO:
Carrie Carda
893 Vanderbilt Beach Road
                                                  NPI:
Naples, FL
           34108
                                                  DEA:
                                                  Phone
                                                  Fax: 855-797-6863
RX INFO:
PROGESTERONE (OLIVE OIL) 50MG CAPSULE streamline (Capsule)
Written Date: 12/05/2022
    NDC Sent:
    NDC used:
              PROGESTERONE (OLIVE OIL) 50MG CAPSULE streamline
        DAW: NO
   Quantity: 60
Directions: Take 1 capsule by mouth at bedtime daily
    Refills: 0
   Comments:
 02400012836
```

```
RAW SURESCRIPTS DATA

Hessage ID= [032fdc27c0df482388ecfa5239a3a500]
Coordination of Benefits Mutually Defined= [253118006]
Coordination of Benefits IIN Number= [610279]
Coordination of Benefits Rayer Name= [077UMRX COMMERCIAL]
Coordination of Benefits Cardholder ID= [16008233400]
Coordination of Benefits Cardholder ID= [1600823400]
Coordination of Benefits Cardholder ID= [1600823400]
Coordination of Benefits Cardholder ID= [1600824474]
Coordination of Benefits Cardholder ID= [160082474]
C
```

```
PATIENT INFO:
                                                  DOB:
Las Vegas, NV
                                                  Phon
PRESCRIBER INFO:
Carrie Carda
893 Vanderbilt Beach Road
                                                  NPI:
Naples, FL 34108
                                                  DEA:
                                                  Phone
                                                  Fax: 855-797-6863
RX INFO:
PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE (Capsule)
Written Date: 01/24/2023
    NDC Sent:
    NDC Used:
              PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE
         DAW: NO
    Quantity: 60
Directions: Take 1 capsule by mouth at bedtime daily.
     Refills: 0
    Comments:
  02400010478 Bill to streamline medical group. See account notes
  for shipping method
```

```
RAW SURESCRIPTS DATA
RAW SURESCRIPTS DATA
Message ID= [77ae99559f25418f803818de885ab6d4]
Coordination of Benefits Mutually Defined= [756787325]
Patient Last Name= [p]
Patient First Name= Patient Birth Date= Patient Gender= Patient Address Line 1= [P]
Patient Address Line 2= [P]
Patient City= [Las Vegas]
Patient State= [NU]
Patient State= [NU]
Patient Country= [US]
Patient Other Phone= [WELLS PHARMACY]
Patient Other Phone=
Pharmacy Pharmacy Name= [WELLS PHARMACY]
Pharmacy Address Line 1= [1210 SW 33RD AVE]
Pharmacy City= [OCALA]
Pharmacy State= [FL]
Pharmacy Zip= [34474]
Pharmacy Country= [US]
Pharmacy Country= [US]
Pharmacy Primary Phone= [3526222913]
Pharmacy Fax Phone= [3526222913]
Pharmacy Fax Phone= [3526222913]
Pharmacy NCPD
Pharmacy NCPD
Pharmacy NPI=
Prescribed Drug Drug Description= [PROGESTERONE (OLIVE OIL) 100MG CAPSULE STREAMLINE]
Prescribed Drug Quantitu= [60]
Prescribed Drug Drug Description: IPROGESTENCINE (OLIVE OIL) 10010 CHFSOLE
STREAMLINE]
Prescribed Drug Quantity= [60]
Prescribed Drug Potency Unit= [Capsule]
Prescribed Drug Written Date= [20230124]
Prescribed Drug DAW= [No]
Prescribed Drug Refills= [0]
Prescribed Drug Refills= [0]
Prescribed Drug Note= [02400010478 Bill to streamline medical group. See account notes for shipping method]
Prescribed Drug Sig Text= [Take 1 capsule by mouth at bedtime daily.]
Prescribed Drug Compound Dosage Form= [Pharmaceutical]
Prescribed Drug Compound Dosage Form= [Pharmaceutical]
Prescriber Last Name= [Carda]
Prescriber Last Name= [Carda]
Prescriber Suffix= [MD]
Prescriber Suffix= [MD]
Prescriber Address Line 1= [893 Vanderbilt Beach Road]
Prescriber Gity= [Naples]
Prescriber State= [FL]
Prescriber Zip= [34108]
Prescriber Country= [US]
Prescriber Primary Phone= [2393259645]
Prescriber State Linense= [130703]
Prescriber State Linense= [130703]
Prescriber DEA=
                                                                 State
DEA=
NPI=
   Prescriber
Prescriber
                                                                                                                                                                                                                                                                                                                          Case#23-050-PH-O. Wells Pharmacy.038
   Prescriber Practice Name= [Streamline Medical Group]
```

```
PATIENT INFO:
                                                  DOB:
Las Vegas, NV
                                                  Phon
PRESCRIBER INFO:
Richard Martinez
838 SW Federal Hwy
                                                  NPI:
stuart, FL 34994
                                                  DEA:
                                                  Phon
                                                  Fax: 772-264-2925
RX INFO:
PROGESTERONE (OLIVE OIL) 125MG CAPSULE (Capsule)
Written Date: 02/06/2023
    NDC Sent:
    NDC Used:
              PROGESTERONE (OLIVE OIL) 125MG CAPSULE
    Quantity: 60
Directions: Take one capsule by mouth daily before bed
    Refills: 0
    Comments:
 02400008864
```

```
Message ID= [8306c797ba5a40638ef9fab977802930]
Coordination of Benefits Mutually Defined= [046325923]
Coordination of Benefits IIN Number= [610279]
Coordination of Benefits IIN Number= [610279]
Coordination of Benefits Payer Name= [0PTUMRX COMMERCIAL]
Coordination of Benefits Cardholder ID= [22009107600]
Coordination of Benefits Facus ID= [UNEVADA]
Patient Last Name= [Material Patient First Name= [Material Patient First Name= [Material Patient First Name= [Material Patient Birth Date-
Patient Birth Date-
Patient Birth Date-
Patient City= [Last Vegas]
Patient City= [Last Vegas]
Patient Zip= [Material Patient Primary Phone= [MELLS PHARMACY]
Pharmacy Pharmacy Name= [WELLS PHARMACY]
Pharmacy City= [DCALA]
Pharmacy City= [DCALA]
Pharmacy City= [DCALA]
Pharmacy Country= [US]
Pharmacy Country= [US]
Pharmacy Primary Phone= [3526222913]
Pharmacy Primary Phone= [3524015650]
Pharmacy NCPI
Pharmac
                     RAW SURESCRIPTS DATA
Prescribed Drug DAW= [No]
Prescribed Drug DAW= [No]
Prescribed Drug Refills= [0]
Prescribed Drug Note= [02400008864]
Prescribed Drug Sig Text= [Take one capsule by mouth daily before bed]
Prescribed Drug Sig Text= [Take one capsule by mouth daily before bed]
Prescribed Drug Compound Dosage Form= [Pharmaceutical]
