Agenda Item 10B

Strive Pharmacy

STRIVE
compounding pharmacy

Dave Wuest, Pharm. D
Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521
dwuest@pharmacy.nv.gov

RE: Out-of-State Pharmacy Application – Supplemental Response

Dear Dr. Wuest:

We hope this letter finds you well and thank you in advance for your consideration of the information included within this supplement to our application for an Out-of-State Pharmacy license. As you may be aware, we applied for an Out-of-State Pharmacy license for our Arizona Strive Pharmacy location on May 10, 2023. At this time, our application is set for review before the Nevada Board of Pharmacy (the "Nevada Board") during the October 12, 2023 meeting as **Agenda Item 8.B**.

While preparing for our appearance before the Nevada Board, we noticed that our answer to Section 3, Question 3, should be changed and supplemented with additional materials that have occurred since we originally filed our application. For ease of reference, Section 3, Question 3 asks the following:

> Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject to an administrative action, board citation, cite find, or proceeding relating to the pharmaceutical industry?

In the original application, we answered "no" to this question addressing our company's history. This was accurate at the time we filed. However, since filing the original application, a series of matters have developed involving the Arizona location and elsewhere in the Strive Pharmacy corporation that fairly require disclosure and our answer be changed in the affirmative. For clarification, we have provided our Strive Pharmacy Business Organizational Chart for review. *See* **Exhibit 1**.

Please understand, this omission was unintentional. Nevertheless, we wanted to apologize for this oversight and amend our answer to Section 3, Question 3 within our original application from "no" to "yes" and provide the following supplemental information for the board's evaluation of our application:

Arizona Board of Pharmacy Complaint 22-0668:

- On December 5, 2022, we received our initial Complaint 22-0668 from the Arizona Board of Pharmacy (the "Arizona Board") alleging we engaged in the compounding of essentially a copy of a commercially available product (compounded semaglutide). *See* **Exhibit 2**. However, Complaint 22-0668 was amended and delayed to accommodate the dynamic nature of this topic and noted improper recordkeeping practices. *See* **Exhibit 3**. Our responses are set out in **Exhibit 4**.
- During the Arizona Board's August 17, 2023 meeting, we appeared before the Arizona Board to address Complaint 22-0668.
- After our appearance before the Arizona Board and addressing the various concerns of the respective Board members, it was determined that our semaglutide compounding practices were in line with the current FDA guidance and good current compounding practices of Arizona.
- However, the Arizona Board did find that our compounding logs contained some recordkeeping discrepancies and plan to issue disciplinary action with a $1,000 fine.
- For reference, a video of our appearance can be found at the following link: here. Our appearance begins at 0:34:56 and continues until 1:33:35.
- At this time, the consent order evidencing this disciplinary action is still being finalized. Once the consent order is completed and signed by the respective parties, we will supply it to the Nevada Board of Pharmacy for review.

Utah Board of Pharmacy Citation #102685:

- On May 22, 2023, our Arizona pharmacy location received a citation alleging we were dispensing bulk nonpatient-specific drug substances for office use without registering as a 503B outsourcing facility. *See* **Exhibit 5**.
- We issued a response to the Utah Pharmacy Board appropriately claiming that Strive acts in accordance with 21 U.S.C. § 353a(a) and only compounds drug products for an identified individual patient that were being shipped to their practitioners acting as the patient's agent in accordance with Utah law. *See* **Exhibit 6**.
- On June 28, 2023, the Utah Pharmacy Board reviewed the response and dismissed the citation taking no further action. *See* **Exhibit 7**.

Colorado Board of Pharmacy Inspection:

- On August 11, 2023, the Colorado Board of Pharmacy (the "Colorado Board") inspected our Denver location and issued an accompanying complaint. *See* **Exhibit 8**.

- We issued two responses to the Colorado Board assuring that our compounding pharmacy practices were not only compliant with both FDA and Colorado law but that any requested changes were appropriated corrected. *See* **Exhibit 9**.
- On September 25, 2023, the Colorado Board alerted us that have reviewed our response to their filed complaint and decided not to commence formal proceedings against our Denver location pharmacy's license. *See* **Exhibit 10**.

FDA Inspection & Form 483:

- The FDA inspected our Texas pharmacy facility between August 14 – September 8, 2023. As a result, the FDA inspector issued a Form 483 on September 9th listing four observations related to the pharmacy's compounding process. *See* **Exhibit 11**.
- To address the FDA's concerns, we issued a Response to the Observations included within the Form 483 on October 2nd to assure the FDA that any issues observed have either been corrected or are in the processed of being corrected. *See* **Exhibit 12**.

California Board of Pharmacy Citations:

- On September 28, 2023, our Arizona pharmacy location received a citation with accompanying fines against their non-resident pharmacy license and compounding license in California alleging our pharmacy is compounding commercially available drug products and other associated compounding prohibited acts. *See* **Exhibit 13**.
- Our plan is to contest these citations by requesting an informal Office Conference with the California Board of Pharmacy by October 12, 2023.

Thank you for your time and consideration of these supplemental responses. In the event Nevada Board representatives have any further questions, please do not hesitate to contact us.

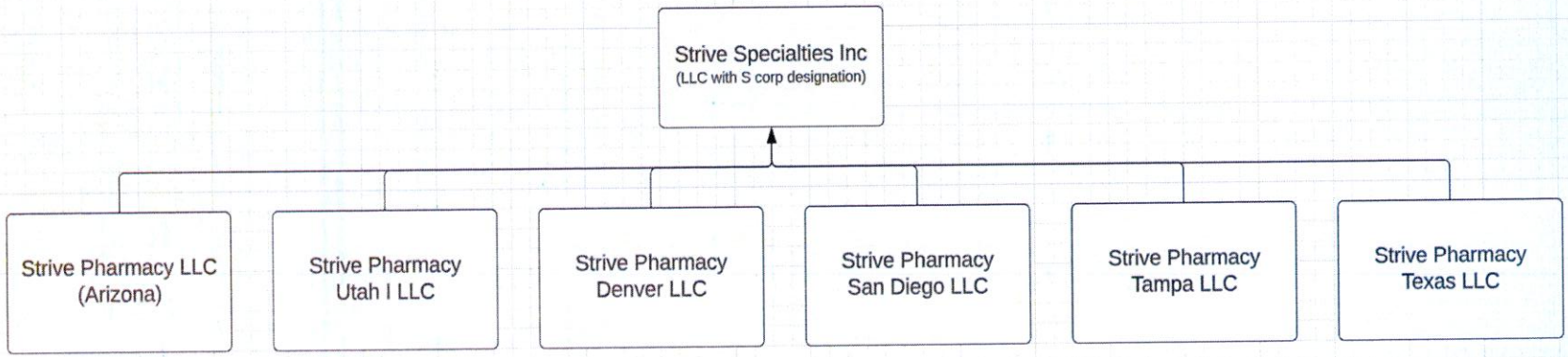
Respectfully,

Matthew Montes De Oca
Managing Pharmacist
Nevada Out-of-State Pharmacy License
Strive Pharmacy
1275 E. Baseline Rd., Suite 104
Gilbert, AZ 85233

STRIVE
compounding pharmacy

Exhibit 1

480.626.4366 480.626.4365 info@strivepharmacy.com strivepharmacy.com
1275 E Baseline Rd Ste 104 Gilbert, AZ 85233


Strive Specialties Inc
(LLC with S corp designation)
Strive Pharmacy LLC
(Arizona)
Strive Pharmacy
Utah I LLC
Strive Pharmacy
Denver LLC
Strive Pharmacy
San Diego LLC
Strive Pharmacy
Tampa LLC
Strive Pharmacy
Texas LLC

STRIVE
compounding pharmacy

Exhibit 2

480.626.4366 480.626.4365 info@strivepharmacy.com strivepharmacy.com
1275 E Baseline Rd Ste 104 Gilbert, AZ 85233

Arizona State Board of Pharmacy
P.O. Box 18520, Phoenix, AZ 85005
P) 602-771-2727 F) 602-771-2749
https://pharmacy.az.gov/

December 5, 2022

Strive Pharmacy
1275 E. BASELINE ROAD 104
GILBERT, AZ 85233

Re: Case No. 22-0668

Dear Permit Holder,

The above-referenced complaint, involving Permit Number Y007406, will be reviewed by the Complaint Review Committee on February 7, 2023. It will then be considered by the Arizona State Board of Pharmacy at their meeting of February 15-16, 2023.

At the Complaint Review Committee meeting, the committee members will review the complaint and make a recommendation to the Board.

At the Board meeting, the Board will determine whether to accept the recommendation of the committee or to choose an alternate course of action. The Board may choose to dismiss the matter, move the case to a conference or offer a consent agreement to resolve the case. The Board cannot impose discipline (apart from offering a Consent Agreement) at this meeting. Therefore, A.R.S. §32-3108 does not apply and the Board is not required to afford the licensee with an opportunity to speak. If the licensee is present, the Board may choose to ask them questions, if time permits, and/or move the case to conference for discussion.

You are welcome to follow the Board meeting online. All Board meetings are streamed live online via YouTube. Please use the search terms Arizona State Board of Pharmacy.

Date & Time: **Complaint Review Committee Meeting –**
February 7, 2023 – 8:30 a.m.

Location: Arizona State Board of Pharmacy Board Room
1110 W. Washington, Suite 255
Phoenix, AZ 85007

Date & Time: **Board Meeting –**
February 15-16, 2023 – 8:30 a.m.

Location: Arizona State Board of Pharmacy Board Room
1110 W. Washington, Suite 245
Phoenix, AZ 85007

If you have any questions, please contact this office.

Sincerely,

Kam Gandhi, PharmD
Executive Director
KG/jcm

Enc.

Arizona State Board of Pharmacy
P.O. Box 18520, Phoenix, AZ 85005
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If you have any questions, please contact this office.

Sincerely,

Kam Gandhi, PharmD
Executive Director
KG/jcm

Enc.

Arizona State Board of Pharmacy
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Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
P) 602-771-2727 F) 602-771-2749 www.azpharmacy.gov

COMPLAINT #22-0668

Board Staff: Karol Hess Compliance Officer
Date: December 1, 2022

Respondent(s):
Strive Pharmacy Y007406
Michael Walker S021357

SUBJECT: A pharmacy was allegedly compounding a commercially available product.

SUMMARY:
On November 15, 2022 Compliance Officer Sharon Richardson received an email from a competitor compounding pharmacy stating that the owner believed that Strive Pharmacy may be compounding a commercially available product. This email was accompanied by an advertisement from Strive Pharmacy for compounding Semaglutide (Ozempic® & Wygovy®). This advertisement indicates that Strive Pharmacy will compound Semaglutide injectable. According to the advertisement, the dosing schedule recommended for this product is exactly the same as the brand name Wygovy®, which is FDA approved for weight loss. The advertisement instructs doctors how to prescribe this product, making the proper conversions to equal the Wygovy® dose titration. A complaint was opened.

In August of 2021, Strive Pharmacy began compounding Semaglutide injectable. On November 15, 2022 Compliance Officer Karol Hess arrived at Strive Pharmacy and spoke with the owner, Michael Walker, regarding the complaint. Mr. Walker admitted to compounding Semaglutide. He stated that originally he had compounded the Semaglutide alone but after the advice of his attorney and concerns of possibly compounding a commercially available drug, he decided to begin marketing it with B12 (cyanacobalamin) to combat the nausea often associated with this medication. Cyanocobalamin injectable is also a commercially available drug and the recommended dosing schedule remained that of Wygovy®. Please see below chart of a comparison of available strengths for Ozempic®, Wygovy®, and Strive Semaglutide.

Drug Name	Strength 1	Strength 2	Strength 3	Strength 4	Strength 5
Ozempic	2mg/ml	4mg/3ml	8mg/3ml	NA	NA
Wygovy	0.25mg/0.5ml	0.5mg/0.5ml	1mg/0.5ml	1.7mg/0.75ml	2.4mg/0.75ml
Strive Semaglutide*	2mg/1ml	2.5/1ml	5mg/1ml	NA	NA

*All of the Semaglutide products compounded that contain Cyanocobalamin contain 1mg/ml of Cyanocobalamin – this does not appear to be patient specific

Mr. Walker also advised CO Hess that both Ozempic® and Wygovy® are currently on the FDA's shortage list and may be compounded. This is true; however, both brand name products appeared on the shortage list March 31, 2022. Mr. Walker began compounding this product in August of 2021, 7 months prior to the shortage. Please see the below chart for totals compounded in 2021 and 2022 prior to it appearing on the shortage list.

Total RX's filled in 2021		
Semagutide Inj	Semglutide/B12 Inj	Grand Total
275	0	283
Total RX's filled in 2022 through 3/31/2022		
Semagutide Inj	Semglutide/B12 Inj	Grand Total
1191	6	1197

Additional fill information is located on the spreadsheet within the evidentiary portion of this report.

Arizona State Board of Pharmacy
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According to this spreadsheet it appears that Mr. Walker often made batches of these compounds. This was confirmed via an email dated December 1, 2022.

According to a guidance document printed by the FDA in January of 2018;
"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."

INVESTIGATION NOTES:

Included for Board review:

- A copy of the complaint letter provided to Strive Pharmacy
- Response from Mr. Walker
- A copy of the fill spread sheet for Strive Semaglutide from 8/2021 through 11/2022
- A copy of the advertisement for Strive Pharmacy's Semaglutide
- A copy of FDA's guidance document entitled, "Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product under Section 503A of the Federal Food, Drug, and Cosmetic Act"
- A copy of two articles provided by Mr. Walker
- Email communications pertaining to complaint

LICENSEE/PERMITEE RESPONSE

Mr. Walker makes several assertions within his response. The first comes from 21 U.S.C. 353. He quotes....

> ""the pharmacy must not compound "regularly or in inordinate amounts" drugs that are "essentially copies of commercially available drug products." 21 U.S.C. 353a (b) (1)(d).""

Mr. Walker offers no definition of "regularly or inordinate amounts".

A guidance document provided by the FDA entitled,
Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product under Section 503A of the Federal Food, Drug, and Cosmetic Act, states the following: .....

> "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 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]

Mr. Walker's second assertion again references 21.U.S.C 353. He states;

> ""The FDCA provides that the phrase "'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.""

> ""21 U.S.C. 353a (b) (2). Similarly, for a drug compounded by a registered 503B outsourcing facility to be exempt from certain requirements of the FDCA, the drug must not be **"essentially a copy of *one or more* approved drugs."** 21 U.S.C. 353b (a) (5).""

The products Mr. Walker was compounding in 2021 did not contain a change. Some of the drugs compounded in 2022 contained Cyanocobalamin, also a FDA approved and commercially available drug. Furthermore, within this document the FDA qualifies "an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner..." to mean;

"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)

Mr. Walker then cites an article that discusses the promise of using B12 with glucagon-like peptide-1 receptor (GLP-1R) agonists to combat the nausea associated with these drugs (attached). Unfortunately, this article and the research it covers were done on rats not humans. Mr. Walker offered no evidence of research done in humans.

POSSIBLE VIOLATIONS:

Strive Pharmacy Y007406

32-1901. Definitions
In this chapter, unless the context otherwise requires:
11. "Compounding" means preparing, mixing, assembling, packaging or labeling a drug by a pharmacist or an intern or pharmacy technician under the pharmacist's supervision, for the purpose of dispensing to a patient based on a valid prescription order. Compounding includes preparing drugs in anticipation of prescription orders prepared on routine, regularly observed prescribing patterns and preparing drugs as an incident to research, teaching or chemical analysis or for administration by a medical practitioner to the medical practitioner's patient and not for sale or dispensing. Compounding does not include preparing commercially available products from bulk compounds or preparing drugs for sale to pharmacies, practitioners or entities for the purpose of dispensing or distribution.

R4-23-410. Current Good Compounding Practices
A. This Section establishes the current good compounding practices to be used by a pharmacist licensed by the Board, in a pharmacy permitted by the Board, and in compliance with applicable federal and state law governing the practice of pharmacy

Michael Walker S021357

32-1901. Definitions
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Arizona State Board of Pharmacy
Physical address: 1110 W Adams Suite 260 Phoenix, AZ 85007; Mailing address: PO Box 18520 Phoenix, AZ 85005-8520
Telephone: 602-771-2727 Fax: 602-771-2749 www.azpharmacy.gov

Mr. Michael Walker
Strive Pharmacy
1275 E. Baseline Rd. #104
Gilbert, AZ 85233
Y007406

Mr. Walker:

The Board office has opened Complaint 22-0668 against Strive Pharmacy holder pharmacy permit Y007406 located at 1275 E Baseline RD. #104 Gilbert, AZ 85233.

It has come to our attention that your pharmacy is compounding a commercially available product. The product in question is Ozempic 2mg/1ml or the brand of Wegovey 2.4mg/ml and 5mg/ml. Arizona law prohibits the compounding of commercially available products. Please see below:

32-1901. Definitions
11. "Compounding" means preparing, mixing, assembling, packaging or labeling a drug by a pharmacist or an intern or pharmacy technician under the pharmacist's supervision, for the purpose of dispensing to a patient based on a valid prescription order. Compounding includes preparing drugs in anticipation of prescription orders prepared on routine, regularly observed prescribing patterns and preparing drugs as an incident to research, teaching or chemical analysis or for administration by a medical practitioner to the medical practitioner's patient and not for sale or dispensing. Compounding does not include preparing commercially available products from bulk compounds or preparing drugs for sale to pharmacies, practitioners or entities for the purpose of dispensing or distribution.

A written response to the complaint should be sent no later than 11/30/22.

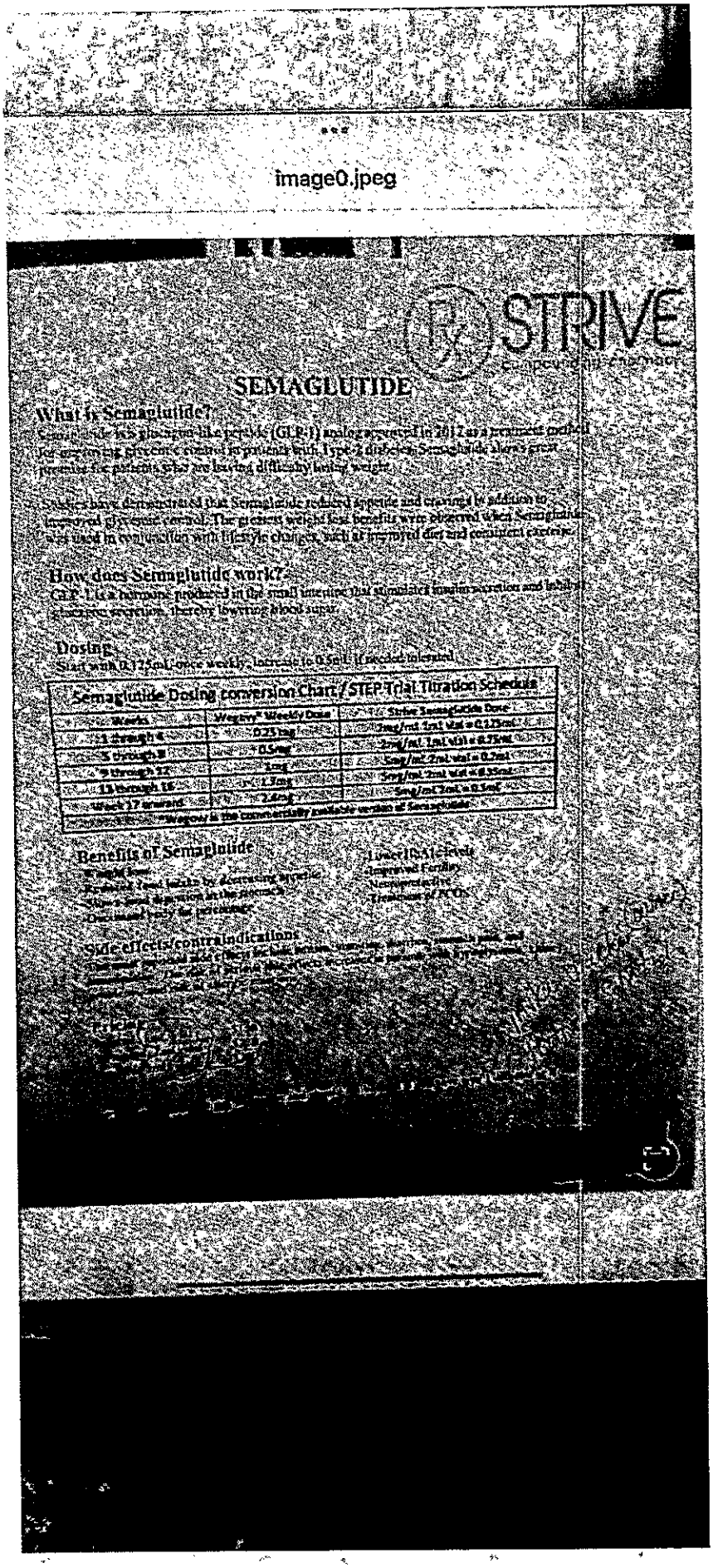
You may send the response and documents to my attention via e-mail (preferred), fax to 602-771-2749, or mail to PO Box 18520 Phoenix, AZ 85005-8520.

The Board will review the complaint and all information received in determining any potential action against permit Y007406.

Please contact me if you have any questions.

Karol Hess Pharm D. Rph
Compliance Officer
623-518-0336
khess@azpharmacy.gov

image0.jpeg



STRIVE
Empowered by pharmacy

SEMAGLUTIDE

What is Semaglutide?

Semaglutide is a glucagon-like peptide (GLP-1) analog approved in 2012 as a treatment method for overweight patients or patients with Type 2 diabetes. Semaglutide shows great promise for patients who are having difficulty losing weight.

Studies have demonstrated that Semaglutide reduced appetite and cravings in addition to improved glycemic control. The greatest weight loss benefits were observed when Semaglutide was used in combination with lifestyle changes, such as improved diet and consistent exercise.

How does Semaglutide work?

GLP-1 is a hormone produced in the small intestine that stimulates insulin secretion and inhibits glucagon secretion, thereby lowering blood sugar.

Dosing

Start with 0.125mL once weekly, increase to 0.5mL if needed/tolerated.

Semaglutide Dosing Conversion Chart / STEP Trial Titration Schedule

Weeks	Wegovy® Weekly Dose	Strive Semaglutide Dose
1 through 4	0.25 mg	2mg/mL 1mL vial = 0.125mL
5 through 8	0.5mg	2mg/mL 1mL vial = 0.25mL
9 through 12	1mg	5mg/mL 2mL vial = 0.2mL
13 through 16	1.7mg	5mg/mL 2mL vial = 0.35mL
Week 17 onward	2.4mg	5mg/mL 2mL vial = 0.5mL

*Wegovy is the commercially available version of Semaglutide

Benefits of Semaglutide

- Weight loss
- Reduced food intake by decreasing appetite
- Slows down digestion in the stomach
- Once weekly easy for patients

- Lower HbA1c levels
- Improved fertility
- Neuroprotective
- Treatment of PCOS

Side effects/contraindications

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Exhibit 3

480.626.4366 480.626.4365 info@strivepharmacy.com strivepharmacy.com
1275 E Baseline Rd Ste 104 Gilbert, AZ 85233

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Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
P) 602-771-2727 F) 602-771-2749
pharmacy.az.gov

March 15, 2023

Strive Pharmacy
1275 E. BASELINE ROAD 104
GILBERT, AZ 85233

Re: Complaint No. 22-0668

Dear Permit Holder:

The above-referenced complaint, involving Permit Number Y007406, will be reviewed by the Arizona State Board of Pharmacy at their meeting of April 5, 2023. Your presence is requested at that meeting.

Please be present at 8:30 a.m. and remain in the audience until your name is called by the President to come forth to speak with the Board Members.

Location: Arizona State Board of Pharmacy
1110 W. Washington, Suite 245
Phoenix, AZ 85007

Date & Time: April 5, 2023 - 8:30 a.m.

If you are unable to appear in person, you may appear virtually using Zoom. Please log on to the meeting using the following link - https://us02web.zoom.us/j/84966647190?pwd=MDhtdEw1Z2xkMEJsZDlBUGdTbGlmQT09.

Please notify Jennifer Mitchell, Executive Staff Assistant at jmitchell@azpharmacy.gov if you intend to appear virtually.

If you have any questions, please contact this office.

Sincerely,

Kam Gandhi

Kam Gandhi, PharmD
Executive Director

KG/jcm

cc: Alexander L. Snyder, Esq.

Arizona State Board of Pharmacy
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
P) 602-771-2727 F) 602-771-2749
pharmacy.az.gov

March 15, 2023

Michael Walker
[redacted] E CAMPBELL CT
GILBERT, AZ 85234

Re: Complaint No. 22-0668

Dear Mr. Walker:

The above-referenced complaint, involving License Number S021357, will be reviewed by the Arizona State Board of Pharmacy at their meeting of April 5, 2023. Your presence is requested at that meeting.

Please be present at 8:30 a.m. and remain in the audience until your name is called by the President to come forth to speak with the Board Members.

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1110 W. Washington, Suite 245
Phoenix, AZ 85007

Date & Time: April 5, 2023 - 8:30 a.m.

If you are unable to appear in person, you may appear virtually using Zoom. Please log on to the meeting using the following link - https://us02web.zoom.us/j/84966647190?pwd=MDhtdEw1Z2xkMEJsZDlBUGdTbGlmQT09.

Please notify Jennifer Mitchell, Executive Staff Assistant at jmitchell@azpharmacy.gov if you intend to appear virtually.

If you have any questions, please contact this office.

Sincerely,

Kam Gandhi

Kam Gandhi, PharmD
Executive Director

KG/jcm

cc: Alexander L. Snyder, Esq.

Arizona State Board of Pharmacy

COMPLAINT # 22-0668 Addendum

Compliance Officer: Sandy Sutcliffe/Dennis Waggoner
Date: 03/14/2023

Respondent(s): Strive Pharmacy Y007406
Michael Walker PIC S021357

Type of complaint: A pharmacy was allegedly compounding a commercially available product.

COMPLAINT SUMMARY

On 12/12/22 Compliance Officer Karol Hess requested additional information from Strive Pharmacy including compounding records for two lot numbers.

After review of the compounding records Compliance Officers Sandy Sutcliffe and Dennis Waggoner visited the pharmacy on 3/6/23 for certificates of analysis (CoA) and invoices.

1) Compounding components

Wegovy and Ozempic contain Semaglutide (base)-under patent by Novo Nordisk.

Information on the Novo Nordisk website for Wegovy or semaglutide indicates it is not sold for the purposes of compounding with other products.

Q and A for Wegovy: Is the semaglutide/Wegovy being offered by compounding pharmacies the same treatment as my Wegovy prescription? "We are aware that there are companies claiming to have availability of Wegovy or semaglutide. We want consumers and healthcare providers to know and be very clear that Novo Nordisk <u>does not</u> sell Wegovy (or its active ingredient, semaglutide) for the purposes of compounding with other products. We have not conducted studies to evaluate the safety and efficacy of Wegovy when compounded with other ingredients. Novo Nordisk is the only company that has FDA approval to market Wegovy and we supply it in a disposable single-use pen available by prescription only.

The pharmacy compounded originally with Semaglutide Acetate then changed to Semaglutide Sodium. See attached FD&C Act summary for 503a human drug compounding.

There is not a USP/NF monograph for Semaglutide

There are no FDA approved products that contain Semaglutide Sodium or Semaglutide Acetate.

Semaglutide is not found on the 503a bulk substances list.

None of the standard suppliers of APIs for pharmacy compounding show a Semaglutide product in their catalog-i.e. PCCA, Medisca, Spectrum, Fagron, Letco.

The pharmacy purchased their semaglutide products from Darmerica AZ permit # W003529 and now use Biopeptek AZ permit # M002065. Darmerica is registered with the FDA and was last inspected on 3/11/22. Biopeptek is a virtual manufacturer. The contracted manufacturing facility for Biopeptek in China is registered with the FDA and had no inspections in the FDA dashboard.

The Darmerica sodium invoices state: "Any products currently covered by valid US Patents are offered for R&D use in accordance with 35 USC 271(e)+A13(a)…Any patent infringement and resulting liability is solely at buyer risk." On the CoA documents for the sodium form there is a disclaimer "This is a bulk sodium salt form ingredient that requires further processing. The buyer is liable for any finished product patent infringement."

The Biopeptek CoA states: " This batch is tested and confirmed to specifications and analytical procedures of BPT-QC-SOP-1182; results comply with specifications. The reference document is the SOP. No semaglutide information was found on their website. The label on the Semaglutide Sodium states: "Caution: For manufacturing, processing, or prescription compounding."

Other online sources indicate the semaglutide products are for research only.

2) Recordkeeping

Compounding records provided at the request of CO Hess were from 3/23/22 for assigned lot LG5009866 and 4/18/22 for assigned lot LG5011288 and indicated the pharmacy compounded with Semaglutide Acetate (Darmerica lots DL6477 and DL6515).

Invoices received for the Darmerica lot numbers show the pharmacy purchased Semaglutide Sodium not Semaglutide Acetate. The compounding records were not updated to reflect the correct component used. LG5009866 was dispensed 38 times. LG5011288 was dispensed 28 times.

Per the PIC the pharmacy changed from compounding with Semaglutide Acetate to Semaglutide Sodium approximately December 2021.

Unknown how many pharmacy compounding records may be inaccurate or the individual pharmacists or technicians involved.

INVESTIGATION NOTES:

Documents:

Novo Nordisk Wegovy summary
APC summary compounding Semaglutide
FD&C Act summary
503a bulk substances list
Darmerica invoices/CoA
Biopeptek invoice/CoA/photos
Online semaglutide examples
Compounding worksheets
Rx detail two lots compounded
Stability/sterility analysis

RESPONSES:

Additional responses received to CO Hess' complaint investigation on 1/6/23 and 1/31/23 and are included.

The response from 1/6/23 indicated the pharmacy compounded the semaglutide product based on valid prescription orders with the intent of directly dispensing to patients. The compounded drug product is not essentially a copy of a commercially available drug product as it does not have the same, similar, or easily substitutable dosage strength.

The response from 1/31/23 indicated that the flexible dosing allowed by the compounded drug product provides practitioners with opportunities to better treat patients on an individual basis. Practitioner testimonials were included.

POSSIBLE VIOLATIONS: Michael Walker S021357

32-1901.01. Definition of unethical and unprofessional conduct; permittees; licensee

B. In this chapter, unless the context otherwise requires, for the purposes of disciplining a pharmacist or pharmacy intern, "unprofessional conduct" means the following, whether occurring in this state or elsewhere:

2. Violating any federal or state law, rule or regulation relating to the manufacture or distribution of drugs and devices or the practice of pharmacy.

10. Violating a federal or state law or administrative rule relating to marijuana, prescription-only drugs, narcotics, dangerous drugs, controlled substances or precursor chemicals when determined by the board or by conviction in a federal or state court.

R4-23-410(A)(I). Current Good Compounding Practices

A. This Section establishes the current good compounding practices to be used by a pharmacist licensed by the Board, in a pharmacy permitted by the Board, and in compliance with applicable federal and state law governing the practice of pharmacy.

I. A pharmacy permittee shall ensure that the pharmacist-in-charge establishes, implements, and complies with pharmaceutical product compounding controls that conform with the standards in this subsection.

1. Pharmaceutical product compounding procedures are available in either written form or electronically stored with printable documentation:

a. To ensure that a finished pharmaceutical product has the identity, strength, quality, and purity it is purported or represented to possess, the procedures include, for each pharmaceutical product compounded, a description of:

i. The components, their manufacturer, lot number, expiration date, and amounts, the order of component addition, if applicable, and the compounding process;

ii. The equipment and utensils used; and

iii. The pharmaceutical product container and closure system proper for the sterility and stability of the pharmaceutical product as it is intended to be used.

POSSIBLE VIOLATIONS: Strive Pharmacy Y007406

32-1901.01. Definition of unethical and unprofessional conduct; permittees; licensees

A. In this chapter, unless the context otherwise requires, for the purposes of disciplining a permittee, "unethical conduct" means the following, whether occurring in this state or elsewhere:

6. Violating a federal or state law or administrative rule relating to marijuana, prescription-only drugs, narcotics, dangerous drugs, controlled substances or precursor chemicals.

Arizona State Board of Pharmacy
Physical Address: 1110 W. Washington St., Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
P) 602-771-2727 F) 602-771-2749 www.azpharmacy.gov

COMPLAINT #22-0668

Board Staff: Karol Hess Compliance Officer
Date: December 1, 2022

Respondent(s):
Strive Pharmacy Y007406
Michael Walker S021357

SUBJECT: A pharmacy was allegedly compounding a commercially available product.

SUMMARY:

On November 15, 2022 Compliance Officer Sharon Richardson received an email from a competitor compounding pharmacy stating that the owner believed that Strive Pharmacy may be compounding a commercially available product. This email was accompanied by an advertisement from Strive Pharmacy for compounding Semaglutide (Ozempic® & Wygovy®). This advertisement indicates that Strive Pharmacy will compound Semaglutide injectable. According to the advertisement, the dosing schedule recommended for this product is exactly the same as the brand name Wygovy®, which is FDA approved for weight loss. The advertisement instructs doctors how to prescribe this product, making the proper conversions to equal the Wygovy® dose titration. A complaint was opened.

In August of 2021, Strive Pharmacy began compounding Semaglutide injectable. On November 15, 2022 Compliance Officer Karol Hess arrived at Strive Pharmacy and spoke with the owner, Michael Walker, regarding the complaint. Mr. Walker admitted to compounding Semaglutide. He stated that originally he had compounded the Semaglutide alone but after the advice of his attorney and concerns of possibly compounding a commercially available drug, he decided to begin marketing it with B12 (cyanacobalamin) to combat the nausea often associated with this medication. Cyanocobalamin injectable is also a commercially available drug and the recommended dosing schedule remained that of Wygovy®. Please see below chart of a comparison of available strengths for Ozempic®, Wygovy®, and Strive Semaglutide.

Drug Name	Strength 1	Strength 2	Strength 3	Strength 4	Strength 5
Ozempic	2mg/ml	4mg/3ml	8mg/3ml	NA	NA
Wygovy	0.25mg/0.5ml	0.5mg/0.5ml	1mg/0.5ml	1.7mg/0.75ml	2.4mg/0.75ml
Strive Semaglutide*	2mg/1ml	2.5/1ml	5mg/1ml	NA	NA

*All of the Semaglutide products compounded that contain Cyanocobalamin contain 1mg/ml of Cyanocobalamin – this does not appear to be patient specific

Mr. Walker also advised CO Hess that both Ozempic® and Wygovy® are currently on the FDA's shortage list and may be compounded. This is true; however, both brand name products appeared on the shortage list March 31, 2022. Mr. Walker began compounding this product in August of 2021, 7 months prior to the shortage. Please see the below chart for totals compounded in 2021 and 2022 prior to it appearing on the shortage list.

Total RX's filled in 2021		
Semagutide Inj	Semglutide/B12 Inj	Grand Total
275	0	283
Total RX's filled in 2022 through 3/31/2022		
Semagutide Inj	Semglutide/B12 Inj	Grand Total
1191	6	1197

Additional fill information is located on the spreadsheet within the evidentiary portion of this report.

(https://drive.google.com/drive/folders/1zWHPNHv6FCTgrVLKwhRc_p8B5hS6N4FK)

According to this spreadsheet it appears that Mr. Walker often made batches of these compounds. This was confirmed via an email dated December 1, 2022.

According to a guidance document printed by the FDA in January of 2018;
"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."

INVESTIGATION NOTES:
Included for Board review:

- A copy of the complaint letter provided to Strive Pharmacy
- Response from Mr. Walker
- A copy of the fill spread sheet for Strive Semaglutide from 8/2021 through 11/2022
- A copy of the advertisement for Strive Pharmacy's Semaglutide
  A copy of FDA's guidance document entitled, "Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product under Section 503A of the Federal Food, Drug, and Cosmetic Act"
- A copy of two articles provided by Mr. Walker
- Email communications pertaining to complaint

LICENSEE/PERMITEE RESPONSE
Mr. Walker makes several assertions within his response. The first comes from 21 U.S.C. 353. He quotes....

> ""the pharmacy must not compound "regularly or in inordinate amounts" drugs that are "essentially copies of commercially available drug products." 21 U.S.C. 353a (b) (1)(d).""

Mr. Walker offers no definition of "regularly or inordinate amounts".

A guidance document provided by the FDA entitled,
Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product under Section 503A of the Federal Food, Drug, and Cosmetic Act, states the following: .....

> "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 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]

Mr. Walker's second assertion again references 21 U.S.C 353. He states;

> ""The FDCA provides that the phrase "'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.""

> ""21 U.S.C. 353a (b) (2). Similarly, for a drug compounded by a registered 503B outsourcing facility to be exempt from certain requirements of the FDCA, the drug must not be "**essentially a copy of *one or more* approved drugs**." 21 U.S.C. 353b (a) (5).""

The products Mr. Walker was compounding in 2021 did not contain a change. Some of the drugs compounded in 2022 contained Cyanocobalamin, also a FDA approved and commercially available drug. Furthermore, within this document the FDA qualifies "an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner..." to mean;

"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)

Mr. Walker then cites an article that discusses the promise of using B12 with glucagon-like peptide-1 receptor (GLP-1R) agonists to combat the nausea associated with these drugs (attached). Unfortunately, this article and the research it covers were done on rats not humans. Mr. Walker offered no evidence of research done in humans.

POSSIBLE VIOLATIONS:

Strive Pharmacy Y007406

32-1901. Definitions
In this chapter, unless the context otherwise requires:
11. "Compounding" means preparing, mixing, assembling, packaging or labeling a drug by a pharmacist or an intern or pharmacy technician under the pharmacist's supervision, for the purpose of dispensing to a patient based on a valid prescription order. Compounding includes preparing drugs in anticipation of prescription orders prepared on routine, regularly observed prescribing patterns and preparing drugs as an incident to research, teaching or chemical analysis or for administration by a medical practitioner to the medical practitioner's patient and not for sale or dispensing. Compounding does not include preparing commercially available products from bulk compounds or preparing drugs for sale to pharmacies, practitioners or entities for the purpose of dispensing or distribution.

R4-23-410. Current Good Compounding Practices
A. This Section establishes the current good compounding practices to be used by a pharmacist licensed by the Board, in a pharmacy permitted by the Board, and in compliance with applicable federal and state law governing the practice of pharmacy

Michael Walker S021357

32-1901. Definitions
In this chapter, unless the context otherwise requires:
11. "Compounding" means preparing, mixing, assembling, packaging or labeling a drug by a pharmacist or an intern or pharmacy technician under the pharmacist's supervision, for the purpose of dispensing to a patient based on a valid prescription order. Compounding includes preparing drugs in anticipation of prescription orders prepared on routine, regularly observed prescribing patterns and preparing drugs as an incident to research, teaching or chemical analysis or for administration by a medical practitioner to the medical practitioner's patient and not for sale or dispensing. Compounding does not include preparing commercially available products from bulk compounds or preparing drugs for sale to pharmacies, practitioners or entities for the purpose of dispensing or distribution.

R4-23-410. Current Good Compounding Practices

A. This Section establishes the current good compounding practices to be used by a pharmacist licensed by the Board, in a pharmacy permitted by the Board, and in compliance with applicable federal and state law governing the practice of pharmacy

STRIVE
compounding pharmacy

Exhibit 4

480.626.4366 480.626.4365 info@strivepharmacy.com strivepharmacy.com
1275 E Baseline Rd Ste 104 Gilbert, AZ 85233

Quarles

One Renaissance Square
Two North Central Avenue
Suite 600
Phoenix, AZ 85004-2322
602-229-5200
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January 6, 2023

VIA ELECTRONIC MAIL
Kam Gandhi
Executive Director
Arizona State Board of Pharmacy
11106 W Adams, Suite 260
Phoenix, Arizona 85007

RE: Supplemental Response to Complaint 22-0668 (Permit No. Y007406)

Dear Mr. Gandhi:

This firm represents Strive Compounding Pharmacy (the "Pharmacy"), Permit No. Y007406. We submit this supplemental response in regard to the Arizona Board of Pharmacy's (the "Board") Complaint 22-0668, which alleges that the Pharmacy compounded semaglutide injection drug products when an alternative commercially available product exists. The commercially available drug products in question include Ozempic and Wegovy. The Pharmacy takes these allegations seriously, but can assure the Board that it was not compounding drug products that would be considered an essential copy of the commercially available products, but rather, it appropriately compounded the semaglutide injection drug products at issue for the purpose of dispensing to patients based on valid prescription orders from practitioners for legitimate medical purposes.

I. Commercial Pharmaceutical Market Landscape

In 2017, Ozempic was approved by the U.S. Food and Drug Administration ("FDA") to improve blood sugar control in patients with type 2 diabetes mellitus ("DM") when used in addition to diet and exercise.[1] Ozempic works as a glucagon-like peptide-1 ("GLP-1") agonist stimulating insulin production and lowering glucagon secretion in a glucose-dependent manner

[1] *See* Drug Trial Snapshot: Ozempic, U.S. Food & Drug Administration, https://www fda.gov/drugs/drug-approvals-and-databases/drug-trial-snapshot-ozempic (last updated Aug. 20, 2020)(citing the FDA approval date as December 5, 2017).

showing particularly positive effects by lowering HbA1c levels in patients.[2] The GLP-1 agonist also target areas of the brain that regulate appetite and food intake, causing patients to feel more satiated while reducing their appetite, leading to weight loss overall. As a result of this notable positive side effect, Novo Nordisk, the manufacturer of Ozempic, sought an additional FDA-approved indication for weight loss separate from DM management. On June 4, 2021, the FDA approved Wegovy for chronic weight management in adults with obesity or who are overweight with at least on weight-related condition (such as hypertension, type 2 DM, or hypercholesterolemia).[3]

As the first weight loss drug approved by the FDA since 2014,[4] Wegovy has received significant popularity due to its weight loss benefits.[5] On March 31, 2022, less than a year after its approval, Wegovy was placed on the FDA drug shortage list.[6] While the supply of Wegovy was diminished, patient demand did not dwindle. As a reasonable alternative to accommodate patients, practitioners turned to Ozempic for off-label use in patients for weight loss.[7] Unsurprisingly, Ozempic was then placed on the FDA drug shortage list on August 23, 2022.[8] As such, diabetic patients who have become dependent on this type of drug therapy have been struggling to find Ozempic or other similar diabetic drugs found to cause weight loss.[9] The approval of Wegovy in 2021 resulted in significant patient demand, which the manufacturer likely did not anticipate, leaving patients who relied upon these types of medications struggling to obtain drugs they needed.

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[2] *See* Ozempic® [package insert]. Plainsboro, NJ: Novo Nordisk Inc; 2017. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209637s003lbl.pdf.

[3] *See* Press Release, U.S. Food & Drug Administration, FDA Approves New Drug Treatment for Chronic Weight Management, First Since 2014 (June 4, 2021), https://www fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weight-management-first-2014.

[4] *Id.*

[5] *See* Janice Kew, *A New Weight-Loss Medicine Is Flying Off the Shelves*, BLOOMBERG (Nov. 3, 2021), https://www.bloomberg.com/news/articles/2021-11-03/drugmaker-struggles-to-meet-demand-for-new-weight-loss-medicine#xj4y7vzkg.

[6] *See* FDA Drug Shortages, Current and Resolved Drug Shortages and Discontinuations Reported to FDA, U.S. Food and Drug Administration: Semaglutide (WEGOVY), https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Semaglutide%20(WEGOVY%C2%AE)%20Injection&st=c (last visited Jan. 4, 2023).

[7] *See generally* HealthDay, *Diabetes Med Ozempic in Short Supply as Americans Use It for Weight Loss*, U.S. NEWS (Dec. 21, 2022), https://www.usnews.com/news/health-news/articles/2022-12-21/diabetes-med-ozempic-in-short-supply-as-americans-use-it-for-weight-loss.

[8] *See* FDA Drug Shortages, Current and Resolved Drug Shortages and Discontinuations Reported to FDA, U.S. Food and Drug Administration, Semaglutide (Ozempic), https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Semaglutide%20(Ozempic)%20Injection&st=c (last visited Jan. 5, 2023).

[9] *See generally* Emma Court, *TikTok trend wipes out Ozempic supply, leaving people with diabetes dizzy, scared*, L.A. TIMES (Dec. 23, 2022), https://www.latimes.com/business/story/2022-12-23/tiktok-trend-sold-out-ozempic-diabetes-drug; *see also* Arianna Johnson, *What To Know About Ozempic: The Diabetes Drug Becomes A Viral Weight Loss Hit (Elon Musk Boasts Using It) Creating A Shortage*, FORBES (Dec. 28, 2022), https://www.forbes.com/sites/ariannajohnson/2022/12/26/what-to-know-about-ozempic/?sh=167ec2f75adb; *see also* Brittany Spanos, *Who Deserves the New 'Miracle' Weight-Loss Drugs?*, ROLLINGSTONE (Dec. 7, 2022), https://www.rollingstone.com/culture/culture-features/ozempic-wegovy-tiktok-miracle-weight-loss-1234642896/.

II. Factual History

The Pharmacy has been licensed for approximately five (5) years with the Board. During this time, the Pharmacy has never been disciplined or received a non-disciplinary warning from the Board. Additionally, Michael Walker, the pharmacist listed on the complaint is properly licensed in Arizona in good standing with no disciplinary action.

In August 2021, only a couple months after Wegovy was approved for use, the Pharmacy began to compound semaglutide injection products at a 2 mg/mL concentration pursuant to practitioner prescription orders. According to the Complaint, the commercially available products the Pharmacy is accused of compounding include Wegovy 2.4 mg/mL and 5 mg/mL and Ozempic 2 mg/mL. It is important to note, however, that there is a slight alteration to the dosage strengths listed in the Complaint, as Ozempic is only available as a concentration of 2 mg/ 1.5 mL, as opposed to the strength listed in the Complaint, and Wegovy's highest available concentration is 2.4 mg/ 0.75 mL, as opposed to the strengths listed in the Complaint.

Over the next eight months, the amount of prescription orders for semaglutide injection products processed by the Pharmacy steadily increased, seemingly in tandem with patient increased demand and decreased supply experienced in the market. As stated previously, Wegovy was first placed on the FDA drug shortage list in March 2022.[10] During that period, the Pharmacy was free to compound semaglutide injection products based on FDA guidance claiming that drugs on the shortage list are no longer considered a commercially available drug product.[11] However, even before the drug was placed on the FDA drug shortage list, the Pharmacy: (1) compounded this drug product pursuant to valid prescription orders from practitioners pursuant to Arizona law; and (2) compounded this drug product at differing dosage strengths, so such compounded drug product was not essentially a copy of commercially available products.

III. Defintion of "Compounding" under Arizona Law

Under Arizona law, FDA 503A compounding pharmacies are permitted to compound drug products from active pharmaceutical ingredients ("API") prepared by FDA registered manufacturers if the patient has decided they would prefer treatments obtained from a compounding pharmacy. *See* Ariz. Rev. Stat. § 32-1971. To that end, Arizona law defines "compounding" as ". . . preparing, mixing, assembling, packaging or labeling a drug by a pharmacist or an intern or pharmacy technician under the pharmacist's supervision, for the purpose of dispensing to a patient *based on a valid prescription orde*r . . . ." Ariz. Rev. Stat. § 32-1901(11)(emphasis added).

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[10] *See* WEGOVY, *supra* note 6.

[11] *See* Food and Drug Administration, Center for Drug Evaluation and Research, Compounding 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 (Jan. 2018), https://www fda.gov/media/98973/download (last visited Dec. 30, 2022).

The Pharmacy has compounded this drug product at the request of practitioners pursuant to valid prescription orders. Pursuant to Arizona law, patients maintain their right to select a compounded drug product. The Pharmacy compounded semaglutide injection drug products with the intent of dispensing directly to patients. As such, the Pharmacy was not engaged in manufacturing and was not acting outside its scope of practice as a properly permitted 503A compounding pharmacy. Accordingly, the Pharmacy's processes are clearly in compliance with the definition of "compounding" under Arizona law. Examples of prescription orders made pursuant to a valid prescription that were filled and dispensed by the Pharmacy are included in **Exhibit A**.

IV. Based on FDA guidance, the compounded semaglutide injection here is not *essentially a copy* of commercially available drug product

Arizona law is clear that "compounding" does not include preparing commercially available drug products. *See* Ariz. Rev. Stat. § 32-1901(11). That said, Arizona law does not include any provision detailing what constitutes "preparing a commercially available product." Fortunately, however, the FDA provides guidance on this issue.[12]

Section 503A of the Food, Drug, and Cosmetic Act allows pharmacists to compound drug products pursuant to a valid prescription drug order for a patient without the need of complying with certain manufacturing requirements so long as certain conditions are met. Relevant to the issue here, a pharmacist may compound drug products so long as the pharmacist "does not compound regularly or in inordinate amounts of any drug products that are *essentially copies* of a commercially available drug product." 21 U.S.C.A. § 353a(b)(1)(D)(emphasis added). When analyzing whether this condition is met, the FDA will first determine whether a compounded drug product is *essentially a copy of a commercially available drug product.*

According to FDA guidance, the FDA considers the following three (3) factors when determining whether a compounded drug product is essentially a copy of a commercially available drug product: (1) the compounded drug product has the same API as the commercially available drug product; (2) the API has the same, similar, or an easily substitutable dosage strength; and (3) the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug.[13]

While the Pharmacy's compounded drug product has the same API as the commercially available drug product and the commercially available drug product can be used by the same route of administration as prescribed for the compounded product (a subcutaneous injectable solution), the compounded drug product does not have the same, similar, or an easily substitutable dosage strength when compared to the commercially available drug product. According to FDA guidance,

[12] *See id.*
[13] *Id.*

two drugs are considered to have similar dosage strength if the dosage strength of the compounded drug is within 10% of the dosage strength of the commercially available drug product.

The Pharmacy's compounded drug product contains semaglutide at a dosage strength of 2 mg/mL available in a vial. On the other hand, Ozempic comes available in pre-filled, disposable, single-patient-use pens for diabetes management.[14] Due to adverse gastrointestinal reactions, Ozempic requires a titration schedule to achieve a 0.5 mg maintenance dose allowing for stronger dosing if necessary or tolerable.[15] Ozempic's pre-filled pens come in various dosage strengths including 2 mg/ 3 mL, 2 mg/ 1.5 mL, 4 mg/ 3 mL, and 8 mg/ 3 mL.[16] Similarly, Wegovy is injected subcutaneously using pre-filled, disposable, single-dose pens, but is instead indicated for weight loss management.[17] Wegovy relies upon a dose escalation schedule to achieve the maintenance dose of 2.4 mg/ 0.75 mL.[18] In both commercial products, the semaglutide solution comes in pre-filled pens designed to simplify the injection process for patients. Again, the Pharmacy's compounded drug product contains semaglutide at a dosage strength of 2 mg/mL. When compared to the commercially available product, the dosage strength of 2 mg/mL is not within 10% of the commercially available drug product dosage strengths alluded to in the Compliant. As a result, the Pharmacy's compounded drug product is not considered to have a similar dosage strength as the commercially available drug product, and therefore, the Pharmacy's compounded drug product is not essentially a copy of a commercially available drug product.

Further, it is important to note that since the compounded drug product comes available in a vial as opposed to the commercial pre-filled pen, it allows practitioners greater flexibility when prescribing semaglutide products on a patient-by-patient basis. Examples of practitioners using the flexibility permitted by the Pharmacy's compounded drug products are included in **Exhibit B**. This flexibility further supports that the Pharmacy's compounded product is not essentially a copy of the commercially available drug product.

V. Conclusion

The Pharmacy understands the seriousness associated with the potential compounding of a commercially available drug product. As the Complaint progresses through the administrative process, we may submit additional supplemental responses as necessary, in hopes of providing the Board with a clearer picture of the facts surrounding this Complaint.

That said, we respectfully request that, when reviewing this Complaint, the Board carefully consider the market conditions specifically related to the supply shortage of theses particular

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[14] *See* Ozempic®, *supra* note 2.
[15] *Id.*
[16] *See* Ozempic: Package Insert/Prescribing information, https://www.drugs.com/pro/ozempic.html (last updated Oct. 1, 2022)
[17] *See* WEGOVY [package insert]. Plainsboro, NJ: Novo Nordisk Inc; 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215256s000lbl.pdf.
[18] *Id.*; Referenced dose escalation schedule requires 0.25 mg/ 0.5 mL, 0.5 mg/ 0.5 mL, 1 mg/ 0.5 mL, and 1.7 mg/ 0.75 mL pre-filled pens.

commercially available drug products and the fact that the Pharmacy compounded drug products with different dosage strengths than the commercially available drug products.

Very truly yours,

Roger N. Morris, JD, RPh

Alexander Snyder, JD, PharmD

- **Exhibit A:**
    - Patient Rx: #525304
    - Patient Rx: #525442
    - Patient Rx: #525529
    - Patient Rx: #525531
- **Exhibit B:**
    - Patient Rx: #526119
    - Patient Rx: #526133
    - Patient Rx: #526003
    - Patient Rx: #525505

EXHIBIT A

VITALITY SCOTTSDALE

8764 E SHEA BLVD, SCOTTSDALE, AZ 85260
Phone: 480-948-3050, Fax: 480-948-1680
Date: Mar/24/2022 11:44:14 AM (PDT)

ELIZABETH SADLER DEA #MS3446540 State Lic. AZAP7554

ELIZABETH SADLER

Electronic Prescription Refill Order

Name:	[redacted]	Last Name:	[redacted]	Middle Name:	
Phone:		Cell Phone:	[redacted]	DOB:	[redacted]
Address:	[redacted]	Address (Cont):		Email:	
City:		State:	AZ	Zip:	
Gender:		Pay Type:		Ins. Name:	
Group Name:		Ins. Phone:		Member ID:	
Ins. Control Number:		Ins. BIN:		Delivery Type:	**Delivery**
Driver's License Number:		Driver's License State:			

#1 Semaglutide INJ
Strength: 2 mg/ml====
Quantity: 1 ml (one)====
Refills: 0====
Directions: INJECT 15 UNITS SUBCUTANEOUSLY ONCE WEEKLY FOR 2 WEEKS, THEN INJECT 25 UNITS SUBCUTANEOUSLY ONCE WEEKLY====
Dispensation: ====
Days Supply: 30====
Special Instructions: ====
Date Written: 03/24/2022 (Mar 24, 2022)====

Special Instructions:

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: ELIZABETH SADLER Date: Mar/24/2022 11:44:14 AM (PDT)
Signed electronically by: ELIZABETH SADLER

Strivepharmacy
1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy System

Order #75289717

Rx: **525304**	Date Written: **03/24/22**
Patient Name: [redacted]	Drug Name: **Semaglutide**
Patient DOB: [redacted]	Strength: **2 mg/ml**
Patient Address: [redacted]	Quantity Ordered: **1**
Doctor Name: **ELIZABETH SADLER**	Quantity Dispensed: **1**
Doctor Address: [redacted] **E SHEA BLVD**	Directions: **INJECT 15 UNITS (0.15ML) SUBCUTANEOUSLY ONCE WEEKLY FOR 2 WEEKS, THEN INJECT 25 UNITS (0.25ML) ONCE WEEKLY**
Doctor DEA: **MS3446540**	Refills: **0**

COME THRU WEIGHT LOSS

17248 W MOLLY LN, SURPRISE, AZ 85387
Phone: 4806405894, Fax:
Date: Mar/24/2022 05:34:54 PM (PDT)

APRIL RENEE FATINA FNP DEA #MF7011808 State Lic. AZ267723

APRIL RENEE FATINA FNP

Electronic Prescription Refill Order

Name:	[redacted]	Last Name:	[redacted]	Middle Name:	
Phone:		Cell Phone:		DOB:	[redacted]
Address:		Address (Cont):		Email:	
City:		State:	AZ	Zip:	
Gender:		Pay Type:		Ins. Name:	
Group Name:		Ins. Phone:		Member ID:	
Ins. Control Number:		Ins. BIN:		Delivery Type:	Delivery
Driver's License Number:	[redacted]	Driver's License State:	AZ		

#1 Semaglutide INJ
Strength: 2 mg/ml====
Quantity: 1 ml (one)====
Refills: 0====
Directions: INJECT 25 UNITS SUBCUTANEOUSLY ONCE WEEKLY====
Dispensation: ====
Days Supply: 30====
Special Instructions: ====
Date Written: 03/24/2022 (Mar 24, 2022)====

Special Instructions: CONTACT PRESCRIBER FOR ALL BILLING INQUIRIES

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: APRIL RENEE FATINA FNP Date: Mar/24/2022 05:34:54 PM (PDT)
Signed electronically by: APRIL RENEE FATINA FNP

Strivepharmacy
1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy System

Order #75295346

Rx: **525442**	Date Written: **03/24/22**
Patient Name: [redacted]	Drug Name: **Semaglutide**
Patient DOB: [redacted]	Strength: **2 mg/ml**
Patient Address: [redacted]	Quantity Ordered: **1**
Doctor Name: **APRIL RENEE FATINA FNP**	Quantity Dispensed: **1**
Doctor Address: [redacted] **N 123rd Ave**	Directions: **INJECT 0.25 ML (25 UNITS) SUBCUTANEOUSLY ONCE WEEKLY**
Doctor DEA: **MF7011808**	Refills: **0**

GENISIS MED SPA

4801 N UNIVERSITY AVE, PROVO, UT 84604
Phone: 801-852-0033, Fax: 801-494-1595
Date: Mar/25/2022 02:09:17 PM (CST)

STANLEY R SMITH MD DEA #BS8562274 State Lic. AZ34173

STANLEY R SMITH MD

Electronic Prescription Order

Name:	[redacted]	Last Name:	[redacted]	Middle Name:	
Phone:		Cell Phone:		DOB:	
Address:		Address (Cont):		Email:	[redacted]
City:		State:		Zip:	
Gender:		Pay Type:		Ins. Name:	
Group Name:		Ins. Phone:		Member ID:	
Ins. Control Number:		Ins. BIN:		Delivery Type:	**UPS Ground**
Driver's License Number:		Driver's License State:			

#1 Semaglutide INJ

Strength: 2 mg/ml====
Quantity: 1 ml (one)====
Refills: 0====
Directions: Inject 0.25 ml (0.5 mg) subcutaneously once weekly for 4 weeks====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 30====
Special Instructions: Weeks 5-8====
Date Written: 03/25/2022 (Mar 25, 2022)====
Ship to: Brown, Jason: 4801 N UNIVERSITY AVE SUITE 150 , PROVO, UT, 84604 , Phone: 801-852-0033 . ====

#2 Semaglutide INJ

Strength: 2 mg/ml====
Quantity: 1 ml (one)====
Refills: 0====
Directions: Inject 0.125 ml (0.25 mg) subcutaneously once weekly for 4 weeks====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 30====
Special Instructions: Weeks 1-4====
Date Written: 03/25/2022 (Mar 25, 2022)====
Ship to: Brown, Jason: 4801 N UNIVERSITY AVE SUITE 150 , PROVO, UT, 84604 , Phone: 801-852-0033 . ====

Special Instructions: - **Allergies:** NO KNOWN ALLERGIES; - **Diagnosis:** Overweight;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: STANLEY R SMITH MD Date: Mar/25/2022 02:09:17 PM (CST)
Signed electronically by: STANLEY R SMITH MD

Strivepharmacy
1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy System

Order #75295628

Rx: **525529**	Date Written: **03/25/22**
Patient Name: [redacted]	Drug Name: **Semaglutide**
Patient DOB: [redacted]	Strength: **2 mg/ml**
Patient Address: [redacted]	Quantity Ordered: **1**
Doctor Name: **STANLEY R SMITH MD**	Quantity Dispensed: **1**
Doctor Address: [redacted] **N UNIVERSITY AVE**	Directions: **INJECT 0.25 ML (25 UNITS) SUBCUTANEOUSLY ONCE WEEKLY WEEKS 5-8**
Doctor DEA: **BS8562274**	Refills: **0**

GENISIS MED SPA

4801 N UNIVERSITY AVE, PROVO, UT 84604
Phone: 801-852-0033, Fax: 801-494-1595
Date: Mar/25/2022 02:09:17 PM (CST)

STANLEY R SMITH MD DEA #BS8562274 State Lic. AZ34173

STANLEY R SMITH MD

Electronic Prescription Order

Name: [redacted]
Phone:
Address:
City:
Gender:
Group Name:
Ins. Control Number:
Driver's License Number:

Last Name: [redacted]
Cell Phone:
Address (Cont):
State:
Pay Type:
Ins. Phone:
Ins. BIN:
Driver's License State:

Middle Name:
DOB:
Email:
Zip:
Ins. Name:
Member ID:
Delivery Type: **UPS Ground**

#1 **Semaglutide INJ**
Strength: 2 mg/ml====
Quantity: 1 ml (one)====
Refills: 0====
Directions: Inject 0.25 ml (0.5 mg) subcutaneously once weekly for 4 weeks====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 30====
Special Instructions: Weeks 5-8====
Date Written: 03/25/2022 (Mar 25, 2022)====
Ship to: Brown, Jason: 4801 N UNIVERSITY AVE SUITE 150 , PROVO, UT, 84604 , Phone: 801-852-0033 . ====

#2 **Semaglutide INJ**
Strength: 2 mg/ml====
Quantity: 1 ml (one)====
Refills: 0====
Directions: Inject 0.125 ml (0.25 mg) subcutaneously once weekly for 4 weeks====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 30====
Special Instructions: Weeks 1-4====
Date Written: 03/25/2022 (Mar 25, 2022)====
Ship to: Brown, Jason: 4801 N UNIVERSITY AVE SUITE 150 , PROVO, UT, 84604 , Phone: 801-852-0033 . ====

Special Instructions: - **Allergies:** NO KNOWN ALLERGIES; - **Diagnosis:** Overweight;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: STANLEY R SMITH MD Date: Mar/25/2022 02:09:17 PM (CST)
Signed electronically by: STANLEY R SMITH MD

Strivepharmacy
1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy System

Order #75295628

Rx: **525530**	Date Written: **03/25/22**
Patient Name: [redacted]	Drug Name: **Semaglutide**
Patient DOB: [redacted]	Strength: **2 mg/ml**
Patient Address: [redacted]	Quantity Ordered: **1**
Doctor Name: **STANLEY R SMITH MD**	Quantity Dispensed: **1**
Doctor Address: [redacted]**N UNIVERSITY AVE**	Directions: **INJECT 0.125 ML (12.5 UNITS) SUBCUTANEOUSLY ONCE WEEKLY WEEKS 1-4**
Doctor DEA: **BS8562274**	Refills: **0**

GENISIS MED SPA

4801 N UNIVERSITY AVE, PROVO, UT 84604
Phone: 801-852-0033, Fax: 801-494-1595
Date: Mar/25/2022 02:09:50 PM (CST)

STANLEY R SMITH MD DEA #BS8562274 State Lic. AZ34173

STANLEY R SMITH MD

Electronic Prescription Order

Name: [redacted]
Phone:
Address:
City:
Gender:
Group Name:
Ins. Control Number:
Driver's License Number:

Last Name: [redacted]
Cell Phone:
Address (Cont):
State:
Pay Type:
Ins. Phone:
Ins. BIN:
Driver's License State:

Middle Name:
DOB:
Email:
Zip:
Ins. Name:
Member ID:
Delivery Type: **UPS Ground**

#1 Semaglutide INJ

Strength: 2 mg/ml====
Quantity: 1 ml (one)====
Refills: 0====
Directions: Inject 0.25 ml (0.5 mg) subcutaneously once weekly for 4 weeks====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 30====
Special Instructions: Weeks 5-8====
Date Written: 03/25/2022 (Mar 25, 2022)====

#2 Semaglutide INJ

Strength: 2 mg/ml====
Quantity: 1 ml (one)====
Refills: 0====
Directions: Inject 0.125 ml (0.25 mg) subcutaneously once weekly for 4 weeks====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 30====
Special Instructions: Weeks 1-4====
Date Written: 03/25/2022 (Mar 25, 2022)====

Special Instructions: - **Allergies:** NO KNOWN ALLERGIES; - **Diagnosis:** Overweight;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: STANLEY R SMITH MD Date: Mar/25/2022 02:09:50 PM (CST)
Signed electronically by: STANLEY R SMITH MD

Strivepharmacy
1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy System

Order #75295631

Rx: **525531**	Date Written: **03/25/22**
Patient Name: [redacted]	Drug Name: **Semaglutide**
Patient DOB:	Strength: **2 mg/ml**
Patient Address: [redacted]	Quantity Ordered: **1**
Doctor Name: **STANLEY R SMITH MD**	Quantity Dispensed: **1**
Doctor Address: [redacted]**N UNIVERSITY AVE**	Directions: **INJECT 0.25 ML (25 UNITS) SUBCUTANEOUSLY ONCE WEEKLY WEEKS 5-8**
Doctor DEA: **BS8562274**	Refills: **0**

GENISIS MED SPA

4801 N UNIVERSITY AVE, PROVO, UT 84604
Phone: 801-852-0033, Fax: 801-494-1595
Date: Mar/25/2022 02:09:50 PM (CST)

STANLEY R SMITH MD DEA #BS8562274 State Lic. AZ34173

STANLEY R SMITH MD

Electronic Prescription Order

Name: [redacted]
Phone:
Address:
City:
Gender:
Group Name:
Ins. Control Number:
Driver's License Number:

Last Name: [redacted]
Cell Phone:
Address (Cont):
State:
Pay Type:
Ins. Phone:
Ins. BIN:
Driver's License State:

Middle Name:
DOB:
Email: [redacted]
Zip:
Ins. Name:
Member ID:
Delivery Type: **UPS Ground**

#1 Semaglutide INJ

Strength: 2 mg/ml====
Quantity: 1 ml (one)====
Refills: 0====
Directions: Inject 0.25 ml (0.5 mg) subcutaneously once weekly for 4 weeks====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 30====
Special Instructions: Weeks 5-8====
Date Written: 03/25/2022 (Mar 25, 2022)====

#2 Semaglutide INJ

Strength: 2 mg/ml====
Quantity: 1 ml (one)====
Refills: 0====
Directions: Inject 0.125 ml (0.25 mg) subcutaneously once weekly for 4 weeks====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 30====
Special Instructions: Weeks 1-4====
Date Written: 03/25/2022 (Mar 25, 2022)====

Special Instructions: - **Allergies:** NO KNOWN ALLERGIES; - **Diagnosis:** Overweight;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: STANLEY R SMITH MD Date: Mar/25/2022 02:09:50 PM (CST)
Signed electronically by: STANLEY R SMITH MD

Strivepharmacy
1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy System

Order #7295631

Rx: **525532**	Date Written: **03/25/22**
Patient Name: [redacted]	Drug Name: **Semaglutide**
Patient DOB: [redacted]	Strength: **2 mg/ml**
Patient Address: [redacted]	Quantity Ordered: **1**
Doctor Name: **STANLEY R SMITH MD**	Quantity Dispensed: **1**
Doctor Address: [redacted] **N UNIVERSITY AVE**	Directions: **INJECT 0.125 ML (12.5 UNITS) SUBCUTANEOUSLY ONCE WEEKLY WEEKS 1-4**
Doctor DEA: **BS8562274**	Refills: **0**

EXHIBIT B

TELEPHONE PRE [redacted]

RX NUMBER

DATE 3/30/22

NAME [redacted]

ADDRESS [redacted]

PHONED BY [redacted] TIME DELIVER WILL CALL

ORIGINAL Rx NO DO NOT REFILL ☐ REFILL 0 TIMES

Semaglutide 2 mg/mL = # 1 mL

inject 10 units q week

(previous dose from other pharmacy) shes on wks 5-8

MC. ☐

PVT. ☐

LABEL: YES ☐ NO

303 669 9227 Wayne Furr

PHARMACIST DR'S PHONE DOCTOR

DEA NO.

DR'S ADDRESS

BioRx Labs 1-888-550-5450 FORM NO.PD2600

Rx: **526119**	Date Written: **03/30/22**
Patient Name: [redacted]	Drug Name: **Semaglutide**
Patient DOB: [redacted]	Strength: **2 mg/ml**
Patient Address: [redacted]	Quantity Ordered: **1**
Doctor Name: **WAYNE CHARLES FURR MD**	Quantity Dispensed: **1**
Doctor Address: **10465 PARK MEADOWS DR**	Directions: **INJECT 0.1 ML (10 UNITS) ONCE WEEKLY**
Doctor DEA: **BF5374602**	Refills: **0**

VITALITY SCOTTSDALE

8764 E SHEA BLVD, SCOTTSDALE, AZ 85260
Phone: 480-948-3050, Fax: 480-948-1680
Date: Mar/30/2022 11:09:39 AM (PDT)

ELIZABETH SADLER DEA #MS3446540 State Lic. AZAP7554
ELIZABETH SADLER

Electronic Prescription Order

Name:	[redacted]	Last Name:	[redacted]	Middle Name:	
Phone:		Cell Phone:		DOB:	[redacted]
Address:		Address (Cont):		Email:	
City:		State:		Zip:	
Gender:		Pay Type:		Ins. Name:	
Group Name:		Ins. Phone:		Member ID:	
Ins. Control Number:		Ins. BIN:		Delivery Type:	**UPS Ground**
Driver's License Number:		Driver's License State:			

#1 Semaglutide INJ
Strength: 2 mg/ml====
Quantity: 1 ml (one)====
Refills: 0====
Directions: inject 15units SQ 1x a week for 2 weeks & then 25units SQ 1x weekly====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 30====
Special Instructions: please include QS insulin needles&alcohol swabs====
Date Written: 03/30/2022 (Mar 30, 2022)====
Ship to: SADLER, ELIZABETH: 8764 E SHEA BLVD SUITE 109 , SCOTTSDALE, AZ, 85260 , Phone: 480-948-3050 , Email: scottsdalevitality@gmail.com. ====

Special Instructions: - Allergies: ; - Diagnosis: ;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: ELIZABETH SADLER Date: Mar/30/2022 11:09:39 AM (PDT)
Signed electronically by: ELIZABETH SADLER

Strivepharmacy
1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy System

Order #75344851

Rx: **526133**	Date Written: **03/30/22**
Patient Name: [redacted]	Drug Name: **Semaglutide**
Patient DOB: [redacted]	Strength: **2 mg/ml**
Patient Address: [redacted]	Quantity Ordered: **1**
Doctor Name: **ELIZABETH SADLER**	Quantity Dispensed: **1**
Doctor Address: [redacted]**E SHEA BLVD**	Directions: **INJECT 0.15 ML (15 UNITS) SUBCUTANEOUSLY ONCE WEEKLY FOR 2 WEEKS & THEN 0.25 ML (25 UNITS) SUBCUTANEOUSLY ONCE WEEKLY**
Doctor DEA: **MS3446540**	Refills: **0**

VITALITY SCOTTSDALE

8764 E SHEA BLVD, SCOTTSDALE, AZ 85260
Phone: 480-948-3050, Fax: 480-948-1680
Date: Mar/25/2022 11:57:19 AM (PDT)

ELIZABETH SADLER DEA #MS3446540 State Lic. AZAP7554
ELIZABETH SADLER

Electronic Prescription Order

Name:	[redacted]	Last Name:	[redacted]	Middle Name:	
Phone:		Cell Phone:		DOB:	[redacted]
Address:		Address (Cont):		Email:	
City:		State:		Zip:	
Gender:		Pay Type:		Ins. Name:	
Group Name:		Ins. Phone:		Member ID:	
Ins. Control Number:		Ins. BIN:		Delivery Type:	**Delivery**
Driver's License Number:		Driver's License State:			

#1 Semaglutide INJ
Strength: 2 mg/ml====
Quantity: 1 ml (one)====
Refills: 0====
Directions: inject 15units SQ 1x a week for 2 weeks & then 25units SQ 1x weekly====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 30====
Special Instructions: please include QS insulin needles&alcohol swabs====
Date Written: 03/25/2022 (Mar 25, 2022)====

Special Instructions: - Allergies: ; - Diagnosis: ;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: ELIZABETH SADLER Date: Mar/25/2022 11:57:19 AM (PDT)
Signed electronically by: ELIZABETH SADLER

Strivepharmacy
1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy System

Order #75303031

Rx: **525505**	Date Written: **03/25/22**
Patient Name: [redacted]	Drug Name: **Semaglutide**
Patient DOB: [redacted]	Strength: **2 mg/ml**
Patient Address: [redacted]	Quantity Ordered: **1**
Doctor Name: **ELIZABETH SADLER**	Quantity Dispensed: **1**
Doctor Address: [redacted] **E SHEA BLVD**	Directions: **INJECT 15 UNITS (0.15ML) SUBCUTANEOUSLY WEEKLY FOR 2 WEEKS & THEN INJECT 25 UNITS (0.25ML) WEEKLY**
Doctor DEA: **MS3446540**	Refills: **0**

Vitality MED SPA
1955 N. Val Vista Dr. #101
Mesa, AZ 85213
Phone: (480) 854-8000 Fax: (480) 854-8020

STRIVE PHARMACY PRESCRIPTION

Elizabeth Sadler- FNP DEA#MS4867935 | Matt Morris- NP-C DEA#MM4034928

Patient Name: [redacted] DOB: [redacted] Date: 3/29/22
Address: [redacted] City: [redacted] State: AZ ZIP: [redacted]
Telephone [redacted]
☑NEW PATIENT ☑NEW RX ☐CHANGE RX

☐	Progesterone ____ mg	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x
☐	Biest 80/20 50/50 ____ mg/g	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x
☐	Estriol ____ mg/vag supp	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x
☐	Testosterone ____ mg/g	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x
☐	Estrodiol ____ mg	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x
☐	Testosterone cypionate 200mg/cc			MCT OIL	#	Sig:		Refill x
☐	Low Dose Naltrexone ____ mg			IR-CAP	#	Sig:		Refill x
☐	Anastrazole 1mg			CAPSULE	#	Sig:		Refill x
☐	Tadalefil ____ mg			TROCHE	#	Sig:		Refill x
☐	Clomid 25mg			CAPSULE	#	Sig:		Refill x
☐	RT-141			INJECTABLE	#	Sig:		Refill x
☐	ECA (EPHENDRINE/CAFFINE/ASPRIN/25/200/21MG				#	Sig:		Refill x
☑	Semaglutide 2mg/1mL				#2mL	Sig:	0.125 mL SQ @ week x 8wks.	Refill x 0
☐	Inject syringe/needles Syg: 1cc 3cc Ndl: 25Gx1in 25Gx1.5in PLUS 18G DRAW NEEDLES				#	Sig:		Refill x
☑	Insulin needles 29, 30 or 31G				#QS	Sig:		Refill x 0

NOTES: ☐TOPICLICK PREFERRED ☐PUMP ☐COMPOUNDING REASON: ____

BILLING, SHIPPING & SPECIAL INSTRUCTIONS
☑ CHARGE TO DOCTOR | ☐ CHARGE PATIENT | ☑ SHIP TO PATIENT ☐ PATIENT PICK UP
SHIPPING TYPE: ☐ OVERNIGHT ☑ 2ND DAY ☐ 3RD DAY ☐GROUND

PROVIDER SIGNATURE [signature] DATE 3/29/22

Rx: **526003**	Date Written: **03/29/22**
Patient Name: [redacted]	Drug Name: **Semaglutide**
Patient DOB: [redacted]	Strength: **2 mg/ml**
Patient Address: [redacted]	Quantity Ordered: **1**
Doctor Name: **MATTHEW MORRIS**	Quantity Dispensed: **1**
Doctor Address: **1955 N VAL VISTA DR**	Directions: **INJECT 0.125 ML (12.5 UNITS) SUBCUTANEOUSLY WEEKLY**
Doctor DEA: **MM4034928**	Refills: **0**

Quarles

One Renaissance Square
Two North Central Avenue
Suite 600
Phoenix, AZ 85004-2322
602-229-5200
Fax 602-229-5690
www.quarles.com

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Chicago
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Milwaukee
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Naples
Phoenix
San Diego
Tampa
Tucson
Washington, D.C.

Writer's Direct Dial: 602-229-5269
E-Mail: Roger.Morris@quarles.com

January 31, 2023

VIA ELECTRONIC MAIL

Kam Gandhi
Executive Director
Arizona Board of Pharmacy
11106 W Adams, Suite 260
Phoenix, AZ 85007

RE: Supplemental Response to Complaint 22-0668 (Permit No. Y007406)

Dear Mr. Gandhi:

As you know, we represent Strive Pharmacy (the "Pharmacy"), Permit No. Y007406, in connection with Complaint 22-0668 (the "Complaint"). This letter is intended to serve as an additional supplemental response to the Complaint, which was issued against the Pharmacy for compounding semaglutide injection drug products when an alternative commercially available product exists. As you know, the commercially available drug products in question include Ozempic and Wegovy. As previously noted, the Pharmacy takes these allegations seriously, but can assure the Board that they were not compounding drug products that are considered essentially a copy of the commercially available products and were compounding for the purpose of dispensing to a patient based on valid prescription orders from practitioners for legitimate medical purposes. This supplemental response is intended to provide the Board of additional relevant materials for their consideration as they examine this Complaint.

I. Dissimilar dosage strength of the Pharmacy's compounded semaglutide drug allows for flexible dosing.

As explained in the previous supplemental response, FDA guidance focuses on three factors to determine whether a compounded drug product is essentially a copy of a commercially

patient outcomes. Practitioners cite the flexible dosing allowed by the Pharmacy's compounded product as the basis for their patient treatment due to concerns over the gastrointestinal issues associated with high dose semaglutide. Due to the drug's gastrointestinal adverse effects, semaglutide requires a titration dosing schedule to acclimatize patients so that these issues may be lessened. On the other hand, the commercially available pens require that the dose be increased at very rigid and specific intervals. Therefore, the flexibility permitted by the compounded drug product allows practitioners to better control a patient's adverse effect profile.

It is also important to note that the Pharmacy has begun to compound a combination drug product containing semaglutide and cyanocobalamin (Vitamin B12). As such, practitioners have started to prescribe their patients the Pharmacy's combination drug product due to the reported anti-nausea effects provided by cyanocobalamin (Vitamin B12). While the individual patient statement of significant difference may not be evidenced consistently on every prescription record, we have attached numerous practitioner testimonials to this supplemental response for the Board's consideration. These practitioner testimonials can be found attached in **Exhibit B**.

III. Conclusion

As we have highlighted, the Pharmacy takes these allegations seriously but can attest they had no intentions of compounding a commercially available drug product. Instead, their primary goal was to provide appropriate and comprehensive patient care pursuant to valid prescriptions. As such, we request the Board take these additional materials into consideration during its review of this matter.

Very truly yours,

Alexander Snyder, PharmD

Roger N. Morris, R.Ph., J.D.

EXHIBIT A

TELEPHONE PRESCRIPT [redacted] RX NUMBER 12/10/24

NAME [redacted] DATE

ADDRESS

PHONED BY Erin TIME DELIVER WILL CALL

ORIGINAL Rx NO DO NOT REFILL ☐ REFILL 0 TIMES

BLO
SIP

Semaglutide 2mg/1.5 ml
15 iu x 1 week then
↑ by 5 iu weekly w/
a max of 25 iu weekly

MC. ☐
PVT. ☐
LABEL: YES ☐ NO ☐ #1

Liz Sadler

PHARMACIST DR'S PHONE DOCTOR

DR'S ADDRESS DEA NO.

BioRx Labs 1-888-550-5450 FORM NO.PD2600

Vitality MED/SPA
1955 N. Val Vista Dr. #101
Mesa, AZ 85213
Phone: (480) 854-8000 Fax: (480) 854-8020

STRIVE PHARMACY PRESCRIPTION

Elizabeth Sadler- FNP DEA#MS4867935 | Matt Morris- NP-C DEA#MM4034928

Patient Name: [redacted] DOB: [redacted] Date: 12-16-21
Address: [redacted] City: [redacted] State: [redacted] ZIP: [redacted]
Telephone [redacted] ☑NEW PATIENT ☐NEW RX ☐CHANGE RX

☐ Progesterone ____ mg	SR-CAP	TROCHE	CREAM/GEL	# ____	Sig: ____	Refill x ____
☐ Biest 80/20 50/50 ____ mg/g	SR-CAP	TROCHE	CREAM/GEL	# ____	Sig: ____	Refill x ____
☐ Estdiol ____ mg/vag supp	SR-CAP	TROCHE	CREAM/GEL	# ____	Sig: ____	Refill x ____
☐ Testosterone ____ mg/g	SR-CAP	TROCHE	CREAM/GEL	# ____	Sig: ____	Refill x ____
☐ Estradiol ____ mg	SR-CAP	TROCHE	CREAM/GEL	# ____	Sig: ____	Refill x ____
☐ Testosterone cypionate 200mg/cc		MCT OIL		# ____	Sig: ____	Refill x ____
☐ Low Dose Naltrexone ____ mg		IR-CAP		# ____	Sig: ____	Refill x ____
☐ Anastrazole 1mg		CAPSULE		# ____	Sig: ____	Refill x ____
☐ Tadalafil ____ mg		TROCHE		# ____	Sig: ____	Refill x ____
☐ Clomid 25mg		CAPSULE		# ____	Sig: ____	Refill x ____
☐ PT-141		INJECTABLE		# ____	Sig: ____	Refill x ____
☐ ECA (EPHEDRINE/CAFFEINE/ASPRIN/25/200/21MG				# ____	Sig: ____	Refill x ____
☒ Semaglutide 2mg/1ml		1 Initial			Sig: Inject 15-25mg SQ weekly	Refill x 8
☐ Inject syringe/needles 5yg: 1cc 3cc Ndl: 25Gx1in 25Gx1.5in PLUS 18G DRAW NEEDLES				# ____	Sig: ____	Refill x ____
☐ Insulin needles 29, 30 or 31G				# ____	Sig: ____	Refill x ____

NOTES: ☐TOPICAL CK PREFERRED ☐PUMP ☐COMPOUNDING REASON: ____

BILLING, SHIPPING & SPECIAL INSTRUCTIONS
☒ CHARGE TO DOCTOR | ☐ CHARGE PATIENT | ☒ SHIP TO PATIENT ☐ PATIENT PICK UP
SHIPPING TYPE: ☐ OVERNIGHT ☐ 2ND DAY ☐ 3RD DAY ☐GROUND

PROVIDER SIGNATURE [signature] **DATE** ____

ACTIVATED HEALTH

1485 S HIGLEY RD , GILBERT, AZ 85296
Phone: 480-571-1000, Fax: 888-366-1983
Date: Dec/20/2021 09:16:32 AM (PDT)

BECKY GOODSON DEA #MG2276992 State Lic. AZRN137766
BECKY GOODSON

Electronic Prescription Order

Name:	[redacted]	Last Name:	[redacted]	Middle Name:	
Phone:		Cell Phone:		DOB:	[redacted]
Address:		Address (Cont):		Email:	
City:		State:	**AZ**	Zip:	[redacted]
Gender:	**Female**	Pay Type:		Ins. Name:	
Group Name:		Ins. Phone:		Member ID:	
Ins. Control Number:		Ins. BIN:		Delivery Type:	**Patient Preference**
Driver's License Number:		Driver's License State:			

#1 **Semaglutide INJ**
Strength: 2.5 mg/ml====
Quantity: 2 ml (two)====
Refills: 0====
Directions: Inject 0.18 ml every week====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 30====
Special Instructions: ====
Date Written: 12/20/2021 (Dec 20, 2021)====

Special Instructions: - **Allergies:** ; - **Diagnosis:** ;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: BECKY GOODSON Date: Dec/20/2021 09:16:32 AM (PDT)
Signed electronically by: BECKY GOODSON

Strivepharmacy
Strivepharmacy
1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy Business System V2

Order #74351449

Vitality MED/SPA
1955 N. Val Vista Dr. #101
Mesa, AZ 85213
Phone: (480) 854-8000 Fax: (480) 854-8020

STRIVE PHARMACY PRESCRIPTION

Elizabeth Sadler- FNP DEA#MS4867935 | Matt Morris- NP-C DEA#MM4034928

Patient Name: [redacted] DOB: [redacted] Date: 1.27.22
Address: _____ City: _____ State: _____ ZIP: _____
Telephone: [redacted] ☐NEW PATIENT ☐NEW RX ☐CHANGE RX

☐ Progesterone _____ mg	SR-CAP	TROCHE	CREAM/GEL.	#	Sig:		Refill x
☐Biest 80/20 50/50 _____ mg/g	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x
☐Estriol _____ mg/vag supp	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x
☐Testosterone _____ mg/g	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x
☐Estrodiol _____ mg	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x
☐Testosterone cypionate 200mg/cc		MCT OIL		#	Sig:		Refill x
☐Low Dose Naltrexone _____ mg		IR-CAP		#	Sig:		Refill x
☐Anastrazole 1mg		CAPSULE		#	Sig:		Refill x
☐Tadalafil _____ mg		TROCHE		#	Sig:		Refill x
☐Clomid 25mg		CAPSULE		#	Sig:		Refill x
☐PT-141		INJECTABLE		#	Sig:		Refill x
☐ECA (EPHEDRINE/CAFFINE/ASPRIN/25/200/21MG				#	Sig:		Refill x
A Semaglutide 2mg/1mL				# 1vial	Sig: inject 15-25 units SQ weekly		Refill x 0
☐ Inject syringe/needles Syg: 1cc 3cc Ndl: 25Gx1in 25Gx1.5in PLUS 18G DRAW NEEDLES				#	Sig:		Refill x
☐Insulin needles 29, 30 or 31G				#	Sig:		Refill x

NOTES: ☐TOPICLICK PREFERRED ☐PUMP ☐COMPOUNDING REASON: _____

BILLING, SHIPPING & SPECIAL INSTRUCTIONS

A CHARGE TO DOCTOR | ☐ CHARGE PATIENT | ☐ SHIP TO PATIENT ☐ PATIENT PICK UP

SHIPPING TYPE: ☐ OVERNIGHT ☑ 2ND DAY ☐ 3RD DAY ☐GROUND

PROVIDER SIGNATURE _____ **DATE** 1.27.22

* ship to Mesa office

Vitality MED SPA
1955 N. Val Vista Dr. #101
Mesa, AZ 85213
Phone: (480) 854-8000 Fax: (480) 854-8020

STRIVE PHARMACY PRESCRIPTION

Elizabeth Sadler- FNP DEA#MS4867935 | Matt Morris- NP-C DEA#MM4034928

Patient Name: [redacted] DOB: [redacted] Date: 1.27.22
Address: [redacted] City: [redacted] State: AZ ZIP: [redacted]
Telephone: [redacted] ☐NEW PATIENT ☐NEW RX ☐CHANGE RX

☐ Progesterone ____ mg	SR-CAP	TROCHE	CREAM/GEL	#	Sig:	Refill x
☐ Biest 80/20 50/50 ____ mg/g	SR-CAP	TROCHE	CREAM/GEL	#	Sig:	Refill x
☐ Estriol ____ mg/vag supp	SR-CAP	TROCHE	CREAM/GEL	#	Sig:	Refill x
☐ Testosterone ____ mg/g	SR-CAP	TROCHE	CREAM/GEL	#	Sig:	Refill x
☐ Estrodiol ____ mg	SR-CAP	TROCHE	CREAM/GEL	#	Sig:	Refill x
☐ Testosterone cypionate 200mg/cc			MCT OIL	#	Sig:	Refill x
☐ Low Dose Naltrexone ____ mg			IR-CAP	#	Sig:	Refill x
☐ Anastrazole 1mg			CAPSULE	#	Sig:	Refill x
☐ Tadalafil ____ mg			TROCHE	#	Sig:	Refill x
☐ Clomid 25mg			CAPSULE	#	Sig:	Refill x
☐ PT-141			INJECTABLE	#	Sig:	Refill x
☐ ECA (EPHEDRINE/CAFFINE/ASPRIN/25/200/21MG				#	Sig:	Refill x
☒ Semaglutide 5mg/1ml			1 Vial	#	Sig: Inject 0.3-0.5ml SQ Weekly	Refill x 6
☐ Inject syringe/needles Syg: 1cc 3cc Ndl: 25Gx1in 25Gx1.5in PLUS 18G DRAW NEEDLES				#	Sig:	Refill x
☒ Insulin needles 29, 30 or 31G				# SS	Sig:	Refill x 6

NOTES: ☐TOPICLICK PREFERRED ☐PUMP ☐COMPOUNDING REASON: _____

BILLING, SHIPPING & SPECIAL INSTRUCTIONS

☒ CHARGE TO DOCTOR | ☐ CHARGE PATIENT | ☒ SHIP TO PATIENT ☐ PATIENT PICK UP

SHIPPING TYPE: ☐ OVERNIGHT ☐ 2ND DAY ☐ 3RD DAY ☐GROUND

PROVIDER SIGNATURE Sfa **DATE** _____

Physician Refill Authorization Request

Strivepharmacy Fax (480) 626-4365

(This fax contains sensitive patient information. If you are not the intended party, please destroy this fax.)

To: SADLER, ELIZABETH
Address: [redacted] W UNION HILLS DR
Phone: [redacted] **Fax:** [redacted]

From: Strivepharmacy
Address: 1275 E Baseline Rd ste 104
Phone: (480) 626-4366 **Fax:** (480) 626-4365

Patient: [redacted]
Address:
Phone: **Birthdate:** [redacted] **Age:** [redacted]

Rx #: 512103
Drug: Semaglutide 2 mg/ml INJ

Quantity: 1 ✓ **Date written:** 01/06/2022
Last refill: 01/10/2022 **Prescription expiration date:** 01/06/2023
Directions: INJECT 20-25 UNITS SUBCUTANEOUSLY ONCE WEEKLY

+ 0 refills

Pharmacy use Only:

Refill Response: Please fax back to the pharmacy at (480) 626-4365

May Refill: (Please complete appropriate refill instructions section)

☐ PRN	___Time(s) as Consistent with State Law	Until___/___/___	☐ Do Not Refill
Other instructions, comments or questions:			

Authorized by: Dr. Sadler **Date** 2.22.22

Date Printed/Faxed/Transmitted: null (null)

Physician Refill Authorization Request

Strivepharmacy Fax (480) 626-4365

(This fax contains sensitive patient information. If you are not the intended party, please destroy this fax.)

To: SADLER, ELIZABETH
Address: [redacted] W UNION HILLS DR
Phone: [redacted] **Fax:** [redacted]

From: Strivepharmacy
Address: 1275 E Baseline Rd ste 104
Phone: (480) 626-4366 **Fax:** (480) 626-4365

Patient: [redacted]
Address:
Phone: **Birthdate:** [redacted] **Age:** [redacted]

Rx #: 512103
Drug: Semaglutide 2 mg/ml INJ

Quantity: 1 ✓ **Date written:** 01/06/2022
Last refill: 01/10/2022 **Prescription expiration date:** 01/06/2023
Directions: INJECT 20-25 UNITS SUBCUTANEOUSLY ONCE WEEKLY

+ 0 refills

Pharmacy use Only:

Refill Response: **Please fax back to the pharmacy at (480) 626-4365**

May Refill: (Please complete appropriate refill instructions section)

☐ PRN	___Time(s) as Consistent with State Law	Until___/___/___	☐ Do Not Refill
Other instructions, comments or questions:			

Authorized by: Dr. Sadler **Date** 2.22.22

VITALITY SCOTTSDALE

8764 E SHEA BLVD, SCOTTSDALE, AZ 85260
Phone: 480-948-3050, Fax: 480-948-1680
Date: Feb/22/2022 01:22:57 PM (PDT)

ELIZABETH SADLER DEA #MS3446540 State Lic. AZAP7554
ELIZABETH SADLER

Electronic Prescription Order

Name:	[redacted]	Last Name:	[redacted]	Middle Name:	
Phone:		Cell Phone:		DOB:	[redacted]
Address:		Address (Cont):		Email:	
City:		State:	AZ	Zip:	[redacted]
Gender:		Pay Type:		Ins. Name:	
Group Name:		Ins. Phone:		Member ID:	
Ins. Control Number:		Ins. BIN:		Delivery Type:	**UPS Ground**
Driver's License Number:		Driver's License State:			

#1 Semaglutide INJ

Strength: 2 mg/ml====
Quantity: 1 ml (one)====
Refills: 0====
Directions: inject 15-25 units once SQ weekly====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 30====
Special Instructions: please include QS insulin needles&alcohol swabs====
Date Written: 02/22/2022 (Feb 22, 2022)====

Special Instructions: - **Allergies:** ; - **Diagnosis:** ;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: ELIZABETH SADLER Date: Feb/22/2022 01:22:57 PM (PDT)
Signed electronically by: ELIZABETH SADLER

Strivepharmacy
Strivepharmacy
1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy Business System V2

Order #74978072

mic b 12 10ml inj
50 u sc tiw refill 0
b/o s/p per erin
2/25/2022 13:10 - smoore

Vitality MED/SPA
8160 W. Union Hills Dr #B202
Glendale, AZ 85308
Phone: 623.792.5800 Fax: 623.256.6155

STRIVE PHARMACY PRESCRIPTION

Elizabeth Sadler, FNP | MS3446540

Patient Name: [redacted] DOB [redacted] Date: 2.23.22
Address: [redacted] City: [redacted] State: AZ ZIP: [redacted]
Telephone: [redacted] ☒NEW PATIENT ☒NEW RX ☐CHANGE RX

☐ Progesterone _____ mg	SR-CAP	TROCHE	CREAM/GEL	#	Sig:	Refill x	
☐ Biest 80/20 50/50 _____ mg/g	SR-CAP	TROCHE	CREAM/GEL	#	Sig:	Refill x	
☐ Estriol _____ mg/vag supp	SR-CAP	TROCHE	CREAM/GEL	#	Sig:	Refill x	
☐ Testosterone _____ mg/g	SR-CAP	TROCHE	CREAM/GEL	#	Sig:	Refill x	
☐ Estrodiol _____ mg	SR-CAP	TROCHE	CREAM/GEL	#	Sig:	Refill x	
☐ Testosterone cypionate 200mg/cc		MCT OIL		#	Sig:	Refill x	
☐ Low Dose Naltrexone _____ mg		IR-CAP		#	Sig:	Refill x	
☐ Anastrazole 1mg		CAPSULE		#	Sig:	Refill x	
☐ Tadalafil _____ mg		TROCHE		#	Sig:	Refill x	
☐ Clomid 25mg		CAPSULE		#	Sig:	Refill x	
☐ PT-141		INJECTABLE		#	Sig:	Refill x	
☐ ECA (EPHENDRINE/CAFFINE/ASPRIN/25/200/21MG				#	Sig:	Refill x	
☒ Semaglutide 2mg				Vial	Sig: inject 15-25 u SQ weekly	Refill x	6
☐ Inject syringe/needles Syg: 1cc 3cc Ndl: 25Gx1in 25Gx1.5in PLUS 18G DRAW NEEDLES				#	Sig:	Refill x	
☒ Insulin needles 29, 30 or 31G				QS	Sig:	Refill x	0

NOTES: ☐TOPICLICK PREFERRED ☐PUMP ☐COMPOUNDING REASON: _____

BILLING, SHIPPING & SPECIAL INSTRUCTIONS

☒ CHARGE TO DOCTOR | ☐ CHARGE PATIENT | ☒ SHIP TO PATIENT ☐ PATIENT PICK UP

SHIPPING TYPE: ☐ OVERNIGHT ☐ 2ND DAY ☐ 3RD DAY ☐GROUND

PROVIDER SIGNATURE _____ **DATE** _____

Vitality MED SPA

1955 N. Val Vista Dr. #101
Mesa, AZ 85213
Phone: (480) 854-8000 Fax: (480) 854-8020

STRIVE PHARMACY PRESCRIPTION

Elizabeth Sadler- FNP DEA#MS4867935 | Matt Morris- NP-C DEA#MM4034928

Patient Name: [redacted] DOB: [redacted] Date: 2.24.22
Address: [redacted] City: [redacted] AZ ZIP: [redacted]
Telephone: [redacted] ☑NEW PATIENT ☐NEW RX ☐CHANGE RX

☐ Progesterone ____ mg	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x
☐Biest 80/10 50/50 ____ mg/g	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x
☐Estriol ____ mg/vag supp	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x
☐Testosterone ____ mg/g	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x
☐Estradiol ____ mg	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x
☐Testosterone cypionate 200mg/cc			MCT OIL	#	Sig:		Refill x
☐Low Dose Naltrexone ____ mg			IR-CAP	#	Sig:		Refill x
☐Anastrazole 1mg			CAPSULE	#	Sig:		Refill x
☐Tadalafil ____ mg			TROCHE	#	Sig:		Refill x
☐Clomid 25mg			CAPSULE	#	Sig:		Refill x
☐PT-141			INJECTABLE	#	Sig:		Refill x
☐ECA (EPHENDRINE/CAFFINE/ASPRIN/25/200/21MG				#	Sig:		Refill x
☒ Semaglutide 2mg/1ml				1 Vial	Sig:	1.5-2.5u, SQ weekly	Refill x 6
☐ Inject syringe/needles Syg: 1cc 3cc Ndl: 25Gx1in 25Gx1.5in PLUS 18G DRAW NEEDLES				#	Sig:		Refill x
☒Insulin needles 29, 30 or 31G				# 6	Sig:		Refill x 6

NOTES: ☐TOPICLICK PREFERRED ☐PUMP ☐COMPOUNDING REASON: _____

BILLING, SHIPPING & SPECIAL INSTRUCTIONS

☒ CHARGE TO DOCTOR | ☐ CHARGE PATIENT | ☒ SHIP TO PATIENT ☐ PATIENT PICK UP

SHIPPING TYPE: ☒ OVERNIGHT ☐ 2ND DAY ☐ 3RD DAY ☐GROUND

PROVIDER SIGNATURE _____ DATE 2.24.22

Vitality MED/SPA
1955 N. Val Vista Dr. #101
Mesa, AZ 85213
Phone: (480) 854-8000 Fax: (480) 854-8020

STRIVE PHARMACY PRESCRIPTION

Elizabeth Sadler- FNP DEA#MS3446540 | Jessica Folz-NMD DEA#MF4543345

Patient Name: [redacted] DOB: [redacted] Date: 2.24.22
Address: [redacted] City: [redacted] State: AZ ZIP: [redacted]
Telephone: [redacted] ☐NEW PATIENT ☐NEW RX ☐CHANGE RX

☐ Progesterone ____ mg	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x	
☐ Biest 80/20 50/50 ____ mg/g	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x	
☐ Estriol ____ mg/vag supp	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x	
☐ Testosterone ____ mg/g	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x	
☐ Estrodiol ____ mg	SR-CAP	TROCHE	CREAM/GEL	#	Sig:		Refill x	
☐ Testosterone cypionate 200mg/cc			MCT OIL	#	Sig:		Refill x	
☐ Low Dose Naltrexone ____ mg			R-CAP	#	Sig:		Refill x	
☐ Anastrazole 1mg			CAPSULE	#	Sig:		Refill x	
☐ Tadalafil ____ mg			TROCHE	#	Sig:		Refill x	
☐ Clomid 25mg			CAPSULE	#	Sig:		Refill x	
☐ PT-141			INJECTABLE	#	Sig:		Refill x	
☐ ECA (EPHENDRINE/CAFFINE/ASPRIN/25/200/21MG				#	Sig:		Refill x	
☐ Sema Glutide 2mg/ml				1 Vial	Sig:	0.15u SQ weekly Max 25u	Refill x	8
☐ Inject syringe/needles 5yg: 1cc 3cc Ndl: 25Gx1in 25Gx1.5in PLUS 18G DRAW NEEDLES				#	Sig:		Refill x	
☐ Insulin needles 29, 30 or 31G				#90	Sig:		Refill x	5

NOTES: ☐TOPICLICK PREFERRED ☐PUMP ☐COMPOUNDING REASON: ____

BILLING, SHIPPING & SPECIAL INSTRUCTIONS

☐ CHARGE TO DOCTOR | ☐ CHARGE PATIENT | ☐ SHIP TO PATIENT ☐ PATIENT PICK UP

SHIPPING TYPE: ☐ OVERNIGHT ☐ 2ND DAY ☐ 3RD DAY ☐GROUND

PROVIDER SIGNATURE [signature] DATE 2.24.22

VITALITY SCOTTSDALE

8764 E SHEA BLVD, SCOTTSDALE, AZ 85260
Phone: 480-948-3050, Fax: 480-948-1680
Date: Feb/25/2022 10:37:34 AM (PDT)

ELIZABETH SADLER DEA #MS3446540 State Lic. AZAP7554
ELIZABETH SADLER

Electronic Prescription Order

Name:	[redacted]	Last Name:	[redacted]	Middle Name:	
Phone:		Cell Phone:		DOB:	[redacted]
Address:		Address (Cont):		Email:	
City:		State:	AZ	Zip:	[redacted]
Gender:		Pay Type:		Ins. Name:	
Group Name:		Ins. Phone:		Member ID:	
Ins. Control Number:		Ins. BIN:		Delivery Type:	**Delivery**
Driver's License Number:		Driver's License State:			

#1 **Semaglutide INJ**
Strength: 5 mg/ml====
Quantity: 2 ml (two)====
Refills: 0====
Directions: inject 10 units SQ 1x weekly. Then increase 5units. Max 40units 1x weekly.====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 60====
Special Instructions: please include insulin syringes&alcohol====
Date Written: 02/25/2022 (Feb 25, 2022)====

Special Instructions: - **Allergies:** NO KNOWN DRUG ALLERGIES; - **Diagnosis:** ;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: ELIZABETH SADLER Date: Feb/25/2022 10:37:34 AM (PDT)
Signed electronically by: ELIZABETH SADLER

Strivepharmacy
Strivepharmacy
1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy Business System V2

Order #75012803

EXHIBIT B

Skinny
RICH SHOT®

As a prescriber, I have found compounded Semaglutide with B12 vials to be an extremely valuable tool in the management of my patients with Obesity and Diabetes. One of the main benefits of using these vials is the ability to customize dosing in order to decrease side effects, increase compliance, and thus better outcomes.

When it comes to diabetes and obesity management, every patient is unique and may have different needs with it comes to their medication regimen. Compounded Semaglutide vials allow me to tailor the dosing to each individual patient, taking into account side effects and effectiveness. In the past with traditional manufactured Ozempic or Wegovy, the patient would double the dose every 4 weeks, and side effects and intolerance would happen with every dose change. Patients would have major diarrhea, vomiting, and severe nausea at each dose increase. This resulted in noncompliance and poor outcomes. The flexibility in dosing which I am able to do has significantly reduced the incidence of side effects and has drastically increased compliance and positive outcomes.

I have been managing Obese and Diabetic patients for years with Semaglutide and am so grateful the option to use compounded Semaglutide in my practice. I truly believe it has led to significantly better outcomes for my patients. The dose of 0.25 mg for 3 weeks then increasing to 0.4mg helps prevent 95% of side effects and patients are better able to adjust to the increased dosage without side effects as compared you Ozempic dosage protocol.

Sign: 

Date: 01/30/2023

Practitioner Ahmed Mahdi, NP
Skinny Rich Shot®
Office: 323 283 9219
Mobile: 256 348 5521
Fax: 323 488 6897
Site: skinnyrichshot.com
Email: info@skinnyrichshot.com
Los Angeles, California

Vitality MED/SPA

8764 E. Shea Blvd #109
Scottsdale, AZ 85260
480.948.3050

January 30, 2023

To Whom It May Concern:

I began prescribing compounded Semaglutide in 2021 for my patients seeking weight loss due to insulin resistance. A majority of patients would call with complaints of severe nausea, vomiting, reflux and other GI disturbances. We would, and still do, instruct our patients to therefore lower the dose and titrate the dose up slowly. We then work on finding a dose that suits each individual's needs. For example, I have some patients who will dose at 17 units or 22units on the 2mg/ml weekly since they find the 25 units to be too much for them. We also can split the dose twice weekly if needed. The addition of B12 has significantly helped decrease nausea as well.