Prescriber Last Name= [Martinez]
Prescriber First Name= [Richard]
Prescriber Suffix= [MD]
Prescriber Suffix= [MD]
Prescriber Address Line 1= [838 SW Federal Hwy]
Prescriber City= [stuart]
Prescriber State= [FL]
Prescriber Zip= [34994]
Prescriber Country= [US]
Prescriber Primary Phone= [7726317266]
Prescriber Fax Phone= [772642925]
Prescriber State License= [ME129112]
Prescriber DEA=
Prescriber NPI=
Prescriber Practice Name= [Stuart ProPerformance]
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      Case#23-050-PH-O. Wells Pharmacy.039
      Prescriber Practice Name= [Stuart ProPerformance]
```

Carolyn Banson Pharmacy Order #1 M10256102



PHARMACY ORDER #: M10256102

PATIENT DEMOGRAPHICS

Patters Name: C. Be ID 9:
Gender: Dote Dote: DOD: DOD: Dote Phone:
Address NV89402, USA

PHYSICIAN INFORMATION

BodyLogicDD of San Jose
Dr. Robert Porzio DO
2025 Forest Avenue, Suite E. San Jose, CA 35128, USA
Office: 888-817-2321
Fax: 877-334-8743
Phys NPI: 1285654921 Corp.NPI: 1285654921
Physician Account #: NVA

ALLERGIES-INTOLERANCE

No Allergies

DIAGNOSIS CODES

R79.A2, R53.B3, E27.39, R94.5, E61.1, E78.00, E23.6, E55.9, E06.3, E34.9

RECURRING MEDICATIONS

60 days				
co ca ya	1	05-20- 2022		01-06- 2022
60 days	1	05-20- 2022	•	01-06- 2022
	60 days ides.		60 02 ys 1 20 ZZ	2022

FHARMACY INFORMATION

Pharmacy Name: Wells Pharmacy Network
Pharmacy Phone: (888) 428-1475
Pharmacy Fax: 3522775650

1450

PHYSICIÁN SIGNATURE ENTERED BY: DR. ROBERT PORZIO DO

DR. ROBERT PORZIO DO DEA 4: BP8344472

Page: 1

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 23-050-PH-O

Petitioner,

v

WELLS PHARMACY NETWORK, LLC, Pharmacy License No. PH01589,

Respondent.

EXHIBIT D

Kenneth C. Scheuber

From:

Kenneth C. Scheuber

Sent:

Friday, March 31, 2023 3:35 PM

To:

Sarah Thron

Cc:

Kenneth C. Scheuber; Joe Dodge RE: Encrypt RE: Case #23-050-PH-O

Subject: Attachments:

Case #23-050-PH-O Wells Pharmacy Network - FDA Guidance for Industry.pdf

Sarah Thron,

The attached FDA information is being provided for your review. Please reference page 8, under #2 - Statement of Significant Difference. This Significant Difference must be documented for each individual prescription that was shipped into Nevada for the product that is an essential copy.

You have a copy of the list of prescriptions we are requesting. It would be for Progesterone (Olive Oil) capsules shipped between 01/01/2022 and 03/31/2023 for all strengths.

Thank you,

Ken

Kenneth Scheuber, Investigator

Nevada State Board of Pharmacy 1140 N Town Center Dr Ste 300 Las Vegas, NV, 89144

Office: 702.486.6420 ext 153

Cel 702.486

Fax: 702.486.7903

E-mail: kscheubera pharmacy.nv.gov

Web Page: www.bop.nv.gov



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This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

From: Sarah Thron @wellsrx.com>
Sent: Wednesday, March 15, 2023 9:56 AM

To: Kenneth C. Scheuber < KSCHEUBER@pharmacy.nv.gov>

Cc: Joe Dodge <j.dodge@pharmacy.nv.gov>
Subject: RE: Encrypt RE: Case #23-050-PH-O

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Encrypted Message

Encrypted Message

KSCHEUBER@pharmacy.nv.gov

Sian Out

2

RE: Encrypt RE: Case #23-050-PH-O

ST

Sarah Thron

pwellsrx.com>

♣ Reply all | ✓

Today, 10:06 AM

Kenneth C. Scheuber <KSCHEUBER@pharmacy.nv.gov>; Joe Dodge <j.dodge@ ➤

Attachment 3 - Progest...

Attachment 2 - Case #2...

RE Encrypt R

3 attachments (2 MB)

Mr. Scheuber,

We are confirming receipt of your March 31, 2023 email (Attachment 1) and request (Attachment 2) for "Statement of Significant Difference" for the Rx's listed on your original request (Attachment 3). The individual prescriptions requested provided on 03/13/23 do not include a "Statement of Significance Difference" as advised per FDA guidance "Compounded Drug Products that are Essentially Copies of a Commercially Available Drug Under Section 503A of the Federal Food, Drug, and Cosmetic Act". Wells Pharmacy Network, LLC. has provided an explanation on the differences of our compounded product(s) to the essential copies commercially available and is committed to maintaining compliance with all federal guidance's and Board of Pharmacy regulations. To eliminate any potential ambiguity, Wells Pharmacy Network has ceased compounding Progesterone 100 mg and 200 mg capsules in olive oil as of April 14, 2023.

From: Kenneth C. Scheuber < KSCHEUBER@pharmacy.nv.gov>

Sent: Friday, March 31, 2023 6:35 PM

To: Sarah Thron www.pwellsrx.com>

Cc: Kenneth C. Scheuber < KSCHEUBER@pharmacy.nv.gov>; Joe Dodge < J.dodge@pharmacy.nv.gov>

Subject: RE: Encrypt RE: Case #23-050-PH-O

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Sarah Thron,

The attached FDA information is being provided for your review. Please reference page 8, under #2 - Statement of Significant Difference. This Significant Difference must be documented for each individual prescription that was shipped into Nevada for the product that is an essential copy.

You have a copy of the list of prescriptions we are requesting. It would be for Progesterone (Olive Oil) capsules shipped between 01/01/2022 and 03/31/2023 for all strengths.

Message Encryption by Microsoft Office 365

Kenneth C. Scheuber

From: Sent: Sarah Thron

@welsrx.com>

To:

Thursday, April 27, 2023 10:07 AM Kenneth C. Scheuber

Cc:

Joe Dodge; regulatoryaffairs@wellsrx.com; Howard Brown; Christopher Ulbricht

Subject:

RE: Encrypt RE: Case #23-050-PH-O

Attachments:

message.html

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Message encryption by Microsoft Office 365

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 23-050-PH-O

Petitioner,

V

WELLS PHARMACY NETWORK, LLC, Pharmacy License No. PH01589,

Respondent.

EXHIBIT E

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

January 2018 Compounding

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

Additional copies are available from:
Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov

https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

January 2018 Compounding

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	PAPERWORK REDUCTION ACT 1	
	PENDIX A	

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or the Agency) on this topic. It does not create any rights for any person and is not binding on FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed in the title page.