Our patients are very happy with the results they are seeing and as a provider I am happy seeing their lab work improving. I absolutely believe having compounded Semaglutide with B12 has led to significantly better outcomes for my patients.

Testimonial from a patient:
I have been on compounded Semaglutide for around 6 months. I have lost 28 lbs and am looking to lose another 12-15 lbs. When I first started, I had significant nausea and vomiting. I didn't think I would be able to continue. I worked with my provider to adjust the dose and am happy with my results! -K.K

Thank you,

Elizabeth Sadler - FNP
Vitality Medical Spa

Jan 29th 2023

Dr. Robb Bird

drbird@transformyou.com

To whom it may concern:

I have using Semaglutide for almost 2 years with many of my patients. One of the main benefits of using compounded Semaglutide is the ability to customize dosing in order to decrease side effects, increased compliance, and try and improve patient outcomes. As a prescriber, I have found compounded Semaglutide with B12 to be an extremely valuable tool in the management of my patients with Obesity and Diabetes. Often times this is the only option for patients who have struggled with these health challenges for years.

Brand named Ozempic or Wegovy suggest that the patient double their dose every 4 weeks. Side effects and intolerance were very common with every dose change. Patients would complain about major diarrhea, vomiting, and severe nausea at each dose increase. These bad side effects most often result in noncompliance and poor outcomes. When it comes to diabetes and obesity management, every patient is unique and may have different needs. Compounded Semaglutide allows me to tailor the dosing to each individual patient, taking into account side effects and effectiveness. The flexibility in dosing which I am able to implement has significantly reduced the incidence of side effects and has drastically increased compliance and positive outcomes.

I have been managing Obese and Diabetic patients for almost 2 years with Semaglutide and 5 years with Exenatide before it. The option to use compounded Semaglutide in my practice has been a game changer and I truly believe it has led to significantly better outcomes for my patients.

Sincerely,

Dr. Robb Bird

Perspective Health
3530 S Val Vista Suite A-111
Gilbert, AZ 85297
(480) 999-2725

January 27, 2023

To Whom it May Concern at Pharmacy:

I am writing on behalf of Strive Pharmacy in regards to the concerns of compounding/production of Semaglutide. As a provider and co-owner of a practice focused on weight loss and regenerative medicine, I have been working and prescribing Semaglutide for my patients since it has been available through Strive Pharmacy. To date, our practice has helped over 350 patients suffering with obesity and unable to tolerate Ozempic/WeGovy dosed per the pen based on a rigorous dosing schedule put out by manufacturer. As you know, this medication can have significant impact on the gastrointestinal tract and can be very difficult for many patients to tolerate. The goal of WeGovy is to aide obese patients in weight loss and decrease their comorbidities related to obesity such as hypertension, hyperlipidemia, sleep apnea, and decrease insulin resistance thereby helping to prevent our patients from developing Type 2 Diabetes.

At Perspective, we work 1:1 with our weight loss patients creating individual dosing schedules based on how well the patient is tolerating their dosing. Because of these side effects, we don't push our patients to reach maximum dose, rather we increase based on weight loss and tolerance and not per the template design dosing schedule put out by manufacturer. Perspective is only able to provide patient specific dosing by utilizing Strive compounding pharmacy for their medication. With the addition of B12 to the compound, we have seen a significant reduction in GI side effects and fatigue. I realize there is a lot of nationwide attention and coverage focused on Semaglutide and the production, I ask you to understand what a life changing impact this has made for hundreds of my patients and countless others using this same formula.

If you have any questions or would like to speak with me and/or Tammy Chesley, FNP, please do not hesitate to contact Perspective Health. We stand beside Strive Pharmacy in providing specialized and individualized weight loss management using Semaglutide.

Thank you,

Rebecca T Lucas, FNP

Quarles

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E-Mail: Alex.Snyder@quarles.com

May 18, 2023

VIA ELECTRONIC MAIL - kgandhi@azpharmacy.gov

Kam Gandhi
Executive Director
Arizona State Board of Pharmacy
1110 W Washington Street, Suite 260
Phoenix, Arizona 85007

RE: Supplement Response to the Amended Complaint 22-0668.

Dear Mr. Gandhi:

We represent Strive Pharmacy (the "Pharmacy"), Permit No. Y007406, in connection with Complaint 22-0668 (the Complaint). This letter is intended to serve as an additional supplemental response to the Amended Complaint, which was issued against the Pharmacy in respect to their use of the salt form of semaglutide bulk substance and recordkeeping practices in relation to their compounding practices of semaglutide.

I. National Landscape of Semaglutide Compounding

During the latter part of 2022, the Pharmacy received a complaint alleging they were compounding a commercially available semaglutide drug products. In the time since the original complaint was filed, it has become clear that the compounding of semaglutide drug products is an issue with national implications. Due to the manufacturer's inability to respond to semaglutide's growing popularity, the FDA placed both Wegovy and Ozempic on their shortage list.[1] In response, compounding pharmacies began compounding semaglutide drug products to meet this new patient demand and medical need. Despite its continued shortage, the FDA and State Boards of Pharmacy have struggled when determining how to regulate this practice moving forward.

[1] *See* U.S. Food & Drug Administration, FDA Drug Shortages, Semaglutide (Ozempic) & Semaglutide (Wegovy), https://www.accessdata.fda.gov/scripts/drugshortages/dsp_SearchResults.cfm (last visited May 4, 2023).

As a result, pharmacies were forced to rely upon vague and ambiguous guidance when they began to compound semaglutide drug products. Only recently have various State Boards of Pharmacy issued statements in response to various inquiries concerning this issue. Even still, the FDA only recently issued a letter to the National Association Boards of Pharmacy ("NABP") to provide some manner of guidance.[2] While their letter was limited, the FDA clarified two pertinent issues. First, the FDA reaffirmed that both Wegovy and Ozempic remain on the FDA drug shortage list and will remain on the list until the shortage has been fully resolved.[3] Second, the FDA confirmed that pharmacies are not permitted to be compounding from the salt form of semaglutide since only the base form is FDA-approved.[4] Regardless, whether pharmacies may compound semaglutide drug products hinges on whether the practice is permissible and, if so, how it may be performed.

II. Permissibility of Compounding Semaglutide

Regarding the issue at hand, there must be a determination as to whether compounding semaglutide drug products is permissible. The FDA has been consistent that while a drug appears on the FDA drug shortage list, compounded drugs can be made and distributed with little restrictions.[5] Despite some claims from certain Boards of Pharmacy, the FDA has reaffirmed that Wegovy and Ozempic continue to be listed on the FDA Drug Shortage list.[6] Even if the website claims that certain strengths of the drug are "available," the FDA still considers the drug product to be in shortage unless the manufacturing issues have been fully resolved.[7] Therefore, as long as both commercial semaglutide products continue to be on shortage, semaglutide is not considered "commercially available" by the FDA and can be compounded accordingly.[8]

III. Process of Compounding Semglutide

Since compounding semaglutide is clearly permissible at this time, the next question is to address how it may be performed. Currently, the FDA has found that pharmacies operating under Section 503A may only compound from bulk drug substances that: (1) comply with the standards of an applicable United States Pharmacopoeia ("USP") or National Formulary ("NF") monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, are drug substances that are *components* of FDA-approved drug products; or (3) if such a monograph does not exist and the drug substance is not a component of

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[2] *See* FDA to NABP Semaglutide Letter, U.S. Food & Drug Administration, April 27, 2023, https://a4pc.org/files/FDA-to-NABP-Semaglutide-letter_April-27-2023.pdf.
[3] *Id.*
[4] *Id.*
[5] *Id.*
[6] *Id.*
[7] *Id.*
[8] *See* U.S. Food & Drug Administration, Center for Drug Evaluation and Research, Compounding 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, p. 10 (Jan. 2018), https://www.fda.gov/media/98973/download.

an approved drug, that it appears on the FDA's list of bulk-substances that can be used in 503A compounding.[9] It is clear, with respect to semaglutide, that no USP or NF monograph exists and that no form of the drug appears on the Section 503A Bulk Substances list.[10] However, prior to the issuance of FDA guidance, State Boards wrestled with whether the salt form of a drug should be considered a *component* of an FDA-approved drug.[11]

Controversially, the FDA and various State Boards of Pharmacy have recently found that the salt form should not be considered a *component* of the FDA-approved semaglutide base.[12] Despite this recently issued guidance, an argument can be made that this interpretation does not take into consideration the FDA's inconsistent definition of "active pharmaceutical ingredient" and "bulk drug substance" within the relevant code and regulations.[13] Prior to the recently issued guidance, the Pharmacy has been operating under relative ambiguity surrounding the permissibility of using a salt form of a drug for compounding, further evidenced by the confusion from State Boards and lack of previous guidance from the FDA. Therefore, the Pharmacy

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[9] *See* 21 U.S.C § 353a(b)(1)(A)(i)(I-III); *see also* Bulk Drug Substances Used in Compounding Under Section 503A of the FD&C Act, U.S. Food & Drug Administration, https://www.fda.gov/drugs/human-drug-compounding/bulk-drug-substances-used-compounding-under-section-503a-fdc-act (last updated Feb. 20, 2020).

[10] *See* 21 C.F.R. § 216.23 (listing the 503A Bulk drug substances list).

[11] *See* Utah State Board of Pharmacy, Minutes, March 28, 2023, p. 3, https://www.utah.gov/pmn/files/970387.pdf (finding that members of the Board believed the salt form does not matter, it is the semaglutide molecule that is being used, the semaglutide component is the active pharmaceutical ingredient); *see also* Utah State Board of Pharmacy, Minutes, March 28, 2023, https://www.utah.gov/pmn/files/959981.mp3 (conversation begins at 00:41:00).

[12] *See* FDA to NABP Semaglutide Letter, *supra* note 2; *see also* Statement Concerning Semaglutide Compounding, N.C. Bd. Pharmacy, http://www.ncbop.org/PDF/SemaglutideCompounding.pdf (last updated April 28, 2023); *see also* K Capehart, Statement Concerning Semaglutide Compounding, W. Va. Bd. Pharmacy, https://www.wvbop.com/admin/attachment/FINALSemaglutideCompoundingStatementUpdated01MAY2023WVBoPFV1.pdf (last updated May 1, 2023); *see also* Compounded Products Due to Shortage or Due to Special Needs, Miss. Bd. Pharmacy, https://www.mbp.ms.gov/sites/default/files/inline-images/Semaglutide.compoundguidance%20%28002%29.pdf.

[13] FDA has been inconsistent when defining drug substances with respect to the active pharmaceutical ingredient. At times, drug substance is defined to differentiate between the base or salt form. While in other sections of the code and regulations the terms is defined more broadly to include the base form and any salt or ester form. First, "bulk drug substance," as referenced in Section 503A(b)(1)(A) of the FD&C Act, is to mean the same as "active pharmaceutical ingredient" in 21 C.F.R. § 207.1. Unfortunately, the definition only provides what an active pharmaceutical ingredient does, however, it does not determine whether it should include only the base or salt and ester forms. However, with respect to animal compounding, a compounded drug's active ingredient is "the same" as that of the approved drug if it uses the same active moiety (i.e., drug base) regardless of any salt or ester. *See* Compounding Animal Drugs from Bulk Drug Substances, GFI #256, August 2022, https://www.fda.gov/media/132567/download. Similarly, the FDA's exclusivity treatment prohibits a new drug application from being filed if it uses the same active moiety regardless of salt form. *See* 21 U.S.C. § 355(c)(3)(E)(ii). It should be noted, the FDA did propose rules that would treat each specific form of the drug (base, salts, or esters) as separate entities. *See* List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 91071, 91076 (Dec. 16, 2016) https://www.govinfo.gov/content/pkg/FR-2016-12-16/pdf/2016-30109.pdf.

reasonably assumed that the salt form of an FDA-approved drug is essentially the "same component" in accordance with FDA law.

IV. Source of Bulk Substances for Compounding in Arizona

Nevertheless, compounding pharmacies in Arizona are beholden to a different standard compared to what is required by the FDA. In Arizona, compounding pharmacies are required to ensure that substances used for compounding purposes "…are obtained from a source that, *in the professional judgment of the pharmacist*, is acceptable and reliable."[14] The Pharmacy, adhered to this standard in two ways. First, the Pharmacy reasonable relied upon the limited FDA guidance and determined that the salt form of semaglutide used to compound was a *component* of an FDA-approved drug in accordance with Section 503A of the Food, Drug & Cosmetic Act ("FD&C Act"). This determination is reasonable, in part, because while a salt form is used as the bulk substance, the finished compounded product only contains the base semaglutide active ingredient. Second, the actual sodium component of the previously supplied salt form of semaglutide merely acted as an excipient to the original molecular structure. *See* **Attachment 1**. Meant to stabilize the product, the salt had no actual bearing on the semaglutide active pharmaceutical ingredient. Furthermore, the lack of clarity with regard to compounding with bulk semaglutide is evidenced by the recent need for the FDA and various State Boards of Pharmacy to provide guidance and statements on the issue.

Regardless, in response to the FDA's stance, the Pharmacy has taken steps to work with their manufacturer to receive and compound with the base form of semaglutide. *See* **Attachment 1**. As such, the Pharmacy remains vigilant as new information and guidance has become available and has adjusted its practices to comply with the recent interpretation. To the extent that it is helpful, the Pharmacy expects to be in full compliance with the relevant regulatory requirements at the end of the current month, May 2023.

V. Recordkeeping Issues

With respect to the improper recordkeeping practices, the Pharmacy has taken steps to update their procedures and employ more diligent oversight of these practices to prevent this type of error from occurring again. Of note, the Pharmacy's new standard operating procedures ("SOP") have been revised to require employees to verify whether the base or salt form of a drug is being used throughout their four-step verification process. *See* **Attachment 2**. As such, the drug must be checked and verified to ensure that the bulk substance matches what was ordered at the following steps of the process: (1) upon receipt, (2) before being entered into active stock, (3) prior to compounding, and (4) during a final verification before dispensing. In short, the new procedure requires the pharmacy personnel to ensure that either the correct salt or base form was received, stocked, and compounded throughout the verification process. In the interest of

[14] *See* Ariz. Admin. Code R4-23-410(B)(1)(c)(emphasis added).

providing a full scope review of the facts at issue, it should be noted, the recordkeeping error only occurred on the compounding logs in relation to which salt form was being used to compound. Since the final compounded drug product only contained the semaglutide base, the final drug product was labeled appropriately and accurately.

VI. Conclusions

In summary, the Pharmacy adhered to the good compounding practices required by Arizona rules when they determined, in the professional judgment of their pharmacists, that the salt form is acceptable and reliable.[15] Nevertheless, as new information has become available from the FDA, they have begun the process of purchasing the base form of semaglutide for patient compounding. Therefore, the Pharmacy is committed to compound semaglutide in a compliant manner moving forward.

Very truly yours,

Alexander L. Snyder

[15] *Id.*

Attachment 1

AFFIDAVIT

I, Yunxia Liu, state the following to be true:

1. I am competent to testify and have personal knowledge of the matters stated herein.
2. I received my Bachelor's and Master of Science in Organic Chemistry at Shandong University.
3. I am the Head of Quality Assurance at Biopeptek Pharmaceuticals, LLC ("Biopeptek").
4. Biopeptek is an FDA-registered manufacturer properly permitted as a virtual manufacturer (M002065) in the State of Arizona.
5. Biopeptek's manufacturing facility is registered with FDA Drug Establishments database. Qingdao Biopeptek Co., Ltd is the name of our manufacturing facility located in Qingdao, China. The FDA Establishment Identifier is # 3009110908.
6. I understand that the U.S. Food & Drug Administration ("FDA") recently issued guidance that the active pharmaceutical ingredient in Wegovy and Ozempic is the base form of semaglutide. As such, the FDA has taken the stance that compounding from the salt form of semaglutide does not meet federal law requirements for compounding.
7. Biopeptek provides Semaglutide base Active Pharmaceutical Ingredient (API) to pharmacies certified for prescription compounding use. Semaglutide API made by Biopeptek is identical to the FDA approved Semaglutide drug substance. Biopeptek's Semaglutide API is the Semaglutide base. Previously, the salt appeared on the previous Certificate of Analysis (COA) is an excipient, not part of the Semaglutide molecular structure.
8. Attached hereto as Exhibit A are the new Certificate of Analysis and Manufacturing Labeling to evidence the manufactured base form of semaglutide.

DATED this 10th day of May 2023.

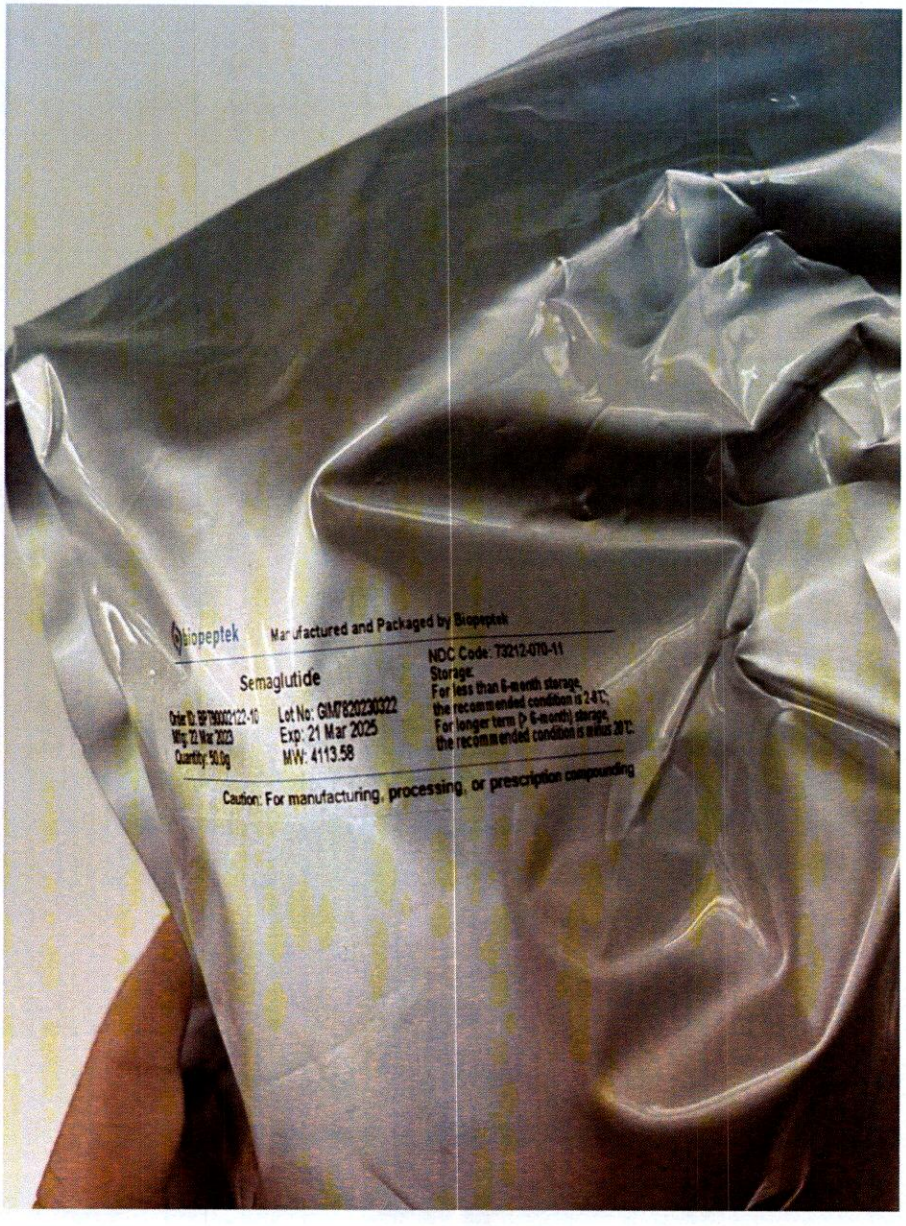
Yunxia Liu

Yunxia Liu

Head of Quality Assurance

Biopeptek Pharmaceuticals

EXHIBIT A



CERTIFICATE OF ANALYSIS

Reference document : BPT-QC-STP-2078 V02

Product Name	Semaglutide
CAS No.	910463-68-2
Molecular Formula	$C_{187}H_{291}N_{45}O_{59}$
Lot No.	GIM7820230322
Sequence	His-Aib-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-Ser-Tyr-Leu-Glu-Gly-Gln-Ala-Ala-Lys(PEG2-PEG2-γ-Glu-17-carboxyheptadecanoyl)-Glu-Phe-Ile-Ala-Trp-Leu-Val-Arg-Gly-Arg-Gly
Modifications	None
Storage Conditions	For less than 6-month storage, the recommended condition is 2-8℃; For longer term (> 6-month) storage, the recommended condition is minus 20℃.

Test Items		**Specifications**	**Results**	**Method**
Appearance		White to off-white powder	White to off-white powder (Conforms)	BPT-QC-SOP-2078 V02
Identification	**Molecular Weight (MS)**	4113.6±1.0Da	4114.5Da	BPT-QC-SOP-2078 V02
	Retention Time (HPLC)	The retention time of the major peak of the sample solution corresponds to that of the standard solution.	Conforms	BPT-QC-SOP-2078 V02
Assay	**Purity (HPLC)**	≥98.0%	99.3%	BPT-QC-SOP-2078 V02
	Related Substances (HPLC)	Total Impurities(%)≤2.0% Largest Single Impurity(%)≤1.0%	0.7% 0.1%	BPT-QC-SOP-2078 V02
	Peptide Content (HPLC)	≥85.0%	93.3%	BPT-QC-SOP-2078 V02
Specific Tests	**Water Content (Karl Fischer)**	≤8.0%	4.6%	BPT-QC-SOP-2078 V02; USP<921>
	Residual Solvent (GC; HPLC)	Acetonitrile≤0.041% Trifluoroacetic≤0.500%	0.0185% N.D	BPT-QC-SOP-2078 V02
	Bacterial Endotoxins (Gel-clot Method)	<10EU/mg	Conforms	BPT-QC-SOP-2078 V02; USP<85>
Conclusion	This batch was tested following the *analytical procedure of BPT-QC-SOP-2078 V02.* The test results met the *specifications of BPT-QC-STP-2078 V02.*			

Date of Mfg	22 Mar 2023	Date of Exp	21 Mar 2025
Date of Test	09 Apr 2023 Lei Zhou	Date of Release	09 Apr 2023 Yongna Zhao
Quality Control: Lei Zhou 09 Apr 2023		Quality Assurance: Yongna Zhao 09 Apr 2023	

Reviewed Approved

Biopeptek Pharmaceuticals,LLC.

Corporate headquarters: 5 Great Valley Parkway. Suite 100 Malvern, PA 19355, U.S.A Tel: 610.643.4881 www.biopeptek.com

Manufactured and Packaged at the FDA registered facility: 218 Shuangyuan Road, Chengyang, Qingdao, Shandong 266000, China (CHN)

The peptide is chemically synthesized

Attachment 2

1. **Purpose**
   1.1. The purpose of this procedure is to establish the process for receiving and storing incoming materials.

2. **Definitions**
   2.1. **Component** – Any ingredient used in the compounding of a preparations, including any active ingredient, added substance, or conventionally manufactured product.
   2.2. **Certificate of Analysis (C of A)** – A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
   2.3. **Certificate of Compliance (C of C)** – A document that certifies that a product or system meets the requirements of a safety regulation or standard.
   2.4. **Safety Data Sheet (SDS)** – A detailed informational document prepared by the manufacturer or importer that describes the physical and chemical properties of the product.
   2.5. **Active Pharmaceutical Ingredient (API)** – Any substance or mixture of substances intended to be used in the compounding of a preparation.

3. **Procedure**
   3.1. **Receiving materials**
      3.1.1. Personnel must wear appropriate PPE when receiving materials into the facility.
         3.1.1.1. The safety data sheet provides information on the appropriate PPE.
      3.1.2. Personnel must inspect the outer packaging for damage when packages arrive at the facility.
         3.1.2.1. If the damaged packaging is deemed severe enough to compromise the product's integrity, the package(s) may be sent back to the supplier for replacement.
         3.1.2.2. Any component found to be of unacceptable quality must be clearly labeled as rejected and segregated from active stock to prevent use before appropriate disposal.
      3.1.3. Personnel must attain a C of A and SDS for all powder or liquid components or a C of C for all components used in sterile compounding.
         3.1.3.1. All certificates must be retained either electronically or hardcopy for a minimum of 3 years.
      3.1.4. After gathering the required certificate(s), personnel must verify that the product label matches the C of A or C of C.

3.1.4.1. Personnel should verify that:
- 3.1.4.1.1. The product's name.
- 3.1.4.1.2. The manufacturer's name.
- 3.1.4.1.3. The NDC number (if applicable).
- 3.1.4.1.4. The correct salt form was received.
- 3.1.4.1.5. The expiration date is acceptable.
  - 3.1.4.1.5.1. If the product does not have an expiration date, an expiration date of 1 year from the date of receipt can be applied.

3.1.5. Personnel must clearly mark the date the material was received on all API containers.

3.1.6. Prior to entering the component into active stock, a second verification must be made by a separate individual.

3.1.6.1. The second verification must ensure that the material matches the formulation the component is intended for.

3.2. **Storage of Materials**

3.2.1. All components must be stored according to the manufacturer's instructions and in a manner that prevents contamination, mix-ups, and deterioration.

3.2.2. All materials must be stored off the floor, on a non-particle generating rack or pallet (Wood pallets are not acceptable)

3.2.3. The storage area must be monitored for temperature and humidity either by continuous monitoring or manually at least once a day.

4. **References**

4.1. USP <797> Pharmaceutical Compounding – Sterile Preparations

5. **Attachments**

5.1. N/A

Current Version	New Version	Description of Changes
1.0	1.0	Original Issue

☐ Draft ☐ Final Approved by _____ This policy implemented on _____	Annual Policy Review Reviewer/Date _____ Reviewer/Date _____ Reviewer/Date _____

1. **Purpose**
   1.1. The purpose of this procedure is to establish the process for releasing compounded preparations.

2. **Definitions**
   2.1. **Component** – Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.
   2.2. **Active Pharmaceutical Ingredient (API)** – Any substance or mixture of substances intended to be used in the compounding of a preparation.

3. **Procedure**
   3.1. **Releasing Non-Sterile Preparations**
      3.1.1. After the completion of a non-sterile preparation and prior to release, a pharmacist must verify that all components were used in the correct quantities and are appropriate for the specific preparation.
      3.1.2. The pharmacist verifying the preparation must check:
         3.1.2.1. The name, strength, and dosage form on the preparation's label matches the compounding record.
         3.1.2.2. The name and salt form of the API is correct.
         3.1.2.3. The lot numbers for all components are correct.
         3.1.2.4. The physical appearance of the preparation (e.g. color, texture, uniformity).
         3.1.2.5. The quantities of ingredients added are within an acceptable range.
      3.1.3. If all aspects of the preparation are deemed acceptable, the non-sterile preparation may be released into active stock and dispensed.
      3.1.4. Any preparation found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.

   3.2. **Releasing Sterile Preparations**
      3.2.1. After the completion of a sterile preparation and prior to release, a pharmacist must verify that all components were used in the correct quantities and are appropriate for the specific preparation.
      3.2.2. The verification of a preparation may be accomplished by verifying ingredients as they're being utilized or via photos taken during the compounding process and attached to the compounding record.

3.2.2.1. If photos are used, they must be clear and include the label of the product and the quantity utilized (e.g. scale weight, a syringe with product, beaker with calibrated lines).

3.2.3. The pharmacist verifying the sterile preparation must check:

3.2.3.1. The name, strength, and dosage form on the preparation's label matches the compounding record.

3.2.3.2. The name and salt form of the API is correct.

3.2.3.3. The lot numbers for all components are correct.

3.2.3.4. The physical appearance of the preparation (e.g. color, texture, uniformity).

3.2.3.5. The quantities of ingredients added are within an acceptable range.

3.2.3.6. Ensure the pH of the product is within range.

3.2.3.7. The filter integrity test was at or above the manufacture's minimum.

3.2.3.8. All analytical testing was performed and within acceptable range.

3.2.3.8.1. Release testing includes, at a minimum, sterility, and endotoxin testing.

3.2.4. If all aspects of the sterile preparation are deemed acceptable, the preparation may be released into active stock and dispensed.

3.2.5. Any preparation found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.

4. References

4.1. USP <797> Pharmaceutical Compounding – Sterile Preparations

4.2. USP <795> Pharmaceutical Compounding – Non-Sterile Preparations

5. Attachments

5.1. N/A

Current Version	New Version	Description of Changes
1.0	1.0	Original Issue

STRIVE compounding pharmacy	Title	Release of Compounded Preparations		
	Document Number	5.25	Version	1.0
Implementation Date				Page **3** of **3**

☐ Draft ☐ Final Approved by _____ This policy implemented on _____	Annual Policy Review Reviewer/Date _____ Reviewer/Date _____ Reviewer/Date _____

STRIVE
compounding pharmacy

Exhibit 5

480.626.4366 480.626.4365 info@strivepharmacy.com strivepharmacy.com
1275 E Baseline Rd Ste 104 Gilbert, AZ 85233

State of Utah
Department of Commerce
Division of Occupational and Professional Licensing
ATTN: Citation Coordinator
160 East 300 South
P.O. Box 146741
Salt Lake City, Utah 84114-6741
Telephone: (801) 530-6628
Fax: (801) 530-6511
Website: www.dopl.utah.gov

102685

CITATION

ISSUED TO: Strive Compounding Pharmacy		
PROFESSION: Pharmacy	LICENSE #: 12334977-1708	CASE #: 144183
DOB: / / n/a	DL #: n/a	SSN/EIN #: Y007406
BUSINESS ADDRESS: 1275 E Baseline Rd St 104	CITY: Gilbert	STATE: AZ ZIP: 85233
BUSINESS PHONE: 480-626-4366	BUSINESS EMAIL: mike@strivepharmacy.com	
HOME ADDRESS: n/a	CITY: n/a	STATE: n/a ZIP: n/a
HOME PHONE: n/a	HOME EMAIL: n/a	
LOCATION OF OFFENSE: Strive Compounding Pharmacy		

OFFENSE CODE	DATE OF OFFENSE: 5 / 16 / 2023 — DESCRIPTION	DATE ISSUED: 5 / 22 / 2023
R156-17b-502(6)	"Unprofessional conduct" includes: failing to abide by applicable federal and state law regarding the practice of pharmacy;	

REMARKS: Strive Compounding Pharmacy was found to be compounding for Office Use. On 5/16/2023, the Division discovered the pharmacy had been dispensing compounded tirzepatide, on multiple occasions, to a clinic in the State of Utah for Office Use. Federal law 21 USC 353a and 353b only allow for office use compounding if the facility is registered with the FDA as an outsourcing facility. Strive Compounding Pharmacy is not registered with the FDA as an outsourcing facility.

*Fine pursuant to R156-17b-402

PERSON SERVED: Sent via email	SERVED BY: Jo Evans
☑ FINE $ 750.00	☑ CEASE AND DESIST ORDER

I ACKNOWLEDGE RECEIPT OF THIS CITATION AND CERTIFY THAT I HAVE READ AND UNDERSTAND THE RIGHTS ADVISEMENT CONTAINED BELOW AND HAVE BEEN PROVIDED A NOTICE OF RESPONSE.	I CERTIFY THAT THE INFORMATION IN THIS CITATION IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF.
Sent via email to mike@strivepharmacy.com / /	5/22/2023
RECIPIENT'S SIGNATURE — DATE	INVESTIGATOR'S SIGNATURE

READ CAREFULLY

1. If you wish to contest this citation at a hearing, you must notify the Division in writing within 20 calendar days of receipt. The hearing will be conducted according to Title 63 G, Chapter 4.
2. If you do not contest the citation within 20 calendar days of receipt, the citation will become a final order of the Division and is not subject to further agency review.
3. Failure to comply with a final order of the Division is a Class A misdemeanor. The Division may refuse to issue or renew or may suspend, revoke, or place on probation a license you hold or apply for.

RECIPIENT COPY

UTAH DEPARTMENT OF COMMERCE
Division of Professional Licensing

CITATION NOTICE OF RESPONSE

You have 20 days* to either pay the fine or respond as follows:

- **Fill out this form & check the applicable box from the options. If preferred, you may type out your response in an email. Submit your response in either format (along with any attachments) to fines@utah.gov.**

OR

- **Pay the fine by scanning the QR code above or by going to www.dopl.utah.gov, then scroll down to the bottom right side of the page and select the blue "Fines" ⚠ Fines button. Both options allow you to submit your response (and other attachments) at the check-out screen.**

Citation #: 102685		**Date of Citation:** 5/22/2023	
Name:			
Address:			
City:		**State:**	**Zip:**
Email:		**Phone:**	

The Division must receive a response or payment within 20 calendar days

*If you fail to timely respond or pay the fine, the citation will become the final order of the Division and may result in denial of future licensure or disciplinary action against a license you currently hold.

	1. I admit committing the offense, choose not to contest the citation, and hereby submit the fine imposed. By doing so, I hereby waive any and all affirmative defenses I may have to this citation.
	2. I admit committing the offense, hereby submit the fine imposed with a written explanation of the circumstances of the offense and request that the fine be reduced or the sanction be modified.
	3. I admit committing the offense, but I request a pre-citation hearing conference to explain the circumstances of the offense. *(On the back of this form please submit a brief written explanation of the circumstances of the offense. You will receive a phone call from an Investigation Supervisor)*
	4. I deny committing the offense and request a hearing to contest the citation. *(On the back of this form please provide a written response to the alleged citation.)*

I certify that I have knowingly and voluntarily made the above election of rights. I understand that if I request a hearing the Division will notify me in writing and/or email of the hearing date and that if I fail to appear at the hearing a default judgment will be entered against me.

Signature:	**Date of Signature:**

STRIVE
compounding pharmacy

Exhibit 6

480.626.4366 480.626.4365 info@strivepharmacy.com strivepharmacy.com
1275 E Baseline Rd Ste 104 Gilbert, AZ 85233

STRIVE
compounding pharmacy

State of Utah
Department of Commerce
Division of Occupational and Professional Licensing
ATTN: Citation Coordinator
160 East 300 South
P.O. Box 146741
Salt Lake City, Utah 84114-6741

RE: Response to Citation #102685 alleging the dispensing of bulk drug substances for office use without registering as an outsourcing facility.

This response is in response to Citation #102685 issued by the Utah Pharmacy Board, alleging that Strive Compounding Pharmacy ("Strive") was supplying bulk nonpatient-specific compounded tirzepatide to a Utah clinic for office use. We deny committing the offense and request a hearing to contest the citation.

We agree with the alleged citation that since Strive is not licensed or registered as an outsourcing facility under 21 U.S.C. § 353b, the preparation of non-patient specific bulk substances would be inappropriate and unlawful. However, as a 503A compounding pharmacy, Strive acts in accordance with 21 U.S.C. § 353a(a) and only compounds drug products for an identified individual patient for a legitimate medical need based on the receipt of a valid prescription order. Please see examples of prescription drug orders for specific patients from a Utah prescribing practitioner for reference in **Exhibit A**. At no time did Strive prepare and ship into Utah non-patient specific bulk substances.

With respect to compounded tirzepatide, Strive compounds this drug product into individual vials that include the necessary drug information on the label. These vials are then placed into a suitable bag container with the patient specific information attached. This process is necessary due to the size constraints of the vials themselves and patients requiring multiple vials per prescription order. Utah Code Ann. § 58-17b-102(22) defines "[d]ispense" to include placing a prescription drug "…in a suitable container appropriately labeled…for use by a patient…." Then, Strive sends the compounded drug product to the prescriber's office to be given to the specific patients. Under this model, Strive believed that patients were being shown how to administer the injectable medication in office and were then sent home with a month supply of the drugs with proper labeling indicating that Strive dispensed the medication pursuant to a valid prescription.

Here, the patient-specific compounded drug products at issue were being sent to the prescriber's office in accordance with the Utah Pharmacy Act. Specifically, under Utah Admin. Code R156-17b-603(3)(b), it is the pharmacist-in-charge's responsibility to ensure that the prescription drug products are safely and accurately delivered to the patient or the *patient's agent*. In turn, Utah Admin. Code R156-17b-102(48)(b)(i) defines "patient's agent" to include an office of a licensed prescribing practitioner. As such, Utah

480.626.4366 480.626.4365 info@strivepharmacy.com strivepharmacy.com
1275 E Baseline Rd Ste 104 Gilbert, AZ 85233

expressly permits pharmacies to deliver medications directly to the prescribing practitioner acting as the patient's agent for specific patient use. Therefore, Strive was acting in accordance with the Utah Pharmacy Practice Act when it delivered the compounded drug product to the prescriber's office. As you know, the pharmacy completes the dispensing process upon delivery of the prescription drug product to the patient's agent.

In an effort to prevent this issue in the future, we plan to advise the Utah prescribing practitioners who send prescriptions to Strive that the drug products dispensed to their offices are meant for the specific patients to which the products were prescribed and should not, under any circumstances, be stored as though they are bulk drug products for office use. In any event, Strive did not engage in "unprofessional conduct" under Utah Admin. Code R156-17b-502(6) by failing to abide by applicable federal and state law regarding the practice of pharmacy. Indeed, as demonstrated above, Strive did comply with applicable federal and state laws. Strive did not prepare and ship into Utah non-patient specific bulk substances. As such, we deny committing the offense alleged in Citation #102685 and request a hearing to contest the citation.

Respectfully,

Michael Walker, PharmD
Pharmacist-in-Charge
Strive Compounding Pharmacy

480.626.4366 480.626.4365 info@strivepharmacy.com strivepharmacy.com
1275 E Baseline Rd Ste 104 Gilbert, AZ 85233

STRIVE
compounding pharmacy

Exhibit 1

480.626.4366 480.626.4365 info@strivepharmacy.com strivepharmacy.com
1275 E Baseline Rd Ste 104 Gilbert, AZ 85233

GOAT AESTHETICS

3561 W 11400 S, SOUTH JORDAN, UT 84095
Phone: 801-676-9755, Fax:
Date: May/23/2023 03:34:59 PM (CST)

KLARYSA THOMPSON
KLARYSA THOMPSON

State Lic. UT9037718-4405

Electronic Prescription Order

Name:	[redacted]	Last Name:	[redacted]	Middle Name:	
Phone:		Cell Phone:		DOB:	[redacted]
Address:		Address (Cont):		Email:	
City:		State:	UT	Zip:	84095
Gender:		Pay Type:		Ins. Name:	
Group Name:		Ins. Phone:		Member ID:	
Ins. Control Number:		Ins. BIN:		Delivery Type:	UPS Next Day Air
Driver's License Number:		Driver's License State:			

#1 Tirzepatide/B12 INJ

Strength: 10mg/500mcg/ml (2ml)====
Quantity: 2 ml (two)====
Refills: 0====
Directions: Inject 25 units (0.25ml) once weekly. Increase by 5 units weekly to a max of 150 units. If side effects increase, may decrease by 5 units weekly until side effects subside then continue titration schedule.====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 28====
Special instructions: NO NEEDLES====
Date Written: 05/23/2023 (May 23, 2023)====
Purpose: WITH B12 TO PREVENT NAUSEA====
Ship to: THOMPSON, KLARYSA: 3561 W 11400 S SUITE B , SOUTH JORDAN, UT, 84095 , Phone: 801-676-9755 . ====

Special Instructions: - **Allergies:** No known allergies; - **Diagnosis:** ;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: KLARYSA THOMPSON Date: May/23/2023 03:34:59 PM (CST)
Signed electronically by: KLARYSA THOMPSON

Strive Pharmacy Arizona
1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy System

Order #87519820

GOAT AESTHETICS

3561 W 11400 S, SOUTH JORDAN, UT 84095
Phone: 801-676-9755, Fax:
Date: May/23/2023 03:40:11 PM (CST)

KLARYSA THOMPSON
KLARYSA THOMPSON

State Lic. UT9037718-4405

Electronic Prescription Order

Name:	[redacted]	Last Name:	[redacted]	Middle Name:	
Phone:		Cell Phone:		DOB:	[redacted]
Address:		Address (Cont):		Email:	
City:		State:	**UT**	Zip:	**84095**
Gender:		Pay Type:		Ins. Name:	
Group Name:		Ins. Phone:		Member ID:	
Ins. Control Number:		Ins. BIN:		Delivery Type:	**UPS Next Day Air**
Driver's License Number:		Driver's License State:			

#1 Tirzepatide/B12 INJ

Strength: 10mg/500mcg/ml (2ml)====
Quantity: 2 ml (two)====
Refills: 0====
Directions: Inject 25 units (0.25ml) once weekly. Increase by 5 units weekly to a max of 150 units. If side effects increase, may decrease by 5 units weekly until side effects subside then continue titration schedule.====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 28====
Special instructions: NO NEEDLES====
Date Written: 05/23/2023 (May 23, 2023)====
Purpose: WITH B12 TO PREVENT NAUSEA====
Ship to: THOMPSON, KLARYSA: 3561 W 11400 S SUITE B , SOUTH JORDAN, UT, 84095 , Phone: 801-676-9755 . ====

Special Instructions: - **Allergies:** NO KNOWN ALLERGIES; - **Diagnosis:** ;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: KLARYSA THOMPSON Date: May/23/2023 03:40:11 PM (CST)
Signed electronically by: KLARYSA THOMPSON

Strive Pharmacy Arizona
1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy System

Order #87513118

GOAT AESTHETICS

3561 W 11400 S, SOUTH JORDAN, UT 84095
Phone: 801-676-9755, Fax:
Date: May/18/2023 05:28:41 PM (CST)

KLARYSA THOMPSON
KLARYSA THOMPSON

State Lic. UT9037718-4405

Electronic Prescription Order

Name:	[redacted]	Last Name:	[redacted]	Middle Name:	
Phone:		Cell Phone:		DOB:	[redacted]
Address:		Address (Cont):		Email:	
City:		State:	**UT**	Zip:	**84095**
Gender:		Pay Type:		Ins. Name:	
Group Name:		Ins. Phone:		Member ID:	
Ins. Control Number:		Ins. BIN:		Delivery Type:	**UPS Next Day Air**
Driver's License Number:		Driver's License State:			

#1 Tirzepatide/B12 INJ

Strength: 10mg/500mcg/ml (2ml)====
Quantity: 4 ml (four)====
Refills: 0====
Directions: Inject 25 units (0.25ml) once weekly. Increase by 5 units weekly to a max of 150 units. If side effects increase, may decrease by 5 units weekly until side effects subside then continue titration schedule.====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 60====
Special instructions: NO NEEDLES====
Date Written: 05/18/2023 (May 18, 2023)====
Purpose: WITH B12 TO PREVENT NAUSEA====
Ship to: THOMPSON, KLARYSA: 3561 W 11400 S SUITE B , SOUTH JORDAN, UT, 84095 , Phone: 801-676-9755 . ====

Special Instructions: - **Allergies:** NO KNOWN ALLERGIES; - **Diagnosis:** ;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: KLARYSA THOMPSON Date: May/18/2023 05:28:41 PM (CST)
Signed electronically by: KLARYSA THOMPSON

Strive Pharmacy Arizona
1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy System

Order #87401694

STRIVE
compounding pharmacy

Exhibit 7

480.626.4366 480.626.4365 info@strivepharmacy.com strivepharmacy.com
1275 E Baseline Rd Ste 104 Gilbert, AZ 85233

From: Jo Evans <jevans@utah.gov>
Date: June 28, 2023 at 8:58:10 AM PDT
To: mike@strivepharmacy.com
Subject: State of Utah - Division of Professional Licensing - Citation 102685

Strive Pharmacy,

The Division of Professional Licensing (DOPL) has reviewed your response to Citation 102685 and dismissed the Citation. No further action is required from your pharmacy. We appreciate the evidence provided and your assistance with this investigation.

Regards,

Jo Evans | Investigator

O: 801-310-9879 | jevans [goog_832884564]@utah.gov [utah.gov]

STRIVE
compounding pharmacy

Exhibit 8

480.626.4366 480.626.4365 info@strivepharmacy.com strivepharmacy.com
1275 E Baseline Rd Ste 104 Gilbert, AZ 85233

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

PERSONAL AND CONFIDENTIAL

August 14, 2023

Strive Pharmacy Denver LLC
Attn: Pharmacist Manager
11405 E Briarwood Ave Ste 300
Centennial, CO 80112-3848

Sent via email to: mike@strivepharmacy.com; Zackery.spears@wilkes.edu

Re: License Number: PDO.1680000218
Case Number: 2023-5699

Dear Pharmacist Manager:

The State Board of Pharmacy ("Board") has received the attached complaint regarding the conduct of the Board-registered prescription drug outlet detailed above, more specifically, a possible violation of the Pharmacists, Pharmacy Business, and Pharmaceuticals Practice Act. The Board is required by law to investigate this complaint. It is being sent to you as the pharmacist manager of the above listed prescription drug outlet. The first step in the process is to obtain your response to the allegations raised in the complaint. At this point, no assumption has been made about the truth or validity of any information provided to the Board.

Please provide a written response to the enclosed materials as they pertain to the allegations made in the complaint and provide any pertinent supporting documentation **within 10 days of the date of this letter**. An earlier response may expedite the Board's review of this matter. To facilitate an efficient and timely review, please type your response. If this is not possible, please legibly print your response. Be sure to include the case number listed above on all correspondence.

We encourage you to respond electronically. Please submit the response to dora_pharmacyboard@state.co.us. The subject line should include your name and case number. If corresponding via mail or fax, your response should be returned to the complaint specialist at the address indicated below.

It is the policy of the Board to copy your attorney on all correspondence in order to assure that your attorney is aware of developments in your case. If you are represented by an attorney in this matter, please provide your attorney's contact information to the Board in writing. If the Board already has your attorney's contact information, your attorney's name should be identified below as a carbon copy or "cc," indicating that a copy of this letter was sent to that attorney. If at any time it appears that the Board does not have the correct information regarding your legal representation, please update the Board and provide your attorney with a copy of all correspondence from the Board.

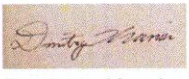
We strongly encourage you to begin preparing your response to the complaint as soon as possible, as extensions to the ten day response time will not be granted except in very limited circumstances. Additionally, if you choose to be represented by an attorney, please contact him or her immediately. A delay in doing so will not be grounds for an extension.

Following receipt of your response, the Board will review the complaint and your response thereto. The Board will then determine what further action, if any, is warranted. Please note you will be advised in writing of the Board's disposition of this complaint.

Thank you for your cooperation and prompt attention to this matter. If you have any questions, please contact me at dora_pharmacyboard@state.co.us or (303) 894-7800.

Sincerely,

FOR THE COLORADO STATE BOARD OF PHARMACY



Dmitry Kunin
Senior Program Director
Colorado Pharmacy Board

Enclosures: Q&A Brochure
Complaint

COLORADO
Department of Regulatory Agencies
Division of Professions and Occupations

MEMORANDUM

BOARD/PROGRAM	State Board of Pharmacy		
INVESTIGATOR	Chris Gassen		
CASE NUMBER	2023-5699	**DATE OF MEMORANDUM**	8/11/23

RESPONDENT INFORMATION	
Name	Strive Pharmacy Denver, LLC

LICENSE TYPE	LICENSE #	STATUS	FIRST ISSUED	EXPIRATION	METHOD
PDO	168-218	Active	8/11/20	10/31/24	Original

RESPONDENT ATTORNEY	

COMPLAINANT INITIALS	Anonymous

SUMMARY

On 8/10/23, staff from the State Board of Pharmacy referred to the Office of Investigations and Inspections a request to investigate a complaint (Attachment 1) received from an anonymous source which alleged that Stride Pharmacy Denver, LLC is "Dispensing compounded medications to medical offices for the office to dispense or administer in office. Dispensing compounded semaglutide salt forms and other peptides that are not FDA listed."

On 8/11/23, I visited Stride Pharmacy Denver, LLC, 11405 E. Briarwood Ave, Ste 300, Centennial, CO 80112 and spoke with Zackery Spears (PHA 23051), who currently is and has been the pharmacist manager of this pharmacy since 2/6/23. Detailed below is what I was able to determine:

- Between at least 1/1/23 and 3/1/23, this pharmacy has dispensed numerous compounded preparations containing semaglutide sodium salt as detailed in a usage report generated by this pharmacy (Attachment - 2).

- While Mr. Spears contends that all semaglutide salt preparations were dispensed pursuant to valid, patient-specific prescription orders, neither Mr. Spears nor I could locate any prescription orders on file at this pharmacy for the transactions detailed in Attachment - 2. This is a violation of Board Rules 11.01.00, 11.02.00(a)(3) and 11.04.10 and section 12-280-126(1)(c)(I), (II) and (III) and (k), C.R.S.

- While this pharmacy procured the semaglutide sodium salt from Biopeptek Pharmaceuticals, LLC, 5 Great Valley Pkwy, Ste 100, Malvern, PA 19355 in at least January 2023 and February 2023 (Attachments - 3, 4, 5 and 6) in addition to various other prescription drugs between at least January 2023 and June 2023, Biopeptek Pharmaceuticals, LLC is not registered by the Board to distribute prescription drug products into Colorado. This is a violation on the part of the pharmacy pursuant to Board Rules 1.00.24 and 7.00.30(b) and section 12-280-126(1)(c)(I), (II) and (III) and (k), C.R.S., and is a violation on the part of the unregistered wholesaler pursuant to Board Rule 15.01.00(b) and section 12-280-303 and 12-280-307, C.R.S. Please also see Board Policy 10-1 (section C), Board Policy 10-6 (section 11) and Board Policy 30-10.

- In addition, it does not appear the semaglutide sodium salt is FDA-approved or is otherwise compliant with Board Rule 21.10.60 to be used as a component in compounding preparations.

- Moreover, the FDA stated the following (Attachment - 7) regarding the use of semaglutide salt:

  "FDA has received adverse event reports after patients used compounded semaglutide. Patients should not use a compounded drug if an approved drug is available to treat a patient. Patients and health care professionals should understand that the agency does not review compounded versions of these drugs for safety, effectiveness, or quality. Additionally, FDA has received reports that in some cases, compounders may be using salt forms of semaglutide, including semaglutide sodium and semaglutide acetate. The salt forms are different active ingredients than is used the approved drugs, which contain the base form of semaglutide. The agency is not aware of any basis for compounding using the salt forms that would meet the FD&C requirements for types of active ingredients that can be compounded. On April 27, 2023, FDA wrote to the National Association of Boards of Pharmacy expressing the agency's concerns with use of the salt forms in compounded products."

- According to Mr. Spears, this pharmacy is not making a duplicate of the FDA-approved manufactured semaglutide version because it adds vitamin B6 or B12 to the semaglutide in a troche dosage form (whereas the FDA-approved manufactured version does not contain a vitamin and is made in a tablet form). In addition, while this pharmacy is still compounding preparations using semaglutide to this day, it stopped using the salt version after March 2023. Nevertheless, it appears that the information from the FDA in Attachment - 7 would still apply due to adverse event reports.

- While Board Rule 21.11.00 requires all compounding records to be uniform, this pharmacy maintains the required elements of a compounding record within multiple windows of its computer system. For instance, for me to examine the required elements of a compounding record, I would have to click through various windows to obtain the source, lot number and expiration date of each ingredient used and another window to obtain the assigned beyond-use date.

- During my visit at this pharmacy, I conducted an inspection (Attachment - 8). I found the following:

1. Please obtain semaglutide and other prescription drugs from Board-registered sources. See examples where it appears the product is being obtained from a source not registered with the Board.

2. While it appears that numerous compounded preparations for semagutide sodium salt have been dispensed from this pharmacy in 2023, neither the pharmacist manager nor I could find any orders for any of the dispensing transactions.

3. Compounding records shall be uniformly maintained and contemporaneous.

4. Please label compounded made in advance of immediate need in accordance with Rule 21.11.10. See hundreds of examples. This is a violation of Board Rule 21.11.00. This was also noted on the 11/29/21 inspection (Attachment - 9).

5. Invoices shall be filed in one of three separate sets of files (C-II, C-III-V and Rx). See numerous examples in 2023. This is a violation of Board Rules 11.01.00 and 11.06.40 and section 12-280-126(1)(c)(I), (II) and (III) and (k), C.R.S.

6. The new pharmacist manager did not conduct a change of pharmacist manager controlled substance inventory. This is a violation of Board Rules 7.00.20(b) and section 12-280-126(1)(c)(I), (II) and (III) and (k), C.R.S.

7. Please file orders in one of three separate sets of files (C-II, C-III-V and Rx). See examples. This is a violation of Board Rules 11.01.00, 11.02.00(a)(3) and 11.04.10 and section 12-280-126(1)(c)(I), (II) and (III) and (k), C.R.S.

8. Please do not store drug products directly on the floor. This is a violation of Board Rules 21.10.30 and 21.10.65 and section 12-280-126(1)(c)(I), (II) and (III) and (k), C.R.S.

9. Refrigerator and freezer temperatures shall be recorded each day. There are no readings recorded on Saturdays and Sundays. This is a violation of Board Rule 5.01.31(j) and (k) and section 12-280-126(1)(c)(I), (II) and (III) and (k), C.R.S. This was also noted on the 11/29/21 inspection (Attachment - 9).

10. Please be able to generate, upon request, a readable daily printout in accordance with Rule 11.04.20. Currently, there is no apparent order issuance date, and other required information is unreadable. REPEAT DEFICIENCY OVER THE LAST 3 CONSECUTIVE INSPECTIONS. This was also noted on the 11/29/21 inspection (Attachment - 9) and 12/20/22 inspection (Attachment - 10) and, as such, is subject to potential Board discipline pursuant to Board Policy 30-16.

11. The pharmacist manager shall review, date and sign the compounding policy and procedure manual within 30 days of assessing the duty in February 2023. This is a violation of Board Rules 7.00.20(j) and 21.10.10(a) and section 12-280-126(1)(c)(I), (II) and (III) and (k), C.R.S. This was also noted on the 11/29/21 inspection (Attachment - 9).

The Board may wish to consider the following citations:

REG	1.00.24	CRS	12-280-126(1)(c)(I), (II) and (III)
REG	5.01.31(j)	CRS	12-280-126(1)(k)
REG	5.01.31(k)		
REG	7.00.20(b)		
REG	7.00.20(j)		
REG	7.00.30(b)		
REG	11.01.00		
REG	11.02.00(a)(3)		
REG	11.04.10		
REG	11.04.20		
REG	11.06.40		
REG	21.10.10(a)		
REG	21.10.30		
REG	21.10.60		
REG	21.10.65		
REG	21.11.00		
REG	21.11.10		

ATTACHMENTS	EXHIBITS
1. Complaint	
2. Usage Report	
3. Biopeptek Pharmaceuticals, LLC Invoice	
4. Biopeptek Pharmaceuticals, LLC Invoice	
5. Biopeptek Pharmaceuticals, LLC Invoice	
6. Biopeptek Pharmaceuticals, LLC Invoice	
7. FDA Advisory	
8. 8/11/23 Inspection Report	
9. 11/29/21 Inspection Report	
10. 12/20/22 Inspection Report	

CRL

Reviewer's Initials

Complaint - Strive Pharmacy Denver LLC, PDO.1680000218

Name

Respondent

Name
Strive Pharmacy Denver LLC

Address
11405 E Briarwood Ave Ste 300
Centennial, Colorado 80112-3848
United States

E-mail
mike@strivepharmacy.com

Work Phone
(303) 953-4533

License Number
PDO.1680000218

Complainant

Name

Address

Anonymous
Yes

Online Complaint - Complaint Form

Division of Professions and Occupations | Online Complaint Form

Thank you for taking the time to file a complaint with the Division of Professions and Occupations. We realize that at times this may be difficult and some subject matters may be hard to discuss. Answering fully and completely all of the questions in this complaint form will provide the Division the best possible opportunity to review and determine if any allegations are a violation of the particular practice act. Please make sure to document as much as possible about the incident(s) so that we can help.

We encourage you to include your name and contact information with your complaint so we may ask follow up questions and confirm additional information. While much of what we need is included in the below, each complaint and allegation is unique and many require additional communication with you to ensure we collect everything. However, if you have chosen to file anonymously, we still appreciate the time you have taken and will work to determine appropriate actions based on what you provide below.

Before starting your complaint, we recommend that you review the Complaint FAQ Information so you have a full understanding of what occurs when a complaint is filed, what the program will do, what information is disclosed to the person or entity being filed against and other important information. The person or business that you file your complaint against will typically be provided with a copy of the complaint and all other documentation you provide. If you provide any contact information, anywhere on this form, like your name or contact address, your complaint will not be treated anonymously regardless of selections on the previous page.

Please be prepared to complete the complaint fully and submit as you will not be able to return and finish the complaint if you leave the form before submitting. Depending on your situation this process can take between 10 - 30 minutes, or possibly more for an extensive submission.

1. Did you select "File Anonymously" on the previous page?

If "Yes" then you will not be required to complete the contact information questions below. However, it is important to note, that complaints filed anonymously have a more difficult time having a case initiated and are more difficult to investigate because there is frequent need for more information and communication from the board. If you selected "File Anonymously" on the previous page and wish to change your response, you may do so here by selecting "No" and entering your contact information.
Yes

2.

- If you said "No" to File Anonymously, please enter your full name:

3.

- If you said "No" to File Anonymously, please enter your contact phone number:

4.

- If you said "No" to File Anonymously, please enter your contact email address:

5. Are you filing this complaint on behalf of someone else?
No

6.

- If you said "Yes" you are filing on behalf of someone else, please enter their full name, your relationship to them and the year of birth of that person:

7. Enter the date(s) of the incident(s). If the incident occurred multiple times, please separate all dates by a comma:
07/24/2023

8. Please provide a description of the event(s) that occurred to you. Make sure to be as detailed as possible and include locations where appropriate. If you need more space you may upload a document with additional description in the following question:
Dispensing compounded medications to medical offices for the office to dispense or administer in office. Dispensing compounded semaglutide salt forms and other peptides that are not FDA listed.

9.

- If you need more space or have additional information to provide, please upload documentation of your description of the event(s) that occurred to you. Make sure your document is as detailed as possible and includes any dates or locations as appropriate:

  Select the "Choose File" button to search for the scanned document(s) on your computer. After deciding which document to use, select the "Upload Document" button to complete uploading the document(s).

10. Were there any witnesses to the event(s) that occurred to you? This would include other professionals, family members, other clients, etc.
No

11.

- If you said "Yes" above, please enter the name(s) and contact information (phone number and email address as available) of the witness(es) below:

12. Have you filed any of the below regarding the event(s)?:

- A police report or law enforcement
- A complaint with another office/agency
- An Expert Review or third party investigator

No

13.

- If you said "Yes" above, please enter the name(s) and contact information (phone number and email address as available) of the investigator(s)/expert(s) AND any case number(s) you may have related to the investigation:

14. Have you retained an attorney regarding the event(s)?
No

15.

- If you said "Yes" above, please enter the name(s) and contact information (phone number and email address as available) of the attorney(s) representing you:

16. Do you have any additional documentation you can provide to the Division that would be helpful to us in investigating your complaint. These documents can include but are not limited to:

- Police Reports
- Medical Records
- Witness Statements

- Letters or Other Correspondence
- Contracts
- Photos of Incident(s)

Select the "Choose File" button to search for the scanned document(s) on your computer. After deciding which document to use, select the "Upload Document" button to complete uploading the document(s).

17. Please enter today's date to serve as your complaint submission date:
07/27/2023

Online Complaint - HEALTHCARE Release Form

Division of Professions and Occupations | Authorization to Release Medical Records

Please complete the information on the following pages. All questions with a red asterisk (*) are required unless otherwise noted.

18. By selecting "Yes" below, you authorize the release of medical records and information pertaining to the client/patient provided by any treating health care provider, hospital, pharmacy or other facility. The records and information may be released to the Department of Regulatory Agencies (DORA) and investigators of the Division or Professions and Occupations (DPO) and others directly involved in the review process.

By authorizing the of release of medical records you agree that:

- You understand this authorization is voluntary;
- You understand that the release of these records and this information is for the purpose of investigation and proceedings involving issues relating to the complaint I have submitted to DORA and may include my personal records;
- You further consent to the use of these records in a criminal investigation or proceeding by any law enforcement agency against the Health Care provider who is the subject of my complaint; AND
- You understand that DORA may use its subpoena authority to obtain records it deems necessary to investigate the complaint.

Additionally, you understand that this release DOES NOT INCLUDE records of identity, diagnosis, prognosis or treatment maintained in connection with the performance of any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States.

IMPORTANT NOTICE: An answer of "No" DOES NOT limit the Division's authority to obtain documents, however, it may delay the investigation of your complaint.
Yes

19.

- If you said "Yes" above, AND you are filing this complaint on behalf of someone else, you agree that you have the authority to authorize the release of these records by selecting one of the options below :

20.

- If you selected "Legal Power of Attorney" above, please provide a copy of the legal document(s) showing your power of attorney.

  Select the "Choose File" button to search for the scanned document(s) on your computer. After deciding which document to use, select the "Upload Document" button to complete uploading the document(s).

Review - Online Complaint

It's a good idea to print this screen for your records as after you submit your complaint you will not be able to access it again. To do so follow the below steps:

- Select the "Print Review" button in the upper right hand corner of this page
- The Print Review window will open in a new browser tab. In that window select "Print" and your document will print to your selected printer.
- After printing, close the Print Review browser tab.

After you close the Print Review tab, you will be returned to this page and can complete your submission.

83378112	01/07/23 13:54	New Rx	01/10/23 10:39 AM	83378112		Denver	eRx	Sophia (sb)		Completed Orders	Dunnam, Gretchen (DOB: 02/06/67)	Blumenthal, Sharon	CO	Colorado Springs		Manage	More
				906540	240677	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Dunnam, Gretchen (DOB: 02/06/67)	Blumenthal, Sharon	CO			Tracking	
83385863	01/07/23 13:37	New Rx	01/10/23 10:39 AM	83385863		Denver	eRx	Sophia (sb)		Completed Orders	Puryear, Pamela (DOB: 10/07/67)	Blumenthal, Sharon	CO	Colorado Springs		Manage	More
				906541	240678	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Puryear, Pamela (DOB: 10/07/67)	Blumenthal, Sharon	CO			Tracking	
83394732	01/09/23 10:06	Refill Rx	01/10/23 03:17 PM	83394732		Denver	autr	Sophia (sb)		Completed Orders	Longfield, James (DOB: 03/24/55)	Metros, Michael	CO	remake and resent. pt had rash on arm. told to discontinue and we would get hi...		Manage	More
				907063	240692	Denver	autr	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Longfield, James (DOB: 03/24/55)	Metros, Michael	CO		Lot Tracking	Tracking	
83395922	01/09/23 10:35	Refill Rx	01/11/23 09:28 AM	83395922		Denver	autr	Sophia (sb)		Completed Orders	Bates, Charles L (DOB: 01/05/54)	Metros, Michael	CO	Patient answered and then hung up? Sending text 1/5 - verify cc and shipping pre...		Manage	More
				907602	240704	Denver	autr	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Bates, Charles L (DOB: 01/05/54)	Metros, Michael	CO			Tracking	
83398855	01/09/23 11:46	New Rx	01/11/23 11:18 AM	83398855		Denver	serx	Sophia (sb)		Completed Orders	NELSON, BRADY A (DOB: 05/10/57)	MALLORY, PATRICK	CO			Manage	More
				906870	240728	Denver	serx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 90 each)	Shipping	NELSON, BRADY A (DOB: 05/10/57)	MALLORY, PATRICK	CO			Tracking	
83401549	01/09/23 12:58	New Rx	01/11/23 01:18 PM	83401549		Denver	serx	Sophia (sb)		Completed Orders	Barnes, Leslie (DOB: 05/16/60)	Walker, Dominique	CO			Manage	More
				906871	240729	Denver	serx	Sophia (sb)	Semaglutide/B12 Mini Troche 500mcg/100mcg (QTY: 30 each)	Shipping	Barnes, Leslie (DOB: 05/16/60)	Walker, Dominique	CO			Tracking	
83408529	01/09/23 16:18	New Rx	01/11/23 01:09 PM	83408529		Denver	serx	Sophia (sb)		Completed Orders	Swast, Karen (DOB: 12/07/64)	Walker, Dominique	CO			Manage	More
				908872	240730	Denver	serx	Sophia (sb)	Semaglutide/B12 Mini Troche 500mcg/100mcg (QTY: 30 each)	Shipping	Swast, Karen (DOB: 12/07/64)	Walker, Dominique	CO			Tracking	
83415518	01/10/23 08:06	New Rx	01/11/23 09:52 AM	83415518		Denver	eRx	Sophia (sb)		Completed Orders	Torrez, JoAnne (DOB: 04/20/53)	Carver-Torres, Brenda	CO	PUEBLO		Manage	More
				906561	240718	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Torrez, JoAnne (DOB: 04/20/53)	Carver-Torres, Brenda	CO			Tracking	
83415626	01/10/23 08:12	New Rx	01/11/23 09:53 AM	83415626		Denver	eRx	Sophia (sb)		Completed Orders	Goettel, Jackie (DOB: 07/10/64)	Carver-Torres, Brenda	CO	PUEBLO		Manage	More
				906562	240719	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 500mcg/100mcg (QTY: 30 each)	Shipping	Goettel, Jackie (DOB: 07/10/64)	Carver-Torres, Brenda	CO			Tracking	
				906563	240720	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 500mcg/100mcg (QTY: 30 each)	Shipping	Goettel, Jackie (DOB: 07/10/64)	Carver-Torres, Brenda	CO			Tracking	
83415831	01/10/23 08:18	New Rx	01/11/23 09:54 AM	83415831		Denver	eRx	Sophia (sb)		Completed Orders	Lipitz, June (DOB: 06/14/61)	Carver-Torres, Brenda	CO	PUEBLO		Manage	More
				906564	240721	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 500mcg/100mcg (QTY: 30 each)	Shipping	Lipitz, June (DOB: 06/14/61)	Carver-Torres, Brenda	CO			Tracking	
83416059	01/10/23 08:26	New Rx	01/11/23 09:55 AM	83416059		Denver	eRx	Sophia (sb)		Completed Orders	Lopez, Johnny (DOB: 04/11/01)	Carver-Torres, Brenda	CO	PUEBLO		Manage	More
				906565	240722	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 500mcg/100mcg (QTY: 30 each)	Shipping	Lopez, Johnny (DOB: 04/11/01)	Carver-Torres, Brenda	CO			Tracking	
83417685	01/10/23 09:16	New Rx	01/11/23 09:55 AM	83417685		Denver	eRx	Sophia (sb)		Completed Orders	Dale, Staci (DOB: 12/31/73)	Carver-Torres, Brenda	CO	PUEBLO		Manage	More
				906566	240723	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 500mcg/100mcg (QTY: 30 each)	Shipping	Dale, Staci (DOB: 12/31/73)	Carver-Torres, Brenda	CO			Tracking	
83417777	01/10/23 09:19	New Rx	01/11/23 09:56 AM	83417777		Denver	eRx	Sophia (sb)		Completed Orders	McAuliffe, Nora (DOB: 01/24/54)	Carver-Torres, Brenda	CO	PUEBLO		Manage	More
				906567	240724	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	McAuliffe, Nora (DOB: 01/24/54)	Carver-Torres, Brenda	CO			Tracking	
83419858	01/10/23 10:11	New Rx	01/11/23 11:02 AM	83419858		Denver	eRx	Sophia (sb)		Completed Orders	Dech, Ursaline (DOB: 08/13/34)	Carver-Torres, Brenda	CO	PUEBLO		Manage	More
				906573	240731	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 500mcg/100mcg (QTY: 30 each)	Shipping	Dech, Ursaline (DOB: 08/13/34)	Carver-Torres, Brenda	CO			Tracking	
83419926	01/10/23 10:13	New Rx	01/11/23 11:03 AM	83419926		Denver	eRx	Sophia (sb)		Completed Orders	Asbury, Lisa (DOB: 01/07/65)	Carver-Torres, Brenda	CO	PUEBLO		Manage	More
				906574	240732	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 500mcg/100mcg (QTY: 30 each)	Shipping	Asbury, Lisa (DOB: 01/07/65)	Carver-Torres, Brenda	CO			Tracking	
83420197	01/10/23 10:19	New Rx	01/11/23 12:36 PM	83420197		Denver	serx	Sophia (sb)		Completed Orders	Woolfolk, Shavon (DOB: 08/08/77)	Metros, Michael	CO			Manage	More
				908586	240746	Denver	serx	Sophia (sb)	Semaglutide/B12 Mini Troche 250mcg/100mcg (QTY: 30 each)	Patient Pay Patient Pickup	Woolfolk, Shavon (DOB: 08/08/77)	Metros, Michael	CO			Tracking	
83426401	01/10/23 13:15	New Rx	01/12/23 09:39 AM	83426401		Denver	call	Sophia (sb)		Completed Orders	YOUNG, LINDA (DOB: 05/05/65)	Cho, KI OK	CO			Manage	More
				909006	240767	Denver	call	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	YOUNG, LINDA (DOB: 05/05/65)	Cho, KI OK	CO			Tracking	
83426437	01/10/23 13:19	New Rx	01/12/23 09:42 AM	83426437		Denver	call	Sophia (sb)		Completed Orders	Stieber, Chris (DOB: 12/25/55)	Cho, KI OK	CO			Manage	More
				909007	240768	Denver	call	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Stieber, Chris (DOB: 12/25/55)	Cho, KI OK	CO			Tracking	

83474540	01/12/23 16:50	New Rx	01/14/23 08:51 AM	83474540		Denver	call	Sophia (sb)			Completed Orders	Stake, Morgan (DOB: 04/14/65)	Cho, Klok	CO			Manage	More
				909041	240816	Denver	call	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 60 each)		Shipping	Stake, Morgan (DOB: 04/14/65)	Cho, Klok	CO			Tracking	
83483318	01/13/23 10:03	New Rx	01/14/23 12:58 PM	83483318		Denver	eRx	Sophia (sb)			Completed Orders	Hughes, Jennifer (DOB: 01/15/75)	Blumenthal, Sharon	CO	colorado springs		Manage	More
				909063	240835	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)		Shipping	Hughes, Jennifer (DOB: 01/15/75)	Blumenthal, Sharon	CO			Tracking	
83484472	01/13/23 10:43	New Rx	01/14/23 01:00 PM	83484472		Denver	eRx	Sophia (sb)			Completed Orders	Beard, Felicia (DOB: 04/05/68)	Blumenthal, Sharon	CO	colorado springs		Manage	More
				909054	240836	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)		Shipping	Beard, Felicia (DOB: 04/05/68)	Blumenthal, Sharon	CO			Tracking	
83486386	01/13/23 11:56	New Rx	01/14/23 01:00 PM	83486386		Denver	eRx	Sophia (sb)			Completed Orders	Sheppard, Linda (DOB: 06/04/51)	Blumenthal, Sharon	CO	colorado springs		Manage	More
				909055	240837	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)		Shipping	Sheppard, Linda (DOB: 06/04/51)	Blumenthal, Sharon	CO		Lot Tracking	Tracking	
83505708	01/16/23 10:01	Refill Rx	01/17/23 10:03 AM	83505708		Denver	mref	Kaeley (kwells)			On Hold	Acevedo, Toshamakia (DOB: 08/30/75)	MONTGOMERY, ASHLEE	CO	clinic asked to be canceled until we hear back with new strengths		Manage	More
				908229	240860	Denver	mref	Kaeley (kwells)	Semaglutide/B12 Mini Troche 250mcg/100mcg (QTY: 30 each)		Rx Cancelled	Acevedo, Toshamakia (DOB: 08/30/75)	MONTGOMERY, ASHLEE	CO			Tracking	
83505985	01/16/23 11:28	New Rx	01/17/23 11:36 AM	83505985		Denver	call	Sophia (sb)			Completed Orders	Rosengrants, Sandy (DOB: 01/17/68)	Cho, Ki Ok	CO			Manage	More
				909079	240883	Denver	call	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)		Shipping	Rosengrants, Sandy (DOB: 01/17/68)	Cho, Ki Ok	CO			Tracking	
83521299	01/17/23 11:25	New Rx	01/18/23 11:58 AM	83531255		Denver	eerx	Sophia (sb)			Completed Orders	Gnerich, Jennifer Lynn (DOB: 05/07/73)	Oster, Heidi	CO			Manage	More
				909110	240920	Denver	eerx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 90 each)		Patient Pay Patient Pickup	Gnerich, Jennifer Lynn (DOB: 05/07/73)	Oster, Heidi	CO			Tracking	
83550145	01/18/23 13:53	New Rx	01/19/23 01:35 PM	83550145		Denver	eRx	Sophia (sb)			Completed Orders	Murer, Outara (DOB: 02/01/51)	Lehner, Cara	CO			Manage	More
				909144	240960	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)		Shipping	Murer, Outara (DOB: 02/01/51)	Lehner, Cara	CO			Tracking	
83550164	01/19/23 14:17	Refill Rx	01/20/23 02:26 PM	83550164		Denver	autr	Sophia (sb)			Completed Orders	Corwin, Sarah E (DOB: 11/17/84)	WALKER, DOMINIQUE	CO			Manage	More
				908818	240553	Denver	autr	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)		Patient Pay Patient Pickup	Corwin, Sarah E (DOB: 11/17/84)	WALKER, DOMINIQUE	CO			Tracking	
83602449	01/21/23 14:54	New Rx	01/24/23 10:13 AM	83602449		Denver	eRx	Sophia (sb)			Completed Orders	Ferreri, Rebekah (DOB: 06/12/86)	BLUMENTHAL, SHARON	CO	COLORADO SPRINGS		Manage	More
				909222	241051	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)		Shipping	Ferreri, Rebekah (DOB: 06/12/86)	BLUMENTHAL, SHARON	CO		Lot Tracking	Tracking	
83604159	01/21/23 14:54	New Rx	01/24/23 10:12 AM	83604159		Denver	eRx	Sophia (sb)			Completed Orders	Golden, Kelly (DOB: 11/15/63)	BLUMENTHAL, SHARON	CO	COLORADO SPRINGS		Manage	More
				909223	241052	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)		Shipping	Golden, Kelly (DOB: 11/15/63)	BLUMENTHAL, SHARON	CO			Tracking	
				909224	241053	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)		Shipping	Golden, Kelly (DOB: 11/15/63)	BLUMENTHAL, SHARON	CO			Tracking	
				909225	241054	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)		Shipping	Golden, Kelly (DOB: 11/15/63)	BLUMENTHAL, SHARON	CO			Tracking	
83604175	01/21/23 14:54	New Rx	01/24/23 10:11 AM	83604175		Denver	eRx	Sophia (sb)			Completed Orders	Moure, Diana (DOB: 09/22/58)	BLUMENTHAL, SHARON	CO	COLORADO SPRINGS		Manage	More
				909226	241055	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)		Shipping	Moure, Diana (DOB: 09/22/58)	BLUMENTHAL, SHARON	CO			Tracking	
83604623	01/21/23 14:56	New Rx	01/24/23 10:10 AM	83604623		Denver	eRx	Sophia (sb)			Completed Orders	Mize, Pamela (DOB: 07/18/61)	BLUMENTHAL, SHARON	CO	COLORADO SPRINGS, mint		Manage	More
				909227	241056	Denver	eRx	Sophia (sb)	SEMAGLUTIDE/B12 GELATIN TROCHE 500/100 MCG (QTY: 30 each)		Shipping	Mize, Pamela (DOB: 07/18/61)	BLUMENTHAL, SHARON	CO		Lot Tracking	Tracking	
83605844	01/21/23 08:05	New Rx	01/24/23 10:28 AM	83605844		Denver	eRx	Sophia (sb)			Completed Orders	West, Kathy (DOB: 11/26/45)	Carver-Torres, Brenda	CO	PUEBLO		Manage	More
				909229	241060	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)		Shipping	West, Kathy (DOB: 11/26/45)	Carver-Torres, Brenda	CO			Tracking	
83605863	01/21/23 08:07	New Rx	01/24/23 10:29 AM	83605863		Denver	eRx	Sophia (sb)			Completed Orders	Dech, Ursaline (DOB: 08/13/54)	Carver-Torres, Brenda	CO	PUEBLO		Manage	More
				909230	241061	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)		Shipping	Dech, Ursaline (DOB: 08/13/54)	Carver-Torres, Brenda	CO			Tracking	
83605867	01/21/23 08:08	New Rx	01/24/23 10:30 AM	83605867		Denver	eRx	Sophia (sb)			Completed Orders	Durning, Christina (DOB: 02/14/72)	Carver-Torres, Brenda	CO	PUEBLO		Manage	More
				909231	241062	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)		Shipping	Durning, Christina (DOB: 02/14/72)	Carver-Torres, Brenda	CO			Tracking	

83606372	01/21/23 05:52	New Rx	01/24/23 10:31 AM	83606372		Denver	eRx	Sophia (sb)		Completed Orders	Wood, Paula (DOB: 01/30/55)	Carver-Torres, Brenda	CO	PUEBLO			Manage	More
				963232	241084	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Shipping	Wood, Paula (DOB: 01/30/55)	Carver-Torres, Brenda	CO				Tracking	
83606383	01/21/23 05:54	New Rx	01/24/23 10:32 AM	83606383		Denver	eRx	Sophia (sb)		Completed Orders	West, Sandy (DOB: 03/12/58)	Carver-Torres, Brenda	CO	PUEBLO			Manage	More
				963234	241085	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Shipping	West, Sandy (DOB: 03/12/58)	Carver-Torres, Brenda	CO				Tracking	
83606353	01/21/23 05:55	New Rx	01/24/23 10:32 AM	83606353		Denver	eRx	Sophia (sb)		Completed Orders	West, Sandy (DOB: 03/12/58)	Carver-Torres, Brenda	CO	PUEBLO			Manage	More
				963235	241086	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Shipping	West, Sandy (DOB: 03/12/58)	Carver-Torres, Brenda	CO				Tracking	
83607154	01/21/23 14:56	New Rx	01/24/23 10:13 AM	83607154		Denver	eRx	Sophia (sb)		Completed Orders	Dozie, Rebecca (DOB: 05/18/81)	BLUMENTHAL, SHARON	CO	colorado springs, mint			Manage	More
				963228	241057	Denver	eRx	Sophia (sb)	SEMAGLUTIDE/B12 GELATIN TROCHE 500/100 MCG (QTY: 30 each)	Shipping	Dozie, Rebecca (DOB: 05/18/81)	BLUMENTHAL, SHARON	CO		Lot Tracking		Tracking	
83614215	01/23/23 08:38	New Rx	01/27/23 10:45 AM	83614215		Denver	serx	Sophia (sb)		Completed Orders	Airy, Leanne (DOB: 08/22/81)	Axman, Joshua	CO				Manage	More
				963342	241199	Denver	serx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Patient Pay Patient Pickup	Airy, Leanne (DOB: 08/22/81)	Axman, Joshua	CO				Tracking	
83621634	01/23/23 11:37	New Rx	01/24/23 11:46 AM	83621634		Denver	eRx	Sophia (sb)		Completed Orders	McBroom, Heather (DOB: 12/12/76)	BLUMENTHAL, SHARON	CO				Manage	More
				963237	241070	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Shipping	McBroom, Heather (DOB: 12/12/76)	BLUMENTHAL, SHARON	CO				Tracking	
83626774	01/23/23 14:00	New Rx	01/24/23 02:05 PM	83626774		Denver	call	Sophia (sb)		Completed Orders	Chandler, Cynthia (DOB: 06/21/52)	Cho, Ki Ok	CO	mint			Manage	More
				963252	241086	Denver	call	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Chandler, Cynthia (DOB: 06/21/52)	Cho, Ki Ok	CO				Tracking	
83631860	01/23/23 18:13	New Rx	01/25/23 01:56 PM	83631860		Denver	serx	Sophia (sb)		Completed Orders	Demos, Anna (DOB: 09/15/52)	Metros, Michael	CO				Manage	More
				963274	241119	Denver	serx	Sophia (sb)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Patient Pay Patient Pickup	Demos, Anna (DOB: 09/15/52)	Metros, Michael	CO				Tracking	
83676736	01/25/23 17:03	New Rx	01/27/23 09:43 AM	83676736		Denver	serx	Sophia (sb)		Completed Orders	Schepis, Ann M (DOB: 12/15/45)	Metros, Michael	CO				Manage	More
				963328	241178	Denver	serx	Sophia (sb)	Semaglutide/B12 Mini Troche 250mcg/100mcg (QTY: 30 each)	Shipping	Schepis, Ann M (DOB: 12/15/45)	Metros, Michael	CO				Tracking	
83738228	01/30/23 12:28	Refill Rx	01/31/23 12:50 PM	83738228		Denver	mref	Sophia (sb)		Completed Orders	Price, Wiley (DOB: 05/22/82)	Metros, Michael	CO				Manage	More
				963709	241274	Denver	mref	Sophia (sb)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Patient Pay Patient Pickup	Price, Wiley (DOB: 05/22/82)	Metros, Michael	CO				Tracking	
83741044	01/30/23 13:53	New Rx	01/31/23 04:41 PM	83741044		Denver	serx	Jeanette (jrutledge)		Completed Orders	Harris, Richelon (DOB: 09/13/60)	Linn, Beatriz	CO				Manage	More
				963423	241256	Denver	serx	Jeanette (jrutledge)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Patient Pay Patient Pickup	Harris, Richelon (DOB: 09/13/60)	Linn, Beatriz	CO				Tracking	
83743654	01/30/23 15:05	New Rx	01/31/23 03:51 PM	83743654		Denver	serx	Sophia (sb)		Completed Orders	Mohrlan, Nancy (DOB: 07/10/61)	CARLSEN, LAURA	CO				Manage	More
				963419	241251	Denver	serx	Sophia (sb)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Shipping	Mohrlan, Nancy (DOB: 07/10/61)	CARLSEN, LAURA	CO				Tracking	
83791482	02/01/23 17:21	New Rx	02/07/23 03:59 PM	83791482		Denver	serx	Jeanette (jrutledge)		Completed Orders	SCHNEIDER, KATHARINE (DOB: 03/26/80)	MALLORY , PATRICK	CO	pt wants 30 days			Manage	More
				963674	241473	Denver	serx	Jeanette (jrutledge)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	SCHNEIDER, KATHARINE (DOB: 03/26/80)	MALLORY , PATRICK	CO				Tracking	
83805321	02/02/23 14:03	New Rx		83805321 Error		Denver	serx	Jeanette (jrutledge)		Deleted	McNamara, Robert L (DOB: 08/15/66)	Metros, Michael	CO	md sent new rx for correct med			Manage	More
						Denver	serx	Jeanette (jrutledge)	Semaglutide/B12 Mini Troche 250mcg/100mcg (QTY: 30 each)		McNamara, Robert L (DOB: 08/15/66)	Metros, Michael	CO				Tracking	
83811885	02/02/23 15:14	New Rx		83811885		Denver	serx	Jeanette (jrutledge)		On Hold	McNamara, Robert L (DOB: 08/15/66)	Metros, Michael	CO	pt will call us with cc 2/2			Manage	More
				963811	241400	Denver	serx	Jeanette (jrutledge)	Semaglutide/B12 Mini Troche 250mcg/100mcg (QTY: 30 each)	On Hold	McNamara, Robert L (DOB: 08/15/66)	Metros, Michael	CO				Tracking	
83829017	02/04/23 15:30	New Rx	02/07/23 09:14 AM	83829017		Denver	eRx	Mark (msanchez)		Completed Orders	Dunnam, Gretchen (DOB: 02/06/67)	BLUMENTHAL, SHARON	CO	COLORADO SPRINGS			Manage	More
				963556	241451	Denver	eRx	Mark (msanchez)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Dunnam, Gretchen (DOB: 02/06/67)	BLUMENTHAL, SHARON	CO				Tracking	
83829056	02/04/23 15:30	New Rx	02/07/23 09:12 AM	83829056		Denver	eRx	Mark (msanchez)		Completed Orders	Hughes, Jennifer (DOB: 01/19/75)	BLUMENTHAL, SHARON	CO	COLORADO SPRINGS			Manage	More
				963554	241445	Denver	eRx	Mark (msanchez)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Hughes, Jennifer (DOB: 01/19/75)	BLUMENTHAL, SHARON	CO				Tracking	
83829091	02/04/23 15:30	New Rx	02/07/23 09:13 AM	83829091		Denver	eRx	Mark (msanchez)		Completed Orders	Woltz, Michelle (DOB: 01/03/66)	BLUMENTHAL, SHARON	CO	COLORADO SPRINGS			Manage	More
				963555	241450	Denver	eRx	Mark (msanchez)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Woltz, Michelle (DOB: 01/03/66)	BLUMENTHAL, SHARON	CO				Tracking	

83823511	02/03/23 16:56	New Rx	02/07/23 09:15 AM	83833511		Denver	eRx	Mark (meanchez)		Completed Orders	Nelson, Amy (DOB: 01/12/79)	Carver-Torres, Brenda	CO	PUEBLO			Manage	More
				969558	241453	Denver	eRx	Mark (meanchez)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Nelson, Amy (DOB: 01/12/79)	Carver-Torres, Brenda	CO		Lot Tracking	Tracking		
83823923	02/03/23 16:57	New Rx	02/07/23 09:16 AM	83833923		Denver	eRx	Mark (meanchez)		Completed Orders	Racine, Julie (DOB: 04/11/57)	Carver-Torres, Brenda	CO	PUEBLO			Manage	More
				969559	241454	Denver	eRx	Mark (meanchez)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Shipping	Racine, Julie (DOB: 04/11/57)	Carver-Torres, Brenda	CO			Tracking		
83823960	02/03/23 16:55	New Rx	02/07/23 09:17 AM	83833960		Denver	eRx	Mark (meanchez)		Completed Orders	Gecewicz, Sandy (DOB: 01/29/52)	Carver-Torres, Brenda	CO	PUEBLO			Manage	More
				969561	241456	Denver	eRx	Mark (meanchez)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Shipping	Gecewicz, Sandy (DOB: 01/29/52)	Carver-Torres, Brenda	CO			Tracking		
83837462	02/04/23 15:31	New Rx	02/07/23 09:17 AM	83837462		Denver	eRx	Mark (meanchez)		Completed Orders	Vinson, Michelle (DOB: 06/14/58)	BLUMENTHAL, SHARON	CO	COLORADO SPRINGS			Manage	More
				969562	241457	Denver	eRx	Mark (meanchez)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 60 each)	Shipping	Vinson, Michelle (DOB: 06/14/58)	BLUMENTHAL, SHARON	CO			Tracking		
83837495	02/04/23 15:32	New Rx	02/07/23 09:17 AM	83837495		Denver	eRx	Mark (meanchez)		Completed Orders	Mize, Pamela (DOB: 07/18/81)	BLUMENTHAL, SHARON	CO	COLORADO SPRINGS			Manage	More
				969563	241458	Denver	eRx	Mark (meanchez)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Mize, Pamela (DOB: 07/18/81)	BLUMENTHAL, SHARON	CO			Tracking		
83837555	02/04/23 15:18	New Rx	02/07/23 09:18 AM	83837555		Denver	eRx	Mark (meanchez)		Completed Orders	Miles, Molly (DOB: 02/10/63)	BLUMENTHAL, SHARON	CO	COLORADO SPRINGS - gelatin troche!!			Manage	More
				969564	241460	Denver	eRx	Mark (meanchez)	SEMAGLUTIDE/B12 GELATIN TROCHE 500/100 MCG (QTY: 30 each)	Shipping	Miles, Molly (DOB: 02/10/63)	BLUMENTHAL, SHARON	CO		Lot Tracking	Tracking		
83837610	02/04/23 15:18	New Rx	02/07/23 09:18 AM	83837610		Denver	eRx	Mark (meanchez)		Completed Orders	Kyger, Debbie (DOB: 11/12/62)	BLUMENTHAL, SHARON	CO	COLORADO SPRINGS - gelatin troche!!			Manage	More
				969565	241461	Denver	eRx	Mark (meanchez)	SEMAGLUTIDE/B12 GELATIN TROCHE 500/100 MCG (QTY: 30 each)	Shipping	Kyger, Debbie (DOB: 11/12/62)	BLUMENTHAL, SHARON	CO			Tracking		
83837625	02/04/23 15:18	New Rx	02/07/23 10:01 AM	83837625		Denver	eRx	Jeanette (jrutledge)		Completed Orders	Lamdin, Will (DOB: 04/11/42)	BLUMENTHAL, SHARON	CO	COLORADO SPRINGS - gelatin troche!!			Manage	More
				969571	241465	Denver	eRx	Jeanette (jrutledge)	SEMAGLUTIDE/B12 GELATIN TROCHE 500/100 MCG (QTY: 30 each)	Shipping	Lamdin, Will (DOB: 04/11/42)	BLUMENTHAL, SHARON	CO			Tracking		
83843476	02/06/23 07:16	New Rx	02/07/23 10:45 AM	83843476		Denver	serx	Jeanette (jrutledge)		Completed Orders	Kingsley, Gregory R (DOB: 05/12/60)	Hedberg, Caleb	CO				Manage	More
				969681	241485	Denver	serx	Jeanette (jrutledge)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Shipping	Kingsley, Gregory R (DOB: 05/12/60)	Hedberg, Caleb	CO			Tracking		
83848373	02/06/23 09:57	New Rx	02/07/23 04:47 PM	83848373		Denver	serx	Jeanette (jrutledge)		Completed Orders	Klein, Paula G (DOB: 06/10/47)	WALKER, DOMINIQUE	CO				Manage	More
				969696	241495	Denver	serx	Jeanette (jrutledge)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Patient Pay Patient Pickup	Klein, Paula G (DOB: 06/10/47)	WALKER, DOMINIQUE	CO			Tracking		
83860566	02/06/23 15:05	New Rx	02/09/23 12:38 PM	83860566		Denver	serx	Jeanette (jrutledge)		Completed Orders	Herbert, Rebecca (DOB: 04/19/75)	Linn, Beatriz	CO				Manage	More
				969648	241535	Denver	serx	Jeanette (jrutledge)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Shipping	Herbert, Rebecca (DOB: 04/19/75)	Linn, Beatriz	CO			Tracking		
83874570	02/07/23 10:17	Refill Rx	02/08/23 10:34 AM	83874570		Denver	autr	Mark (meanchez)		Completed Orders	Barnes, Leslie (DOB: 05/16/60)	WALKER, DOMINIQUE	CO				Manage	More
				968571	241517	Denver	autr	Mark (meanchez)	Semaglutide/B12 Mini Troche 500mcg/100mcg (QTY: 30 each)	Shipping	Barnes, Leslie (DOB: 05/16/60)	WALKER, DOMINIQUE	CO			Tracking		
83875166	02/07/23 10:33	Refill Rx	02/08/23 10:40 AM	83875166		Denver	autr	Mark (meanchez)		Completed Orders	Woolfolk, Shavon (DOB: 08/08/77)	Metros, Michael	CO				Manage	More
				968586	241518	Denver	autr	Mark (meanchez)	Semaglutide/B12 Mini Troche 250mcg/100mcg (QTY: 30 each)	Patient Pay Patient Pickup	Woolfolk, Shavon (DOB: 08/08/77)	Metros, Michael	CO			Tracking		
83877252	02/07/23 11:32	Refill Rx	02/08/23 11:48 AM	83877252		Denver	autr	Mark (meanchez)		Completed Orders	Birnberg, Caprice D (DOB: 12/11/55)	Hedberg, Caleb	CO				Manage	More
				969015	241534	Denver	autr	Mark (meanchez)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Patient Pay Patient Pickup	Birnberg, Caprice D (DOB: 12/11/55)	Hedberg, Caleb	CO			Tracking		
83884548	02/07/23 15:01	Refill Rx	02/08/23 03:47 PM	83884548		Denver	autr	Sophia (sb)		Completed Orders	Sweat, Karen (DOB: 12/07/64)	WALKER, DOMINIQUE	CO				Manage	More
				968572	241550	Denver	autr	Sophia (sb)	Semaglutide/B12 Mini Troche 500mcg/100mcg (QTY: 30 each)	Shipping	Sweat, Karen (DOB: 12/07/64)	WALKER, DOMINIQUE	CO			Tracking		
83901353	02/08/23 11:16	New Rx	02/09/23 03:39 PM	83901353		Denver	call	Nicole (nkerns)		Completed Orders	WILHITE, BOBBIE (DOB: 08/14/54)	Cho, KI OK	CO				Manage	More
				969683	241592	Denver	call	Nicole (nkerns)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	WILHITE, BOBBIE (DOB: 08/14/54)	Cho, KI OK	CO			Tracking		
83909892	02/09/23 15:11	New Rx	02/28/23 11:39 AM	83909892		Denver	serx	Zackery (zspears)		Completed Orders	Demos, Anna (DOB: 09/15/52)	Metros, Michael	CO	cancelled per md			Manage	More
				910065	242102	Denver	serx	Zackery (zspears)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Patient Pay Patient Pickup	Demos, Anna (DOB: 09/15/52)	Metros, Michael	CO			Tracking		
83911354	02/09/23 16:24	Refill Rx	02/09/23 04:45 PM	83911354		Denver	mref	Alexis (aazarate)		Completed Orders	Kreiter, Dennis D (DOB: 04/04/51)	Hedberg, Caleb	CO				Manage	More
				968695	241599	Denver	mref	Alexis (aazarate)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Patient Pay Patient Pickup	Kreiter, Dennis D (DOB: 04/04/51)	Hedberg, Caleb	CO			Tracking		

84627621	02/15/23 12:16	Refill Rx	02/16/23 12:36 PM	84627621		Denver	autr	Sophia (sb)		Completed Orders	Bates, Charles L (DOB: 01/06/54)	Metros, Michael	CO	aherman			Manage	More
				907002	241786	Denver	autr	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Bates, Charles L (DOB: 01/06/54)	Metros, Michael	CO				Tracking	
84628585	02/15/23 12:39	New Rx	02/16/23 01:16 PM	84628585		Denver	eerx	Sophia (sb)		Completed Orders	Szmajda, Carena (DOB: 07/10/89)	Linn, Beatriz	CO	amaldonado			Manage	More
				905805	241768	Denver	eerx	Sophia (sb)	Semaglutide/B12 Mini Troche 750mcg/100mcg (QTY: 30 each)	Patient Pay Patient Pickup	Szmajda, Carena (DOB: 07/10/89)	Linn, Beatriz	CO		Lot Tracking		Tracking	
84665601	02/17/23 08:26	New Rx		84665601		Denver	eerx	Mark (msanchez)		Deleted	Whitt, Agnes (DOB: 07/23/74)	Bohm, Shelby	CO	Duplicate			Manage	More
				905849	241839	Denver	eerx	Mark (msanchez)	SEMAGLUTIDE/B12 5/1 MG/ML (ML) (QTY: 2)	Rx Typed	Whitt, Agnes (DOB: 07/23/74)	Bohm, Shelby	CO				Tracking	
84678685	02/17/23 14:19	New Rx	02/18/23 02:30 PM	84678685		Denver	eRx	Zackery (zspears)		Completed Orders	West, Sandy (DOB: 05/12/58)	Carver-Torres, Brenda	CO	PUEBLO - CHARGED FOR SHIPPING			Manage	More
				905862	241855	Denver	eRx	Zackery (zspears)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	West, Sandy (DOB: 05/12/58)	Carver-Torres, Brenda	CO				Tracking	
84678832	02/17/23 14:49	New Rx	02/18/23 03:13 PM	84678832		Denver	eRx	Mark (msanchez)		Completed Orders	Dach, Ursaline (DOB: 08/13/54)	Carver-Torres, Brenda	CO	PUEBLO			Manage	More
				905867	241864	Denver	eRx	Mark (msanchez)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Dach, Ursaline (DOB: 08/13/54)	Carver-Torres, Brenda	CO				Tracking	
84679061	02/17/23 14:53	New Rx	02/18/23 02:54 PM	84679061		Denver	eRx	Mark (msanchez)		Completed Orders	Goettel, Jackie (DOB: 07/10/64)	Carver-Torres, Brenda	CO	PUEBLO			Manage	More
				905864	241861	Denver	eRx	Mark (msanchez)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Goettel, Jackie (DOB: 07/10/64)	Carver-Torres, Brenda	CO				Tracking	
84679098	02/17/23 14:54	New Rx	02/18/23 03:00 PM	84679098		Denver	eRx	Mark (msanchez)		Completed Orders	McAuliffe, Nora (DOB: 01/24/54)	Carver-Torres, Brenda	CO	PUEBLO			Manage	More
				905865	241862	Denver	eRx	Mark (msanchez)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	McAuliffe, Nora (DOB: 01/24/54)	Carver-Torres, Brenda	CO				Tracking	
84679105	02/23/23 10:49	New Rx	02/24/23 12:45 PM	84679105		Denver	eRx	Jeanette (jrutledge)		Completed Orders	Mize, Pamela (DOB: 07/18/51)	BLUMENTHAL, SHARON	CO	COLORADO SPRINGS			Manage	More
				910002	242025	Denver	eRx	Jeanette (jrutledge)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Mize, Pamela (DOB: 07/18/51)	BLUMENTHAL, SHARON	CO		Lot Tracking		Tracking	
84679173	02/17/23 14:56	New Rx	02/18/23 03:01 PM	84679173		Denver	eRx	Mark (msanchez)		Completed Orders	Martin-Serrano, Linda (DOB: 11/14/53)	Carver-Torres, Brenda	CO	PUEBLO			Manage	More
				905866	241863	Denver	eRx	Mark (msanchez)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Shipping	Martin-Serrano, Linda (DOB: 11/14/53)	Carver-Torres, Brenda	CO				Tracking	
84679286	02/23/23 10:49	New Rx	02/24/23 12:46 PM	84679286		Denver	eRx	Zackery (zspears)		Completed Orders	Moure, Diana (DOB: 05/22/58)	BLUMENTHAL, SHARON	CO	COLORADO SPRINGS			Manage	More
				910003	242026	Denver	eRx	Zackery (zspears)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Moure, Diana (DOB: 05/22/58)	BLUMENTHAL, SHARON	CO				Tracking	
84679428	02/23/23 10:49	New Rx	02/24/23 12:51 PM	84679428		Denver	eRx	Jeanette (jrutledge)		Completed Orders	Freshman, Joni (DOB: 12/23/54)	BLUMENTHAL, SHARON	CO	COLORADO SPRINGS			Manage	More
				910004	242027	Denver	eRx	Jeanette (jrutledge)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 90 each)	Shipping	Freshman, Joni (DOB: 12/23/54)	BLUMENTHAL, SHARON	CO				Tracking	
84681012	02/17/23 15:05	New Rx	02/18/23 04:26 PM	84681012		Denver	eRx	Sophia (sb)		Completed Orders	Lopez, Johnny (DOB: 04/11/01)	Carver-Torres, Brenda	CO	PUEBLO			Manage	More
				905877	241874	Denver	eRx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Lopez, Johnny (DOB: 04/11/01)	Carver-Torres, Brenda	CO				Tracking	
84682224	02/23/23 10:51	New Rx	02/24/23 12:53 PM	84682224		Denver	eRx	Jeanette (jrutledge)		Completed Orders	Alls, Kari (DOB: 04/04/65)	BLUMENTHAL, SHARON	CO	COLORADO SPRINGS			Manage	More
				910005	242028	Denver	eRx	Jeanette (jrutledge)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Shipping	Alls, Kari (DOB: 04/04/65)	BLUMENTHAL, SHARON	CO				Tracking	
84682316	02/23/23 10:52	New Rx	02/24/23 12:54 PM	84682316		Denver	eRx	Jeanette (jrutledge)		Completed Orders	Spann, Kelly (DOB: 08/19/64)	BLUMENTHAL, SHARON	CO	COLORADO SPRINGS			Manage	More
				910006	242029	Denver	eRx	Jeanette (jrutledge)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Shipping	Spann, Kelly (DOB: 08/19/64)	BLUMENTHAL, SHARON	CO				Tracking	
84687194	02/19/23 15:01	Refill Rx	02/21/23 09:28 AM	84687194		Denver	autr	Zackery (zspears)		Completed Orders	Corwin, Sarah E (DOB: 11/17/84)	WALKER, DOMINIQUE	CO				Manage	More
				908619	241875	Denver	autr	Zackery (zspears)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Patient Pay Patient Pickup	Corwin, Sarah E (DOB: 11/17/84)	WALKER, DOMINIQUE	CO				Tracking	
84694695	02/20/23 09:46	New Rx	02/21/23 11:42 AM	84694695		Denver	eerx	Sophia (sb)		Completed Orders	Barnes, Leslie (DOB: 05/16/60)	WALKER, DOMINIQUE	CO				Manage	More
				908858	241903	Denver	eerx	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Barnes, Leslie (DOB: 05/16/60)	WALKER, DOMINIQUE	CO				Tracking	
84697774	02/20/23 11:05	Refill Rx	02/21/23 11:20 AM	84697774		Denver	autr	Sophia (sb)		Completed Orders	Longfield, James (DOB: 03/24/55)	Metros, Michael	CO				Manage	More
				907053	241906	Denver	autr	Sophia (sb)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Shipping	Longfield, James (DOB: 03/24/55)	Metros, Michael	CO				Tracking	
84108594	02/20/23 19:15	New Rx	02/22/23 08:43 AM	84108594		Denver	eRx	Kaeley (kwells)		Completed Orders	McCullough, Brendan (DOB: 07/11/50)	BLUMENTHAL, SHARON	CO	mint			Manage	More
				909918	241927	Denver	eRx	Kaeley (kwells)	Semaglutide/B12 Mini Troche 1500mcg/100mcg (QTY: 30 each)	Shipping	McCullough, Brendan (DOB: 07/11/50)	BLUMENTHAL, SHARON	CO		Lot Tracking		Tracking	

StrivePharmacy111

Search Results

Doc ID	Date	Item	Due Date	ID	Fill ID	Location	Source	Manager	Title	Status	Patient	Doctor	State	Memo	Activity	Actions
84123059	02/21/23 11:12	New Rx	02/22/23 11:53 AM	84123059		Denver	serx	Mark (msanchez)		Completed Orders	Schepis, Ann M (DOB: 12/15/45)	Metros, Michael	CO			Manage More
				909342	241556	Denver	serx	Mark (msanchez)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Shipping	Schepis, Ann M (DOB: 12/15/45)	Metros, Michael	CO			Tracking
84123171	02/21/23 11:16	New Rx	02/22/23 11:38 AM	84123171		Denver	serx	Mark (msanchez)		Completed Orders	Kreifer, Dennis D (DOB: 04/04/51)	Hedberg, Caleb	CO	PT WILL PICK UP THURS 3/9		Manage More
				909540	241553	Denver	serx	Mark (msanchez)	Semaglutide/B12 Mini Troche 1000mcg/100mcg (QTY: 30 each)	Patient Pay Patient Pickup	Kreifer, Dennis D (DOB: 04/04/51)	Hedberg, Caleb	CO			Tracking
84125548	02/21/23 12:16	New Rx	02/22/23 01:30 PM	84125548		Denver	serx	Mark (msanchez)		Completed Orders	Dermody, Gina (DOB: 12/03/71)	Linn, Beatriz	CO			Manage More
				909543	241556	Denver	serx	Mark (msanchez)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Patient Pay Patient Pickup	Dermody, Gina (DOB: 12/03/71)	Linn, Beatriz	CO			Tracking
84129558	02/21/23 14:01	New Rx	02/22/23 05:12 PM	84129558		Denver	serx	Mark (msanchez)		Completed Orders	Lackey, Tracy (DOB: 09/08/76)	Linn, Beatriz	CO	mint		Manage More
				909557	241571	Denver	serx	Mark (msanchez)	Semaglutide/B12 Mini Troche 250mcg/100mcg (QTY: 30 each)	Shipping	Lackey, Tracy (DOB: 09/08/76)	Linn, Beatriz	CO		Lot Tracking	Tracking
84134121	02/21/23 16:23	New Rx	02/23/23 05:17 AM	84134121		Denver	serx	Mark (msanchez)		Completed Orders	Wilson, James (DOB: 12/12/67)	Linn, Beatriz	CO			Manage More
				909872	241586	Denver	serx	Mark (msanchez)	Semaglutide/B12 Mini Troche 250mcg/100mcg (QTY: 30 each)	Patient Pay Patient Pickup	Wilson, James (DOB: 12/12/67)	Linn, Beatriz	CO			Tracking
84159080	02/22/23 16:15	New Rx	02/25/23 10:15 AM	84159080		Denver	serx	Zackery (zspears)		Completed Orders	Tung, Chung Wai (DOB: 06/29/56)	Metros, Michael	CO	amaldonado		Manage More
				910026	242051	Denver	serx	Zackery (zspears)	Semaglutide/B12 Mini Troche 250mcg/100mcg (QTY: 30 each)	Patient Pay Patient Pickup	Tung, Chung Wai (DOB: 06/29/56)	Metros, Michael	CO			Tracking
84169124	02/22/23 16:22	New Rx	02/23/23 04:24 PM	84169124		Denver	eRx	Mark (msanchez)		Deleted	Miller, Traci (DOB: 12/28/78)	MARTIN, DEBRA	CO	sending to AZ		Manage More
				909891	242010	Denver	eRx	Mark (msanchez)	Semaglutide/B12 INJ 5/1 mg/ml (2ml) (QTY: 2 ml)	Rx Deleted	Miller, Traci (DOB: 12/28/78)	MARTIN, DEBRA	CO			Tracking
84177752	02/23/23 13:10	New Rx	02/24/23 02:43 PM	84177752		Denver	serx	Jeanette (jrutledge)		Completed Orders	Klein, Paula G (DOB: 06/10/47)	WALKER, DOMINIQUE	CO			Manage More
				910011	242034	Denver	serx	Jeanette (jrutledge)	Semaglutide/B12 Mini Troche 1000/100mcg (QTY: 30 each)	Patient Pay Patient Pickup	Klein, Paula G (DOB: 06/10/47)	WALKER, DOMINIQUE	CO			Tracking
84916881	03/01/23 09:09	New Rx	03/02/23 10:05 AM	84916881		Denver	eRx	Zackery (zspears)		Completed Orders	Leite, Sheila (DOB: 08/08/53)	BLUMENTHAL, SHARON	CO			Manage More
				910132	242186	Denver	eRx	Zackery (zspears)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Shipping	Leite, Sheila (DOB: 08/08/53)	BLUMENTHAL, SHARON	CO			Tracking
84916947	03/01/23 09:12	New Rx	03/02/23 10:06 AM	84916947		Denver	eRx	Zackery (zspears)		Completed Orders	Mercia, Jan (DOB: 10/14/57)	BLUMENTHAL, SHARON	CO			Manage More
				910136	242190	Denver	eRx	Zackery (zspears)	Semaglutide/B12 Mini Troche 500/100mcg (QTY: 30 each)	Shipping	Mercia, Jan (DOB: 10/14/57)	BLUMENTHAL, SHARON	CO			Tracking

biopeptek

PACKING SLIP

Biopeptek Pharmaceuticals, LLC.
Your reliable peptides partner

5 Great Valley Parkway, Suite 100
Malvern, PA 19355
Phone: 1-800-123-4567 (toll free)
Fax: 1-800-121-4567
Email: info@biopeptek.com

CUSTOMER ID: 208001

Ship To:
Strive Pharmacy (Colorado)
ATTN: Christina
11405 E Briarwood Ave Ste 300
Centennial, CO 80112

Notes: Overnight Ice
1) All peptide prices include HPLC and MS analysis.
2) 100% quality satisfaction guarantee with each order.
3) A Certificate of Analysis will be provided with each peptide.