I. INTRODUCTION AND SCOPE

To qualify for exemptions under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a drug product must be compounded by a licensed pharmacist or physician who does not compound regularly or in inordinate amounts any drug products that are essentially copies of a commercially available drug product, among other conditions. This guidance sets forth FDA's policies regarding this provision of section 503A, including the terms commercially available, essentially a copy of a commercially available drug product, and regularly or in inordinate amounts.²

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

¹ This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research, in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

² This guidance does not apply to drugs compounded for use in animals, to biological products subject to licensure in a biologics license application, or to repackaged drug products. For policies pertaining to mixing, diluting, and repackaging biological products, see FDA's guidance, Mixing, Diluting, and Repackaging Biological Products Outside the Scope of an Approved Biologics License Application. For policies pertaining to repackaged drug products, see FDA's guidance, Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities.

All FDA guidances are available on the FDA guidance web page. FDA updates guidances regularly. To make sure you have the most recent version of a guidance, always consult the guidance web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

II. BACKGROUND

A. Section 503A of the FD&C Act

Section 503A, added to the FD&C Act by the Food and Drug Administration Modernization Act of 1997 and amended by the Drug Quality and Security Act in 2013, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a Statelicensed pharmacy or Federal facility, or by a licensed physician, to qualify for exemptions from the following three sections of the FD&C Act:³

- Section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP) requirements)
- Section 502(f)(1) (concerning the labeling of drugs with adequate directions for use)
- Section 505 (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs))

One of the conditions that must be met for a compounded drug product to qualify for the exemptions under section 503A of the FD&C Act is that it must be compounded by a licensed pharmacist or a licensed physician that "does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product."

The statute further states that "the term 'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug."

A complete list of the conditions that must be met for a compounded drug product to qualify for the exemptions in section 503A appears in the FDA guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.*

B. Compounding, Generally

Compounded drug products serve an important role for patients whose clinical needs cannot be met by an FDA-approved drug product, such as a patient who has an allergy and needs a medication to be made without a certain dye, an elderly patient who cannot swallow a pill and needs a medicine in a liquid form that is not otherwise available, or a child who needs a drug in a strength that is lower than that of the commercially available product. Drug products for identified individual patients can be compounded by licensed pharmacists in state-licensed

³ In addition, under section 581(13) of the FD&C Act, the term "product," for purposes of pharmaceutical supply chain security requirements, does not include a drug compounded in compliance with section 503A.

⁴ See section 503A(b)(1)(D).

⁵ See section 503A(b)(2).

pharmacies and Federal facilities and by licensed physicians operating under section 503A of the FD&C Act. Drug products can also be compounded by outsourcing facilities under section 503B of the FD&C Act for identified individual patients pursuant to prescriptions or for distribution to health care practitioners without first receiving a prescription. Both sections 503A and 503B restrict compounding drug products that are essentially a copy of a commercially available drug product (section 503A) or an approved drug product (section 503B).

C. Risks Associated with Compounded Drug Products

Although compounded drugs can serve an important need, they can also pose a higher risk to patients than FDA-approved drugs. Compounded drug products are not FDA-approved, which means they have not undergone FDA premarket review for safety, effectiveness, and quality. In addition, licensed pharmacists and licensed physicians who compound drug products in accordance with section 503A are not required to comply with CGMP requirements. Furthermore, FDA does not interact with the vast majority of licensed pharmacists and licensed physicians who compound drug products and seek to qualify for the exemptions under section 503A of the FD&C Act for the drug products that they compound because these compounders are not licensed by FDA and generally do not register their compounding facilities with FDA. Therefore, FDA is often not aware of potential problems with their compounded drug products or compounding practices unless it receives a complaint, such as a report of a serious adverse event or visible contamination.

FDA has investigated numerous serious adverse events associated with compounded drug products that were contaminated or otherwise compounded improperly, including the adverse events associated with the 2012 fungal meningitis outbreak in which contaminated injectable drug products resulted in more than 60 deaths and 750 cases of infection. FDA has also identified many pharmacies that compounded drug products under insanitary conditions such that the drug products may have been contaminated with filth or rendered injurious to health and that shipped the compounded drug products made under these conditions to patients and health care practitioners across the country, sometimes in large amounts.

D. Compounded Drugs That Are Essentially Copies of Commercially Available Drug Products

Section 503A provides exemptions from new drug approval, labeling with adequate directions for use, and CGMP requirements of the FD&C Act, so that drug products can be compounded as customized therapies for identified individual patients whose medical needs cannot be met by commercially available drug products. The restrictions on making drugs that are essentially copies ensure that pharmacists and physicians do not compound drug products under the exemptions for patients who could use a commercially available drug product. Such a practice would create significant public health risks because patients would be unnecessarily exposed to drug products that have not been shown to be safe and effective and that may have been prepared

⁶ Section 503B of the FD&C Act describes the conditions that must be met for a human drug product compounded by an ontsourcing facility to qualify for exemptions from sections 505, 502(f)(I), and 582 (concerning drug supply chain security requirements) of the FD&C Act. The conditions applicable to outsourcing facilities are discussed in separate guidances applicable to those facilities.

under substandard manufacturing conditions. FDA has investigated serious adverse events in patients who received contaminated compounded drugs when a comparable approved drug, made in a facility subject to CGMP requirements, was available.

In addition to these immediate public health risks, section 503A's limitations on producing a drug product that is essentially a copy of a commercially available drug product protects the integrity and effectiveness of the new drug and abbreviated new drug approval processes that Congress put in place to protect patients from unsafe, ineffective, or poor quality drugs. Furthermore, sponsors may be less likely to invest in and seek approval of innovative, life-saving medications if a compounder could, after a drug is approved, compound "substitutes" that may be less expensive because they have not had to demonstrate safety and effectiveness and are not produced in accordance with CGMP requirements or labeled with adequate directions for use.

Sponsors might also be less likely to seek approval of an ANDA for a generic drug if compounders were permitted to compound drugs that are essentially copies of commercially available drugs without going through the ANDA process. An ANDA must include data to demonstrate that the drug has the same active ingredient and is bioequivalent to an approved drug. FDA also conducts premarketing inspections of proposed manufacturing facilities.

The copies restriction also protects FDA's drug monograph process. FDA has an ongoing process for evaluating the safety and effectiveness of certain over-the-counter (OTC) medications, and if the Agency determines that an OTC drug meets certain conditions and is generally recognized as safe and effective, it will publish a final monograph specifying those conditions. Products that comply with a final monograph may be marketed, but manufacturers are required to meet CGMP standards. Restrictions in section 503A prevent compounders from producing drugs without having to comply with monograph standards, or CGMP requirements.

III. POLICY

As stated above, to qualify for the exemptions under section 503A of the FD&C Act, a drug must be compounded by a licensed pharmacist or a licensed physician that does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product. This means that a compounded drug product is not eligible for the exemptions in section 503A if it is (1) essentially a copy of a commercially available drug product, and (2) compounded regularly or in inordinate amounts. Accordingly, and as discussed below, when evaluating whether a drug product meets the condition in section 503A regarding essentially copies, FDA intends to determine whether a compounded drug product is essentially a copy of a commercially available drug product: if it is, FDA intends to determine whether the drug product was compounded regularly or in inordinate amounts.

⁷ Sec section 503A(b)(1)(D).

⁸ FDA is considering the applicability of the policies described in this guidance to hospitals and health systems and intends to address these issues in separate guidance or rulemaking. FDA regards a health system as collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients. There is no definition of "health system" that applies to all sections of the FD&C Act.

FDA's policies with regard to the terms (1) commercially available drug product, (2) essentially a copy of a commercially available drug product, and (3) regularly or in inordinate amounts, are as follows:

A. Commercially Available Drug Product

For purposes of this guidance, a drug product is commercially available if it is a marketed drug product.

We do not consider a drug product to be commercially available if

- the drug product has been discontinued and is no longer marketed⁹ or
- the drug product appears on the FDA drug shortage list in effect under section 506E of the FD&C Act.¹⁰ A drug "appears on the drug shortage list in effect under section 506E" if the drug is in "currently in shortage" status (and not in "resolved" status) in FDA's drug shortage database.

Commercially available drugs are available on the market, and they are generally subject to FD&C Act requirements relating to approval, labeling, and CGMP requirements, and the copies restriction applies to all such drugs because section 503A is not intended to provide a means for compounders to produce compounded drugs exempt from the Act's requirements that are essentially copies of commercially available drug products.

B. Essentially a Copy of a Commercially Available Drug Product

1. What is Essentially a Copy?

FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if:

- the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product;
- the API(s) have the same, similar, or an easily substitutable dosage strength; and

However, this is the definition of a "health system" used in section 506F of the Act concerning hospital repackaging of drugs in shortage.

⁹ FDA maintains a list of approved drug products that sponsors have indicated are not marketed in the discontinued section of the list of Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). See http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Specifically, the list includes approved drug products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined were withdrawn for safety or effectiveness reasons, or have had their approvals withdrawn for reasons other than safety or effectiveness subsequent to being discontinued from marketing.

¹⁰ See http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

 the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug,

unless, as provided by section 503A(b)(2), a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product.

The limitations in section 503A(b)(1)(D) apply to the compounding of drug products that are essentially copies of a commercially available drug product—not only to drugs that are exact copies or even to drugs that are nearly identical. This is to ensure that compounders do not evade the limits in this section by making relatively small changes to a compounded drug product and then offering the drug to the general public without regard to whether a prescribing practitioner has determined that the change produces for the patient a significant difference. For example, Congress contemplated that a compounded drug may be essentially a copy of a commercially available drug if "minor changes in strength (such as from .08% to .09%) are made that are not known to be significant . . ." for the patient for whom the drug was prescribed. 11

a. Same API

With regard to the characteristics listed above, an API is the substance in a drug product that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body. When a compounded drug product offers the same API as a commercially available drug product, in the same, similar, or easily substitutable dosage strength and for use through the same route of administration, we generally intend to consider such a drug product essentially a copy, unless a prescriber determines that there is a change, made for an identified individual patient, that will produce a significant difference for that patient,

We recognize that, for some patients, a drug product that has the same API, strength, and route of administration may include a change that produces a significant difference for a particular patient. For example, a drug product compounded without a particular inactive ingredient may produce a significant difference for a patient who has an allergy to the inactive ingredient in the commercially available drug product. However, for other patients, this change may produce no difference at all. Congress did not intend for compounders to use, for example, the fact that some patients may have allergies as a basis to compound a drug without the inactive ingredient for other patients who do not have the allergy under the exemptions in section 503A (i.e., without meeting requirements for premarket approval, labeling with adequate directions for use, or

¹¹ U.S. House, Food and Drug Administration Modernization Act of 1997, Conference Report (to Accompany S. 830), (105 H. Rpt, 399).

¹² Section 503A refers to bulk drug substances. A bulk drug substance is defined as any substance that is intended for incorporation into a finished drug product and is intended to finnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. It does not include intermediates used in the synthesis of the substance. This definition is the same as the definition of active pharmaceutical ingredient. See 21 CFR 207.1, 207.3,

CGMP requirements).¹³ In the context of compounding and consistent with the statute, we generally intend to consider such a drug essentially a copy unless a prescriber determines that there is a change that will produce a significant difference for the patient for whom it is prescribed.

b. Same, Similar or Easily Substitutable Strength

FDA generally intends to consider two drugs to have a similar dosage strength if the dosage strength of the compounded drug is within 10% of the dosage strength of the commercially available drug product.

With regard to the concept of easily substitutable strength, in some cases, the same or similar dosage strength can be achieved by administration of fractional or multiple doses of a drug product. For example, if FDA-approved Drug X tablets have a dosage strength of 25 mg and a patient needs 50 mg of Drug X, FDA would generally consider a compounded Drug X 50 mg tablet to have an easily substitutable strength because the patient could take two Drug X 25 mg tablets to achieve the required dose. ¹⁴

c. Same Route of Administration

Route of administration is a way of administering a drug to a site in a patient (e.g., topical, intravenous, oral).¹⁵ In general, FDA does not intend to consider a compounded drug product with the same API and similar or easily substitutable strength to be essentially a copy of a commercially available drug product if the compounded drug product and the commercially available drug product have different routes of administration (e.g., if the commercially available drug product is oral and the compounded drug product is topical). However, if the compounded drug product has the same API and similar or easily substitutable strength as the commercially available drug product and the commercially available drug product can be used (regardless of how it is labeled) by the route of administration prescribed for the compounded drug, FDA generally intends to consider the compounded drug to be essentially a copy of the commercially available drug. In this case, the compounded drug product generally would not produce a significant difference for an identified individual patient relative to the commercially available drug product.

For example, if the commercially available drug is an injectable drug sold in a vial that is labeled for intra-muscular use, but the drug also can be drawn from the vial by a smaller needle for subcutaneous administration, a compounded drug product with the same API and similar or

¹³ See note 11.

¹⁴ If a commercially available tablet must be split to achieve the prescribed dosage strength, and such tablet is not suitable for splitting, FDA would not consider the compounded drug made to the prescribed dosage strength to have an easily substitutable strength. For example, some tablets may be too small or crumble too easily when split, making splitting an inappropriate option. Information regarding tablet splitting may be printed in the "HOW SUPPLIED" section of the professional label insert and in the patient package insert of an approved drug product.

¹⁵ See http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/D ataStandardsManualmonographs/ucm071667.htm.

easily substitutable strength prescribed for sub-cutaneous administration would generally be considered to be essentially a copy, unless the prescriber documents on the prescription that the compounded drug product produces a significant difference for the identified individual patient.