PO NUMBER	SHIP VIA	PACKING ID	SHIP DATE
PO01/05/2023	UPS	1ZA72W251339393331	1/9/2023

ORDER ID	CATALOG NO.	DESCRIPTION	Quantity
BPT90002079-76	IM78	Semaglutide Sodium salt	1 g

Lot: GIM7820221217
Exp: 12/16/24

NDC 71052-0691-01

Received 1/11/23
gef

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CERTIFICATE OF ANALYSIS

Reference document : BPT-QC-SOP-1182

Product Name	Semaglutide Sodium salt
CAS No.	910463-68-2
Molecular Formula	$C_{187}H_{291}N_{45}O_{59}$
Lot No.	GIM7820221217
Sequence	His-Aib-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-Ser-Tyr-Leu-Glu-Gly-Gln-Ala-Ala-Lys(PEG2-PEG2-γ-Glu-17-carboxyheptadecanoyl)-Glu-Phe-Ile-Ala-Trp-Leu-Val-Arg-Gly-Arg-Gly
Modifications	None
Storage Conditions	For less than 6-month storage, the recommended condition is 2-8℃; For longer term (> 6-month) storage, the recommended condition is minus 20℃.

Test Items		**Specifications**	**Results**	**Method**
Appearance		White to off-white powder	White to off-white powder (Conforms)	BPT-QC-SOP-1182
Identification	**Molecular Weight (MS)**	4113.6±1.0Da	4114.4Da	BPT-QC-SOP-1182
	Retention Time (HPLC)	The retention time of the major peak of the sample solution corresponds to that of the standard solution.	Conforms	BPT-QC-SOP-1182
Assay	**Purity (HPLC)**	≥98.0%	99.3%	BPT-QC-SOP-1182
	Related Substances (HPLC)	Total Impurities(%)≤2.0% Largest Single Impurity(%)≤1.0%	0.7% 0.4%	BPT-QC-SOP-1182
	Peptide Content (HPLC)	≥85.0%	93.4%	BPT-QC-SOP-1182
Specific Tests	**Sodium ion (IC)**	≤4.0%	1.2%	BPT-QC-SOP-1182
	Water Content (Karl Fischer)	≤8.0%	4.7%	BPT-QC-SOP-1182; USP<921>
	Residual Solvent (GC; HPLC)	Acetonitrile≤0.041% Trifluoroacetic≤0.500%	0.025% N.D	BPT-QC-SOP-1182
	Bacterial Endotoxins (Gel-clot Method)	<10EU/mg	Conforms	BPT-QC-SOP-1182; USP<85>
Conclusion	This batch is tested and conformed to *Specification and Analytical Procedure of BPT-QC-SOP-1182;* Results: ☑comply with/ ☐do not comply with specifications			

Date of Mfg	17 Dec 2022	Date of Exp	16 Dec 2024
Date of Test	20 Dec 2022	Date of Release	20 Dec 2022
Quality Control: Yang Xu Yang Xu 20 Dec 2022 Reviewed		Quality Assurance: Yongna Zhao Yongna Zhao 20 Dec 2022 APPROVED	

Biopeptek Pharmaceuticals,LLC.

Corporate headquarters: 5 Great Valley Parkway. Suite 100 Malvern, PA 19355, U.S.A Tel: 610.643.4881 www.biopeptek.com

Manufactured and Packaged at the FDA registered facility: 218 Shuangyuan Road, Chengyang, Qingdao, Shandong 266000, China (CHN)

The peptide is chemically synthesized

biopeptek

PACKING SLIP

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Your reliable peptides partner

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Phone: 1-800-123-4567 (toll free)
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CUSTOMER ID: 208001

Ship To:
Strive Pharmacy (Colorado)
ATTN: Christina
11405 E Briarwood Ave Ste 300
Centennial, CO 80112

Notes: Overnight Ice
1) All peptide prices include HPLC and MS analysis.
2) 100% quality satisfaction guarantee with each order.
3) A Certificate of Analysis will be provided with each peptide.

PO NUMBER	SHIP VIA	PACKING ID	SHIP DATE
PO02/10/2023	UPS	1ZA72W251322891842	2/13/2023

ORDER ID	CATALOG NO.	DESCRIPTION	Quantity
BPT90002089-07	IM78	Semaglutide Sodium salt	5 g

Rate
$2,500.00

NDC 73212-056-05

Recv'd
2/14/23

biopeptek

CERTIFICATE OF ANALYSIS

Reference document : BPT-QC-SOP-1182

Product Name	Semaglutide Sodium salt
CAS No.	910463-68-2
Molecular Formula	$C_{187}H_{291}N_{45}O_{59}$
Lot No.	GIM7820230202
Sequence	His-Aib-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-Ser-Tyr-Leu-Glu-Gly-Gln-Ala-Ala-Lys(PEG2-PEG2-γ-Glu-17-carboxyheptadecanoyl)-Glu-Phe-Ile-Ala-Trp-Leu-Val-Arg-Gly-Arg-Gly
Modifications	None
Storage Conditions	For less than 6-month storage, the recommended condition is 2-8℃; For longer term (> 6-month) storage, the recommended condition is minus 20℃.

Test Items		**Specifications**	**Results**	**Method**
Appearance		White to off-white powder	White to off-white powder (Conforms)	BPT-QC-SOP-1182
Identification	**Molecular Weight (MS)**	4113.6±1.0Da	4114.4Da	BPT-QC-SOP-1182
	Retention Time (HPLC)	The retention time of the major peak of the sample solution corresponds to that of the standard solution.	Conforms	BPT-QC-SOP-1182
Assay	**Purity (HPLC)**	≥98.0%	99.6%	BPT-QC-SOP-1182
	Related Substances (HPLC)	Total Impurities(%)≤2.0% Largest Single Impurity(%)≤1.0%	0.4% 0.2%	BPT-QC-SOP-1182
	Peptide Content (HPLC)	≥85.0%	93.1%	BPT-QC-SOP-1182
Specific Tests	**Sodium ion (IC)**	≤4.0%	2.1%	BPT-QC-SOP-1182
	Water Content (Karl Fischer)	≤8.0%	4.5%	BPT-QC-SOP-1182; USP<921>
	Residual Solvent (GC; HPLC)	Acetonitrile≤0.041% Trifluoroacetic≤0.500%	0.002% N.D	BPT-QC-SOP-1182
	Bacterial Endotoxins (Gel-clot Method)	<10EU/mg	Conforms	BPT-QC-SOP-1182; USP<85>
Conclusion	This batch is tested and conformed to *Specification and Analytical Procedure of BPT-QC-SOP-1182;* Results: ☑comply with/ ☐do not comply with specifications			

Date of Mfg	02 Feb 2023	Date of Exp	01 Feb 2025
Date of Test	07 Feb 2023 Lei Zhou	Date of Release	07 Feb 2023 Yongna Zhao
Quality Control: Lei Zhou 07 Feb 2023		Quality Assurance: Yongna Zhao 07 Feb 2023	

Revie wed Biopeptek Pharmaceuticals,LLC. Approved

Corporate headquarters: 5 Great Valley Parkway. Suite 100 Malvern, PA 19355, U.S.A Tel: 610.643.4881 www.biopeptek.com

Manufactured and Packaged at the FDA registered facility: 218 Shuangyuan Road, Chengyang, Qingdao, Shandong 266000, China (CHN)

The peptide is chemically synthesized

Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss

What is semaglutide?

Semaglutide belongs to a class of medications known as glucagon-like peptide-1 (GLP-1) receptor agonists. It mimics the GLP-1 hormone that is released in the gastrointestinal tract in response to eating. One role of GLP-1 is to prompt the body to produce more insulin, which reduces blood glucose (sugar). GLP-1 in higher amounts also interacts with the parts of the brain that reduce appetite and signal a feeling of fullness.

There are currently three FDA-approved semaglutide products:

- Ozempic injection (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209637s012lbl.pdf) and Rybelsus tablets (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213051s012lbl.pdf) are approved to lower blood sugar levels in adults with type 2 diabetes mellitus, in addition to diet and exercise. Ozempic is also approved to reduce the risk of heart attack, stroke, or death in adults with type 2 diabetes mellitus and known heart disease.
- Wegovy injection (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215256s005lbl.pdf) is approved to help adults and children aged 12 years and older with obesity or some adults with excess weight (overweight), who also have weight-related medical problems, to lose weight and keep the weight off, in addition to diet and exercise.

All three medications are only available with a prescription, and there are no approved generic versions.

What is compounding?

Drug compounding (/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers) is the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounding includes the combining of two or more drugs. Compounded drugs are not FDA-approved, and the agency does not verify the safety or effectiveness of compounded drugs.

Can semaglutide be compounded?

When a drug is in shortage, compounders may be able to prepare a compounded version of that drug if they meet certain requirements in the Federal Food, Drug, and Cosmetic (FD&C) Act. As of May 2023, Ozempic and Wegovy are both listed on FDA's Drug Shortages list (/drugs/drug-safety-and-availability/drug-shortages).

Are there concerns with compounded semaglutide?

FDA has received adverse event reports after patients used compounded semaglutide. Patients should not use a compounded drug if an approved drug is available to treat a patient. Patients and health care professionals should understand that the agency does not review compounded versions of these drugs for safety, effectiveness, or quality.

Additionally, FDA has received reports that in some cases, compounders may be using salt forms of semaglutide, including semaglutide sodium and semaglutide acetate. The salt forms are different active ingredients than is used the approved drugs, which contain the base form of semaglutide. The agency is not aware of any basis for compounding using the salt forms that would meet the FD&C requirements for types of active ingredients that can be compounded. On April 27, 2023, FDA wrote to the National Association of Boards of Pharmacy (/media/168390/download?attachment) expressing the agency's concerns with use of the salt forms in compounded products.

What should patients know?

Patients should be aware that some products sold as 'semaglutide' may not contain the same active ingredient as FDA-approved semaglutide products and may be the salt formulations. Products containing these salts, such as semaglutide sodium and semaglutide acetate, have not been shown to be safe and effective.

Patients should only obtain drugs containing semaglutide with a prescription from a licensed health care provider, and only obtain medicines from state-licensed pharmacies or outsourcing facilities registered with FDA.

Purchasing medicine online from unregulated, unlicensed sources can expose patients to potentially unsafe products that have not undergone appropriate evaluation or approval, or do not meet quality standards. If you choose to use an online pharmacy, FDA's BeSafeRx (/drugs/quick-tips-buying-medicines-over-internet/besaferx-your-source-online-pharmacy-information) campaign resources and tools can assist in making safer, more informed decisions when purchasing prescription medicine online.

What should health care professionals know?

Health care professionals who are considering working with compounders to obtain semaglutide products should be aware that compounders may be using salt forms of semaglutide. FDA is not aware of any basis for compounding a drug using semaglutide salts that would meet federal requirements.

Reporting issues to the FDA

FDA encourages health care professionals, patients, and compounders to report adverse events or quality problems with these or any medications to FDA's MedWatch Adverse Event Reporting (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program) program:

- Complete and submit the report online (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm); or
- Download and complete the form (https://www.fda.gov/media/85598/download), then submit it via fax at 1-800-FDA-0178.

More Resources

- Drug Compounding and Drug Shortages (/drugs/human-drug-compounding/drug-compounding-and-drug-shortages)
- Compounding and the FDA: Questions and Answers (/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers)

COLORADO
Department of Regulatory Agencies
Division of Professions and Occupations

THE COLORADO STATE BOARD OF PHARMACY
1560 Broadway, Suite 1300, Denver, CO 80202-5146
303-894-7800 FAX 303-894-7692 V/TDD 303-894-7880

PRESCRIPTION DRUG OUTLET INSPECTION REPORT

Date of Inspection: 8/11/23 **Time In/Out:** _____/_____

PDO Name Strive Pharmacy Denver, LLC **Registration No** 168-218 **Expiration Date** 10/24

Address 11405 E. Briarwood Ave, Ste 300 **City** Centennial **Zip** 80112

Pharmacist Manager Zackery Spears **Llc No** 23051 **Email** _____

RPH on Duty _____ **Lic No** _____ **Email** _____

Physical/Postings	Compliant?
5.01.31b&c: Clean, sanitary, adequate space	N/A
5.01.31d,f&g: Hot & cold water, frig & freezer	N/A
5.01.50: Pharmacy security	N/A
CRS 12-280-122:RPH/tech ratio____ nametags	N/A
CRS 12-280-118:Licenses and registrations posted	N/A
11.08.00, 7.00.30b: Employee list, tech posting	N/A
5.01.31l: Prior inspection _____# deficiencies	N/A
3.00.51: Initial interpretation and final evaluation	N/A
23.00.60: PDMP notice, 20.00.70; CPP notice	N/A
5.01.31h: Professional reference library	N/A
Recordkeeping	
11.03.00: CS Inventory date _____	N/A
11.06.00: CII, CIII-V, RX drug receipts dated	N/A
11.06.05: Receipts from registered sources	N/A
11.07.20: Casual Sale records	N/A
11.07.10: Floor stock distribution	N/A
11.04.20: Daily printouts	N/A
3.00.90b: RTS records	N/A
25.00.16: SPDO: CS inv., distribution, use records	N/A
27.00.30: HSP: CS inv., records of distribution	N/A
Dispensing	
11.04.10: Hardcopy of order filed appropriately	N/A
CII orders reviewed:_____	N/A
CIII-V orders reviewed:_____	N/A
RX orders reviewed:_____	N/A
2.01.53: Required order transfer information	N/A
2.01.10: Information to appear on each order	N/A
3.00.55: Prescription flavoring	N/A
Dispensing errors/valid prescription orders	N/A
Prescription labeling	N/A

Immunizations	Compliant?
19.01.10: Authorization, ACPE training, CPR	N/A
19.01.40: Administration records	N/A
19.01.50: Off-site administration	N/A
Non-Sterile Compounding	
21.10.10: P&P Manual annual review_____	N/A
21.10.20: Training of personnel	N/A
21.10.60: Components-expiration dating	N/A
21.10.90: Formulation records	N/A
21.11.00: Compounding records/labeling	N/A
21.10.80: Beyond use dating, studies on site	N/A
Central Prescription Processing/Remote Pharmacy Practice	
20.01.20 &26.00.20: Policy and procedure manual, written agreements _____	N/A
20.00.90: Records of receipt/delivery	N/A
3.00.90e: Return to stock records	N/A
	N/A
Prepackaging/Labeling/Return Drug	N/A
3.01.20: Prepack labeling and records	N/A
3.01.22: Automated cassette labeling & records	N/A
3.03.00: Customized medication packages	N/A
3.00.80: Return for dispensing or donation	N/A
21.00.20: Casual sale of compounded products	N/A
Drug Therapy Management	
6.00.40: General authorization plan/protocols	N/A
6.00.30: Pharmacist qualifications	N/A
6.00.60: Recordkeeping	N/A
E-kits	
10.00.40: Labeling & contents of kit	N/A
10.00.71: Removal and replacement of med	N/A

PRESCRIPTION DRUG OUTLET INSPECTION REPORT

PDO Name Strive Pharmacy Denver, LLC Pharmacist Manager Zackery Spears

Sterile Compounding

Risk Level	Compliant?
Low- greater than 12 hr BUD	N/A
Low - less than 12 hr BUD/ Radiopharmaceuticals	N/A
Medium	N/A
High	N/A
Policy and Procedure Manual/Reference	
21.20.30: P&P Manual annual review_____	N/A
5.01.31h: Sterile compounding reference	N/A
Environmental/Equipment	
21.20.70a: ISO area certification date_____	N/A
21.20.60c: Cleanroom surfaces compliant	N/A
21.20.70d: Airborne microorganism testing	N/A
21.20.70f: Pressure differential recorded daily	N/A
21.20.80: Daily, weekly, monthly cleaning	N/A
21.21.20: Daily ACD accuracy assessments	N/A
Personnel training	
21.20.50: Didactic/media fill testing	N/A
21.20.70e: Glove fingertip sampling performed	N/A
Recordkeeping/Labeling	
21.21.50: Formulation records	N/A
21.21.60: Compounding records	N/A
21.21.40: Beyond use dating	N/A
21.21.70: Labeling of dispensed CSPs	N/A
High Risk Compounding/Extended BUD	
21.21.30c: Sterility testing	N/A
21.21.30d: Endotoxin testing	N/A
21.21.40d: Lab testing of product stability, potency	N/A

Cytotoxic Drug Preparation	Compliant?
5.01.31: Cytotoxic compounding reference	N/A
21.22.10a: ISO 7, physically separated, negative pressure	N/A
21.22.10b: Appropriate PPE	N/A
Sterile Product Packaging	
3.01.30c: P&P Manual annual review_____	N/A
3.01.30d: Didactic and experiential training	N/A
3.01.30h: Appropriate BUD	N/A
3.01.30i: Recalls	N/A
Casual sale/distribution	
21.00.20a: Distribution to in-state hospital/practitioner for administration	N/A
21.00.20b: Distribution no more than 10%	N/A
21.21.70: Labeling of distributed CSPs	N/A
Radiopharmaceuticals	
Compounding: YES_____ NO_____	
12.00.40: Nuclear Pharmacist training	N/A
12.00.32: Professional reference library	N/A
12.00.45: CDPHE Radioactive materials license	N/A
12.00.70c: Labeling of radiopharmaceuticals	N/A
12.00.71: Dispensing records - filed by date	N/A
12.00.72: Distribution records: up to 10%	N/A

PRESCRIPTION DRUG OUTLET INSPECTION REPORT

PDO Name Strive Pharmacy Denver, LLC **Pharmacist Manager** Zackery Spears

1. Please obtain semaglutide and other prescription drugs from Board-registered sources. See examples where it appears the product is being obtained from a source not registered with the Board.

2. While it appears that numerous compounded preparations for semagutide sodium salt have been dispensed from this pharmacy in 2023, neither the pharmacist manager nor I could find any orders for any of the dispensing transactions.

3. Compounding records shall be uniformly maintained and contemporaneous.

4. Please label compounded made in advance of immediate need in accordance with Rule 21.11.10. See hundreds of examples.

5. Invoices shall be filed in one of three separate sets of files (C-II, C-III-V and Rx). See numerous examples in 2023.

6. The new pharmacist manager did not conduct a change of pharmacist manager controlled substance inventory.

7. Please file orders in one of three separate sets of files (C-II, C-III-V and Rx). See examples.

8. Please do not store drug products directly on the floor.

9. Refrigerator and freezer temperatures shall be recorded each day. There are no readings recorded on Saturdays and Sundays.

10. Please be able to generate, upon request, a readable daily printout in accordance with Rule 11.04.20. Currently, there is no apparent order issuance date, and other required information is unreadable.
REPEAT DEFICIENCY OVER THE LAST 3 CONSECUTIVE INSPECTIONS.

11. The pharmacist manager shall review, date and sign the compounding policy and procedure manual within 30 days of assessing the duty in February 2023.

Tier 3

Pursuant to CRS 12-280-108, the Colorado State Board of Pharmacy has the authority to inspect all registered outlets and investigate violations of the Board's Rules and Regulations, CRS Title 12, 280 of the Pharmacists, Pharmacy Business, and Pharmaceuticals Act; and the CRS Title 18, Article 18 of the Uniform Controlled Substance Act of 1992

I ACKNOWLEDGE THAT THE CONTENTS OF THIS INSPECTION REPORT HAVE BEEN EXPLAINED TO ME.	INSPECTOR'S SIGNATURE
8/11/23	OTHER INSPECTORS PRESENT:
PHARMACIST'S SIGNATURE DATE	

COLORADO
Department of Regulatory Agencies
Division of Professions and Occupations

THE COLORADO STATE BOARD OF PHARMACY
1560 Broadway, Suite 1300, Denver, CO 80202-5146
303-894-7800 FAX 303-894-7692 V/TDD 303-894-7880

PRESCRIPTION DRUG OUTLET INSPECTION REPORT

Clear Form

Date of Inspection: 11/29/21 **Time In/Out:** 9:15 am / 12:00 pm

PDO Name Strive Pharmacy **Registration No** 168-218 **Expiration Date** _____

Address 11405 E. Briarwood Ave. - Ste. 300 **City** Centennial **Zip** 80112

Pharmacist Manager Joseph Sandahl **Llc No** 23395 **Email** _____

RPH on Duty Same. **Lic No** _____ **Email** Colorado@strivepharmacy.com

Physical/Postings	Compliant?
5.01.31b&c: Clean, sanitary, adequate space	YES
5.01.31d,f&g: Hot & cold water, frig & freezer	NO
5.01.50: Pharmacy security	YES
CRS 12-280-119:RPH/tech ratio 1:2 nametags	YES
CRS 12-280-116:Licenses and registrations posted	YES
11.08.00, 7.00.30b: Employee list, tech posting	NO
5.01.31l: Prior inspection 0 # deficiencies	NO
3.00.51: Initial interpretation and final evaluation	YES
23.00.60: PDMP notice, 20.00.70; CPP notice	NO
5.01.31h: Professional reference library	YES
Recordkeeping	
11.03.00: CS Inventory date 5/12/21 Open	YES
11.06.00: CII, CIII-V, RX drug receipts dated	NO
11.06.05: Receipts from registered sources	YES
11.07.20: Casual Sale records	N/A
11.07.10: Floor stock distribution	N/A
11.04.20: Daily printouts	NO
3.00.90b: RTS records	NO
25.00.16: SPDO: CS inv., distribution, use records	N/A
27.00.30: HSP: CS inv., records of distribution	N/A
Dispensing	
11.04.10: Hardcopy of order filed appropriately	YES
CII orders reviewed: None.	N/A
CIII-V orders reviewed: C0106200	YES
RX orders reviewed: 106200	YES
2.01.53: Required order transfer information	N/A
2.01.10: Information to appear on each order	NO
3.00.55: Prescription flavoring	YES
Dispensing errors/valid prescription orders	N/A
Prescription labeling	YES

Immunizations	Compliant?
19.01.10: Authorization, ACPE training, CPR	N/A
19.01.40: Administration records	N/A
19.01.50: Off-site administration	N/A
Non-Sterile Compounding	
21.10.10: P&P Manual annual review_____	NO
21.10.20: Training of personnel	NO
21.10.60: Components-expiration dating	YES
21.10.90: Formulation records	YES
21.11.00: Compounding records/labeling	NO
21.10.80: Beyond use dating, studies on site	NO
Central Prescription Processing/Remote Pharmacy Practice	
20.01.20 &26.00.20: Policy and procedure manual, written agreements _____	N/A
20.00.90: Records of receipt/delivery	N/A
3.00.90e: Return to stock records	N/A
	N/A
Prepackaging/Labeling/Return Drug	NO
3.01.20: Prepack labeling and records	N/A
3.01.22: Automated cassette labeling & records	N/A
3.03.00: Customized medication packages	N/A
3.00.80: Return for dispensing or donation	N/A
21.00.20: Casual sale of compounded products	N/A
Collaborative Pharmacy Practice for Drug Therapy Management	
17.00.70: General authorization plan/ protocols	N/A
17.00.30: Pharmacist qualifications	N/A
17.01.00: Recordkeeping	N/A
E-kits	
10.00.40: Labeling & contents of kit	N/A
10.00.71: Removal and replacement of med	N/A

PRESCRIPTION DRUG OUTLET INSPECTION REPORT

PDO Name Strive Pharmacy **Pharmacist Manager** Joseph Sandahl

Sterile Compounding

Risk Level	Compliant?
Low- greater than 12 hr BUD	N/A
Low - less than 12 hr BUD/ Radiopharmaceuticals	N/A
Medium	N/A
High	N/A
Policy and Procedure Manual/Reference	
21.20.30: P&P Manual annual review_____	N/A
5.01.31h: Sterile compounding reference	N/A
Environmental/Equipment	
21.20.70a: ISO area certification date_____	N/A
21.20.60c: Cleanroom surfaces compliant	N/A
21.20.70d: Airborne microorganism testing	N/A
21.20.70f: Pressure differential recorded daily	N/A
21.20.80: Daily, weekly, monthly cleaning	N/A
21.21.20: Daily ACD accuracy assessments	N/A
Personnel training	
21.20.50: Didactic/media fill testing	N/A
21.20.70e: Glove fingertip sampling performed	N/A
Recordkeeping/Labeling	
21.21.50: Formulation records	N/A
21.21.60: Compounding records	N/A
21.21.40: Beyond use dating	N/A
21.21.70: Labeling of dispensed CSPs	N/A
High Risk Compounding/Extended BUD	
21.21.30c: Sterility testing	N/A
21.21.30d: Endotoxin testing	N/A
21.21.40d: Lab testing of product stability, potency	N/A

Cytotoxic Drug Preparation	Compliant?
5.01.31: Cytotoxic compounding reference	N/A
21.22.10a: ISO 7, physically separated, negative pressure	N/A
21.22.10b: Appropriate PPE	N/A
Sterile Product Packaging	
3.01.30c: P&P Manual annual review_____	N/A
3.01.30d: Didactic and experiential training	N/A
3.01.30h: Appropriate BUD	N/A
3.01.30i: Recalls	N/A
Casual sale/distribution	
21.00.20a: Distribution to in-state hospital/practitioner for administration	N/A
21.00.20b: Distribution no more than 10%	N/A
21.21.70: Labeling of distributed CSPs	N/A
Radiopharmaceuticals	
Compounding: YES _____ NO_____	
12.00.40: Nuclear Pharmacist training	N/A
12.00.32: Professional reference library	N/A
12.00.45: CDPHE Radioactive materials license	N/A
12.00.70c: Labeling of radiopharmaceuticals	N/A
12.00.71: Dispensing records - filed by date	N/A
12.00.72: Distribution records: up to 10%	N/A

PRESCRIPTION DRUG OUTLET INSPECTION REPORT

PDO Name Strive Pharmacy **Pharmacist Manager** Joseph Sandahl

1. Pharmacy shall post technician posting page.

2. Pharmacy shall post current Board inspection.

3. Pharmacy shall post PDMP notice to patients.

4. Pharmacy staff shall wear name badges.

5. Pharmacy shall label compounded products made in anticipation of orders per Rule 21.11.10(c).

6. RPH manager shall date, review, and sign the compounding P & P manual annually.

7. Pharmacy shall keep a RTS record.

8. Pharmacy shall not assign a BUD beyond Rule 21.00.00 for creams unless the appropriate studies are available in the pharmacy.

9. Aqueous suspensions shall not have a BUD exceeding 14 days. See baclofen suspension.

10. 11.04.30(e) - Pharmacy shall be able to print a compliant daily report. Please forward a example to Board inspector within 30 days.

11. Non-controlled legend invoices shall be dated upon date of receipt. See all current files.

13. Refrigerator temps shall be monitored daily electronically.

Comments:

1. No CII in inventory at the time of inspection.

Tier 3

Pursuant to CRS 12-280-106, the Colorado State Board of Pharmacy has the authority to inspect all registered outlets and investigate violations of the Board's Rules and Regulations, CRS Title 12, 280 of the Pharmacists, Pharmacy Business, and Pharmaceuticals Act; and the CRS Title 18, Article 18 of the Uniform Controlled Substance Act of 1992

I ACKNOWLEDGE THAT THE CONTENTS OF THIS INSPECTION REPORT HAVE BEEN EXPLAINED TO ME.	INSPECTOR'S SIGNATURE M O'Neill 12:00 pm
11/29/21	OTHER INSPECTORS PRESENT:
PHARMACIST'S SIGNATURE DATE	

COLORADO
Department of Regulatory Agencies
Division of Professions and Occupations

THE COLORADO STATE BOARD OF PHARMACY
1560 Broadway, Suite 1300, Denver, CO 80202-5146
303-894-7800 FAX 303-894-7692 V/TDD 303-894-7880

PRESCRIPTION DRUG OUTLET INSPECTION REPORT

Clear Form

Date of Inspection: 12/20/22 **Time In/Out:** 8:20 am / _____

PDO Name Strive Pharmacy **Registration No** 168-218 **Expiration Date** 10-2024

Address 11405 E. Briarwood Ave. Ste. 300 **City** Centennial **Zip** 80112

Pharmacist Manager Christina Wern **LIc No** 22022 **Email** _____

RPH on Duty Same. **Lic No** _____ **Email** _____

Physical/Postings	Compliant?
5.01.31b&c: Clean, sanitary, adequate space	YES
5.01.31d,f&g: Hot & cold water, frig & freezer	YES
5.01.50: Pharmacy security	YES
CRS 12-280-119:RPH/tech ratio 1:4 nametags	YES
CRS 12-280-116:Licenses and registrations posted	YES
11.08.00, 7.00.30b: Employee list, tech posting	YES
5.01.31l: Prior inspection 13 # deficiencies	YES
3.00.51: Initial interpretation and final evaluation	YES
23.00.60: PDMP notice, 20.00.70; CPP notice	YES
5.01.31h: Professional reference library	YES
Recordkeeping	
11.03.00: CS Inventory date 1/24/22 Open	YES
11.06.00: CII, CIII-V, RX drug receipts dated	YES
11.06.05: Receipts from registered sources	YES
11.07.20: Casual Sale records	N/A
11.07.10: Floor stock distribution	N/A
11.04.20: Daily printouts	NO
3.00.90b: RTS records	YES
25.00.16: SPDO: CS inv., distribution, use records	N/A
27.00.30: HSP: CS inv., records of distribution	N/A
Dispensing	
11.04.10: Hardcopy of order filed appropriately	YES
CII orders reviewed: None.	YES
CIII-V orders reviewed: C908200	YES
RX orders reviewed: 905000	YES
2.01.53: Required order transfer information	YES
2.01.10: Information to appear on each order	YES
3.00.55: Prescription flavoring	N/A
Dispensing errors/valid prescription orders	N/A
Prescription labeling	YES

Immunizations	Compliant?
19.01.10: Authorization, ACPE training, CPR	N/A
19.01.40: Administration records	N/A
19.01.50: Off-site administration	N/A
Non-Sterile Compounding	
21.10.10: P&P Manual annual review 9/6/22	YES
21.10.20: Training of personnel	YES
21.10.60: Components-expiration dating	YES
21.10.90: Formulation records	YES
21.11.00: Compounding records/labeling	YES
21.10.80: Beyond use dating, studies on site	YES
Central Prescription Processing/Remote Pharmacy Practice	
20.01.20 &26.00.20: Policy and procedure manual, written agreements _____	NO
20.00.90: Records of receipt/delivery	N/A
3.00.90e: Return to stock records	N/A
	N/A
Prepackaging/Labeling/Return Drug	N/A
3.01.20: Prepack labeling and records	N/A
3.01.22: Automated cassette labeling & records	N/A
3.03.00: Customized medication packages	N/A
3.00.80: Return for dispensing or donation	N/A
21.00.20: Casual sale of compounded products	N/A
Collaborative Pharmacy Practice for Drug Therapy Management	
17.00.70: General authorization plan/ protocols	N/A
17.00.30: Pharmacist qualifications	N/A
17.01.00: Recordkeeping	N/A
E-kits	
10.00.40: Labeling & contents of kit	N/A
10.00.71: Removal and replacement of med	N/A

PRESCRIPTION DRUG OUTLET INSPECTION REPORT

PDO Name Strive Pharmacy Pharmacist Manager Christina Wern

Sterile Compounding

Risk Level	Compliant?
Low- greater than 12 hr BUD	N/A
Low - less than 12 hr BUD/ Radiopharmaceuticals	N/A
Medium	N/A
High	N/A
Policy and Procedure Manual/Reference	
21.20.30: P&P Manual annual review_____	N/A
5.01.31h: Sterile compounding reference	N/A
Environmental/Equipment	
21.20.70a: ISO area certification date_____	N/A
21.20.60c: Cleanroom surfaces compliant	N/A
21.20.70d: Airborne microorganism testing	N/A
21.20.70f: Pressure differential recorded daily	N/A
21.20.80: Daily, weekly, monthly cleaning	N/A
21.21.20: Daily ACD accuracy assessments	N/A
Personnel training	
21.20.50: Didactic/media fill testing	N/A
21.20.70e: Glove fingertip sampling performed	N/A
Recordkeeping/Labeling	
21.21.50: Formulation records	N/A
21.21.60: Compounding records	N/A
21.21.40: Beyond use dating	N/A
21.21.70: Labeling of dispensed CSPs	N/A
High Risk Compounding/Extended BUD	
21.21.30c: Sterility testing	N/A
21.21.30d: Endotoxin testing	N/A
21.21.40d: Lab testing of product stability, potency	N/A

Cytotoxic Drug Preparation	Compliant?
5.01.31: Cytotoxic compounding reference	N/A
21.22.10a: ISO 7, physically separated, negative pressure	N/A
21.22.10b: Appropriate PPE	N/A
Sterile Product Packaging	
3.01.30c: P&P Manual annual review_____	N/A
3.01.30d: Didactic and experiential training	N/A
3.01.30h: Appropriate BUD	N/A
3.01.30i: Recalls	N/A
Casual sale/distribution	
21.00.20a: Distribution to in-state hospital/practitioner for administration	N/A
21.00.20b: Distribution no more than 10%	N/A
21.21.70: Labeling of distributed CSPs	N/A
Radiopharmaceuticals	
Compounding: YES _____ NO_____	
12.00.40: Nuclear Pharmacist training	N/A
12.00.32: Professional reference library	N/A
12.00.45: CDPHE Radioactive materials license	N/A
12.00.70c: Labeling of radiopharmaceuticals	N/A
12.00.71: Dispensing records - filed by date	N/A
12.00.72: Distribution records: up to 10%	N/A

PRESCRIPTION DRUG OUTLET INSPECTION REPORT

PDO Name Strive Pharmacy **Pharmacist Manager** Christina Wern

Christina@strivepharmacy.com

1. 11.04.30(e) - pharmacy shall be able to print a compliant daily report. Please inform the Board inspector when this is completed. REPEAT deficiency.

2. Please complete a Central Prescription Processing manual for initial interpretations being completed at another Strive facility. Inform Board inspector within 30 days that this is done.

Comment:

No sterile compounding.

No CII substances in stock.

Tier 3

Pursuant to CRS 12-280-106, the Colorado State Board of Pharmacy has the authority to inspect all registered outlets and investigate violations of the Board's Rules and Regulations, CRS Title 12, 280 of the Pharmacists, Pharmacy Business, and Pharmaceuticals Act; and the CRS Title 18, Article 18 of the Uniform Controlled Substance Act of 1992

I ACKNOWLEDGE THAT THE CONTENTS OF THIS INSPECTION REPORT HAVE BEEN EXPLAINED TO ME.	INSPECTOR'S SIGNATURE M O'Neill
12/20/22	OTHER INSPECTORS PRESENT:
PHARMACIST'S SIGNATURE DATE	

STRIVE
compounding pharmacy

Exhibit 9

Quarles

One Renaissance Square
Two North Central Avenue
Suite 600
Phoenix, AZ 85004-2322
602-229-5200
Fax 602-229-5690
www.quarles.com

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Madison
Milwaukee
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Naples
Phoenix
San Diego
Tampa
Tucson
Washington, D.C.

Writer's Direct Dial: 602-229-5301
E-Mail: Alex.Snyder@quarles.com

August 24, 2023

VIA ELECTRONIC TRANSMISSION – dora_pharmacyboard@state.co.us

Dmitry Kunin, PharmD
Colorado Pharmacy Board
Department of Regulatory Agencies
1560 Broadway
Suite 1350
Denver, CO 80202

Dear Dmitry Kunin:

We represent Strive Pharmacy Denver LLC (the "Pharmacy"), License No. PDO.1680000218, in connection with Colorado Pharmacy Board (the "Board") Case No. 2023-5699 (the "Complaint"). This letter is the Pharmacy's written response to the Complaint, which alleges possible violations of the Colorado Pharmacists, Pharmacy Business, and Pharmaceuticals Practice Act (the "Act"). We address each alleged violation in turn below.

I. The use of semaglutide salt between January and March 2023.

First, the Complaint alleges a violation of Board regulations related to the use of semaglutide salt when compounding drug products.[1] As the Board is undoubtedly aware, the compounding of semaglutide drug products has been a dynamic and rapidly changing space. Currently, Wegovy and Ozempic are the only two commercially available semaglutide injection products on the market. However, due to the growing popularity of these drugs and lack of adequate supply, Wegovy was placed on the FDA Drug Shortage List in March 2022, closely followed by Ozempic.[2]

[1] *See* 3 Colo. Code Regs. § 719-1:21.10.60.
[2] *See* U.S. Food & Drug Administration, FDA Drug Shortages, Semaglutide (Ozempic) & Semaglutide (Wegovy), https://www.accessdata.fda.gov/scripts/drugshortages/dsp_SearchResults.cfm (last visited Aug. 23, 2023).

Federal statute provides that pharmacies operating under Section 503A may only compound from bulk drug substances that: (1) comply with the standards of an applicable United States Pharmacopoeia ("USP") or National Formulary ("NF") monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, are drug substances that are *components* of FDA-approved drug products; or (3) if such a monograph does not exist and the drug substance is not a component of an approved drug, that it appears on the FDA's list of bulk-substances that can be used in 503A compounding.[3] It is clear, with respect to semaglutide, that no USP or NF monograph exists and that no form of the drug appears on the Section 503A Bulk Substances list.[4] However, prior to the FDA issuing guidance on the issue of compounding semaglutide, , State Boards of Pharmacy wrestled with the question of whether the salt form of a drug should be considered a *component* of an FDA-approved drug.[5]

Controversially, the FDA and various State Boards of Pharmacy have recently found that the salt form should not be considered a *component* of the FDA-approved semaglutide base.[6] Despite this position, this interpretation does not take into consideration the FDA's inconsistent definition of "active pharmaceutical ingredient" and "bulk drug substance" within the relevant code and regulations.[7] Prior to this guidance, the Pharmacy had been operating under relative ambiguity surrounding the permissibility of using a salt form of a drug for compounding. Initially, the State Boards lacked guidance from the FDA with respect to this issue, leading to

---

[3] *See* 21 U.S.C § 353a(b)(1)(A)(i)(I-III); *see also* Bulk Drug Substances Used in Compounding Under Section 503A of the FD&C Act, U.S. Food & Drug Administration, https://www.fda.gov/drugs/human-drug-compounding/bulk-drug-substances-used-compounding-under-section-503a-fdc-act (last updated Feb. 20, 2020).

[4] *See* 21 C.F.R. § 216.23 (listing the 503A Bulk drug substances list).

[5] *See, e.g.,* Utah State Board of Pharmacy, Minutes, March 28, 2023, p. 3, https://www.utah.gov/pmn/files/970387.pdf (finding that members of the Board believed the salt form does not matter, it is the semaglutide molecule that is being used, the semaglutide component is the active pharmaceutical ingredient); *see also* Utah State Board of Pharmacy, Minutes, March 28, 2023, https://www.utah.gov/pmn/files/959981.mp3 (conversation begins at 00:41:00).

[6] *See* FDA to NABP Semaglutide Letter, *supra* note 2; *see also* Statement Concerning Semaglutide Compounding, N.C. Bd. Pharmacy, http://www.ncbop.org/PDF/SemaglutideCompounding.pdf (last updated April 28, 2023); *see also* K Capehart, Statement Concerning Semaglutide Compounding, W. Va. Bd. Pharmacy, https://www.wvbop.com/admin/attachment/FINALSemaglutideCompoundingStatementUpdated01MAY2023WVBoPFV1.pdf (last updated May 1, 2023); *see also* Compounded Products Due to Shortage or Due to Special Needs, Miss. Bd. Pharmacy, https://www.mbp.ms.gov/sites/default/files/inline-images/Semaglutide.compoundguidance%20%28002%29.pdf.

[7] FDA has been inconsistent when defining bulk drug substances to either differentiate between or include the salt and base form of the drug. First, "bulk drug substance," as referenced in Section 503A(b)(1)(A) of the FD&C Act, is to mean the same as "active pharmaceutical ingredient" in 21 C.F.R. § 207.1. Unfortunately, this definition does not address whether it should include only the base or salt and ester forms. The FDA's animal compounding guidance claims that a compounded drug's active ingredient is "the same" as that of the approved drug regardless of any salt or ester form. *See* Compounding Animal Drugs from Bulk Drug Substances, GFI #256, August 2022, https://www.fda.gov/media/132567/download. Similarly, the FDA's exclusivity statutes treat the salt form of a drug as the base form. *See* 21 U.S.C. § 355(c)(3)(E)(ii). The FDA did propose rules that would treat each specific form of the drug (base, salts, or esters) as separate entities. *See* List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 91071, 91076 (Dec. 16, 2016) https://www.govinfo.gov/content/pkg/FR-2016-12-16/pdf/2016-30109.pdf.

evidenced confusion.[8] Therefore, the Pharmacy reasonably assumed that the salt form of an FDA-approved drug is essentially the "same component" as is permitted under federal law.

Colorado compounding practice regulations mirror the federal requirements enforced by the FDA. Specifically, ingredients used to compound drug products must adhere to one of the following: (1) be composed of a USP/NF grade substance when not available and on the drug shortage list; (2) be a substance with either a Chemically Pure, Analytical Reagent, American Chemical Society, or Food Chemical Codex chemical grade; or (3) *originate* from FDA-approved sources.[9] According to the Cambridge dictionary, "originate" means "to come from a particular place, time, situation, etc."[10] Therefore, prior to the FDA using its guidance, it was reasonable for the Pharmacy to determine that the salt form "originated" from the base form of semaglutide. Nevertheless, in response to the FDA guidance issued on April 27, 2023, the Pharmacy adjusted its practices to compound with the base form of semaglutide, an FDA-approved drug product.[11] Currently, the Pharmacy is in full compliance with federal and state requirements in its compounding of semaglutide drug products.

The Complaint also suggested that since the FDA stated that it has received adverse event reports after patients used compounded semaglutide, the Pharmacy would be prohibited from compounding the drug product. Colorado regulation provides the following as it relates to appropriate drug ingredients and components: "[d]rug preparations that have been withdrawn or removed from the market for safety reasons shall not be compounded."[12] However, the FDA has not withdrawn or removed compounded semaglutide from the market. The mere evidence of reported adverse events does not automatically withdraw or remove a product from the market. If this were the case, no bulk drug substance could be used to compound within the state. Simply put, nearly every drug has some record of reported adverse events when used by patients, so the mere existence reported adverse events does not prohibit the compounding of such a drug.

II. Compounded semaglutide products are not essentially a copy of a commercially available drug product.

Under federal law, pharmacies are not permitted to compound drug products that are essentially a copy of what is commercially available.[13] However, once a commercially available

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[8] *See* Utah State Board of Pharmacy, Minutes, March 28, 2023, p. 3, https://www.utah.gov/pmn/files/970387.pdf (finding that members of the Board believed the salt form does not matter, it is the semaglutide molecule that is being used, the semaglutide component is the active pharmaceutical ingredient); *see also* Utah State Board of Pharmacy, Minutes, March 28, 2023, https://www.utah.gov/pmn/files/959981.mp3 (conversation begins at 00:41:00).

[9] *See* 3 Colo. Code Regs. § 719-1:21.21.10(b), (c).

[10] *See Originate*, Cambridge Dictionary, https://dictionary.cambridge.org/us/dictionary/english/originate (last visited Aug. 22, 2023).

[11] [11] *See* FDA to NABP Semaglutide Letter, U.S. Food & Drug Administration, April 27, 2023, https://a4pc.org/files/FDA-to-NABP-Semaglutide-letter_April-27-2023.pdf.

[12] *See* 3 Colo. Code Regs. 719-1:21.21.10(f).

[13] *See* 21 U.S.C § 353a(b)(1)(D).

drug is placed on the FDA shortage list, the FDA allows pharmacies to compound essentially copies of these drug products because the FDA no longer considered the drug to be "commercially available".[14]

Nevertheless, the types of semaglutide drug products the Pharmacy compounds would be permitted even if Wegovy and Ozempic were not on the shortage list. A compounded drug product is considered "essentially a copy" of a commercially available drug product if (1) the compounded drug product has the same active pharmaceutical ingredient(s) ("API") as the commercially available drug product, (2) the API(s) has the same, similar, or an easily substitutable dosage strength, and (3) *the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug.*[15]

Currently, the Pharmacy only compounds semaglutide to be administered buccally or sublingually as a troche drug product. There are currently no commercially available semaglutide drug products that rely upon this route of administration. Wegovy and Ozempic are both administered as a subcutaneous injection. Furthermore, another popular semaglutide drug product on the market, Rybelsus, is administered orally as a tablet. Since the Pharmacy's compounded drug product is not administered via the same route of administration as what is commercially available, its product is not "essential copy" of a commercially available semaglutide drug product. Therefore, compounding such products does not violate federal law.

Colorado law mirrors the federal limitations related to the preparation of commercially available drug products. Specifically, Colorado regulation provides that "[c]ompounding does not include the preparation of copies of commercially available drug products."[16] The regulation then clarifies that "[c]ompounded preparations that produce, for patient, a significant difference between the compounded drug and the comparable commercially available drug product as determined, by the prescriber, as necessary for the medical best interest of the patient are not copies of commercially available products."[17] "'Significant differences' may include, but are not limited to, modifications such as changes in strength, and changes in dosage form or *delivery mechanism*."[18] Again, the Pharmacy's semaglutide troche drug product is a different "delivery mechanism" than what is commercially available. Therefore, the Pharmacy's semaglutide troche drug product is not "a copy of commercially available drug products".

III. Obtaining semaglutide from an out-of-state manufacturer, a source not registered with the Board.

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[14] *See* U.S. Food & Drug Administration, Center for Drug Evaluation and Research, Compounding 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, p. 5 (Jan. 2018), https://www.fda.gov/media/98973/download.
[15] *Id.* p. 5-6.
[16] 3 Colo. Code Regs. § 719-1:21.00.30(e)(2).
[17] *Id.* (emphasis added)
[18] *Id.*

The Pharmacy currently sources semaglutide from Biopeptek, an out-of-state manufacturer located in Malvern, Pennsylvania. While it is true that Biopeptek is not currently registered with the Board, Biopeptek's and the Pharmacy's initial compliance review revealed that there is no out-of-state manufacturer licensure process in Colorado. The Board has implemented a process for applying to be registered as an in-state manufacturer, but has not implemented a similar process for applying to be registered as an out-of-state manufacturer.[19] Based on the allegations contained in Complaint, it appears that the Board expects Biopeptek to be registered as an out-of-state wholesaler instead.

The Act defines "[m]anufacturers" and "[w]holesalers" differently.[20] A "[m]anufacturer" is defined as "an entity that either cultivates, grows, or prepares by other process, drugs for sale to wholesalers or other persons entitled to purchase drugs other than the patient."[21] Based on this definition, Biopeptek reasonably concluded that it would qualify as a manufacturer since their business practices better align with this description when compared to the definition of "wholesaler."[22] And because Colorado does not issue registrations for out-of-state manufacturers, it reasonably concluded that it did not need to be registered.

We understand that the Board requires every *wholesaler* to be registered with the Board if it distributes or ships drugs into the state regardless of where it is located.[23] However, it appears that the Board expects Biopepek to be registered as a *wholesaler*—even though its primary business activity is that of a manufacturer—because it distributes prescription drugs into Colorado. The Pharmacy was not aware of this registration requirement until it received the Complaint from the Board. As a result, the Pharmacy has been in communication with Biopeptek regarding the registration requirements and is looking to find an alternative manufacturer that is properly registered as a wholesaler or manufacturer until Biopeptek successfully obtains a wholesale registration.