d. Same Characteristics as Two or More Commercially Available Drug Products

FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if the compounded drug product contains the same APIs as two or more commercially available drug products in the same, similar, or easily substitutable strength and if the commercially available drug products can be used (regardless of how they are labeled) by the same route of administration prescribed for the compounded drug, unless there is documentation as described in section III.B.2. Such drug products present the same kinds of concerns as drug products that have a single API and in some respects may be more dangerous because of the potential for unintended drug interactions or formulation issues. For example, if drug X and drug Y are commercially available oral drug products, FDA generally intends to consider a compounded oral drug product that combines drug X and drug Y in strengths that are within 10% of the strengths of the respective commercially available products to be essentially a copy of the commercially available drug product, unless a prescriber determination of a significant difference has been documented.

2. Statement of Significant Difference

Pursuant to section 503A(b)(2) of the FD&C Act, a compounded drug product is not essentially a copy of a commercially available drug product if a change is made for an identified individual patient, and the prescribing practitioner has determined that the change will produce a significant difference for that patient. If a compounder intends to rely on such a determination to establish that a compounded drug is not essentially a copy of a commercially available drug product, the compounder should ensure that the determination is documented on the prescription.

FDA does not believe that a particular format is needed to document the determination, provided that the prescription makes clear that the prescriber identified the relevant change and the significant difference that the change will produce for the patient. For example, the following would be sufficient:

- "No Dye X, patient allergy" (if the comparable drug contains the dye)
- "Liquid form, patient can't swallow tablet" (if the comparable drug is a tablet)
- "6 mg, patient needs higher dose" (if the comparable drug is only available in 5 mg dose)

However, if a prescription identifies only a patient name and drug product formulation, this would not be sufficient to establish that the prescriber made the determination described by section 503A(b)(2). Note also that the significant benefit that the prescriber identifies must be produced by the change the compounder will make to a commercially available drug product (i.e., a change in drug product formulation). Other factors, such as a lower price, are not

sufficient to establish that the compounded drug product is not essentially a copy of the commercially available drug product. 16

If a prescription does not make clear that the prescriber made the determination required by section 503A(b)(2), or a compounded drug is substituted for the commercially available drug product, the compounder can contact the prescriber and if the prescriber confirms it, make a notation on the prescription that the compounded drug product contains a change that makes a significant difference for the patient. The notations should be as specific as those described above, and the date of the conversation with the prescriber should be included on the prescription.¹⁷

It is not possible to offer exhaustive guidance about when a difference will be "significant" to an identified individual patient. At this time, FDA generally does not intend to question prescriber determinations that are documented in a prescription or notation. However, we do intend to consider whether a prescription or notation relied upon by a compounder to establish that a drug is not essentially a copy documents that the determination was made.

If the compounder produces drugs in anticipation of receiving valid prescriptions for identified individual patients, and the compounder obtains the statement of significant difference from the prescriber when it receives the prescription for the compounded drug, prior to distribution, FDA does not intend to consider the compounded drug that is then distributed to be essentially a copy.

3. Documentation of Shortage

If the drug was compounded because the approved drug product was not commercially available because it was on the FDA drug shortage list, the prescriber or compounder should include a notation on the prescription that it was on the drug shortage list and the date the list was checked. ¹⁸

4. Regularly or in Inordinate Amounts

A drug product is not eligible for the exemptions in section 503A if it is prepared by a pharmacist or physician who compounds "regularly or in inordinate amounts (as defined by the Secretary)" any drug products that are essentially copies of a commercially available drug

¹⁶ Congress noted that "where it is readily apparent, based on the circumstances, that the 'significant difference' is a mere pretext to allow compounding of products that are essentially copies of commercially available products, such compounding would be considered copying of commercially available products and would not qualify for the compounding exemptions if it is done regularly or in inordinate amounts. Such circumstances may include, for example, instances in which minor changes in strength (such as from .08% to .09%) are made that are not known to be significant or instances in which the prescribing physician is receiving financial remomeration or other financial incentives to write prescriptions for compounded products." See the U.S. House. Food and Drug Administration Modernization Act of 1997, Conference Report (to Accompany S. 830). (105 H. Rpt. 399).

¹⁷ See section IV of this guidance.

¹⁸ See section IV of this guidance.

product.¹⁹ FDA interprets this to mean that, in order to be compounded in accordance with section 503A, a drug product that is essentially a copy of a commercially available drug product cannot be compounded regularly—i.e., it cannot be compounded at regular times or intervals, usually, or very often. Nor can the amounts compounded be inordinate, in light of the purpose of section 503A.

Section 503A is intended to protect patients from the public health risks of providing compounded drugs to patients whose medical needs could be met by commercially available drug products and to protect the integrity and efficiency of the drug approval process. Under the statutory scheme, only very rarely should a compounded drug product that is essentially a copy of a commercially available drug product be offered to a patient. We conclude, therefore, that a drug product that is essentially a copy of a commercially available drug product is compounded regularly or in inordinate amounts if it is compounded more frequently than needed to address unanticipated, emergency circumstances, or in more than the small quantities needed to address unanticipated, emergency circumstances.

It is important to note that the regularly or in inordinate amounts provision is not implicated if the compounded drug is not essentially a copy of a commercially available drug product. For example, a compounded drug product that has the same API, dosage strength, and route of administration as a drug product on FDA's shortage list would not be considered essentially a copy of a commercially available drug because a drug product is not considered commercially available if it is on FDA's drug shortage list. In addition, a compounded drug product is not essentially a copy of a commercially available drug product if a prescriber has determined that the compounded drug has a change that produces a significant difference for a patient. Once it has been determined that a compounded drug is essentially a copy of a commercially available drug product as described above, the following are examples of factors that may be the basis for concluding that it has been compounded regularly or in inordinate amounts:

- The compounded drug product amounts to more than a small number of prescriptions or a small percentage of the compounded drug products that a compounder prepares.
- The compounder routinely substitutes compounded drugs that are essentially copies of commercially available drugs upon receiving prescriptions for patients.
- The compounder offers pre-printed prescription pads that a prescriber can use to write a
 prescription for the drug product that is essentially a copy without making a
 determination that there is a change that will produce a significant difference for a
 patient.
- The compounded drug product is not compounded on an as-needed basis, but on a routine
 or pre-set schedule.

The foregoing list is not intended to be exhaustive. Other factors may be appropriate for consideration in a particular case.

To focus enforcement on the most significant cases, as a matter of policy, at this time FDA does not intend to take action against a compounder for compounding a drug product that is

¹⁹ See section 503A(b)(1)(D).

essentially a copy of a commercially available drug product regularly or in inordinate amounts if the compounder fills four or fewer prescriptions for the relevant compounded drug product in a calendar month.²⁰ As noted above, a compounded drug product is not essentially a copy of a commercially available drug product if a prescriber has determined that the compounded drug has a change that produces a significant difference for a patient; thus, a prescription that documents such a prescriber determination would not be counted towards the four prescriptions.

Compounders may produce a limited amount of drugs in anticipation of receiving valid prescriptions for identified individual patients. See section 503A(a)(2). FDA generally intends to consider whether such drugs are essentially a copy at the time the drug is distributed rather than the time it is produced.

5. Recordkeeping

A licensed pharmacist or physician seeking to compound a drug product under section 503A should maintain records to demonstrate compliance with section 503A(b)(1)(D). For example, records should be kept of notations on prescriptions for identified individual patients that a prescriber has determined that the compounded drug has a change that produces a significant difference for the identified patient.

Compounders under section 503A should also maintain records of the frequency in which they have compounded drug products that are essentially copies of commercially available drug products and the number of prescriptions that they have filled for compounded drug products that are essentially copies of commercially available drug products to document that such compounding has not been done regularly or in inordinate amounts.²¹

FDA recommends that compounders maintain the records described above for a period of at least three years.

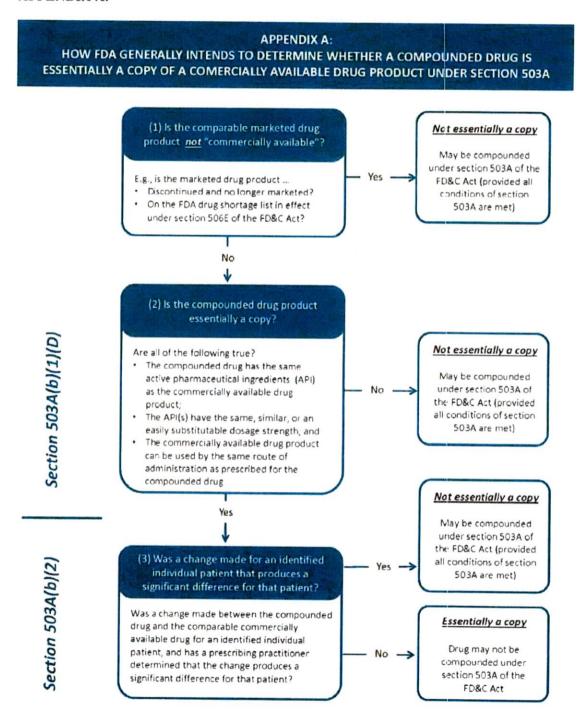
IV. PAPERWORK REDUCTION ACT

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). See footnotes 17, 18, and 21. These provisions require review and are not in effect until they display a currently valid OMB control number. The information collection provisions in this guidance have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. FDA will publish a notice in the *Federal Register* announcing OMB's decision regarding the information collection provisions in this guidance.

²⁰ For purposes of this policy, FDA intends to consider each refill of a prescription as an additional prescription.

²¹ See section IV of this guidance.

APPENDIX A.



BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 23-050-PH-O

Petitioner,

V.

WELLS PHARMACY NETWORK, LLC, Pharmacy License No. PH01589,

Respondent.

EXHIBIT F

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

CASE NO. 23-050-PH-O

Petitioner,

V.

WELLS PHARMACY NETWORK, LLC, Pharmacy License No. PH01589,

Respondent.

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 Tim	e – Kenneth Scheuber			
Date(s)	Description	Hours	Rate	Amount
SEE ATTACHED	SEE ATTACHED	8.50	\$53.00/hr	\$450.50
Subtotal (Investig	ation): \$450.50	!	<u> </u>	
Attorney Time - E	Brett Kandt			
Date(s)	Description	Amount		
3/24/25	Confer with staff and review investigative case file in case 23-050-PH-O; research, draft and Notice of Intended Action and Accusation.	5.25	\$104.00/hr	\$546.00
5/20/25	Confer with counsel for respondent and grant extension to file Answer and Notice of Defense.	0.25	\$104.00/hr	\$26.00
5/23/25	Review Answer and Notice of Defense.	1.50	\$104.00/hr	\$156.00

6/10/25	Confer with staff and prepare for hearing re: witnesses and exhibits; confer with opposing counsel re: Answer and affirmative defenses.	7.75	\$104.00/hr	\$806.00
6/23/25	Confer with staff on hearing.	1.00	\$104.00/hr	\$104.00
7/7/25	Confer with staff re: case file and exhibits.	0.25	\$104.00/hr	\$26.00
7/8/25	Confer with staff and counsel for respondent on motion to associate counsel and potential exhibits for hearing.	1.75	\$104.00/hr	\$182.00
7/10/25	Confer with staff and prepare for hearing; prepare exhibits; prepare memorandum of attorney's fees and costs; review motion to associate counsel and respond. \$104.00/hr		\$572.00	
7/11/25	Confer with staff; finalize memo of fees and costs and submit to counsel.	1.00	\$104.00/hr	\$104.00
7/14/25	Travel to Las Vegas and meet with witnesses.	4.75	\$104.00/hr	\$494.00
7/15/25	Final hearing preparation; draft proposed findings of fact, conclusions of law and order.	2.25	\$104.00/hr	\$234.00
7/16/25	Hearing in case 23-050- PH-O; finalize order.	1.00	\$104.00/hr	\$104.00
Subtotal (Attorn	ney Time): \$3,354.00			

Administrativ	e Costs			
Date(s)	Description	Hours	Rate	Amount
4/22/25	Erin Miller finalized, filed and served Accusation via certified/regular mail.	0.50	\$25.00/hr	\$12.50
6/10/25	Jessette Phaynarikone compiled discovery file.	1.00	\$25.00/hr	\$25.00
6/12/25	Jessette Phaynarikone served Notice of Hearing for July 16, 2025.	0.50	\$25.00/hr	\$12.50
Subtotal (Adm	ninistrative Costs): \$50.00		-	<u> </u>
Additional Re	coverable Costs: Postage/Mailing	Costs: \$	30.35	
Total Attorne	ey's Fees and Recoverable Costs	: \$3,884	.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 recoverable costs incurred by the Board in the above-entitled action.

DATED this 11^{th} day of July, 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,

Case No. 19-013-CS-S 25-241-CS-S

Petitioner,

STIPULATION AND ORDER

v.

MATTHEW OKEKE, M.D., Certificate of Registration No. CS10935,

Respondents.

- J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through its Senior General Counsel, Gregory L. Zunino, and Respondent Matthew Okeke, M.D. ("Respondent"), 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 on file in Case No. 19-013-CS-S, together with the Statement to Respondent and Notice of Hearing.
- 3. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation on file in Case No. 25-241-CS-S, together with the Statement to Respondent and Notice of Hearing.
- 4. In both Case Nos. 19-013-CS-S and 25-241-CS-S, the Board and Respondent agreed to delay the date for submitting a Notice of Answer and Defense as the parties pursued settlement negotiations.
- 5. Respondent acknowledges that he understands the terms of this Stipulation and Proposed Order ("Stipulation"), and he has executed it knowingly and voluntarily in consultation with his attorney.
- 6. Respondent is aware of the right to a hearing on the matters alleged in the Accusations in Case Nos. 19-013-CS-S and 25-241-CS-S, 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 Controlled Substances Act.

- 7. 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 waives his rights to a hearing, reconsideration, appeal, and other rights related to this action as identified above.
- 8. Respondent does not contest the allegations stated in the Accusations in Case Nos. 19-013-CS-S and 25-241-CS-S, and he further 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 against him.
- 9. To resolve the charges in Case Nos. 19-013-CS-S and 25-241-CS-S without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree:
 - A. That Respondent's Certificate of Registration No. CS10934 is REVOKED, effective immediately.