The Complaint also alleged the Pharmacy violated its responsibility to ensure that they may procure components from Biopeptek.[24] However, pharmacies only have a duty to ensure the procure *prescription drugs* from a Board-registered source.[25] The term "prescription drug" is narrowly defined to only include drugs that meet one of the following qualifications: "(a) . . . required by any applicable federal or state law or rule to be dispensed only pursuant to an order; (b) . . . restricted by any applicable federal or state law or rule to use by practitioners only; or (c)

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[19] *See* Colorado Department of Regulatory Agencies, State Board of Pharmacy: Business Applications and Forms, https://dpo.colorado.gov/Pharmacy/ApplicationsBusiness (last visited Aug. 22, 2023).
[20] *See generally* Colo. Rev. Stat. Ann. § 12-280-103.
[21] *See* Colo. Rev. Stat. Ann. § 12-280-103(26), (27).
[22] *See* Colo. Rev. Stat. Ann. § 12-280-103(54)(a), (55)(defining a wholesaler to broadly mean a person engaged in the wholesale distribution, or distribution of prescription drugs to persons or entities other than a consumer or patient, that are authorized by law to possess prescription drugs).
[23] *See* 3 Colo. Code Regs. 719-1:15.01.00(b).
[24] *See* 3 Colo. Code Regs. § 719-1:1.00.24; *see also* 3 Colo. Code Regs. § 719-1:7.00.30(b).
[25] *Id.*

. . . required under federal law to be labeled with either 'Rx only' or 'Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.'"[26] Significantly, not all *components* used as ingredients for compounding products fall under the definition of "prescription drugs".

In any event, the Complaint alleges that the Pharmacy was not using an FDA-approved drug for compounding, but at the same time alleges that the Pharmacy procured a "prescription drug" from a source not registered with the Board. Based on this, the semaglutide procured by the Pharmacy cannot reasonably be found to be a "prescription drug" as the basis of an alleged violation of these provisions.

IV. Alleged dispensing of compounded drug products to practitioners for "office use" pursuant to non-patient specific orders.

The anonymous complaint initially received by the Board alleged that the Pharmacy was dispensing compounded medications to medical offices pursuant to non-patient specific prescription orders. While it appears the Board's inspector found no evidence of this practice, the Pharmacy wishes to dispel any notions they engage in such a practice. Under the Board's regulations, a pharmacist may not dispense pursuant to a non-patient specific prescription order.[27] Therefore, a prescription order for "office use" is not a valid prescription order.[28] The Pharmacy would like to emphasize that it only dispenses compounded medications pursuant to valid patient-specific prescription orders in order to address a recognized medical need or utility.[29] To evidence this practice, please see **Attachment A**. Included within the attachment, the Pharmacy has provided examples of patient-specific prescription order forms. In summary, the Pharmacy does not engage in the practice alleged in the anonymous complaint and only dispenses pursuant to valid patient-specific prescription orders.

V. Additional citations issued in response to on-site inspection.

a. *Difficulty identifying orders for any of semaglutide sodium dispensing transactions.*

The Pharmacy utilizes LifeFile as their pharmacy management system. LifeFile is a nation-leading pharmacy management system, used by some of the largest compounding pharmacies in the nation.[30] While LifeFile offers a state-of-the-art, cloud-based system

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[26] *See* Colo. Rev. Stat. Ann. § 12-280-103(42).
[27] *See* 3 Colo. Code Regs. § 719-1:3.00.20(d).
[28] *Id.*
[29] *See* 3 Colo. Code Regs. § 719-1:3.00.20(a).
[30] *See* LifeFile, https://www.lifefile.net/ (last visited Aug. 23, 2023).

specifically designed for the management of compounding pharmacies, the Pharmacy also selected the LifeFile system for its proven track record of excellent customer service.[31]

Following the Board's Complaint, the Pharmacy immediately contacted LifeFile's support team to address the inspector's difficulties in identifying orders as discussed in the Complaint. To evidence the Pharmacy's discussions via email with LifeFile, please see **Attachment B**. The Pharmacy first contacted LifeFile on August 15th and have followed-up repeatedly to emphasis to LifeFile the need for a solution. Throughout their discussion, the Pharmacy remained adamant and relayed to LifeFile the importance of rectifying this issue in a timely manner. LifeFile assured the Pharmacy they are working on a solution. However, the Pharmacy is still awaiting confirmation that the solution is in place. The Pharmacy will update the Board accordingly as the situation progresses.

b. *Compounding records shall be uniformly maintained and contemporaneous.*

In accordance with the Board's regulations, the Pharmacy must ensure that their compounding records are readily retrievable in both a printed and contemporaneous format immediately upon the request of the Board's inspectors.[32] The Pharmacy understands the importance of allowing Board inspectors to access and review their compounding records in a succinct and timely manner. To that end, the Pharmacy has also begun discussions with LifeFile to ensure that the Pharmacy's compounding records will no longer require the user to click through multiple tabs and windows in order to review. The Pharmacy has taken affirmative steps to ensure that its compounding records are uniformly maintained and contemporaneous moving forward.

c. *Labeling of compounded products made in anticipation of orders and associated recordkeeping.*

When compounding drug products in anticipation of prescription orders, the Board's regulations require that these products be properly labeled.[33] In response to the allegation of failure to properly label, the Pharmacy has fixed their label printer to include the following: "(1) [n]ame and address of the outlet; (2) [n]ame and strength of the drug(s) / active ingredient(s) in the final product; (3) [t]otal quantity in package; (4) [a]ssigned BUD; (5) [b]atch (lot) number; (6) [s]pecific route of administration; (7) [s]torage directions, when appropriate; (8) 'Rx only'; and (9) 'This product was compounded by the pharmacy.'"[34] These changes ensure compliance with Colorado regulations related to anticipatory compounding labeling. Furthermore, the

[31] *Id.*
[32] *See* 3 Colo. Code Regs. § 719-1:11.03.05(c).
[33] *See* 3 Colo. Code Regs. § 719-1:21.11.10(c).
[34] *Id.*

Pharmacy implemented an action plan with respect to training of its pharmacy personnel as it relates to labeling of anticipatory compounds.

d. *Invoices and prescription drug orders filed separately as schedule II, schedule III-V, and prescription drugs.*

All pharmacies licensed with the Board must maintain their records of invoices, transaction receipts, and prescription drug orders in a manner consistent with the Board's regulations.[35] The Pharmacy is required to maintain and file each respective record as follows: (1) schedule II controlled substance prescription orders, (2) schedule II-V controlled substance prescription orders, and (3) non-controlled substance prescription orders.[36] In response to the cited irregularities and issues surrounding proper recordkeeping practices alleged in the Complaint, the Pharmacy implemented a program to re-train its personnel to ensure compliance with Colorado requirements. Primarily, the program aimed to educate pharmacy personnel on the requirement of three differing filing locations discussed above. For instance, the Pharmacy has identified the required filing locations for various commonly processed drugs for their personnel's reference. Nevertheless, the Pharmacy will conduct audits of their recordkeeping files over the next twelve months to ensure compliance.

e. *Change of pharmacist manager controlled substance inventory.*

The pharmacist manager is responsible for ensuring that the pharmacy's operations adhere to all state and federal laws, rules, and regulations.[37]Additionally, in the event there is a change of pharmacist manager, the new pharmacist manage must take a controlled substance inventory within seventy-two hours of assuming the position.[38] The Pharmacy now understands that pharmacist manager cannot retroactively conduct an inventory to ensure compliance with these requirements. Nevertheless, the Pharmacy updated their standard operating procedures to ensure the inventory is conducted within 72-hours of a change in the pharmacist manager. Furthermore, even though the Board's regulations only requires that the inventory be taken every two years,[39] the Pharmacy scheduled a date to conduct a controlled substance inventory in January and will continue to do so on an annual basis. The Pharmacy remains committed to addressing this issue in its entirety and ensuring that similar issues occur in the future.

f. *Storage of compounded drug products on floor.*

A pharmacy may not store any components, non-freestanding equipment, packaging and drug preparation containers, and other compounding materials on the floor to prevent

[35] *See* 3 Colo. Code Regs. § 719-1:11.01.00.
[36] *See* 3 Colo. Code Regs. § 719-1:11.06.30; *see also* 3 Colo. Code Regs. § 719-1:11.06.40; *see also* 3 Colo. Code Regs. § 719-1:11.04.10; *see also* 3 Colo. Code Regs. § 719-1:11.02.00(a)(3).
[37] *See* 3 Colo. Code Regs. § 719-1:7.00.30(a).
[38] *See* 3 Colo. Code Regs. § 719-1:7.00.20(b).
[39] *See* 3 Colo. Code Regs. § 719-1:11.03.00(d).

contamination.[40] In response to the Complaint, the Pharmacy removed all compounding products, non-freestanding equipment, and containers from the floor to a safe, secured, and raised location. The Pharmacy has also re-trained its personnel on this issue.

g. *Daily recording of refrigerator and freezer temperatures.*

If a pharmacy stores refrigerated or frozen drug products, such products must be stored in accordance with the Board's regulations. To that end, the Pharmacy's refrigerator must maintain a temperature between two and eight degrees Celsius (2-8 degrees C.) or thirty-six and forty-six degrees Fahrenheit (36-46 degrees F.).[41] Additionally, the Pharmacy's freezer must maintain a temperature between twenty-five degrees below zero and ten degrees below zero Celsius (-- 25 and -- 10 degrees C.) or thirteen degrees below zero and fourteen degrees Fahrenheit (-- 13 and 14 degrees F.).[42] In order to ensure these temperatures are maintained, the Board requires that they be electronically monitored each calendar day.[43] The Complaint alleged that the Pharmacy did not have a process in place to monitor these temperatures in accordance with state requirements. Specifically, the Complaint noted the Pharmacy's inability to monitor these temperatures over the weekend when the Pharmacy is closed. However, the Pharmacy does, in fact, employ a digital continuous monitoring system. To evidence this capability, please see **Attachment C**. As the attachment demonstrates, the Pharmacy can continuously and electronically monitor the temperature of the refrigerator and freezer in compliance with Colorado law. Therefore, the Pharmacy respectfully disagrees with the allegation that the Pharmacy did not have the ability to monitor temperatures when the Pharmacy is closed.

h. *Generate, upon request, a readable daily printout.*

The Board requires that a pharmacy's system have the ability to produce a hard-copy document every twenty-four hours or a "daily printout."[44] This "daily printout" must include the following: "(1) The serial number; (2) The name of the patient; (3) The name of the practitioner: (4) For each controlled substance dispenses, the practitioner's Drug Enforcement Administration registration number; (5) The date of issue by the practitioner, the date dispensed shall be presumed to be the date of issue; (6) The total number of refills authorized; (7) Date dispensed; (8) The name and strength of the drug dispensed; (9) The quantity of the drug dispensed; [and] (10) In the case of a refill, the total number of refills dispensed to date."[45] The Complaint alleges that the Pharmacy's "daily printout" did not include the "date of issue by the practitioner" and that the other required information was illegible. In response to this allegation, the Pharmacy quickly identified the root cause of this issue. Unfortunately, the Pharmacy's software had turned off the feature to print out hard copy "daily reports". As previously discussed, the Pharmacy

[40] *See* 3 Colo. Code Regs. § 719-1:21.10.30(f); *see also* 3 Colo. Code Regs. § 719-1:21.10.65(c).
[41] *See* 3 Colo. Code Regs. § 719-1:5.01.31(j).
[42] *See* 3 Colo. Code Regs. § 719-1:5.01.31(k).
[43] *Id.*
[44] *See* 3 Colo. Code Regs. § 719-1:11.04.20(b).
[45] *See* 3 Colo. Code Regs. § 719-1:11.04.20(c).

established contact with LifeFile to find a solution to this issue moving forward. To evidence the Pharmacy's discussions via email with LifeFile, please see **Attachment B**. The Pharmacy is still waiting for confirmation that solution is in place. The Pharmacy will update the Board accordingly as the situation progresses.

i. *Pharmacist managers shall review, date, and sign the compounding policy and procedure manual within 30 days of assuming the duty in February 2023.*

If there is a change of pharmacist manager, the newly appointed pharmacist manager must review, sign, and date the policy and procedure manual within their first thirty days.[46] Regrettably, the Pharmacy's current pharmacist manager did not review the policy and procedure manual within 30 days and now cannot retroactively sign and date the manual. Nevertheless, the current pharmacist manager has reviewed and signed the manual following the Board's inspection. Looking forward, the Pharmacy remains committed to taking proactive steps to ensure that this does not happen again. As such, the Pharmacy updated its relevant standard operating procedures to ensure that any future pharmacist managers will review, sign and date their manual within their first 30 days of assuming position in compliance with the Board's regulations.

VI. Conclusion

The Pharmacy remains committed to engaging in the lawful practice of compounding pharmacy within Colorado. While each issue cited in the Complaint has been addressed above, we understand that there are still issues outstanding specifically as it relates to the LifeFile system. Should the Board request further information, the Pharmacy will be pleased to accommodate additional requests. To that end, please let us know if there are any further issues or questions that we may address.

Very truly yours,

Alexander L. Snyder

ALS

[46] *See* 3 Colo. Code Regs. § 719-1:7.00.20(j); *see also* 3 Colo. Code Regs. § 719-1:21.10.10(a).

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August 31, 2023

VIA ELECTRONIC TRANSMISSION – dora_pharmacyboard@state.co.us

Dmitry Kunin, PharmD
Colorado Pharmacy Board
Department of Regulatory Agencies
1560 Broadway
Suite 1350
Denver, CO 80202

Dear Dmitry Kunin:

We represent Strive Pharmacy Denver LLC (the "Pharmacy"), License No. PDO.1680000218, in connection with Colorado Pharmacy Board (the "Board") Case No. 2023-5699 (the "Complaint"). This letter is the Pharmacy's supplemental written response to the Complaint, which alleges possible violations of the Colorado Pharmacists, Pharmacy Business, and Pharmaceuticals Practice Act (the "Act"), including procuring bulk drug substances from an out-of-state manufacturer not registered with the Board and difficulties associated with the Pharmacy's management system, LifeFile. As a reminder, LifeFile's system created issues identify orders of semaglutide sodium dispensing transactions and generating a readable daily printout upon request.[1] This supplemental response aims to provide additional information for the Board's consideration that were only made available to the Pharmacy after the 10-day due date for the original response.

The Pharmacy has been in continuous contact with Biopeptek Pharmaceuticals, LLC ("Biopeptek"), their out-of-state manufacturer cited within the Complaint. As noted in the previous response, Biopeptek was not aware that Colorado had a requirement or licensure process for out-of-state manufacturers. Nevertheless, Biopeptek quickly sought Colorado licensure to rectify this error and ensure compliance moving forward. As such, the Pharmacy has

[1] *See generally* 3 Colo. Code Regs. § 719-1:11.01.00; *see also* 3 Colo. Code Regs. § 719-1:11.04.20(b).

just been notified that Biopeptek received their Colorado Wholesaler Out-of-State license on August 25, 2023. A copy of Biopeptek's license can be found for review in **Attachment A**.

As discussed in the previous response, the Pharmacy has been in contact with LifeFile to address the Board's concerns since they received the Complaint. During these initial conversations, LifeFile and the Pharmacy worked together to identify the causal factors and potential solutions related to these citations. As of the writing of this supplemental response, LifeFile was able to update their pharmacy management system to accommodate aspects of the Board's recordkeeping rules. Specifically, the updated system now allows for the following: (1) printing back tags for both legend and controlled substance prescription order dispensing transactions and (2) the ability to produce a hard-copy daily printout of the Pharmacy's fulfilled prescription orders. Examples of printed hard copies for semaglutide drug products and the daily printout for both August 30 and 31, 2023 are available for review in **Attachment B**. Therefore, the Pharmacy's current version of LifeFile's pharmacy management system is compliant with the Board's rules.

In conclusion, this supplemental response aims to address any outstanding issues while providing evidence of the Pharmacy's continued commitment to their compliant practice of pharmacy moving forward. However, in the event the Board has any further questions or requires additional clarification, the Pharmacy would be happy to accommodate any additional request.

Very truly yours,

Alexander L. Snyder

ALS

Attachment A

COLORADO
Department of Regulatory Agencies
Division of Professions and Occupations

Below are your electronic wallet cards to use as proof of your license. You can also print your license at any time by visiting www.colorado.gov/dora/DPO_Print_License and following the instructions listed.

While all Temporary Licenses are given an expiration date of 12/31/20, this license may be cancelled prior to that date if the temporary license is determined to be no longer needed. This license does not replace an existing or previous credential and is non-renewable. Additionally this license is not eligible for any intrastate compact agreements and cannot be used for verification purposes in other states.

This license is temporary and does not constitute a property right. It was created and is available as a result of Executive Order D 2020 038 and may be discontinued prior to the current expiration date.

Should you have questions about your credential, or need other information please contact our Customer Service Team dora_dpo_licensing@state.co.us. Be sure to visit the Division of Professions and Occupations website often for specific updates during the COVID-19 crisis at dpo.colorado.gov.

Colorado Department of Regulatory Agencies
Division of Professions and Occupations

State Board of Pharmacy
Biopeptek Pharmaceuticals, LLC

Wholesaler Out-of-State

WHO.0008710 — **Number**
08/25/2023 — **Issue Date**
Active — **Credential Status**
10/31/2024 — **Expire Date**
Verify this credential at: dpo.colorado.gov

Division Director: Sam Delp
Credential Holder Signature

Colorado Department of Regulatory Agencies
Division of Professions and Occupations

State Board of Pharmacy
Biopeptek Pharmaceuticals, LLC

Wholesaler Out-of-State

WHO.0008710 — **Number**
08/25/2023 — **Issue Date**
Active — **Credential Status**
10/31/2024 — **Expire Date**
Verify this credential at: dpo.colorado.gov

Division Director: Sam Delp
Credential Holder Signature

1560 Broadway, Suite 1350, Denver, CO 80202 P 303.894.7800 F 303.894.7693 dpo.colorado.gov

Attachment B

Strive Pharmacy Denver

Order #88924905 (Source: Multi Refill)

Patient Information

[redacted]

Patient Allergies

Patient Diseases

Order Information

Order Date: 08/26/2023 03:34 pm **By:** Cintron, Cintron, (zannakin)
Priority: Normal, **Document Type:** Refill Rx
PMS Interface: lifefile
Due On: , **Memo:**

Prescriber Information

Hedberg, Caleb
Hedberg Caleb
165 S. Union Blvd. Suite 800
Lakewood, CO 80228,
(303) 988-2680, caleb.hedberg@nwphysicians.com
License: 57367

Shipping Information

[redacted]

Free Shipping: No, **Shipping Email Notification:** Yes
Delivery Service: UPS Ground, **Handling Options:** Insulated BOX with ICE (temperature sensitive)
Signature Type:
Residential Addres Indicator:
Saturday Delivery: No, **Shipping Insurance:**
Delivery Date:
Shipping Notes:

Billing Information

Payor Type: Patient/Guardian
Flycin, Carrie
2517 S Eldridge Ct
Lakewood, CO 80228-4836

Payment Note:

RX Number	Fill ID	Medication	Qty/Units
9012498		SEMAGLUTIDE/B12 1000/100 MCG Mini Troche	30 each

- **Refills:** 3
- **Directions:** DISSOLVE 1 TROUCHE UNDER TONGUE IN THE MORNING 15 MINUTES PRIOR TO FOOD AND DRINK.
- **Dispensation:** Therapeutically equivalent generic drug may be substituted
- **Days Supply:** 30

Rx: 9012498	Date Written: 05/23/23
Patient Name: [redacted]	Drug Name: SEMAGLUTIDE/B12/CHROMIUM PIC/PYRIDOXINE
Patient DOB: [redacted]	Strength: 1000MCG/100MCG/500MCG/12.5MG
Patient Address: [redacted] S Eldridge Ct Lakewood CO 80228-4836	Quantity Ordered: 30
Doctor Name: Caleb Hedberg	Quantity Dispensed: 30
Doctor Address: 165 S. Union Blvd. Suite 800	Directions: DISSOLVE 1 TROUCHE UNDER TONGUE IN THE MORNING 15 MINUTES PRIOR TO FOOD AND DRINK.
Doctor DEA: FH7478402	Refills: 3

Strive Pharmacy
11405 E. Briarwood Ave. Ste. 300 Englewood CO 80112

Surescripts RX information

Written Date: 08/23/2023
Message ID: 2501111M631973H16653
Type: NewRx
Patient: [redacted]

Drug: SEMAGLUTIDE 750 MCG TROCHE (UNIT(S)). QTY: 30

Sig: Dissolve 1 troche under tongue once daily at noon at least 15 minutes before food/drink

Refills: 1 Substitution Allowed

Prescriber: WHITING, HEATHER
5420 S Quebec St #100 Englewood, CO, 801112803
Phone: 3032216797 NPI: 1104007202 DEA: MJ1668803 SPI: 6135021007011

Supervisor:

Notes: **Please call patient with cost and delivery options. Thank you!

Rx: 9015203	Date Written: 08/23/23
Patient Name: [redacted]	Drug Name: SEMAGLUTIDE/B12/CHROMIUM PIC/PYRIDOXINE
Patient DOB: [redacted]	Strength: 750MCG/100MCG/500MCG/12.5MG
Patient Addres[redacted] Ave Denver CO 80222	Quantity Ordered: 30
Doctor Name: HEATHER WHITING	Quantity Dispensed: 30
Doctor Address: 5420 S Quebec St	Directions: DISSOLVE 1 TROCHE UNDER TONGUE ONCE DAILY AT NOON AT LEAST 15 MINUTES BEFORE FOOD/DRINK
Doctor DEA: MJ1668803	Refills: 1

Location	Script numbe	Patient name	Prescriber name	DEA	Written date o	Dispensing date	Name of di	Strength of	Quantity o	Total numl	Total number of refills dispensed to date
Strive Pharm	9014642	Krater, James	WEIR, RONDA	MW7036785	8/7/2023	8/31/2023	NALTREXO	3 MG	90	2	2
Strive Pharm	9015260	Cimino, Laura	STOESZ, ERIN	MS4040224	8/24/2023	8/31/2023	THYROID T	76/20 MCC	30	0	0
Strive Pharm	9015274	Cunningham, J	FLAUDING, JAMES	MF4297291	8/25/2023	8/31/2023	IBUTAMOF	25 MG	30	0	0
Strive Pharm	9015286	Verity, William	DIMPUDUS, DELISA	MD5911107	8/27/2023	8/31/2023	TESTOSTER	200 MG	90	0	0
Strive Pharm	9012669	FRIDAY, MICKI	MARTINEZ, ANGIE	BM8755716	5/31/2023	8/31/2023	PROGESTE	50 MG	60	6	3
Strive Pharm	9012646	Vega- employe	STOESZ, ERIN	MS4040224	5/30/2023	8/31/2023	PROGESTE	200 MG IR	90	5	4
Strive Pharm	9015364	INMAN, JENNI	NICKELL, REBECCA	BN8984343	8/29/2023	8/31/2023	TESTOSTER	1.5 MG	60	2	2
Strive Pharm	9015372	BOONSTRA, KI	Russak, Floyd	AR2330227	8/29/2023	8/31/2023	PROGESTE	200 MG IR	90	5	5
Strive Pharm	9015391	Groce, Kaden	STOESZ, ERIN	MS4040224	8/29/2023	8/31/2023	IBUTAMOF	25 MG	30	0	0
Strive Pharm	9014504	SHANKEN, GRE	PLANES, YVETTE	MP4914823	8/1/2023	8/31/2023	KETAMINE,	125 MG/2(	45	1	0
Strive Pharm	9012770	Smith, Tara	Stoneberger, Brienne	MS3186447	6/3/2023	8/31/2023	PROGESTE	200 MG IR	90	1	0
Strive Pharm	9015413	Robinson, Gre	LEE, JONATHAN		8/30/2023	8/31/2023	3CC 20G 1'	SYRINGE W	2	3	3
Strive Pharm	910968	Koehn, Darcy	ROGERS, CYNTHIA	MR0279201	4/3/2023	8/31/2023	TESTOSTER	10 MG	30	5	0
Strive Pharm	9015431	Del-Cuore, Mis	Corzatt, Allison	MC6191958	8/30/2023	8/31/2023	SEMAGLUT	500MCG/1	30	0	0
Strive Pharm	9015429	Hawkins, Anne	STOESZ, ERIN	MS4040224	8/30/2023	8/31/2023	HAIR FORC	250mg/12.	120	0	0
Strive Pharm	9015424	Lopez, Amand	STOESZ, ERIN	MS4040224	8/30/2023	8/31/2023	PROGESTE	180 MG ER	30	0	0

Location	Script num	Patient nar	Prescriber	DEA	Written da	Dispensing	Name of dı	Strength of	Quantity o	Total numt	Total number of refills dispensed to date
Strive Phar	9012744	Rosen, Ben	MARTINEZ,	BM875571	6/2/2023	8/30/2023	OLYMPUS I	20IU/1MG,	15	1	0
Strive Phar	9014100	DAUER, VII	MALLORY ,	BM701636	7/19/2023	8/30/2023	CJC/IPAMC	1000/1000	90	3	3
Strive Phar	9014750	Marsh, Ste	FLAUDING,	MF429729	8/10/2023	8/30/2023	ESTRADIOL	0.5/100/4 I	30	0	0
Strive Phar	9015320	GODWIN-C	DICKMAN,	BD3657410	8/28/2023	8/30/2023	TESTOSTER	15 MG	30	5	5
Strive Phar	9014922	MCDONAL	WILKINSOI	MF229336	8/14/2023	8/30/2023	CJC/IPAMC	1000/1000	90	3	3
Strive Phar	9015007	McLaughlir	STOESZ, ER	MS404022	8/17/2023	8/30/2023	PROGESTEI	225 MG	30	0	0
Strive Phar	9015173	SKRAMSTA	ALUMBAUC	MA424515	8/23/2023	8/30/2023	TESTOSTER	7.5 MG	180	1	1
Strive Phar	9015252	Crow, Sanc	WEIR, RON	MW703678	8/23/2023	8/30/2023	NALTREXO	3 MG	90	2	2
Strive Phar	9015186	HARTLEY, I	CARNAHAI	BC937248	8/23/2023	8/30/2023	IVERMECTI	16 MG	30	0	0
Strive Phar	9015197	Berges, Ho	STOESZ, ER	MS404022	8/23/2023	8/30/2023	HAIR FORC	250mg/12.	120	0	0
Strive Phar	9015316	Daniel, Cec	DECKER, Al	MD616589	8/24/2023	8/30/2023	TESTOSTER	20 MG/GM	30	0	0
Strive Phar	9015253	Alumbaugh	ALUMBAUC	MA424515	8/25/2023	8/30/2023	BENZOCAII	20/6/4% Li	480	6	6
Strive Phar	910421	Giellis, Chr	Gattoni, Le	MG151950	3/13/2023	8/30/2023	POWER HA	5/0.025/0.:	50	11	8
Strive Phar	9012107	Pope, Barb	Stoneberge	MS318644	5/10/2023	8/30/2023	BIEST/DHE	1.8/6.5/0.5	30	2	0
Strive Phar	9015306	Smith, Cath	Russak, Flo	AR233022	8/28/2023	8/30/2023	BIEST/PRO	2.5/50/2 M	90	1	1
Strive Phar	9015305	Montemar	Benson, Ki	MB799035	8/28/2023	8/30/2023	BIEST/PRO	1/100/2.5 I	30	0	0
Strive Phar	9015288	Orozco, Mi	FLAUDING,	MF429082	8/25/2023	8/30/2023	DIAMOND	10/5/0.01/	30	0	0
Strive Phar	9015313	Lowe, Mat	LARNER, D	ML117732	8/28/2023	8/30/2023	BPC-157 Ca	1 MG	90	0	0
Strive Phar	9013031	Edman, Jar	Morrison, I	FM205761	6/13/2023	8/30/2023	BACLOFEN	2/10/10/5:	60	5	4
Strive Phar	9015321	Sims Plank	FLAUDING,	MF429082	8/28/2023	8/30/2023	ESTRADIOL	0.5/100/6 I	30	0	0
Strive Phar	9015366	Harney, Na	CARLSEN, I	MC627198	8/28/2023	8/30/2023	SEMAGLUT	500MCG/1	30	1	1
Strive Phar	9015357	Garcia, Car	Russak, Flo	AR233022	8/28/2023	8/30/2023	NALTREXO	3 MG	30	1	1
Strive Phar	9015367	HRITZ, DA\	McIntosh, (	MM33182	8/29/2023	8/30/2023	IVERMECTI	36 MG	7	1	1
Strive Phar	9015382	Hritz, peyt	McIntosh, (	MM33182	8/29/2023	8/30/2023	IVERMECTI	19 MG	5	1	1
Strive Phar	9015368	Hritz, Chlo	McIntosh, (	MM33182	8/29/2023	8/30/2023	IVERMECTI	21 MG	5	1	1
Strive Phar	9015369	HRITZ, ANI	McIntosh, (	MM33182	8/29/2023	8/30/2023	IVERMECTI	13 MG	30	1	1
Strive Phar	9015352	Hoskins, Cc	FLAUDING,	MF429729	8/28/2023	8/30/2023	EPHEDRINI	25/200/81	60	0	0
Strive Phar	9015354	Noland, Jar	FLAUDING,	MF429082	8/28/2023	8/30/2023	BPC-157 Ca	1 MG	60	0	0
Strive Phar	9015359	MOULTHR(	Bruice, Ker	BB419632	8/28/2023	8/30/2023	IPAMOREL	1000/1000	60	0	0
Strive Phar	9015374	Holmes, Rl	PIERSON, TOD		8/29/2023	8/30/2023	Ondansetro	4mg	10	0	0
Strive Phar	9015360	Austin, Prir	FLAUDING,	MF429082	8/28/2023	8/30/2023	82F S(MIN(	5/0.25/0.0	30	0	0
Strive Phar	9015362	Fightmaste	FIGHTMAS	MF301882	8/29/2023	8/30/2023	AOD 9604	1000 MCG	90	2	2
Strive Phar	9015381	Emerson, F	PIERSON, TOD		8/29/2023	8/30/2023	Ondansetro	4mg	20	0	0
Strive Phar	9015377	Wagner, Sl	HEISSER, SI	MH221872	8/29/2023	8/30/2023	TESTOSTER	10 MG/GM	45	1	1
Strive Phar	9015409	Fehn, Brad	Anselmi, E	BA737453	8/29/2023	8/30/2023	IVERMECTI	15 MG	15	2	2
Strive Phar	9015373	Collins, Sta	FLAUDING,	MF429082	8/29/2023	8/30/2023	ESTRADIOL	1/6 MG	90	0	0
Strive Phar	9015386	ARCHULET	HUNT, RAC	MH587796	8/29/2023	8/30/2023	AOD 9604	1000 MCG	30	4	4
Strive Phar	9015385	Romero, La	PIERSON, TOD		8/29/2023	8/30/2023	Ondansetro	4mg	20	0	0
Strive Phar	9015383	PIPER, MIR	Bruice, Ker	BB419632	8/29/2023	8/30/2023	IPAMOREL	1000/1000	60	0	0
Strive Phar	9015406	HURT, DAV	HURT, DAVID		8/30/2023	8/30/2023	Ceftriaxon	500mg	10	0	0
Strive Phar	9015387	Schultz, Ca	Russak, Flo	AR233022	8/29/2023	8/30/2023	TESTOSTER	1 MG	90	0	0
Strive Phar	9015397	McLerran,	Yoder, Ann	MO169345	8/29/2023	8/30/2023	NALTREXO	3 MG	90	1	1
Strive Phar	9015390	Tisdale, Ke	STOESZ, ER	MS404022	8/29/2023	8/30/2023	TESTOSTER	6 MG/GM	30	0	0
Strive Phar	9015403	Fabian, Ma	KESLER, CAMILLE		8/30/2023	8/30/2023	Ondansetro	4mg	6	0	0
Strive Phar	908398	VanNote, A	ALUMBAUC	MA424515	########	8/30/2023	PROGESTEI	225 MG	90	3	0
Strive Phar	9015396	Bosshart, T	LARNER, D	ML117732	8/30/2023	8/30/2023	NATURE TH	32.5 MG	30	0	0
Strive Phar	9012434	Young, Gin	Mooney, Je	MM16647	5/19/2023	8/30/2023	NALTREXO	4.5 MG	90	1	-1
Strive Phar	910254	PERRET, D/	HEISSER, SI	MH221872	3/6/2023	8/30/2023	TESTOSTER	3 MG	30	5	4
Strive Phar	9011860	MAYNARD,	YEMAN, JO	MY418872	5/2/2023	8/30/2023	TESTOSTER	5 MG/GM	30	4	2
Strive Phar	9012297	FAIR, ELISE	RITCHIE, SI	ML134066	5/16/2023	8/30/2023	CJC/IPAMC	1000/1000	30	11	9
Strive Phar	9015410	McDonald,	Logan, Sha	ML232903	8/30/2023	8/30/2023	PROGESTEI	225 MG	90	1	1
Strive Phar	9015400	Lips, Laurie	VARNER, JEFFREY		8/30/2023	8/30/2023	MAGIC MC	150ML/20I	240	2	2
Strive Phar	9015405	Miller, Sha	FLAUDING,	MF429729	8/30/2023	8/30/2023	OXANDROI	50 MG	30	0	0
Strive Phar	9015408	Reardon, N	BLUMENTH	MB253242	8/30/2023	8/30/2023	AOD 9604	500 mcg	30	0	0
Strive Phar	9015411	Rutledge, E	LARNER, D	ML117732	8/30/2023	8/30/2023	BPC-157 M	1 MG	60	0	0

STRIVE
compounding pharmacy

Exhibit 10

480.626.4366 480.626.4365 info@strivepharmacy.com strivepharmacy.com
1275 E Baseline Rd Ste 104 Gilbert, AZ 85233

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

PERSONAL AND CONFIDENTIAL

September 25, 2023

Strive Pharmacy Denver LLC
Attn: Pharmacist Manager
11405 E Briarwood Ave Ste 300
Centennial, CO 80112-3848

Sent via email to: mike@strivepharmacy.com

Case No. 2023-5699 -

Dear Strive Pharmacy Denver LLC

The above referenced case concerning the complaint filed against you was recently reviewed by our office. After thorough review and discussion, it was determined that the matter does not warrant the commencement of formal proceedings against your license. Please be advised that the decision was based on the conclusion that there was no reasonable cause to warrant further action at this time. Therefore, the Board is dismissing the case with the issuance of this confidential letter of concern to you.

Compounding a drug, semaglutide sodium salt, in a form that is not approved by the FDA, and then failing to properly document the appropriate prescription orders, violates Board Rules 11.01.00, 11.02.00(a)(3) and 11.04.10, which in turn violates sections 12-280-126(1)(c(I)(II)(III) and (k), C.R.S.

It is the expectation of the Board that, if you have not already done so, you will take prompt steps to prevent a recurrence of this type of situation. As noted above, the Board has dismissed this case and considers this matter closed; however, this confidential letter of concern will remain on file for five (5) years. Moreover, this case may be reopened if another complaint is received that suggests additional review is warranted.

Thank you for your cooperation and attention in resolving this matter. If you have further questions or concerns, please visit our website at dpo.colorado.gov or contact our office by calling (303) 894-7800.

FOR THE COLORADO STATE BOARD OF PHARMACY

Dmitry Kunin
Senior Program Director
Colorado Pharmacy Board

Alexander L Snyder, Respondent Attorney: Alex.Snyder@quarles.com

Please complete a short survey at https://www.surveymonkey.com/r/B5JR27T regarding aspects of the service you received. Your anonymous response will be used to evaluate the service experience and to identify areas where improvements may be appropriate.

STRIVE
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Exhibit 11

480.626.4366 480.626.4365 info@strivepharmacy.com strivepharmacy.com
1275 E Baseline Rd Ste 104 Gilbert, AZ 85233

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	8/14/2023-9/8/2023* FEI NUMBER 3015826784

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher C. Freeman, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Strive Pharmacy Texas LLC dba Strive Pharmacy	1430 S Main St Ste 105
CITY, STATE, ZIP CODE, COUNTRY Boerne, TX 78006-3334	TYPE ESTABLISHMENT INSPECTED Producer (Compounder) of Sterile & Non-sterile Drug Products

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The facility design was observed to allow the influx of lesser quality air into a classified area containing higher quality air.

Specifically,

A. During an inspection of your ISO 7 classified cleanroom, a gap approximately 2-inches wide was observed between the edge of the flap and the modular cleanroom corner, along the back wall of the cleanroom. The opening exposes the cleanroom, which houses an ISO 5 classified hood where drug products intended to be sterile are produced, to the lower quality air of the surrounding unclassified space (i.e., the "general pharmacy area"). It is further observed that this unclassified space houses difficult to clean items, particle generating equipment (e.g., autoclave), and is where non-sterile hazardous drug products are produced.

B. Your unclassified pass-through, used to transfer materials between the ISO 7 classified cleanroom and the unclassified general pharmacy area may allow the influx of lower quality air into the cleanroom, which houses an ISO 5 classified hood where drug products intended to be sterile are produced. The pass-through is not supplied with HEPA-filtered air. It is further observed that this unclassified space houses difficult to clean items and particle generating equipment (e.g., autoclave).

OBSERVATION 2

Personnel performed aseptic manipulations with exposed hair or skin.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator	X	9/8/2023

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	8/14/2023-9/8/2023* FEI NUMBER 3015826784

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Christopher C. Freeman, Pharmacist in Charge	
FIRM NAME Strive Pharmacy Texas LLC dba Strive Pharmacy	STREET ADDRESS 1430 S Main St Ste 105
CITY, STATE, ZIP CODE, COUNTRY Boerne, TX 78006-3334	TYPE ESTABLISHMENT INSPECTED Producer (Compounder) of Sterile & Non-sterile Drug Products

Specifically, on 8/14/2023, during aseptic processing observations, I observed your firm's compounding pharmacy technician exhibit poor aseptic practices by allowing her head to cross into ISO5 LAF unit exposing facial skin and hair while processing the drug product, Semaglutide/B12 2/1 mg/ml (1ml) Inj., Lot ID LG10989644, Date Made 8/14.2023/ Expiry 9/28/2023 drug product intended to be sterile.

OBSERVATION 3

Failure to appropriately and regularly clean and disinfect or sterilize equipment located in the ISO 5 area.

Specifically, vial crimpers are stored in the unclassified area. When transferred to the ISO 7 classified cleanroom, and then to the ISO 5 classified hood, they are subject only to sanitization by spraying with sterile isopropyl alcohol and wiping with a sterile wipe. Considering their design (i.e., moving parts and small, difficult to access crevices, etc.), there is no assurance your method of cleaning is effective in: (1) disinfecting the crimpers, and (2) removing debris and other reside. Consequently, use of the crimpers in this manner, without adequate cleaning and disinfection poses a contamination risk to your drug products.

OBSERVATION 4

Cleaning of equipment and glassware is inadequate.

Specifically, prior to sterilization, glassware, and utensils, used to produce drug products intended to be sterile, are cleaned and sanitized with household detergents, including Dawn dish detergent (for hand washing) and Cascade Platinum Plus pods (for dishwashing machine). There is no assurance that your cleaning process is adequate to remove detergent residue from glassware and other utensils.

***DATES OF INSPECTION**

8/14/2023(Mon), 8/15/2023(Tue), 8/16/2023(Wed), 8/17/2023(Thu), 8/18/2023(Fri), 8/21/2023(Mon), 8/22/2023(Tue), 8/23/2023(Wed), 8/24/2023(Thu), 8/25/2023(Fri), 8/28/2023(Mon), 9/08/2023(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator	X _____	9/8/2023

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	8/14/2023-9/8/2023*
	FEI NUMBER 3015826784

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher C. Freeman, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Strive Pharmacy Texas LLC dba Strive Pharmacy	1430 S Main St Ste 105
CITY, STATE, ZIP CODE, COUNTRY Boerne, TX 78006-3334	TYPE ESTABLISHMENT INSPECTED Producer (Compounder) of Sterile & Non-sterile Drug Products

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator	X	9/8/2023

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

STRIVE
compounding pharmacy

Exhibit 12

480.626.4366 480.626.4365 info@strivepharmacy.com strivepharmacy.com
1275 E Baseline Rd Ste 104 Gilbert, AZ 85233

STRIVE
compounding pharmacy

Re: Response to FDA's Observations on form 483 dated September 9, 2023, issues to Strive Pharmacy Texas LLC.

Dear Mr. Moore:

This letter is in response to the observations made by the U.S. Food and Drug Administration
(the "FDA) on form 483 issued on September 9, 2023, as a result of an inspection of Strive Pharmacy Texas LLC ("Strive") conducted from August 14, 2023 to September 8, 2023. The inspection took place at Strive's 503A pharmacy facility located at 1201 Main Street, Suite 7200, Dallas, TX 75202.

Strive is committed to upholding the highest standards for pharmaceutical compounding, and always seeks to continually improve in making quality pharmaceuticals for our patients.
Strive has carefully considered all of FDA comments and recommendations throughout the inspection and will implement appropriate changes and corrective actions.

With regard to the observations from the FDA form 483, below are those observations, followed by Strive's response.

Below are each of the 483 observations followed by our response.

Observation 1.A.

The facility design was observed to allow the influx of lesser quality air into a classified area containing higher quality air. Specifically,

A. *During an inspection of your ISO 7 classified cleanroom, a gap approximately 2-inches wide was observed between the edge of the flap and the modular cleanroom corner, along the back wall of the cleanroom. The opening exposes the cleanroom, which houses an ISO 5 classified hood where drug products intended to be sterile are produced, to the lower quality air of the surrounding unclassified space (i.e., the "general pharmacy area"). It is further observed that this unclassified space houses difficult to clean items, particle generating equipment (e.g., autoclave), and is where non-sterile hazardous drug products are produced.*

Strive Response

Strive recognizes the issue this observation potentially represents. Strive would like to note that even with this design deficiency, this sterile compounding suite still passes all certifications and holds required positive pressure. To permanently address the concern, the primary objective is to repair the gap spanning approximately 2-inches wide and prevent any risk of lesser quality air entering the ISO 7 classified cleanroom (which contains the ISO 5 classified hood). Once this gap is repaired, Strive will provide the FDA with a supplemental response evidencing the change. In the interim, Strive has implemented additional environmental monitoring of space. To that end, Strive personnel will verify the air pressures are within range up to three times a day. Simultaneously, personnel will collect viable samples in both the ISO 5 and 7 classified areas daily to ensure that the area continues to meet USP 797 requirements and document accordingly.

Observation 1.B.

B. *Your unclassified pass-through, used to transfer materials between the ISO 7 classified cleanroom and the unclassified general pharmacy area may allow the influx of lower quality air into the cleanroom, which houses an ISO 5 classified hood where drug products intended to be sterile are produced. The pass-through is not supplied with HEPA-filtered air. It is further observed that this unclassified space houses difficult to clean items and particle generating equipment (e.g., autoclave).*

Company Response

Strive understands that the unclassified pass-through used to transfer materials between the ISO 7 classified classroom and the unclassified general pharmacy area may contribute to the influx of lower air quality to the area where sterile drug products are produced. Due to this issue, Strive personnel no longer use this pass-through to prevent any risk or concern of lesser quality of air moving forward.

Observation 2.

Personnel performed aseptic manipulations with exposed hair or skin.

Company Response

In order to preserve the good compounding practices, Strive must adhere to expected standards of pharmaceutical compounding expected of a 503A pharmacy facility. Strive's goal remains to reduce additional incidences of this observed issue occurring moving forward. As such, pharmacy personnel have received additional training regarding aseptic manipulations and the relevant policies and procedures have been addressed.

Observation 3.

Failure to appropriately and regularly clean and disinfect or sterilize equipment located in the ISO 5 area.

Specifically, vial crimpers are stored in the unclassified area. When transferred to the ISO 7 classified cleanroom, and then to the ISO 5 classified hood, they are subject only to sanitization by spraying with sterile isopropyl alcohol and wiping with a sterile wipe. Considering their design (i.e., moving parts and small, difficult to access crevices, etc.), there is no assurance your method of cleaning is effective in: (1) disinfecting the crimpers, and (2) removing debris and other residue. Consequently, use of the crimpers in this manner, without adequate cleaning and disinfection poses a contamination risk to your drug products.

Company Response

While not considered industry standard, Strive plans to acquire vial crimpers that are autoclavable. At this time, we have not found any that are autoclavable. As autoclaving would be the ideal situation to ensure decontamination, we will continue to look for this product. In the interim, Strive continues their policy of disinfecting, sanitizing, and cleaning vial crimpers prior to each use. Strive's pharmacy personnel are aware of the concerns raised regarding the design of vial crimpers and the ability to prevent contamination risk to compounded drug products. As such, the pharmacy personnel have been retrained to ensure the vial crimpers are effectively disinfected and debris removed so as to address any concerns raised by this observation.

Observation 4

Cleaning of equipment and glassware is inadequate.
Specifically, prior to sterilization, glassware, and utensils, used to produce drug products intended to be sterile, are cleaned and sanitized with household detergents, including Dawn dish detergent (for hand washing) and Cascade Platinum Plus pods (for dishwashing machine). There is no assurance that your cleaning process is adequate to remove detergent residue from glassware and other utensils.

Company Response

In response to this observation, Strive has discontinued the use of various household cleaners (i.e., Dawn Dish Detergent, Cascade Platinum Plus Pods) and have implemented the use of Contrad NF. This product is particularly recommended for

critical cleaning of labware and high-pressure cleaning applications. *See* **Attachment 1**. Switching to a product specifically designed with lab equipment and glassware in mind removes any concern of detergent residue being present after the cleaning process.

* * *

You, (Mr. Moore), also made several informal comments that were not included as observations in the form 483. We are actively reviewing those comments and will make any changes or corrections required to meet the highest standards of patient safety, and with the legal requirements for pharmacies under the Food, Drug, and Cosmetic Act, and appropriate state law.

Please do not hesitate to contact Christopher Freeman at cfreeman@strivepharmacy.com if you have any questions or concerns.

Respectfully,

Christopher Freeman
Pharmacist-in-Charge
Strive Pharmacy
1430 South Main St., Suite 105
Boerne, TX 78006

STRIVE
compounding pharmacy

Attachment 1

830.816.5911 texas@strivepharmacy.com strivepharmacy.com
1430 S. Main Street Suite 105 Boerne, Texas 78006

Decon Labs, Inc.

CONTRAD® NF

Contrad® NF is a non-foaming concentrated liquid detergent designed for high-pressure cleaning applications – laboratory and industrial automatic washing machines, CIP systems, steam washers, etc. Phosphate-free and chlorine-free, ***Contrad® NF*** is particularly recommended for critical cleaning of labware, where total rinsability and residue-free results are vital; and for plant cleaning, such as biotechnology and pharmaceutical production equipment.

DIRECTIONS FOR USE: ***Contrad® NF*** should be diluted using deionized or distilled water where available to avoid the likelikhood of precipitating hardness salts from untreated water. Similarly, for best results, deionized or distilled water should be used for rinse cycles.

Dispense ***Contrad® NF*** according to labware washing machine manufacturer's instructions. If you do not have an automatic dispensing unit, calculated the gallon volume in the dishwasher's wash cycle, Add one oz. of ***Contrad® NF*** per gallon of water to arrive at a solution suitable for most applications. The concentration can be increased if contaminants are difficult to remove.

Contrad® NF is stable across a wide temperature range and may be used with cold or hot water wash systems. It is totally non-foaming, although it may create mild saponification when used in removing proteins, Rinse thoroughly while still wet.

RINSABILITY: Presented as a liquid concentrate, ***Contrad® NF*** presents no solubility problems and has proven totally rinsable from glass, plastic, and metal surfaces. It contains no chlorine and is considered safe to use on stainless steel.

TOTAL ORGANIC CARBON: ***Contrad® NF*** has a Total Organic Carbon content of 3.7 % by weight in its concentrated form. A TOC analysis may therefore be used to determine rinsed state of a surface cleaned with ***Contrad® NF*** .

DISPOSAL: ***Contrad® NF*** contains no generally recognized pollutants and therefore may be disposed directly to drain. It is highly alkaline and some neutralization of effluent may be required.

PRECAUTIONARY STATEMENT: ***Contrad® NF*** is highly alkaline and must be handled and used with care. Always wear hand, face, eye, and clothing protection when handling Contrad NF. Severe eye irritant, treat as caustic burns.

Packaging

Size	Case QTY	Decon #
1 Gallon (3.8L)	4	6002
2.64 Gallon (10L)	2	6001
30 Gallon (115L)	-	6003
55 Gallon (210L)	-	6055

Rev. 12/2022

460 Glennie Circle • King of Prussia, PA 19406 • (610) 755-0800 • Fax (610) 270-8905 • www.deconlabs.com

STRIVE
compounding pharmacy

Exhibit 13

480.626.4366 480.626.4365 info@strivepharmacy.com strivepharmacy.com
1275 E Baseline Rd Ste 104 Gilbert, AZ 85233

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

September 28, 2023

DATED MATERIAL ENCLOSED

STRIVE PHARMACY
ATTN: NATHAN LAWRENCE HILL, CEO
1275 E BASELINE RD STE 104
GILBERT, AZ 85233

RE: CI 2023 101661
STRIVE PHARMACY
NRP 2446

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- October 12, 2023: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- October 28, 2023: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

Anne Sodergren
EXECUTIVE OFFICER

By:

Joshua Monforte
Citation and Fine Analyst

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

Unless contested, Citations are final 30 days from the date of service. Acceptance of a Citations is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than October 12, 2023 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than October 28, 2023 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have any questions regarding any enclosed documents please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2023 101661	STRIVE PHARMACY, NRP 2446

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
Title 21 US Code § 353a subd. (a)(b)(1)(A)	(a) In general Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section ..(b) Compounded Drugs (1) A drug product may be compounded under subsection (a) if the licensed pharmacist... (A) compounds the drug product using bulk drug substances as defined in...
Title 21 US Code § 353a subd. (a)(b)(1)(D)	(a) In general Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section ..(b) Compounded Drugs (1) A drug product may be compounded under subsection (a) if the licensed pharmacist... (D) compounds the drug product using bulk drug substances as defined in...
CCR, Title 16, § 1751.7 subd. (e)(1)	Sterile Compounding Quality Assurance and Process Validation; Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients shall be subject to...
CCR, Title 16, § 1735.2 subd. (d)(3)	Compounding commericially available products

Bus. & Prof. Code § 4169 subd. (a)(2)/Health & Safety Code § 111295/Title 21 USC § 351(a)(1)(2)(A)(B)/Health & Safety Code § 111255/Health & Safety Code § 111250	**Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to that the person knew or reasonably should have known were adulterated.../ It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated./ Adulterated drugs and devicesA drug or device shall be deemed to be adulterated—(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice .../ Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been rendered injurious to health/Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance**
Bus. & Prof. Code § 4301 subd. (b)	**Unprofessional Conduct - Incompetence.**

CONDUCT:

Use of a non-compliant bulk drug substance: 21 U.S.C. 353a(a)(b)(1)(A), compounded drugs, section 503A (a) In General. --Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient. (b) compounded drugs (1) Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician (D) 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. (b) compounded drugs (1) A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician— (A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations— (i) that—(I) comply with the standard of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding : (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary: or (III) if such a monograph does not exist and the substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d). Strive Pharmacy (NSC 101707) located at 1275 E. Baseline Road, Suite 104, Gilbert, AZ 85233 was not compliant. Specifically, Strive Pharmacy compounded with semaglutide sodium when making semaglutide/cyanocobalamin. Semaglutide sodium does not have a USP drug monograph, it is not a drug substance in an approved drug, and is not on the list

approved by the Secretary (21 CFR 216.23). This is a violation of 21 U.S.C. 353a(a)(b)(1)(A), compounded drugs, section 503A.