 - B. That Respondent shall be ineligible to petition for reinstatement for a period of one (1) year from the date of entry set forth below.
 - C. That as condition of submitting any petition for reinstatement, Respondent shall pay an administrative fine of Ten Thousand and 00/100 Dollars (\$10,000.00), payable by cashier's check, certified check, or money order written'to the "State of Nevada, Office of the Treasurer."
 - D. That as condition of submitting any petition for reinstatement, Respondent shall pay to Nevada State Board of Pharmacy the sum of Three Thousand and 00/100 Dollars (\$3,000.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting the above-referenced cases.
- 10. Pursuant to NRS 622.330, the Board's Senior General Counsel will present this Stipulation to the Board for approval at the Board's regularly scheduled public meeting on July 16,

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 as provided by NRS 622.330, and it 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. 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 Accusations on file in Case Nos. 19-013-CS-S and 25-241-CS-S, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of entry set forth below.

Respondent has fully considered the charges and allegations contained in the *Notices of Intended Action and Accusation* in Case Nos. 19-013-CS-S and 25-241-CS-S, 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:	U. H.
Signed this day of July 2025.	Signed this day of July 2025.
MATTHEW OKEKE, M.D. Certificate of Registration No. CS10935	NEVADA STATE BOARD OF PHARMACY By GREGORY L. ZUNINO Senior General Counsel Nevada Bar No. 4805
Approved as to Form and Content:	
LIBORIUS AGWARA, ESQ. Attorney for Respondent	

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 as provided by NRS 622.330, and it 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. 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 Accusations on file in Case Nos. 19-013-CS-S and 25-241-CS-S, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of entry set forth below.

Respondent has fully considered the charges and allegations contained in the *Notices of Intended Action and Accusation* in Case Nos. 19-013-CS-S and 25-241-CS-S, 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.

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Signed this 14 day of July 2025.

MATTHEW ÖKEKE, M.D.

Certificate of Registration No. CS10935

Signed this ____ day of July 2025.

NEVADA STATE BOARD OF PHARMACY

By_____GREGORY L. ZUNINO

Senior General Counsel Nevada Bar No. 4805

Approved as to Form and Content:

LIBORIUS AGWARA, ESQ.

Attorney for Respondent

DECISION AND ORDER

As to Respondent Matthew Okeke, M.D., in Case Nos. 19-013-CS-S and 25-241-CS-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in those matters and orders that its terms be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this _____day of July 2025.

Helen Park, President Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY.

CASE NO. 22-490-CS-S

Petitioner,

v.

STIPULATION AND ORDER

MIGUEL VARGAS-LAGUNAS, M.D., Certificate of Registration No. CS15547,

Respondent.

Gregory Zunino, Senior General Counsel for Petitioner the Nevada State Board of Pharmacy (the "Board"), and Respondent Miguel Vargas-Lagunas, M.D. ("Respondent"), Certificate of Registration No. CS15547, by and through counsel, Randall Tindell, Esq., HEREBY STIPULATE AND AGREE THAT:

- 1. The Board has jurisdiction over Respondent and this matter.
- 2. On or about June 13, 2025, Respondent was served with the Notice of Intended Action and Accusation (the "Accusation") on file in this matter together with the Statement to Respondent and Notice of Hearing.
- 3. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation and [Proposed] Order (the "Stipulation").
- 4. The Board and Respondent agreed to delay the date for submitting a Notice of Answer and Defense as the parties pursued settlement negotiations.
- 5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be afforded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), NRS Chapter 639 (Nevada Pharmacy Act), and NRS Chapter 453 (The Nevada Controlled Substances Act).
- 6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with

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the provisions of this Stipulation, Respondent hereby freely and voluntarily waives his rights to hearing, reconsideration, appeal and any and all other rights described above.

- 7. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, to wit:
- A. In 2022 and 2023, Respondent, a licensed physician, served as the medical director for Imagen Med Spa ("Imagen"), located at 2605 South Decatur Boulevard, Suite 218, in Las Vegas, Nevada.
- B. During Respondent's tenure as Imagen's medical director, Liliana Ramos, a non-practitioner, received, possessed, stored and/or administered dangerous drugs outside of Respondent's presence.
- C. As the medical director for Imagen, Respondent had a duty to lock or otherwise secure the dangerous drugs in Imagen's possession and to take reasonable steps to prevent Liliana Ramos and other non-practitioners from receiving, storing, possessing, and/or administering dangerous drugs in Respondent's absence.
- D. Respondent did not lock or otherwise secure the dangerous drugs in Imagen's possession when he was absent, and he did not take reasonable steps to prevent Liliana Ramos and other non-practitioners from receiving, storing, possessing, and/or administering dangerous drugs in his absence.
- 8. The violations stated in the Accusation are pleaded with particularity and are grounds for action pursuant to NRS 639.210, NRS 639.255, NRS 453.236, NAC 639.945, and NAC 639.955.
- 9. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent agree to the following penalties:
- A. Respondent shall accept this Stipulation and Order as a public reprimand for unprofessional conduct as alleged in the Accusation;

- B. Respondent shall pay a fine of Five Thousand and 00/100 Dollars (\$5,000.00) for the violations alleged in the Accusation, payable by cashier's check or certified check or money order made payable to the "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway Suite 206, Reno, Nevada 89521, not later than August 31, 2025;
- C. Respondent shall pay 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 this matter, payable by cashier's check or certified check or money order made payable to the "Nevada Sinte Board of Pharmacy," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway Suite 206, Reno, Nevada 89521, not later than August 31, 2025.
- 10. Any failure by Respondent to comply with the terms of this Stipulation may result in issuance by the Executive Secretary of an Order to Show Cause pursuant to NAC 639.965 directing that Respondent appear before the Board at the next regularly scheduled meeting for a show cause hearing. The Board may impose additional discipline upon Respondent consistent with the provisions of NRS Chapter 639.
- 11. Senior General Counsel will present this Stipulation to the Board for approval at the Board's regularly scheduled public meeting on July 16, 2025. Respondent and/or Counsel for Respondent will appear at the meeting in person or by video conference to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation even if Respondent is not present at the meeting.
- 12. The Board has discretion to 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.
- 13. 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 a full hearing on

the merits of this matter may be heard by the Board. The terms and agreements herein may not be used or referred to in a full hearing on the merits of this matter.

- 14. This matter will be reported to the National Practitioner Data Bank as required by 45 C.F.R. §§ 60.3, 60.5, and 60.9.
- 15. 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 the facts set forth in the Accusation, whether known or unknown, that might otherwise have existed on or before the effective date of this Stipulation.

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 has waived certain rights, as stated herein.

Signed this 3 day of June 2025.

Nevada State Board of Pharmacy

GREGORY ZUNINO

Senior General Counsel

AGREED:

Signed this

day of June 2025.

day of June 2025.

MIGUEL VARGAS-LACITAAS, M.D. Certificate of Registration No. CS15547

APPROVED AS TO FORM AND CONTENT this 70 day of June 2025.