Compounding a copy or essentially a copy of a commercially available drug product: 21 U.S.C. 353a(a)(b)(1)(D) section 503A Pharmacy compounding states (a) In General. -- Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient. (b) compounded drugs (1) Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician (D) 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. As related to 21 U.S.C. 353a(b)(1)(D)(2) which states Definition.--For purposes of paragraph (1)(D), 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 product. Strive Pharmacy (NSC 101707) located at 1275 E. Baseline Road, Suite 104, Gilbert, AZ 85233 was not compliant. Specifically, on all 90 semaglutide/cyanocobalamin compounded prescriptions reviewed, none identified the need for a compounded product for the prescribed patients and none contained statement of significant difference from the commerically available drug product need for the prescribed patients. Futhermore, the semaglutide/cyanocobalamin were compounded regularly and in inordiante amounts while commercially available. The compounded semaglutide/cyanocobalamin was a copy or essentially a copy of a commercially available drug product. This is a violation of 21 U.S.C. 353a(a)(b)(1)(D).

Failure to perform compliant end product testing: California Code of Regulations 1751.7(e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile." Strive Pharmacy (NSC 101707) located at 1275 E. Baseline Road, Suite 104, Gilbert, AZ 85233 was not compliant. Specifically, on at least 39 lots of non-sterile to sterile semaglutide/cyanocobalamin were compounded, filled and dispensed did not have proper USP chapter 71 end product sterility testing. Instead sterility were performed with Scan RDI which is not a USP chapter 71 compliant method of sterility testing. Furthermore, after being educated and issued a correcton on 4/12/2023 for the requirement to comply with USP chapter 71 sterility testing requirments,Strive Pharmacy compounded and dispensed 9 additional non-compliant lots into California. This is a violation of California Code of Regulations (CCR) section 1751.7(e)(1).

Compounding a copy or essentially a copy of one or more commercially available drug product: California Code of Regulations (CCR) section 1735.2(d)(3) states no pharmacy or pharmacist shall compound a drug preparation that: (3) is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation. As related to CCR section1735.1(k) which states "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product. Strive Pharmacy (NSC 101707) located at 1275 E. Baseline Road, Suite 104, Gilbert, AZ 85233 was not compliant. Specifically, on 90 semaglutide/cyanocobalamin compounded prescriptions reviewed, none identified any drug shortages at the time of compounding or at the time of dispense. Additionally, there were no documentations made known to the pharmacist prior to compounding of medical need. The compounded semaglutide/cyanocobalamin was a copy or essentially a copy of a commercially available drug product. This is a violation of California Code of Regulations (CCR) section 1735.2(d)(3).

Prohibited acts: adulterated preparations: Business and professions code (B&PC) section 4169(a) states a person or entity shall not do any of the following: (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code. As related to H&SC section 111295 which states it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated. As related to H&SC section 111255 which states, any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. And H&SC 111250 which states any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance. As related to 21 U.S.C. 351(a)(2)(A)-(B) which states (A drug or device shall be deemed to be adulterated – (a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;. Strive Pharmacy (NSC 101707) located at 1275 E. Baseline Road, Suite 104, Gilbert, AZ 85233 was not compliant. Specifically, Strive Pharmacy utilized semaglutide sodium when compounding and dispensing non-sterile to sterile semaglutide/cyanobalamin. Semaglutide sodium is not a compliant bulk drug substance under section 503a therefore, adulterating the semaglutide/cyanocobalamin compounds. Additionally, the certificate of analysis (COA) demonstrated the semaglutide sodium utilized were ungraded, of unknown purity again adulterating the semaglutide/cyanocobalamin compounds. This is a violation of BPC 4169 (a)(2), H &SC section 111295 and 21 U.S.C. 351(a)(2)(A)-(B) as related to H&SC section 111255 and 111250.

Unprofessional conduct: Business and professions code (B&PC) 4301 states the board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following: (b) Incompetence. Strive Pharmacy (NSC 101707) located at 1275 E. Baseline Road, Suite 104, Gilbert, AZ 85233 was not compliant. Specifically, on 4/12/2023 when Strive Pharmacy was educated and issued a correction on 4/12/2023 on the requirement to comply with USP chapter 71 end product sterilty testing, Strive Pharmacy compounded and dispensed 9 additional non-compliant lots after being provided this education. This is unprofessional conduct and shows incompetence. This is a violation of B&PC 4301(b).

CITATION ISSUED ON: September 28, 2023

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

September 28, 2023

DATED MATERIAL ENCLOSED

STRIVE PHARMACY
ATTN: NATHAN LAWRENCE HILL, CEO
1275 E BASELINE RD STE 104
GILBERT, AZ 85233

RE: CI 2022 100114
STRIVE PHARMACY
NSC 101707

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- October 28, 2023: Unless the Citation is contested payment of fine(s) must be received by the Board.
- October 12, 2023: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- October 28, 2023: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

Anne Sodergren
EXECUTIVE OFFICER

By:

Joshua Monforte
Citation and Fine Analyst

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **October 28, 2023.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Cashier
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than October 12, 2023 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than October 28, 2023 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have any questions regarding any documents enclosed please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2022 100114	STRIVE PHARMACY, NSC 101707

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1735.2 subd. (d)(3)	Compounding commericially available products	$2,000.00
CCR, Title 16, § 1751.7 subd. (e)(1)	Sterile Compounding Quality Assurance and Process Validation; Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients shall be subject to...	$1,000.00
Bus. & Prof. Code § 4169 subd. (a)(2)/Health & Safety Code § 111295/Title 21 USC § 351(a)(1)(2)(A)(B)/Health & Safety Code § 111255/Health & Safety Code § 111250	Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to that the person knew or reasonably should have known were adulterated.../ It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated./ Adulterated drugs and devicesA drug or device shall be deemed to be adulterated—(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice .../ Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been rendered injurious to health/Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance	$2,000.00

Title 21 US Code § 353a subd. (a)(b)(1)(A)	(a) In general Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section ...(b) Compounded Drugs (1) A drug product may be compounded under subsection (a) if the licensed pharmacist... (A) compounds the drug product using bulk drug substances as defined in...	Citation without a fine
Title 21 US Code § 353a subd. (a)(b)(1)(D)	(a) In general Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section ...(b) Compounded Drugs (1) A drug product may be compounded under subsection (a) if the licensed pharmacist... (D) compounds the drug product using bulk drug substances as defined in...	Citation without a fine
Bus. & Prof. Code § 4301 subd. (b)	Unprofessional Conduct - Incompetence.	Citation without a fine

CONDUCT:

Compounding a copy or essentially a copy of one or more commercially available drug product: California Code of Regulations (CCR) section 1735.2(d)(3) states no pharmacy or pharmacist shall compound a drug preparation that: (3) is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation. As related to CCR section1735.1(k) which states "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product. Strive Pharmacy (NSC 101707) located at 1275 E. Baseline Road, Suite 104, Gilbert, AZ 85233 was not compliant. Specifically, on 90 semaglutide/cyanocobalamin compounded prescriptions reviewed, none identified any drug shortages at the time of

compounding or at the time of dispense. Additionally, there were no documentations made known to the pharmacist prior to compounding of medical need. The compounded semaglutide/cyanocobalamin was a copy or essentially a copy of a commercially available drug product. This is a violation of California Code of Regulations (CCR) section 1735.2(d)(3).

Failure to perform compliant end product testing: California Code of Regulations 1751.7(e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile." Strive Pharmacy (NSC 101707) located at 1275 E. Baseline Road, Suite 104, Gilbert, AZ 85233 was not compliant. Specifically, on at least 39 lots of non-sterile to sterile semaglutide/cyanocobalamin were compounded, filled and dispensed did not have proper USP chapter 71 end product sterility testing. Instead sterility were performed with Scan RDI which is not a USP chapter 71 compliant method of sterility testing. Furthermore, after being educated and issued a correcton on 4/12/2023 for the requirement to comply with USP chapter 71 sterility testing requirments,Strive Pharmacy compounded and dispensed 9 additional non-compliant lots into California. This is a violation of California Code of Regulations (CCR) section 1751.7(e)(1).

Prohibited acts: adulterated preparations: Business and professions code (B&PC) section 4169(a) states a person or entity shall not do any of the following: (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code. As related to H&SC section 111295 which states it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated. As related to H&SC section 111255 which states, any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. And H&SC 111250 which states any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance. As related to 21 U.S.C. 351(a) (2)(A)-(B) which states (A drug or device shall be deemed to be adulterated – (a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;. Strive Pharmacy (NSC 101707) located at 1275 E. Baseline Road, Suite 104, Gilbert, AZ 85233 was not compliant. Specifically, Strive Pharmacy utilized semaglutide sodium when compounding and dispensing non-sterile to sterile semaglutide/cyanobalamin. Semaglutide sodium is not a compliant bulk drug substance under section 503a therefore, adulterating the semaglutide/cyanocobalamin compounds. Additionally, the certificate of analysis (COA) demonstrated the semaglutide sodium utilized were ungraded, of unknown purity again adulterating the semaglutide/cyanocobalamin compounds. This is a violation of BPC 4169 (a)(2), H &SC section 111295 and 21 U.S.C. 351(a)(1)(2)(A)-(B) as related to H&SC section 111255 and 111250.

Use of a non-compliant bulk drug substance: 21 U.S.C. 353a(a)(b)(1)(A), compounded drugs, section 503A states (a) In General. --Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient. (b) compounded drugs (1) A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician— (A)compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations— (i) that—(I) comply with the standard of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding : (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary: or (III) if such a monograph does not exist and the substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d). Strive Pharmacy (NSC 101707) located at 1275 E. Baseline Road, Suite 104, Gilbert, AZ 85233 was not compliant. Specifically, Strive Pharmacy compounded with semaglutide sodium when making semaglutide/cyanocobalamin. Semaglutide sodium does not have a USP drug monograph, it is not a drug substance in an approved drug, and is not on the list approved by the Secretary (21 CFR 216.23). This is a violation of 21 U.S.C. 353a(a)(b)(1)(A), compounded drugs, section 503A.

Compounding a copy or essentially a copy of a commercially available drug product: 21 U.S.C. 353a(a)(b)(1)(D) section 503A Pharmacy compounding states (a) In General. -- Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient. (b) compounded drugs (1) Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician (D) 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. Strive Pharmacy (NSC 101707) located at 1275 E. Baseline Road, Suite 104, Gilbert, AZ 85233 was not compliant. Specifically, on all 90 semaglutide/cyanocobalamin compounded prescriptions reviewed, none identified the need for a compounded product for the prescribed patients and none contained statement of significant difference from the commerically available drug product need for the prescribed patients. Futhermore, the semaglutide/cyanocobalamin were compounded regularly and in inordiante amounts while commercially available. The compounded semaglutide/cyanocobalamin was a copy or essentially a copy of a commercially available drug product. This is a violation of 21 U.S.C. 353a(a)(b)(1)(D).

Unprofessional conduct: Business and professions code (B&PC) 4301 states the board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following: (b) Incompetence. Strive Pharmacy (NSC 101707) located at 1275 E. Baseline Road, Suite 104, Gilbert, AZ 85233 was not compliant. Specifically, on 4/12/2023 when Strive Pharmacy was educated and issued a correction on 4/12/2023 on the requirement to comply with USP chapter 71 end product sterilty testing, Strive Pharmacy compounded and dispensed 9 additional non-compliant lots after being provided this education. This is unprofessional conduct and shows incompetence. This is a violation of B&PC 4301(b).

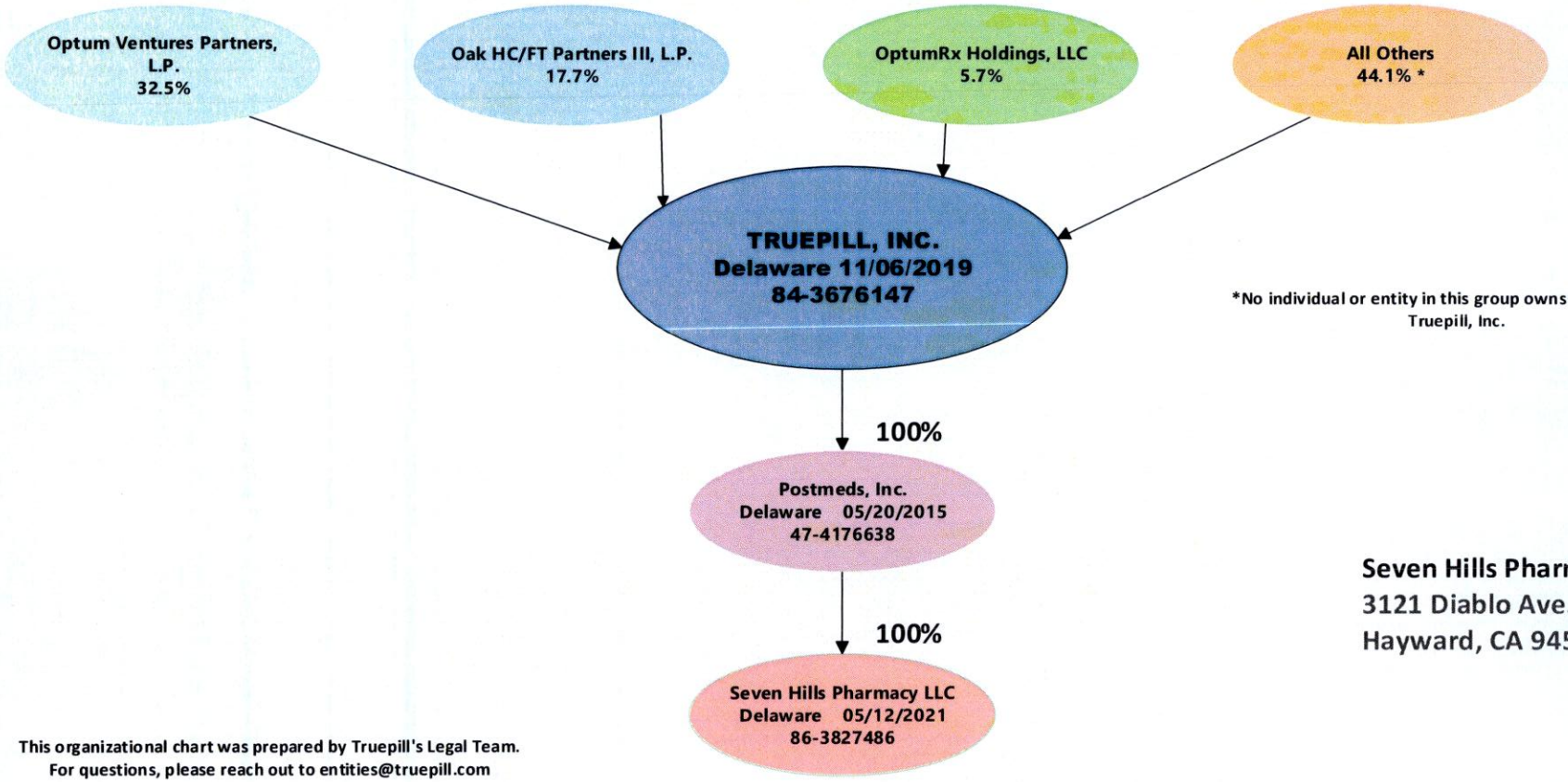
CITATION ISSUED ON: September 28, 2023	**TOTAL AMOUNT OF FINE(S): $5,000.00**
PAYMENT OF FINE(S) DUE BY: October 28, 2023	

As of 08/18/2023

SEVEN HILLS PHARMACY LLC
Ownership

CONFIDENTIAL!

Do not distribute to third parties



*No individual or entity in this group owns 5% or more of Truepill, Inc.

This organizational chart was prepared by Truepill's Legal Team.
For questions, please reach out to entities@truepill.com

Seven Hills Pharmacy LLC
3121 Diablo Ave.
Hayward, CA 94545

StrivePharmacy181

STRIVE
compounding pharmacy

Exhibit 14

State of Idaho
Division Of Occupational and Professional Licenses
Board of Pharmacy

BRAD LITTLE
Governor
RUSSELL BARRON
Administrator

11341 W Chinden Blvd.
P.O. Box 83720
Boise, ID 83720-0063
(208) 334-3233
dopl.idaho.gov

September 29, 2023

Delivered via Certified Mail

Strive Pharmacy
1275 E Baseline Rd. Ste 104
Gilbert AZ 85233

Re: Case #BOP-23-234

Dear Strive Pharmacy Representative,

The staff of the Idaho State Board of Pharmacy (Board) received a complaint that suggest your facility may have violated one or more of the rules or laws the Board is responsible for enforcing. Specifically, the Board staff reviewed records that indicate compounding of semaglutide and tirzepatide when commercially available products although short supply is available. These activities appear to violate Idaho Rules, IDAPA 24.36.01.700.04.

The Board is initiating an investigation to determine whether to take disciplinary action. Please supply the following records and responses to the following questions.

- A copy of all prescription hard copies for prescriptions that were compounded for semaglutide and tirzepatide from April 1, 2023 to the date of this letter.

- IDAPA 24.36.01.700.02.a -Proof that semaglutide and tirzepatide ingredients are being obtained from an FDA registered manufacturer.
    - *FDA has given guidance on the use of salt forms of semaglutide for compounding, are you currently using or have used the salt form of semaglutide for compounding?*

- IDAPA 24.36.01.700.04.b.i-It is medically warranted to provide an alternate ingredient, dosage form, or strength of significance- *Please respond to the requirement that compounded product must have an alternative ingredient or the difference in strength which is significant and that those doses cannot be obtained from the commercially available product.*

- IDAPA 24.36.01.700.04.b.ii -The commercial product is not reasonably available in the market in time to meet the patient's needs. *Even though semaglutide and tirzepatide is on the FDA shortage list please provide proof that product was ordered but not received.*

We ask that you provide your written response to this letter no later than **October 15, 2023**. You should include any documentation that supports your response.

While disciplinary proceedings have not begun, Board rules require your cooperation with Board staff investigations. See IDAPA 24.36.01.103.05. We encourage you to provide the requested information to assist Board staff in its review of this matter.

Sincerely,

Berkeley Fraser RPh
Chief Investigator, Health Professions
Idaho Division of Occupational and Professional Licenses
Fax 208-334-2363
berk.fraser@dopl.idaho.gov

STATE OF IDAHO DOPL
HEALTH PROFESSIONS
P.O. BOX 83720
BOISE, ID 83720-0063

USPS CERTIFIED MAIL

9214 8901 9403 8332 0506 76

STRIVE PHARMACY
STE 104
1275 E BASELINE RD
GILBERT AZ 85233-1224

9/29/23 BF
Username: M'lissa McCloud
Letter ID:
Account#:
Case ID:BOP-23-234
First Name:
Last Name:

Postage: $7.1800

StrivePharmacy185

STRIVE
compounding pharmacy

Exhibit 15

Berkeley Fraser, RPh
Chief Investigator, Health Professions
Idaho Division of Occupational and Professional Licenses
Fax: 208-334-2363
berk.fraser@dopl.idaho.gov

RE: Strive Pharmacy – Case #BOP-23-234 Response

Dear Deputy Director & Chief Investigator Fraser:

First, we would like to express our appreciation for allowing us additional time to respond. As we understand the issue at hand, the Idaho State Board of Pharmacy (the "Board") received a complaint related to our pharmacy's compounding of semaglutide and tirzepatide. Accordingly, Board staff issued this inquiry to ensure our compounding practices adhere to the relevant Idaho rules.[1] As you would expect, we too want to be fully compliant with our home state's rules and Idaho rules and we believe we are. With respect to the concerns raised by the Board, we address each below.

I. *Copy of Prescription Hard Copies*

First, we are in the process of pulling and processing all hard copy prescription orders for compounded semaglutide and trizepatide drug products, as requested. Unfortunately, this process has proven to require a considerable amount of time. Therefore, please find our spreadsheet evidencing the number of prescriptions processed, filled, and dispensed during the requested time period. *See* **Exhibit 1**. We continue to work on this request and will supplement our response with additional hard copies as they are compiled.

II. *Semaglutide & Tirzepatide Bulk Substance Ingredients*

Furthermore, the Board requires proof that the bulk semaglutide and tirzepatide ingredients used for compounding are obtained from an FDA registered manufacturer.[2] We appreciate the Board's concern and would like to emphasize that all of our suppliers of bulk drug substances are FDA registered and inspected. Thus, to address this preliminary concern, please see **Exhibit 2** as evidence of FDA registration of our suppliers for both drug components.

[1] *See generally* Idaho Admin. Code r. 24.36.01.700.04.
[2] Idaho Admin. Code r. 24.36.01.700.02.a.

More specifically, the Board raised concerns as to whether we are compliant with current FDA guidance concerning the use of salt or base form of semaglutide for compounding. As the Board is aware, Novo Nordisk did not anticipate the patient demand for both Ozempic and Wegovy. As a result, the FDA placed both commercial drug products on the FDA Drug Shortage List,[3] allowing for compounding pharmacies to produce semaglutide drug products to meet patient demand and medical need. That said, at the onset of the shortage, compounding pharmacies had limited guidance, from both the FDA and State Boards of Pharmacy alike, addressing the proper procedural process for compounding these products. Fortunately, the FDA issued some manner of guidance in a letter to the National Board of Pharmacy Boards ("NABP") on April 27, 2023.[4]

By way of background, the FDA has found that pharmacies operating under Section 503A may only compound using bulk drug substances that: (1) comply with the standards of an applicable United States Pharmacopoeia ("USP") or National Formulary monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, are drug substances that are *components* of FDA-approved drug products; or (3) if such a monograph does not exist and the drug substance is not a component of an approved drug, that it appears on the FDA's list of bulk-substances that can be used in 503A compounding.[5] Prior to the FDA's letter to the NABP, there was some confusion within the industry and State Boards of Pharmacy as to whether the salt form of semaglutide could properly be deemed a *component* of FDA-approved semgalutide drug products in compliance with FDA law.[6] Furthermore, we were scheduled to appear before the Arizona Board of Pharmacy ("Arizona Board") in April 2023 but it was tabled due to the lack of guidance from the FDA that they could reasonably rely upon. Of note, the Arizona Board subsequently approved of and found no issues with our semaglutide compounding practices during their August 17, 2023 meeting.

Nevertheless, we continued to monitor the industry and accurately predicted that compounding with the salt form would soon not be deemed permissible practice. Therefore, we

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[3] *See* FDA Drug Shortages, U.S. Food & Drug Administration, https://www.accessdata.fda.gov/scripts/drugshortages/dsp_SearchResults.cfm (last visited October 24, 2023)(showing results of search for "Semaglutide Injection" showing the product is currently in shortage).

[4] *See* FDA to NABP Semaglutide Letter, U.S. Food & Drug Administration, April 27, 2023, https://a4pc.org/files/FDA-to-NABP-Semaglutide-letter_April-27-2023.pdf; *see also* Memorandum, Lemrey "Al" Carter, FDA Provides Updated Drug Shortage and Compounding Information for Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss, https://dopl.idaho.gov/wp-content/uploads/2023/06/MEMO-EO-FDA-Provides-Updates-on-FDA-Approved-Semaglutide-Products-Ozempic-and-Rybelsus-and-Wegovy.pdf.

[5] *See* 21 U.S.C § 353a(b)(1)(A)(i)(I-III); *see also* Bulk Drug Substances Used in Compounding Under Section 503A of the FD&C Act, U.S. Food & Drug Administration, https://www.fda.gov/drugs/human-drug-compounding/bulk-drug-substances-used-compounding-under-section-503a-fdc-act (last updated Feb. 20, 2020).

[6] *See* Utah State Board of Pharmacy, Minutes, March 28, 2023, p. 3, https://www.utah.gov/pmn/files/970387.pdf (finding that members of the Board believed the salt form does not matter, it is the semaglutide molecule that is being used, the semaglutide component is the active pharmaceutical ingredient); see also Utah State Board of Pharmacy, Minutes, March 28, 2023, https://www.utah.gov/pmn/files/959981.mp3 (conversation begins at 00:41:00).

began the process of procuring the *base* form of semaglutide from our manufacturer even before the FDA released their guidance on April 27, 2023. Accordingly, we have been compounding with base form of semaglutide since April 18, 2023. To the extent it is helpful, please see the following bulk drug orders from the manufacturer for the base form of semaglutide with appropriate certificate of analysis documentation. *See* **Exhibit 3**.

III. *Permissibility of Compounding Commercially Available Products*

Lastly, the Board raises concerns as to whether we are compliant with Idaho rules concerning the compounding of commercially available drug products.[7] As we understand the relevant Idaho rule, a commercially available drug product may only be compounded under any of the following circumstances: (1) the drug product is not compounded regularly or in inordinate amounts; (2) it is medically warranted to provide an alternate ingredient, dosage form, or strength of significance; or (3) the commercial product is not reasonably available in the market in time to meet the patient's needs.[8] We appreciate the Board raising these concerns as it allowed for us to reassess our compounding pharmacy practice. However, we believe that our compounded drug products comply with Idaho rules for the following reasons: (1) our compounded drug products are medically warranted due to the flexible dosing regimen and alternative ingredient incorporated within our compounded drug product and (2) the commercial drug product not being reasonably available within the market to accommodate patient's needs.

Analogous to Idaho Admin. Code r. 24.36.01.700.04.b.i requiring compounded drug products be medically warranted, FDA guidance notes that compounded drug products are no longer considered essentially a copy of what is commercially available if it is being compounded for the specific medical need of an individual patient.[9] In compliance with both Idaho rule and FDA guidance, our compounded drug product allows for flexible dosing schedules not available with the commercially available pens. Namely, our compounded product is dispensed to patients in a vial, allowing for lower doses and customized titration schedules to better control the gastrointestinal issues commonly associated with semaglutide use. In short, this flexible dosing allows practitioners to address these gastrointestinal adverse effects associated with high dose semaglutide on a patient-specific basis without adhering to the strict dosing regimen of the commercially available pens. This enables healthcare providers to better manage the common adverse effects associated with semaglutide. It is also important to note that we have the ability to compound our drug product as a combination drug product containing semaglutide and cyanocobalamin (Vitamin B12). As such, practitioners have started to prescribe their patients our combination drug product due to the reported anti-nausea effects provided by cyanocobalamin

[7] Idaho Admin. Code r. 24.36.01.700.04
[8] *Id.*
[9] Food and Drug Administration, Center for Drug Evaluation and Research, Compounding 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 (Jan. 2018), https://www.fda.gov/media/98973/download.

(Vitamin B12). To the extent that it is helpful, please review prescription records evidencing our compounded drug products being prescribed and dispensed in compliance with this rule. *See* **Exhibit 4**.

Furthermore, Idaho rules require an examination of whether the commercial product is *reasonably available in the market* in time to meet the patient's needs.[10] Based on the relevant FDA guidance, if the drug is placed on the FDA shortage list, then it is not considered to be commercially available allowing pharmacies to compound accordingly to address patient need.[11] However, the Board's letter seems to suggest that pharmacies are not permitted to solely rely upon the FDA shortage list to comply with this rule, but must seek additional information to address or confirm whether the drug product is "…not reasonably available in the market…."[12] Specifically, the Idaho Board requires that the pharmacies prove that a supply of the commercially available semaglutide or tirzepatide drug products are not available by providing proof the commercial product was ordered but not received.

We understand that Idaho may enforce stricter standards than the FDA concerning the practice of pharmacy. However, we believe the Board's request for proof the commercial product was ordered and not received goes beyond a reasonable interpretation of the Idaho rule. First, the Rule does not include any expressed requirement for the compounding pharmacy to order commercial drug products to assess their availability. Nor are we aware of any practice within the compounding pharmacy industry where a pharmacy would be expected or required to issue a faux drug order of the commercial drugs to assess availability. This is particularly nonsensical in the context of compounded medication. The prescriber wrote a prescription for a patient specific compounded product that the patient chose to send to our pharmacy for fulfillment. To confirm drug availability beyond the FDA drug shortage list would require us to ask the prescriber for a second prescription for the name brand product. We are not aware of any other state that requires such an action to assess the "…reasonable availability…" of the commercially available drug products.

Furthermore, the Rule does not define or elaborate further upon what is deemed "…reasonable available in the *market*…", nor does it detail *which* market the pharmacy would be expected to assess. Our pharmacy acts as a properly licensed non-resident pharmacy located within Arizona shipping our compounded drug products into Idaho. Taking the Board staff's request to its fullest application, our pharmacy would be expected to complete faux drug orders for our own local Arizona market in addition to each market area our Idaho patients are domiciled. Unfortunately, this request goes above and beyond our capabilities to reasonably accommodate.

[10] Idaho Admin. Code r. 24.36.01.700.04.b.ii.
[11] *See* Food and Drug Administration, *supra* note 8.
[12] *Supra* note 9.

As we understand, Idaho applies a "…reasonable and prudent…" standard when evaluating a licensee or registrant's practice of pharmacy.[13] Interestingly, the Board staff's request for additional information fails to adhere to this standard of review enforced by the Idaho law. Despite the Board's best intentions, this request for additional information is an ineffective and impractical means of assessing whether a commercially available drug product is reasonably available.

For instance, even if we were to successfully order the commercial drug product, it does not necessarily mean the patient has access to the correct dosage strength of the commercial product. To best manage the shortage, Novo Nordisk decided to prioritize the maintenance dosage strengths so that patients already receiving either Ozempic or Wegovy do not have to suddenly discontinue treatment.[14] As a result, the lower doses used for titration purposes have lesser availability. In those instances, the compounded drug product helps fill the market gap and address patient need pursuant to these patient-specific prescriptions. Requiring that a pharmacy order the commercial product does not even guarantee the market availability can be reasonably assessed. Therefore, it is not only reasonable, but prudent, to rely upon the FDA Drug Shortage list to determine whether the commercial drug product is available so to ensure that the health and treatment of Idaho patients is not jeopardized.

IV. *Conclusion*

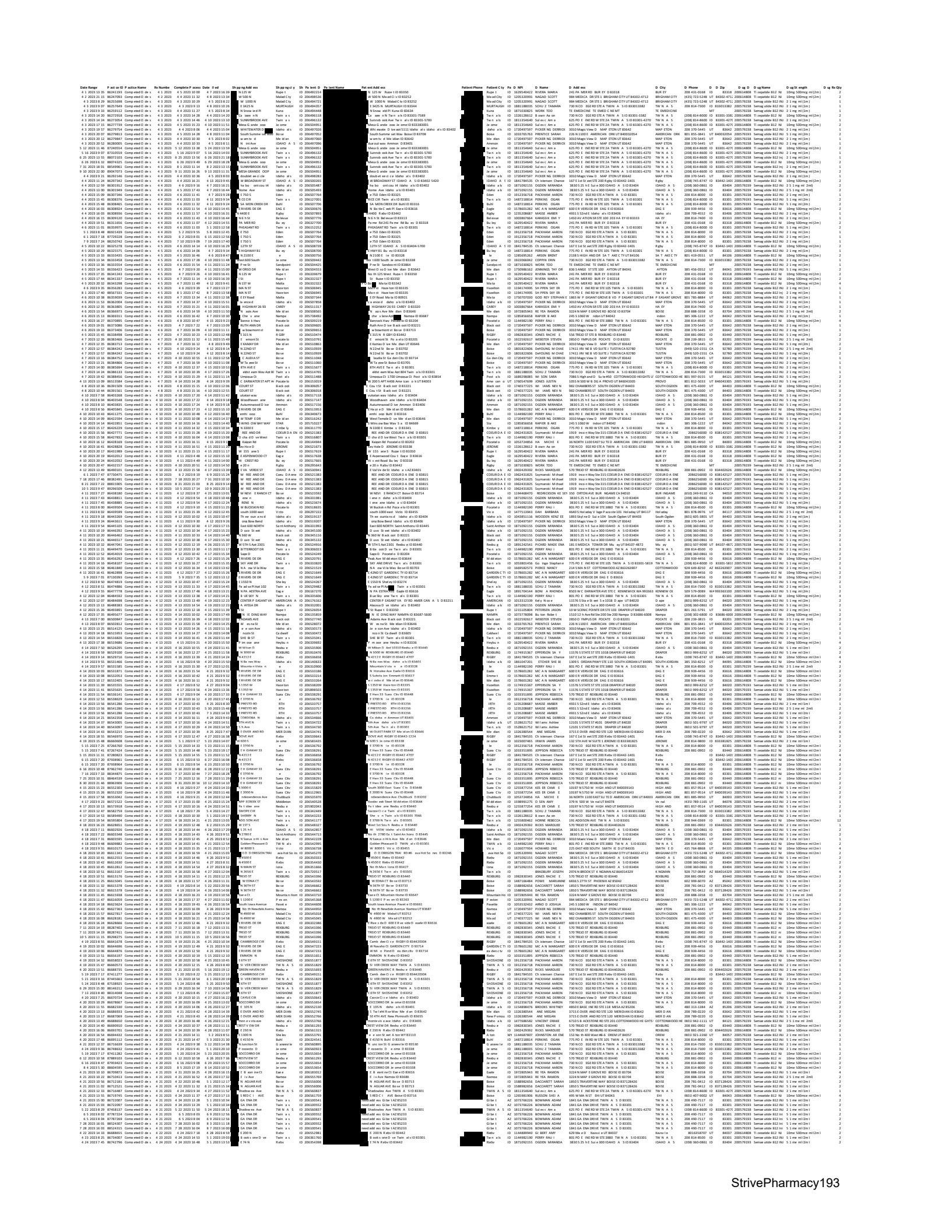
We understand the Board's duty to assess our compounding pharmacy practice and ensure compliance with Idaho rules. However, we believe that our current practice remains in compliance with Idaho rules as it relates to compounding drug products deemed commercially available. Nevertheless, should the Board staff have any further questions or concerns, we are happy to accommodate. We thank you for your time and understanding.

Respectfully,

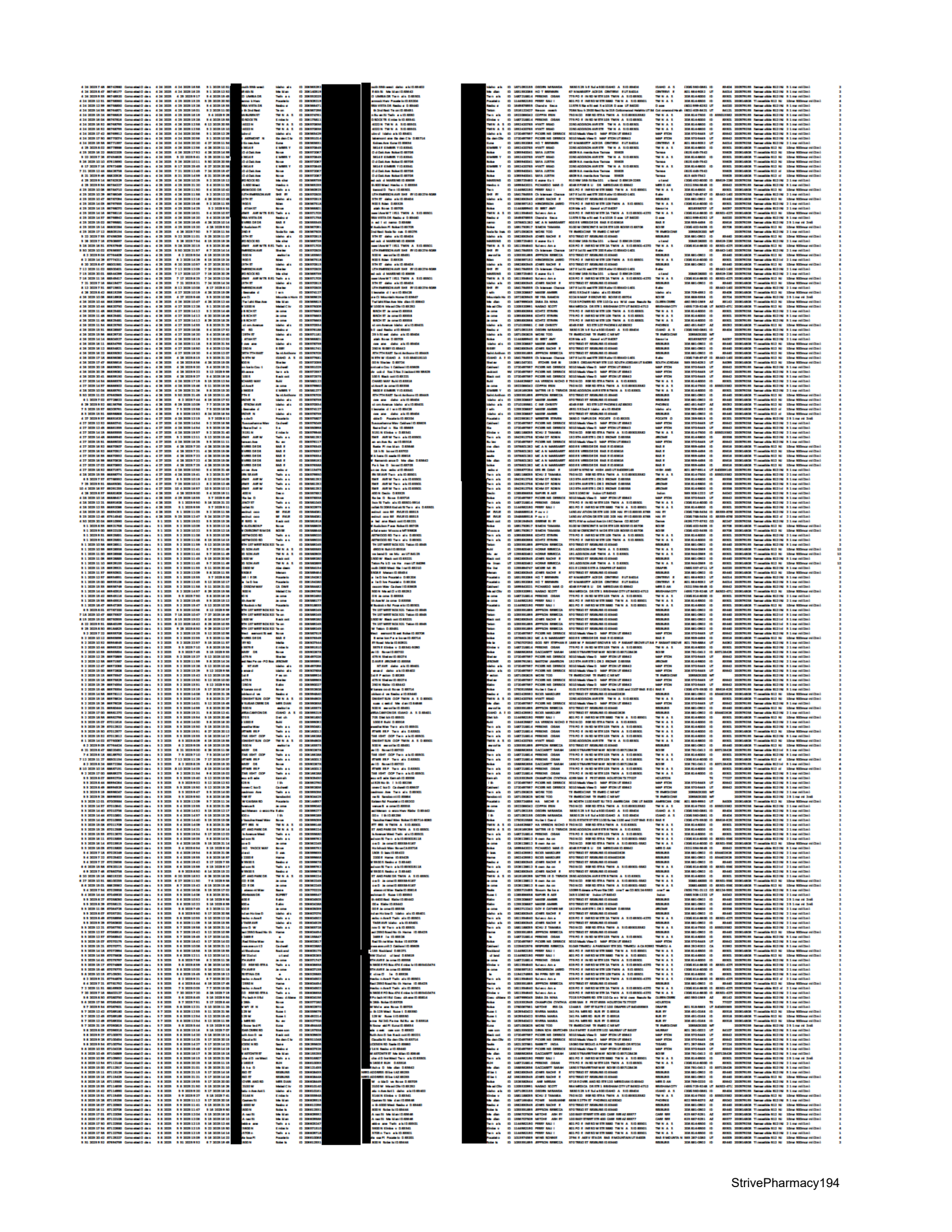
Michael Walker
Pharmacist-in-Charge/Owner
Strive Pharmacy

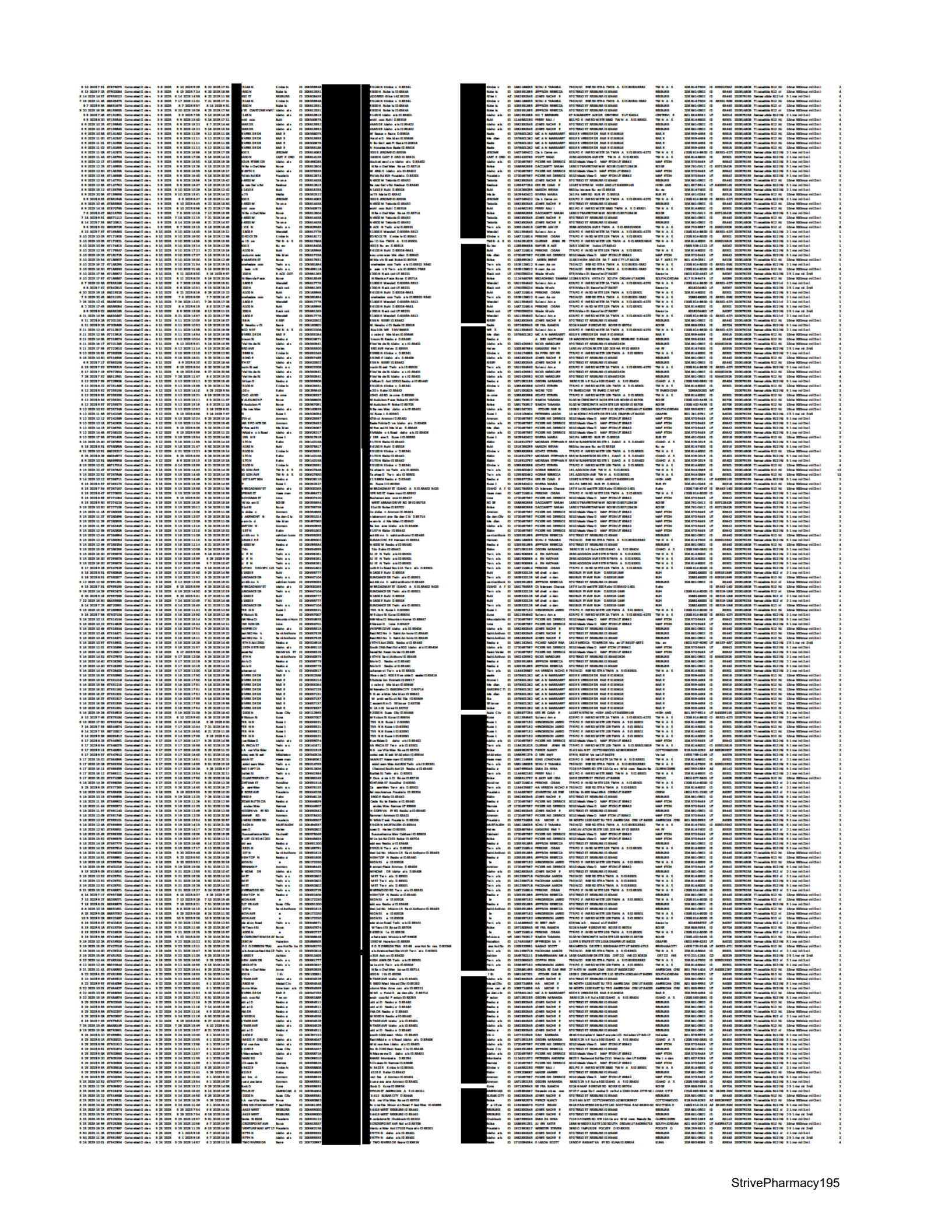
[13] Idaho Admin. Code r. 24.36.01.100.03.
[14] *See* Nikolaj Skydsgaard, Novo Nordisk extends U.S. supply curbs on weight-loss drug Wegovy, Reuters, Aug. 10, 2023, 3:39 AM, https://www.reuters.com/business/healthcare-pharmaceuticals/novo-nordisk-hikes-fy-outlook-demand-weight-loss-drug-wegovy-soars-2023-08-10/.