RANDALL TINDALL, ESQ.

Managing Partner - Resnick & Louis, P.C.

Attorney for Miguel Vargas-Lagunas, M.D.

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DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Miguel Vargas-Lagunas, M.D., Certificate of Registration No. CS15547, in Case No. 22-490-CS-S and hereby orders that its terms be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 16thy day of July 2025.

Helen Park, President Nevada State Board of Pharmacy 18A

NRS 639.0727 Regulations: Remote sites, satellite consultation sites and telepharmacies; dispensing practitioners and dispensing technicians; practicing electronically, telephonically or by fiber optics. The Board shall adopt regulations:

- 1. As are necessary for the safe and efficient operation of remote sites, satellite consultation sites and telepharmacies;
- 2. To define the terms "dispensing practitioner" and "dispensing technician," to provide for the registration and discipline of dispensing practitioners and dispensing technicians, and to set forth the qualifications, powers and duties of dispensing practitioners and dispensing technicians;
- 3. To authorize registered pharmacists to engage in the practice of pharmacy electronically, telephonically or by fiber optics, including, without limitation, through telehealth, from within or outside this State; and
- 4. To authorize prescriptions to be filled and dispensed to patients as prescribed by practitioners electronically, telephonically or by fiber optics, including, without limitation, through telehealth, from within or outside this State or the United States.

(Added to NRS by 2009, 1319; A 2013, 2020; 2015, 627)

NRS 639.0065 "Dispense" defined.

- 1. "Dispense" means to deliver a controlled substance or dangerous drug to an ultimate user, patient or subject of research by or pursuant to the lawful order of a practitioner, including the prescribing by a practitioner, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.
- 2. The term does not include the furnishing of a controlled substance by a hospital pharmacy for inpatients.

(Added to NRS by 1995, 287)

NRS 639.0053 "Compound" and "compounding" defined. "Compound" or "compounding" means to form or make up a composite product by combining two or more different ingredients.

(Added to NRS by 1979, 1696)

NAC 639.010 Definitions. (NRS 639.070, 639.0727) As used in this chapter, unless the context otherwise requires:

- 1. "Automated drug dispensing system" means a system that performs operations, other than compounding or administration, related to the storage and dispensing of drugs.
 - 2. "Board" means the State Board of Pharmacy.
 - 3. "Controlled substance" has the meaning ascribed to it in NRS 0.031.
 - "Dangerous drug" has the meaning ascribed to it in NRS 454.201.
- 5. "Direct supervision" means the direction given by a supervising pharmacist or dispensing practitioner who is:
- (a) On the premises of the pharmacy or telepharmacy at all times when the person he or she is supervising is working at the pharmacy or telepharmacy or at a remote site or satellite consultation site; and
- (b) Aware of the activities of that person related to the preparation and dispensing of medications, including the maintenance of appropriate records.
 - 6. "Dispensing practitioner" means:
- (a) A practitioner to whom the Board has issued a certificate of registration pursuant to <u>NAC 639.742</u> to dispense controlled substances or dangerous drugs, or both, for human consumption; or
- (b) A licensed veterinarian to whom the Board has issued a certificate of registration pursuant to NAC 639.7423 to dispense controlled substances or dangerous drugs, or both, not for human consumption.
- 7. "Dispensing technician" means a person who performs technical services in a pharmacy under the direct supervision of a dispensing practitioner and is registered with the Board pursuant to NAC 639.7425.
- 8. "Dispensing technician in training" means a person who is registered with the Board pursuant to NAC 639.7424 in order to obtain the training and experience required to be a dispensing technician pursuant to subparagraph (1) of paragraph (c) of subsection 2 of NAC 639.7425.
- 9. "Executive Secretary" means the Executive Secretary employed by the Board pursuant to NRS 639.040.

- 10. "Federally-qualified health center" has the meaning ascribed to it in 42 U.S.C. § 1396d(l)(2)(B).
- 11. "Federally-qualified health center vehicle" means a vehicle that meets the requirements of paragraph (c) of subsection 1 of NAC 639.7422.
 - 12. "Licensed veterinarian" has the meaning ascribed to it in NRS 638.007.
- 13. "Oncology group practice" means two or more dispensing practitioners who practice oncology in a group practice.
- 14. "Pharmaceutical technician" means a person who performs technical services in a pharmacy under the direct supervision of a pharmacist and is registered with the Board pursuant to NAC 639.240.
- 15. "Pharmaceutical technician in training" means a person who is registered with the Board pursuant to NAC 639.242 in order to obtain the training and experience required to be a pharmaceutical technician pursuant to subparagraph (3) of paragraph (d) of subsection 2 of NAC 639.240, or who is enrolled in a program of training for pharmaceutical technicians that is approved by the Board.
 - 16. "Practitioner" has the meaning ascribed to it in NRS 639.0125.
 - 17. "Prescription drug" means a drug or medicine as defined in NRS 639.007 which:
 - (a) May be dispensed only upon a prescription order that is issued by a practitioner; and
 - (b) Is labeled with the symbol "Rx only" pursuant to federal law or regulation.
- 18. "Public or nonprofit agency" means a health center as defined in 42 U.S.C. § 254b(a) which:
 - (a) Provides health care primarily to medically underserved persons in a community;
- (b) Is receiving a grant issued pursuant to 42 U.S.C. § 254b or, although qualified to receive such a grant directly from the Federal Government, is receiving money from such a grant under a contract with the recipient of that grant; and
 - (c) Is not a medical facility as defined in NRS 449.0151.
- 19. "Reproductive healthcare center" means a health facility owned and operated by a nonprofit corporation or a public health center, as defined in subsection 8 of NRS 449.260, principally engaged in providing family planning services and reproductive healthcare, including, without limitation, the testing, diagnosis and treatment of, or providing of

medication to prevent, a sexually transmitted infection or other infection of the urogenital system.

- 20. "Surgical center for ambulatory patients" has the meaning ascribed to it in NRS 449.019.
- 21. "User-based access technology" means software or hardware that restricts access to an automated drug dispensing system to authorized users by requiring two-factor authentication. Authentication factors may include, without limitation, knowledge, hardware tokens or biometric information.

[Bd. of Pharmacy, § 639.010, 6-26-80]—(NAC A 3-27-90; 6-14-90; 10-1-93; 11-15-93; 5-22-96; 10-24-97; R014-99, 11-3-99; R019-03, 10-21-2003; R041-04, 5-25-2004; R036-07, 1-30-2008; R098-13, 3-28-2014; R004-19, 12-30-2019; R072-19, 2-7-2020; R025-21, 4-11-2022; R007-21, 6-13-2022; R178-22, R180-22 & R181-22, 12-29-2022)

NAC 639.031 "Dispensing practitioner" defined. (NRS 639.070, 639.0727) For the purposes of NRS 639.0727, the Board defines the term "dispensing practitioner" as set forth in subsection 6 of NAC 639.010.

(Added to NAC by Bd. of Pharmacy by R004-19, eff. 12-30-2019)