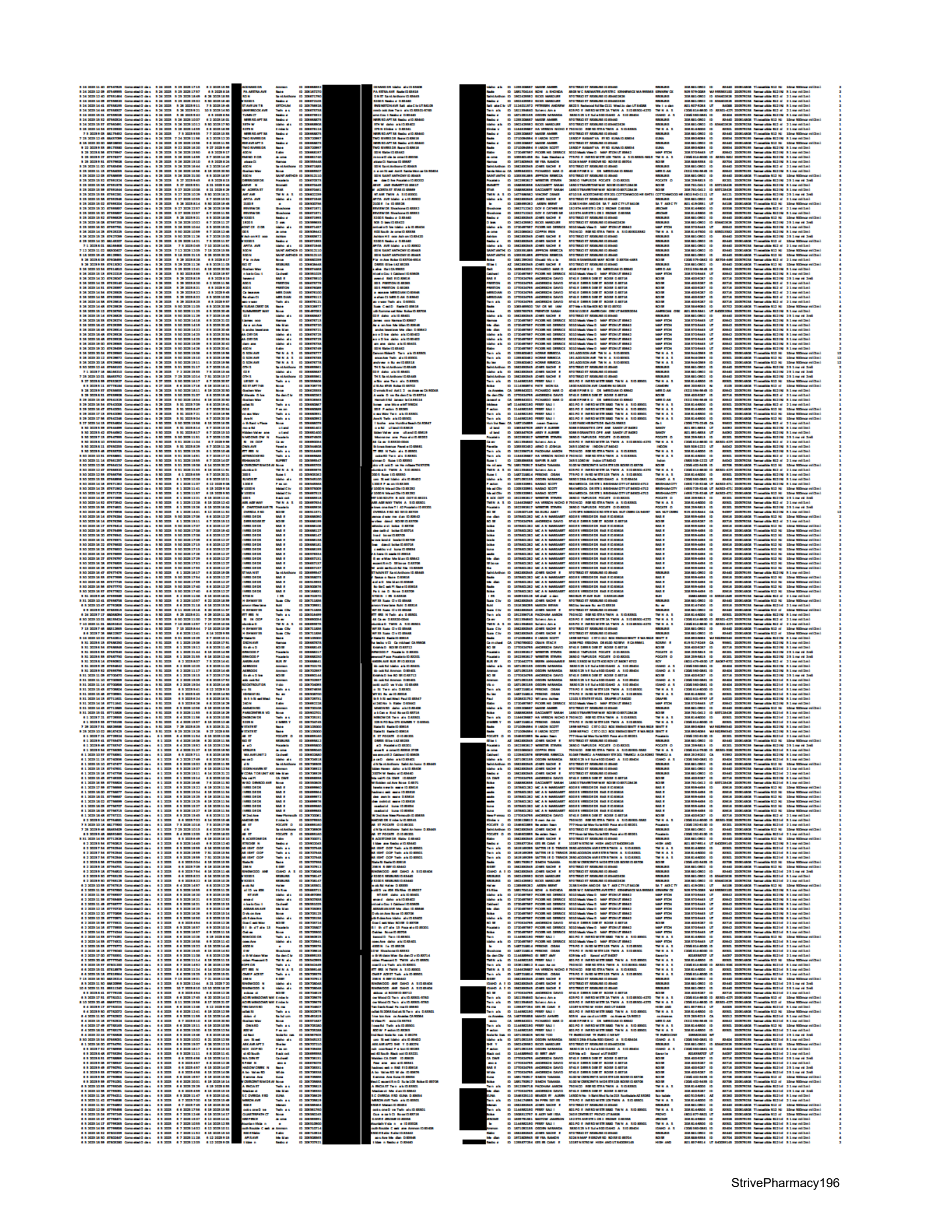
Exhibit 1

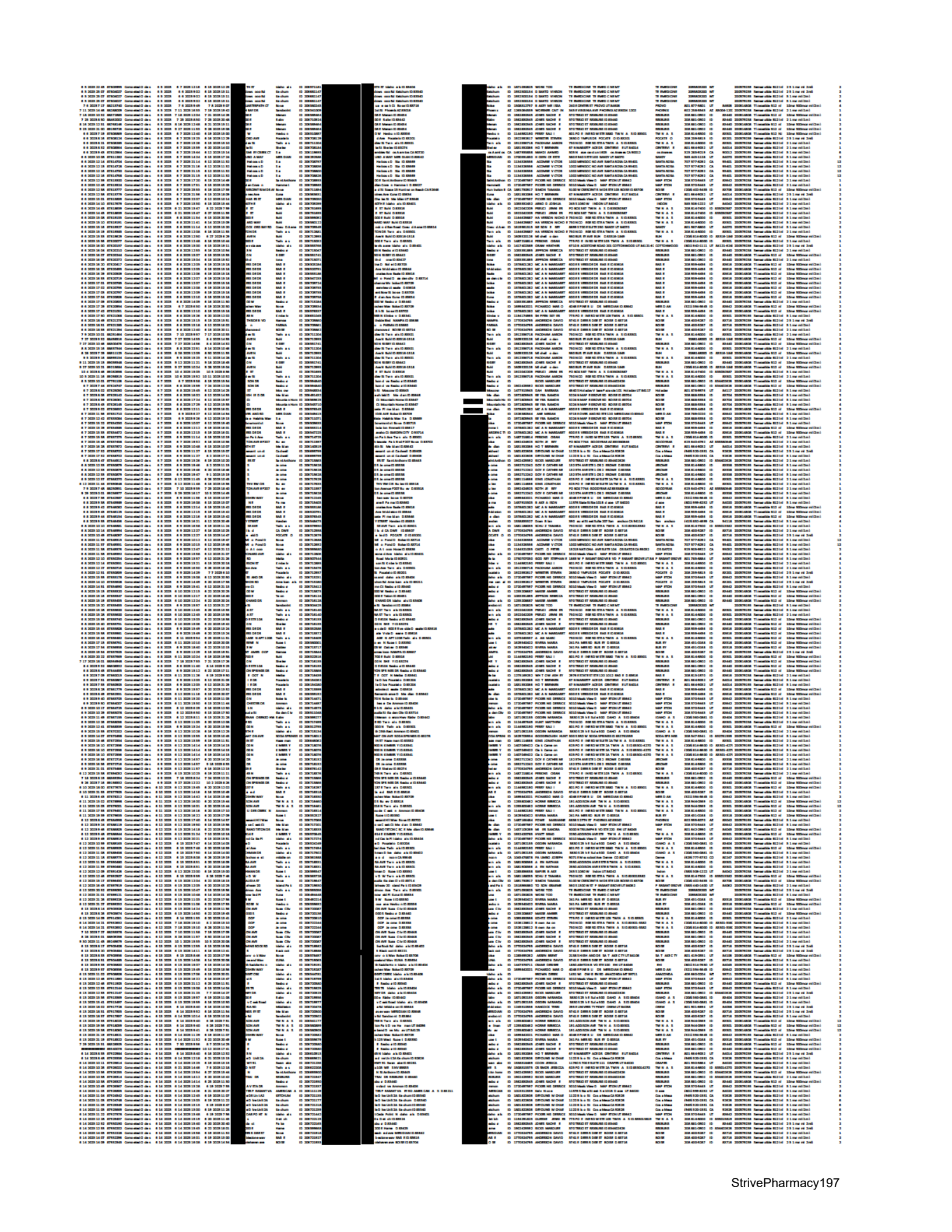


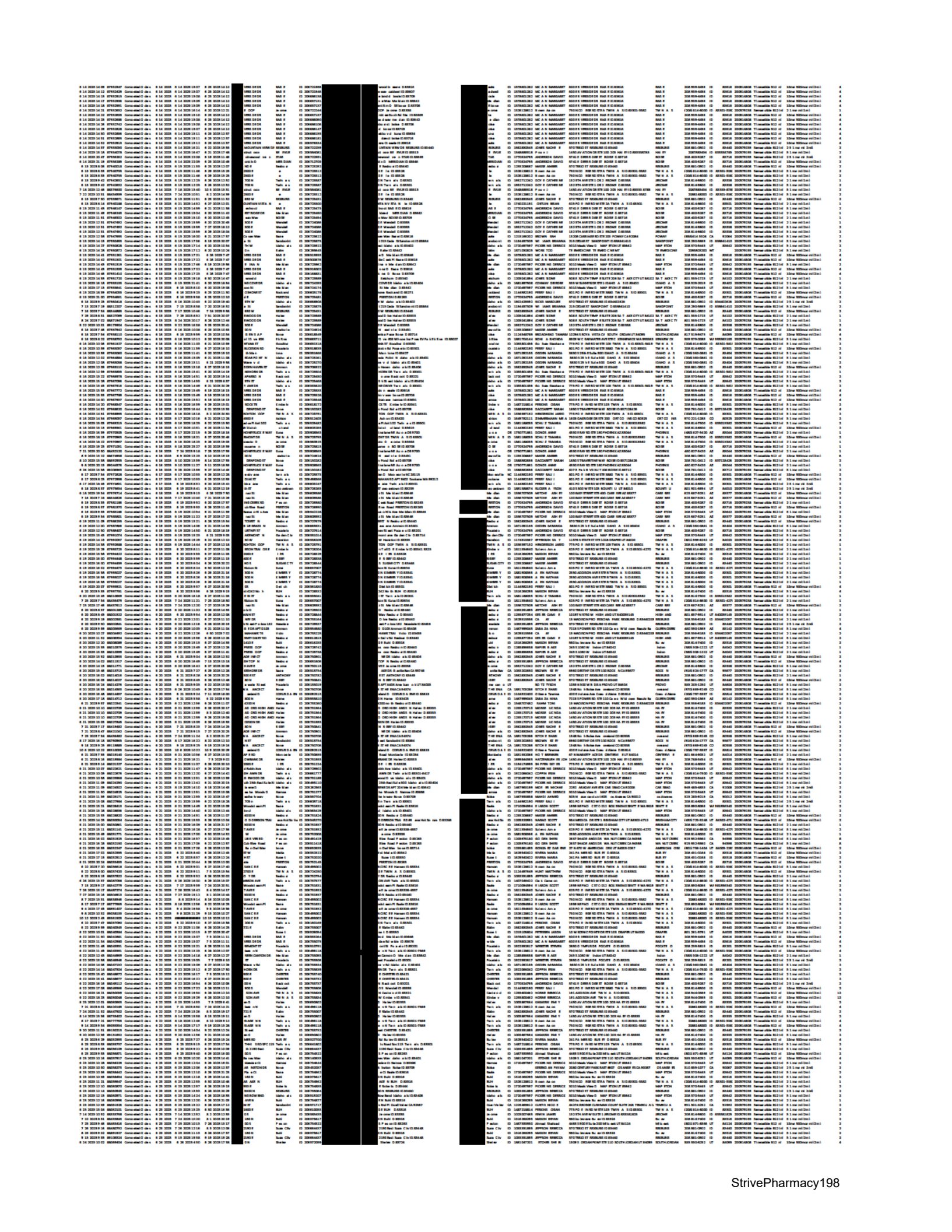
StrivePharmacy193

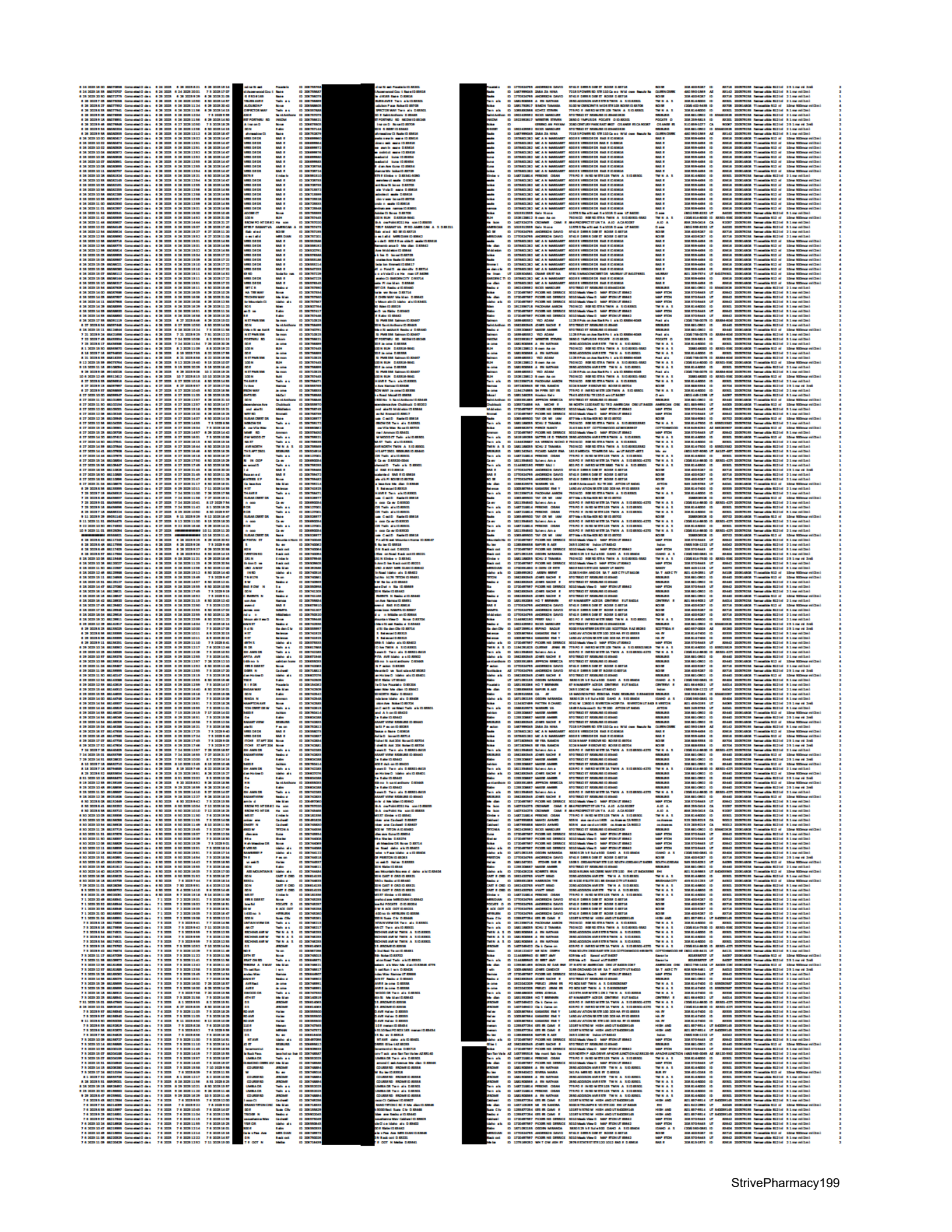


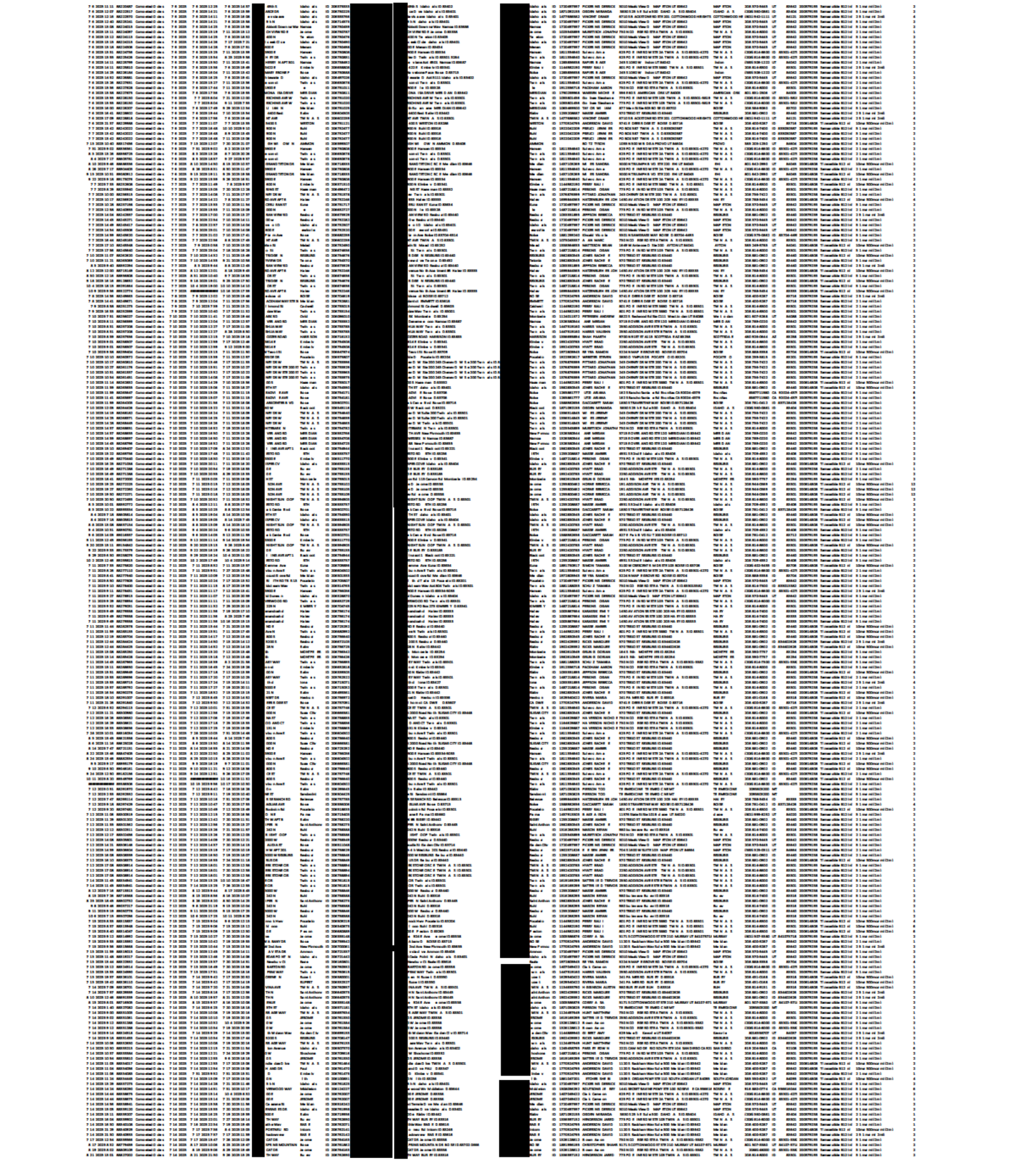


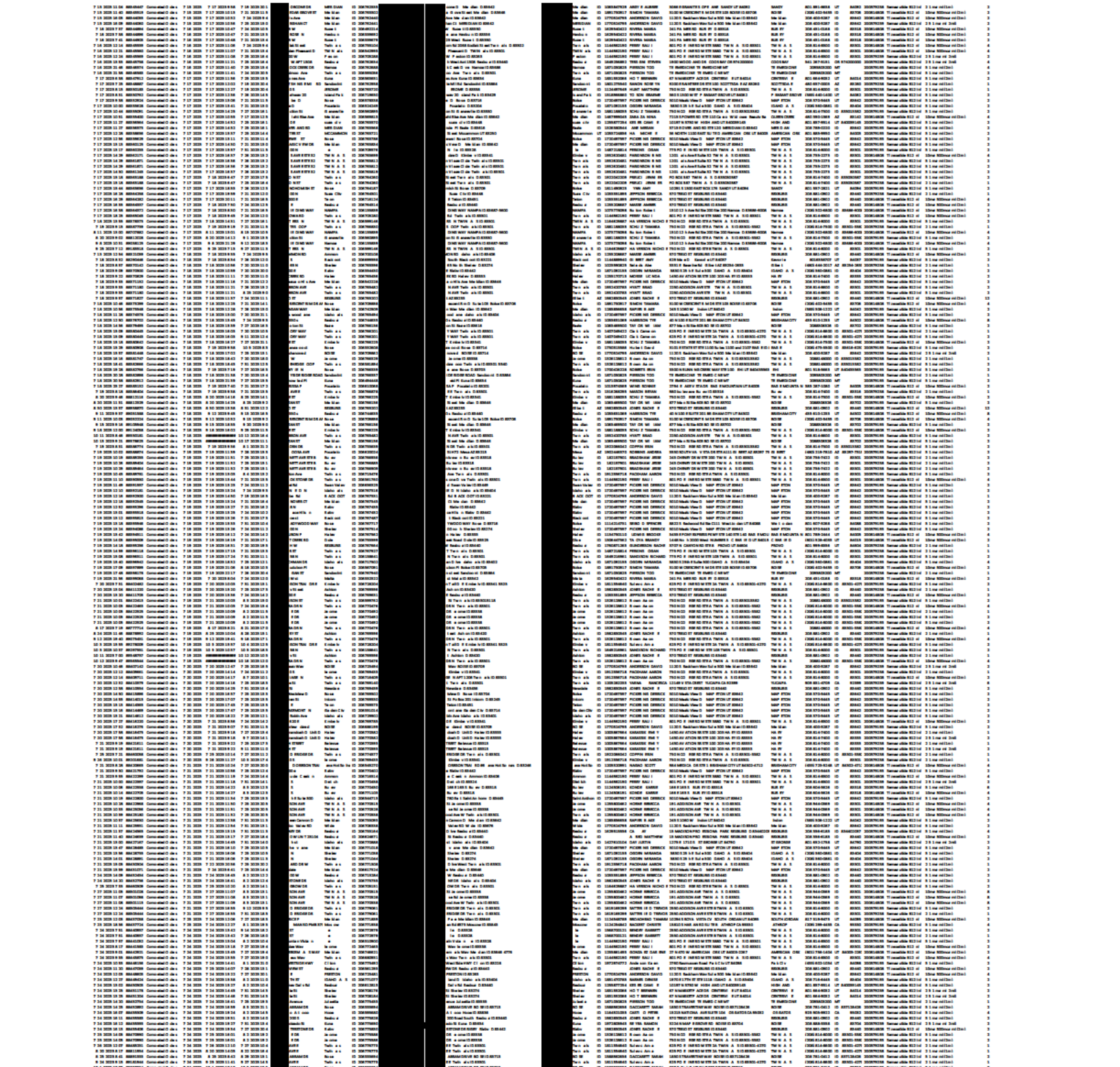


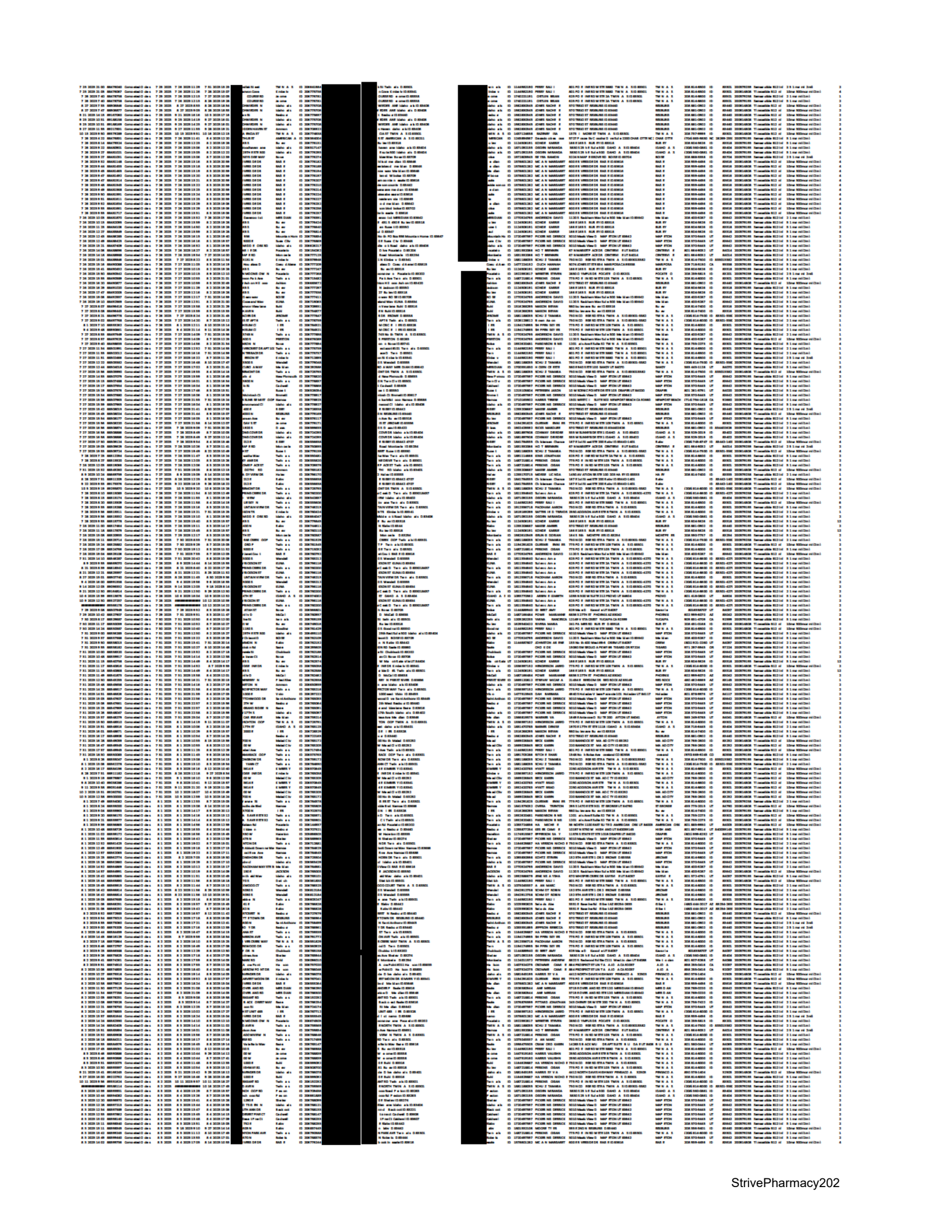


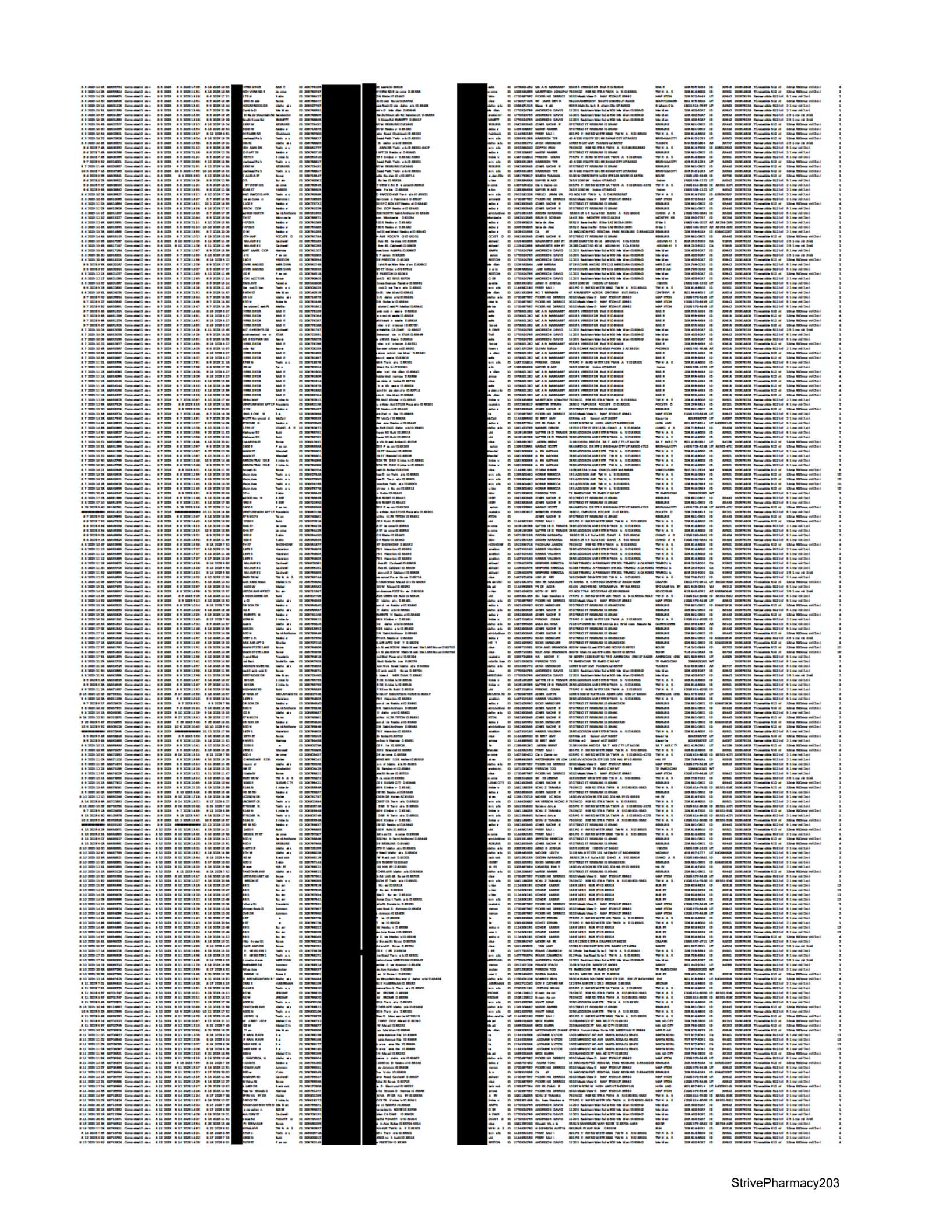


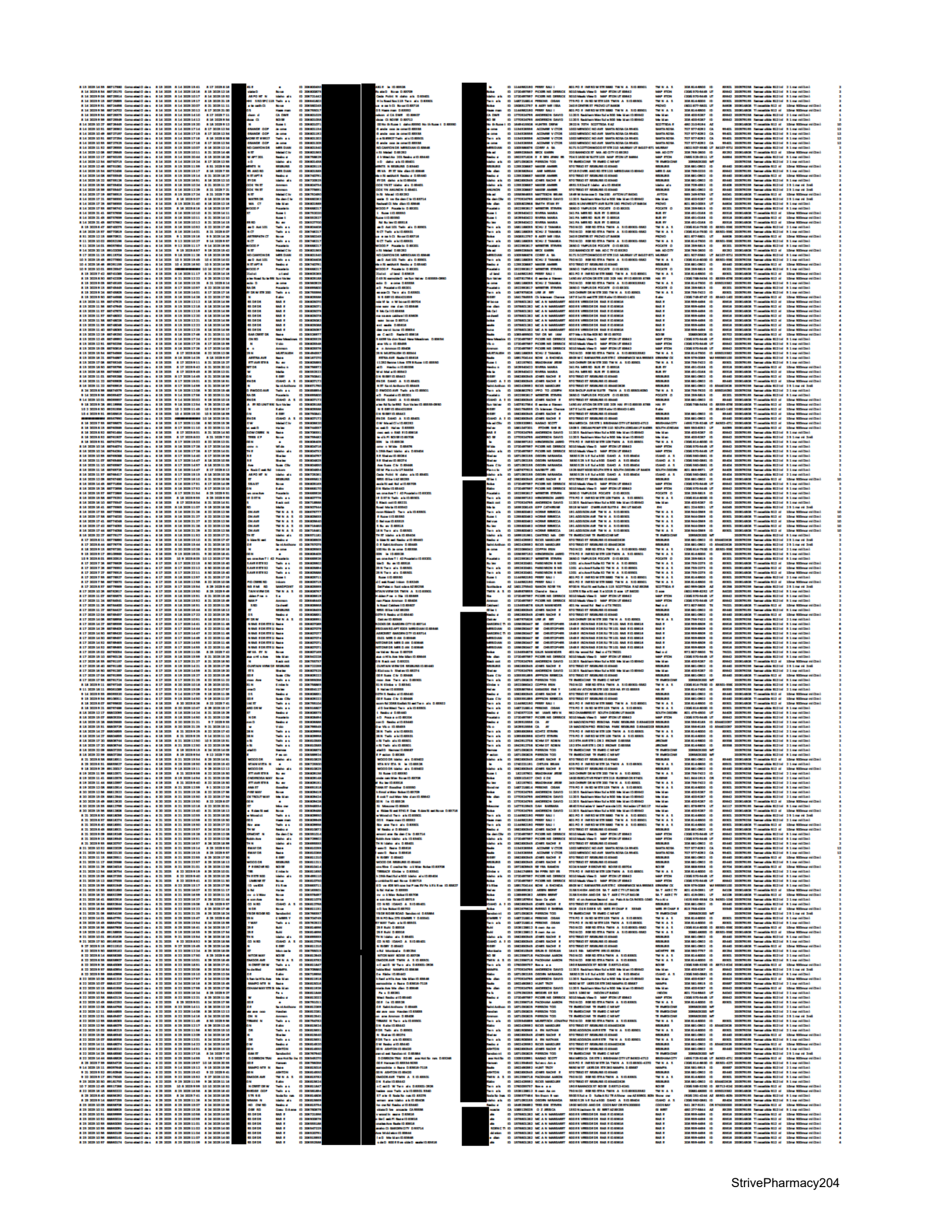


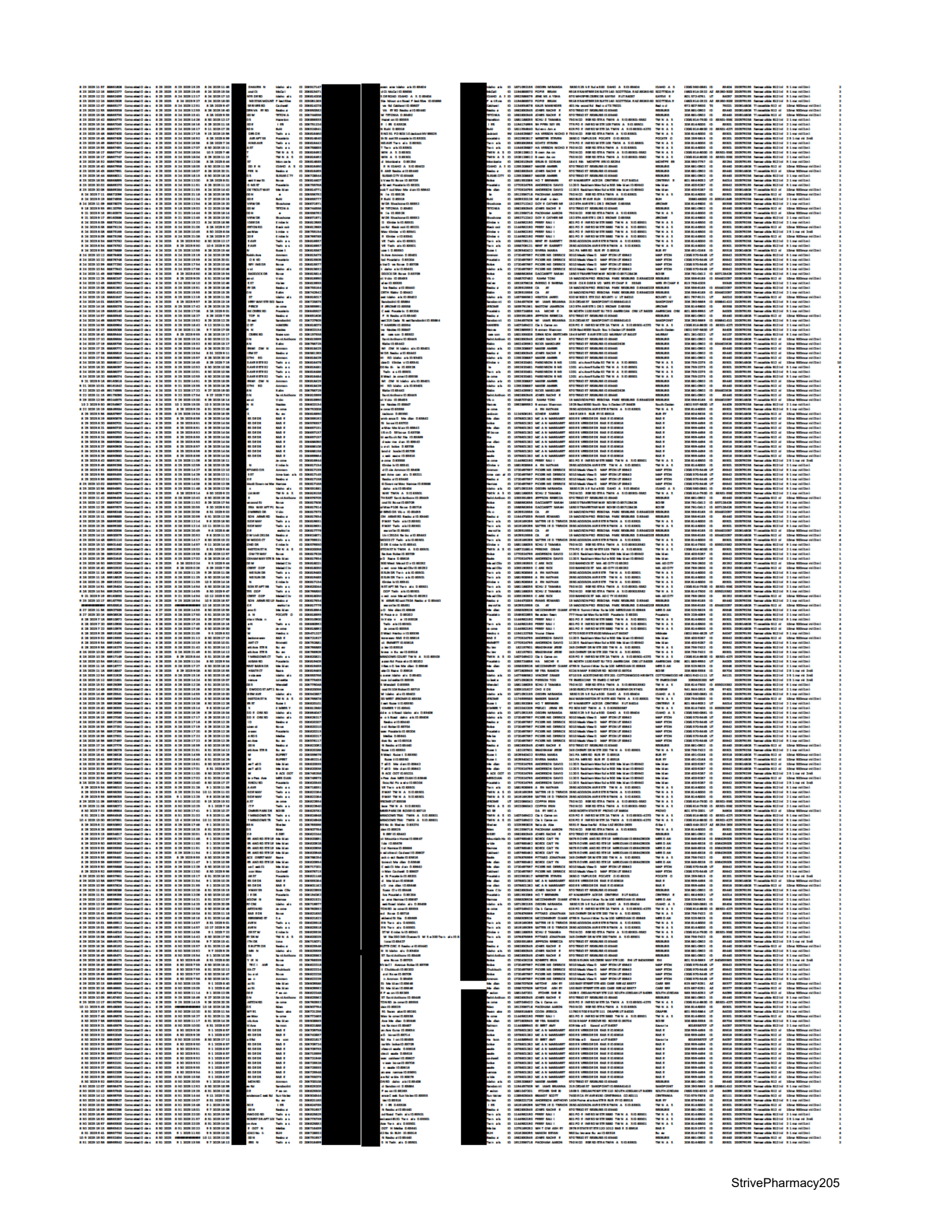


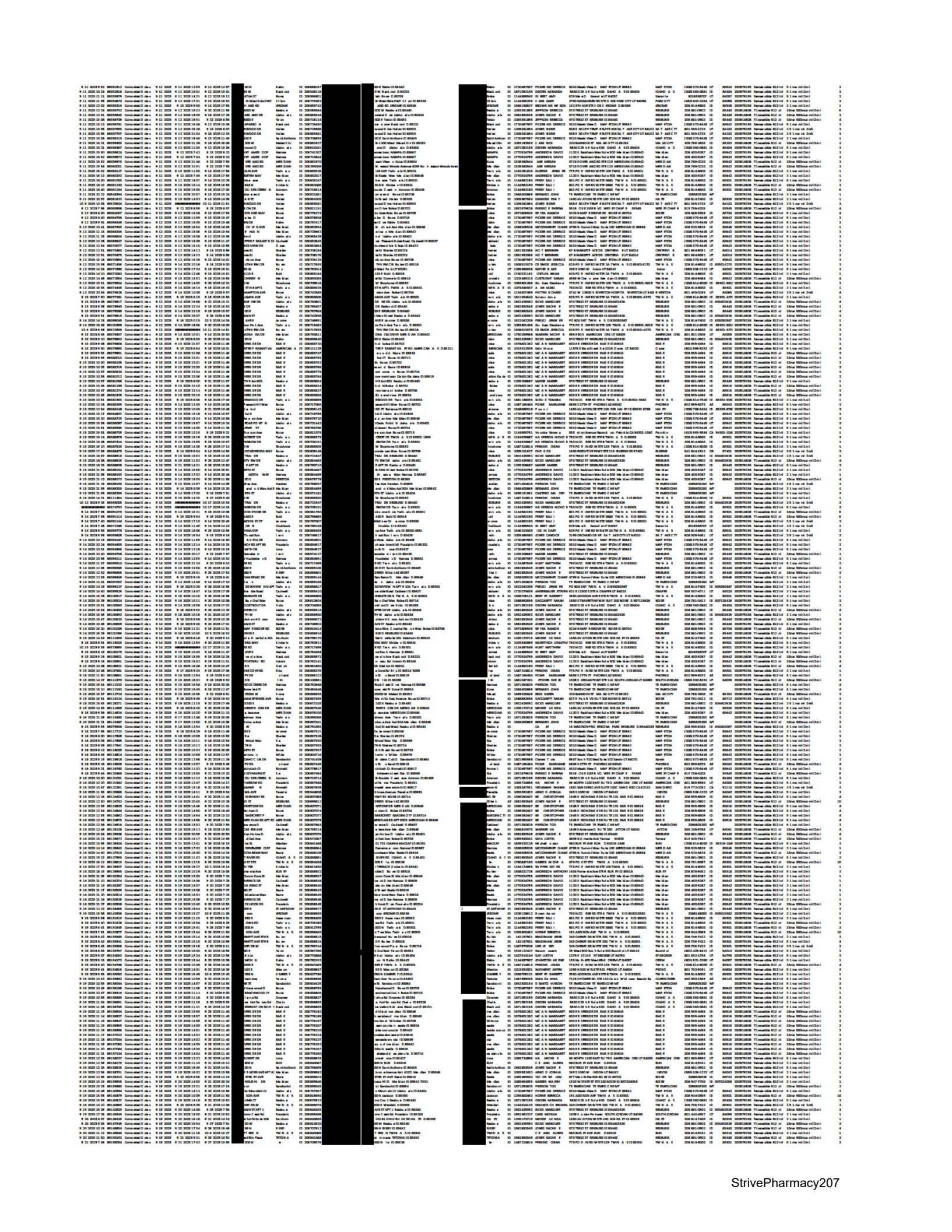












StrivePharmacy207

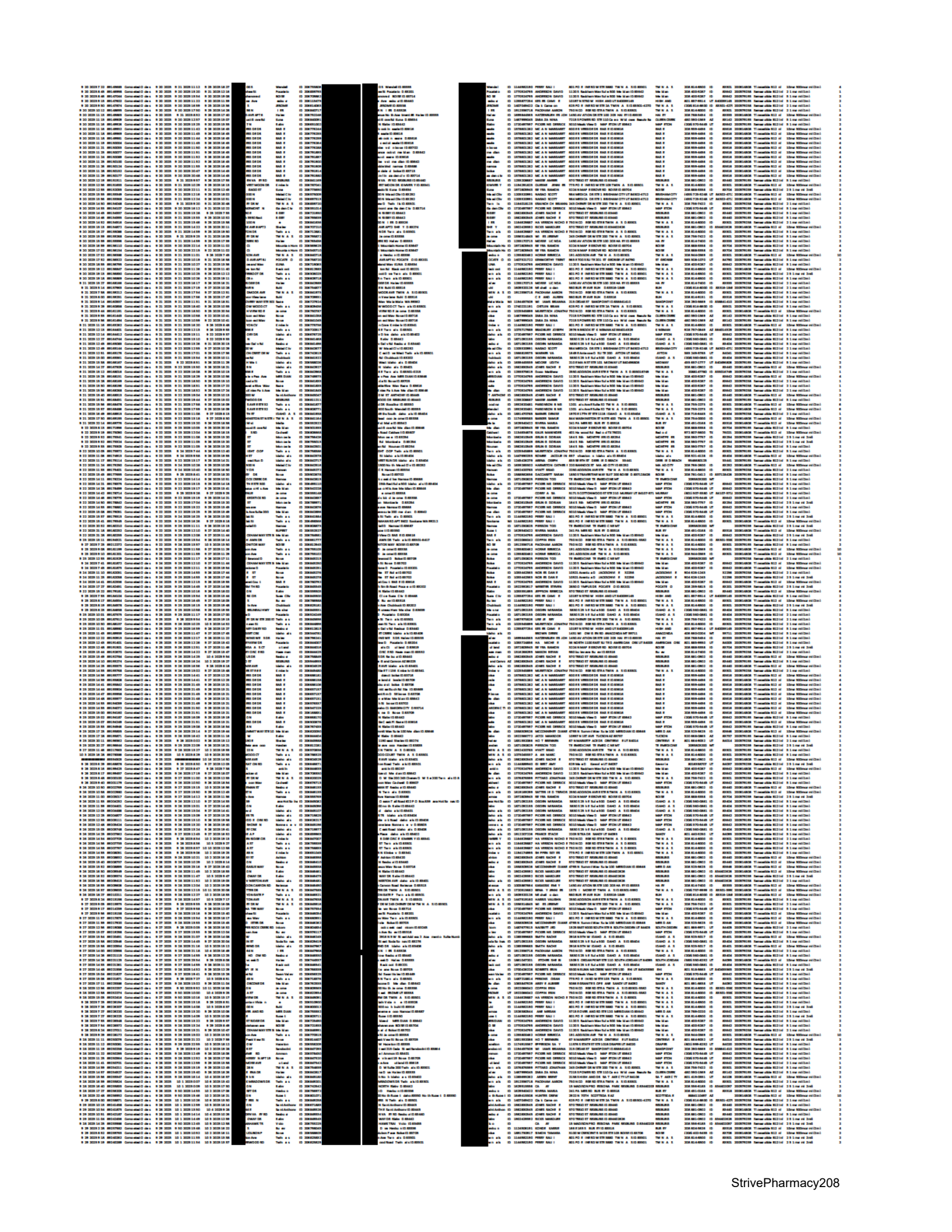


Exhibit 2

Quality Questionnaire

1. Company Overview

Company Name	Biopeptek Pharmaceuticals, LLC
Address	5 Great Valley Pkwy STE 100, Malvern, PA 19355
Manufacturing Site (if different from above)	218 Shuangyuan Road, Chengyang, Qingdao, Shandong 266000, China (CHN)
Year Established	2010
Division / Subsidiary of (if applicable)	
Telephone	+1(610)643-4881
Website	https://biopeptek.com/
Quality Contact (Name / Title / E-mail)	Ricky Yang, Chief Operating Officer, rickyyang@biopeptek.com

2. General

Activities	Warehousing ☐
	Manufacturing ■
	Quality Control Testing ■
	Packaging / Labeling ☐
	Distribution ☐
Facility Size (sq. ft.)	150,000
Number of Employees	126
Hours of Operation	
Number of Shifts in Operation	
Liability Insurance Coverage	YES ■ NO ☐
Would you allow Pharma Source to inspect your facility?	YES ■ NO ☐

3. FDA

Registered with FDA?	YES ■ NO ☐
Last Inspection Date	The inspection was rescheduled three times due to COVID pandemic. We did a virtual one on 7/13/2021

Inspection Results	NAI ■ VAI ☐ OAI ☐
Has your firm ever received a FDA form 483?	YES ☐ (Provide a copy of the most recent) NO ■
Has your firm ever received a Warning Letter or Consent Decree from the FDA?	YES ☐ (Provide a copy of the most recent) NO ■
Number of recalls in the past five (5) years	0

§ 4. – 10. Any questions for which the answer is "NO", provide an explanation in the comments section.

4. Organization and Personnel	
Is there a separate Quality Unit overseeing operations with a presence on each shift?	YES ■ NO ☐
Are responsibilities of the Quality Unit defined in a written SOP?	YES ■ NO ☐
Is there a written organization structure or chart?	YES ■ NO ☐
Are there written job descriptions describing the required qualifications and training for each job?	YES ■ NO ☐
Are there written procedures for employee training?	YES ■ NO ☐
Are there written procedures for employee hygiene?	YES ■ NO ☐
Does the Quality Unit have authority to reject and quarantine nonconforming material?	YES ■ NO ☐
Does the Quality Unit regularly prepare and report quality metrics?	YES ■ NO ☐
Comments	

5. Facilities	
Is the facility owned or leased?	Owned ■ Leased ☐
Is production equipment owned or leased?	Owned ■ Leased ☐
Are manufacturing and warehouse areas designed to provide adequate:	
Lighting?	YES ■ NO ☐
Ventilation?	YES ■ NO ☐
Temperature / Humidity control?	YES ■ NO ☐
Sanitation?	YES ■ NO ☐
Space?	YES ■ NO ☐
Security?	YES ■ NO ☐
Is a security system in place to assure no unauthorized access?	YES ■ NO ☐
Is there a Pest Control program describing approved pesticides and areas of application?	YES ■ NO ☐

Are there written procedures describing: cleaning agents, schedule, and methods?	YES ■ NO ☐
Are cleaning methods validated?	YES ■ NO ☐
Comments	

6. Equipment	
Are manufacturing and laboratory equipment qualified according to written procedures and FDA standards?	YES ■ NO ☐
Is equipment maintained and calibrated according to a written procedure?	YES ■ NO ☐
Are equipment calibration frequencies based on manufacturers' specifications?	YES ■ NO ☐
Are standards used for calibration traceable to NIST?	YES ■ NO ☐
Are new measuring devices or test equipment calibrated prior to use?	YES ■ NO ☐
Are records of manufacturing / laboratory equipment use, maintenance, and calibration maintained?	YES ■ NO ☐
Is there a system in place to ensure unclean equipment is not used?	YES ■ NO ☐
Is the storage of not-in-use equipment designed to prevent contamination?	YES ■ NO ☐
Does the change management system require evaluating the need for re-qualification of manufacturing and laboratory equipment?	YES ■ NO ☐
Comments	

7. Laboratory Controls	
Do you have an on-site laboratory for testing incoming, in-process, and finished materials?	YES ■ NO ☐
Is there a procedure for investigating Out of Specification test results?	YES ■ NO ☐
Have all laboratory methods been validated?	YES ■ NO ☐
Has each product been tested for stability based on a written protocol?	YES ■ NO ☐
Comments	

8. Materials / Supplier Management	
Is there a system in place to ensure materials are only sourced from approved suppliers?	YES ■ NO ☐
Is an Approved Supplier List maintained?	YES ■ NO ☐
Has each supplier of raw materials been inspected for proper controls?	YES ■ NO ☐
Are agreements in place with suppliers requiring notification of changes to products / processes?	YES ■ NO ☐
Are there written specifications for each material used for manufacturing activities?	YES ■ NO ☐
Are incoming materials inspected?	YES ■ NO ☐
Are incoming materials quarantined until approved for use?	YES ■ NO ☐
Are there written procedures for receipt, inspection, and quality release of materials?	YES ■ NO ☐
Are rejected materials quarantined and clearly marked to prevent their use?	YES ■ NO ☐
Comments	

9. Production and Process Control	
Is traceability of materials used in manufacturing maintained?	YES ■ NO ☐
Are batch records used to document materials and equipment used in manufacturing?	YES ■ NO ☐
Have manufacturing processes been validated?	YES ■ NO ☐
Is in-process inspection / testing performed?	YES ■ NO ☐
Is final inspection / testing performed for finished products?	YES ■ NO ☐
Are sampled of finished products retained?	YES ■ NO ☐
Are deviations (planned or unplanned) from manufacturing procedures documented?	YES ■ NO ☐
Is each batch of material provided to Pharma Source assigned a unique identifier for traceability?	YES ■ NO ☐
Comments	

10. Quality Program	
Document Control	
Is there a written Quality Manual?	YES ■ NO ☐

Are there written procedures for all manufacturing activities?	YES ■ NO ☐
Are procedures periodically reviewed and updated as necessary?	YES ■ NO ☐
Are documents' revision history maintained?	YES ■ NO ☐
Is there a procedure for document control?	YES ■ NO ☐
Is there a procedure for record retention?	YES ■ NO ☐
Change Control	
Do you have a Change Control program?	YES ■ NO ☐
Are customers notified in advance of significant changes to processes?	YES ■ NO ☐
Nonconforming Product	
Is there a procedure for the documentation and investigation of nonconforming product?	YES ■ NO ☐
Is nonconformance data reviewed and are trends monitored?	YES ■ NO ☐
Are adverse trends addressed?	YES ■ NO ☐
Is there a written procedure for corrective and preventive action?	YES ■ NO ☐
Complaint Handling	
Is there a written procedure for handling complaints, complaint investigations, and implementing corrective actions when appropriate?	YES ■ NO ☐
Are reports of complaints and investigations provided to appropriate parties, including customers?	YES ■ NO ☐
Quality Audit Program	
Is there an internal quality audit program to determine effectiveness of the quality management system?	YES ■ NO ☐
Is there a third party audit program?	YES ■ NO ☐
Comments	

11. Records

Please include pdf copies of the following documents with the completed Quality Questionnaire

- Organizational Chart
- Federal and/or State manufacturing licenses or registrations
- Most recent FDA 483, warning letter and/or consent decree, if applicable
- Quality Manual
- Index of Standard Operating Procedures
- Facility floor plan / Site Map

Exhibit 3

biopeptek

CERTIFICATE OF ANALYSIS

Reference document : BPT-QC-STP-2098 V02

Product Name	Semaglutide
CAS No.	910463-68-2
Molecular Formula	$C_{187}H_{291}N_{45}O_{59}$
Lot No.	GIM9820230830
Sequence	His-Aib-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-Ser-Tyr-Leu-Glu-Gly-Gln-Ala-Ala-Lys(PEG2-PEG2-γ-Glu-17-carboxyheptadecanoyl)-Glu-Phe-Ile-Ala-Trp-Leu-Val-Arg-Gly-Arg-Gly
Modifications	None
Storage Conditions	For less than 6-month storage, the recommended condition is 2-8℃; For longer term (> 6-month) storage, the recommended condition is minus 20℃.

Test Items		**Specifications**	**Results**	**Method**
Appearance		White to off-white powder	White to off-white powder (Conforms)	BPT-QC-SOP-2098 V02
Identification	**Molecular Weight (MS)**	4113.6±1.0 Da	4113.8 Da	BPT-QC-SOP-2098 V02
	Retention Time (HPLC)	The retention time of the major peak of the sample solution corresponds to that of the standard solution.	Conforms	BPT-QC-SOP-2098 V02
Assay	**Purity (HPLC)**	≥98.0%	99.8%	BPT-QC-SOP-2098 V02
	Related Substances (HPLC)	Total Impurities(%)≤2.0% Largest Single Impurity(%)≤1.0%	0.2% 0.1%	BPT-QC-SOP-2098 V02
	Peptide Content (HPLC)	≥85.0%	91.4%	BPT-QC-SOP-2098 V02
Specific Tests	**Water Content (Karl Fischer)**	≤8.0%	6.2%	BPT-QC-SOP-2098 V02; USP<921>
	Residual Solvent (GC; HPLC)	Acetonitrile≤0.041% Trifluoroacetic≤0.500% Acetic Acid≤0.100%	0.006% <0.05% <0.05%	BPT-QC-SOP-2098 V02
	Bacterial Endotoxins (Gel-clot Method)	<10 EU/mg	Conforms	BPT-QC-SOP-2098 V02; USP<85>
Conclusion	This batch was tested following the analytical procedure of BPT-QC-SOP-2098 V02. The test results met the specifications of BPT-QC-STP-2098 V02.			

Date of Mfg	30 Aug 2023	Date of Exp	29 Aug 2025
Date of Test	07 Sep 2023	Date of Release	07 Sep 2023
Quality Control: Shaohua Wang Shaohua Wang 07 Sep 2023 Reviewed		Quality Assurance: Yongna Zhao Yongna Zhao 07 Sep 2023 Approved	

Biopeptek Pharmaceuticals,LLC

Corporate headquarters: 5 Great Valley Parkway. Suite 100 Malvern, PA 19355, U.S.A Tel: 610.643.4881 www.biopeptek.com

Manufactured and Packaged at the FDA registered facility: 218 Shuangyuan Road, Chengyang, Qingdao, Shandong 266000, China (CHN)

The peptide is chemically synthesized

Exhibit 4

SHEDRX

TELEMEDICINE, TELEMEDICINE, MT
Phone: 2093803200, Fax:
Date: Oct/11/2023 09:26:34 PM (CST)

TOD PIERSON NP-C State Lic. MTAP60726755
TOD PIERSON NP-C

Electronic Prescription Order

Name:	[redacted]	Last Name:	[redacted]	Middle Name:	
Phone:		Cell Phone:		DOB:	[redacted]
Address:	**2622 n lorton pl**	Address (Cont):		Email:	
City:	**Kuna**	State:	**ID**	Zip:	**83634**
Gender:	**Female**	Pay Type:		Ins. Name:	
Group Name:		Ins. Phone:		Member ID:	
Ins. Control Number:		Ins. BIN:		Delivery Type:	**UPS Ground**
Driver's License Number:		Driver's License State:			

#1 Semaglutide/B12 Inj

Strength: 2/1 mg/ml (1ml)====
Quantity: 1 ml (one)====
Refills: 0====
Directions: Inject 0.125 ml (12.5 units) subcutaneously once weekly for 4 weeks then 0.25 ml (25 units) subcutaneously once weekly for 2 weeks====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 42====
Special instructions: Include Insulin Needles====
Date Written: 10/11/2023 (Oct 11, 2023)====
Purpose: Add B12 to prevent nausea/vomiting and use compounded vials that offer flexible dosing for patients and lowest effective dose to minimize side effects and increase outcomes====

#2 Ondansetron Tab Orally Dis

Strength: 4mg----
Quantity: 20 each (twenty)====
Refills: 0====
Directions: Take 1 tablet by mouth daily as needed for nausea and vomiting====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 20====
Special instructions: ====
Date Written: 10/11/2023 (Oct 11, 2023)====

Special Instructions: - **Allergies:** NO KNOWN ALLERGIES; - **Diagnosis:** No known medical conditions;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: TOD PIERSON NP-C Date: Oct/11/2023 09:26:34 PM (CST)
Signed electronically by: TOD PIERSON NP-C

Strive Pharmacy Arizona
1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy System

Order #89360550

BELLE MEDICAL - BOISE

3010 MAGIC VIEW DR, MAPLETON, UT 83642
Phone: 208-370-5445, Fax:
Date: Apr/18/2023 08:31:04 AM (CST)

DERRICK EVAN PICKERING N.P. State Lic. UT7675886-4405

DERRICK EVAN PICKERING N.P.

Electronic Prescription Order

Name:	[redacted]	Last Name:	[redacted]	Middle Name:	
Phone:	**2089948631**	Cell Phone:	[redacted]	DOB:	[redacted]
Address:	**5136 N Saguaro Hills Ave**	Address (Cont):		Email:	
City:	**Meridian**	State:	**ID**	Zip:	**83646**
Gender:	**Female**	Pay Type:		Ins. Name:	
Group Name:		Ins. Phone:		Member ID:	
Ins. Control Number:		Ins. BIN:		Delivery Type:	**UPS 2nd Day Air**
Driver's License Number:		Driver's License State:			

#1 Semaglutide/B12 INJ

Strength: 2/1 mg/ml (1ml)====
Quantity: 1 ml (one)====
Refills: 0====
Directions: Inject 0.125 ml (12.5 units) subcutaneously once weekly for 2 weeks then 0.25 ml (25 units) subcutaneously once weekly for 2 weeks. Then inject 50 units once a week====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 28====
Special instructions: Include Insulin Needles====
Date Written: 04/18/2023 (Apr 18, 2023)====
Purpose: WITH B12 TO PREVENT NAUSEA====

Special Instructions: - **Allergies:** NO KNOWN ALLERGIES; - **Diagnosis:** No known medical conditions;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: DERRICK EVAN PICKERING N.P. Date: Apr/18/2023 08:31:04 AM (CST)

Signed electronically by: DERRICK EVAN PICKERING N.P.

Strive Pharmacy Arizona

1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy System

Order #86603595

BELLE MEDICAL - BOISE

3010 MAGIC VIEW DR, MAPLETON, UT 83642
Phone: 208-370-5445, Fax:
Date: Jun/14/2023 11:49:55 AM (CST)

DERRICK EVAN PICKERING N.P. State Lic. UT7675886-4405

DERRICK EVAN PICKERING N.P.

Electronic Prescription Order

Name:	[redacted]	Last Name:	[redacted]	Middle Name:	
Phone:		Cell Phone:	**2089323916**	DOB:	[redacted]
Address:	**1143 villa vista drive**	Address (Cont):		Email:	
City:	**Ammon**	State:	**ID**	Zip:	**83406**
Gender:	**Female**	Pay Type:		Ins. Name:	
Group Name:		Ins. Phone:		Member ID:	
Ins. Control Number:		Ins. BIN:		Delivery Type:	**UPS 2nd Day Air**
Driver's License Number:		Driver's License State:			

#1 Semaglutide/B12 Inj

Strength: 5/1 mg/ml (2ml)====
Quantity: 2 ml (two)====
Refills: 0====
Directions: Inject 0.1 ml (10 units) Subcutaneously weekly for 2 weeks, then 0.2 ml (20 units) Subcutaneously weekly for 4 weeks====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 90====
Special instructions: Please include 12 needles====
Date Written: 06/14/2023 (Jun 14, 2023)====
Purpose: WITH B12 TO PREVENT NAUSEA====

Special Instructions: - **Allergies:** ; - **Diagnosis:** ;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: DERRICK EVAN PICKERING N.P. Date: Jun/14/2023 11:49:55 AM (CST)

Signed electronically by: DERRICK EVAN PICKERING N.P.

Strive Pharmacy Arizona

1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy System

Order #87926567

SHED RX

TELEMEDICINE, TELEMEDICINE, MT
Phone: , Fax:
Date: Apr/03/2023 09:33:42 AM (PDT)

TOD PIERSON WORK NP-C State Lic. MTAP60726755
TOD PIERSON WORK NP-C

Electronic Prescription Order

Name:	[redacted]	Last Name:	[redacted]	Middle Name:	
Phone:		Cell Phone:		DOB:	[redacted]
Address:	**1636 N Snowfield Pl**	Address (Cont):		Email:	
City:	**Kuna**	State:	**ID**	Zip:	**83634**
Gender:	**Female**	Pay Type:		Ins. Name:	
Group Name:		Ins. Phone:		Member ID:	
Ins. Control Number:		Ins. BIN:		Delivery Type:	**UPS Ground**
Driver's License Number:		Driver's License State:			

#1 Semaglutide/B12 INJ

Strength: 2/1 mg/ml (1ml)====
Quantity: 1 ml (one)====
Refills: 0====
Directions: Inject 0.125 ml (12.5 units) subcutaneously once weekly for 4 weeks then 0.25 ml (25 units) subcutaneously once weekly for 2 weeks====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 28====
Special instructions: Include Insulin Needles====
Date Written: 04/03/2023 (Apr 03, 2023)====
Purpose: WITH B12 TO PREVENT NAUSEA====

Special Instructions: - **Allergies:** No known allergies; - **Diagnosis:** No known medical conditions;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: TOD PIERSON WORK NP-C Date: Apr/03/2023 09:33:42 AM (PDT)

Signed electronically by: TOD PIERSON WORK NP-C

Strive Pharmacy Arizona
1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy System

Order #86259112

BOISE BIOLOGICS AND REGENERATIVE

3224 N MAPLE GROVE RD, BOISE, ID 83704
Phone: 530-520-7796, Fax: 208-600-0876
Date: Jul/24/2023 05:12:09 PM (CST)

RAMON ADDISON RELYEA PA-C DEA #MR7273965 State Lic. IDPA-1084

RAMON ADDISON RELYEA PA-C

Electronic Prescription Order

Name:	[redacted]	Last Name:	[redacted]	Middle Name:	[redacted]
Phone:		Cell Phone:		DOB:	
Address:	**1097 E. Folgado St**	Address (Cont):		Email:	
City:	**Kuna**	State:	**ID**	Zip:	**83634**
Gender:	**Female**	Pay Type:		Ins. Name:	
Group Name:		Ins. Phone:		Member ID:	
Ins. Control Number:		Ins. BIN:		Delivery Type:	**UPS Ground**
Driver's License Number:		Driver's License State:			

#1 Semaglutide/B12 Inj

Strength: 2.5/1 mg/ml (2ml)====
Quantity: 2 ml (two)====
Refills: 0====
Directions: Week 1-4 Inject 0.1 ML (10 units) subcutaneously weekly. Week 5-8 Inject 0.2 ML (20 units) weekly. Week 9-12 Inject 0.4 ML (40 units) weekly, Week 13-16 Inject 0.68 ML (68 units) weekly, Week 17+ inject 0.96 ML (96 units) weekly====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 70====
Special instructions: NO NEEDLES====
Date Written: 07/24/2023 (Jul 24, 2023)====
Purpose: W/B12 to prevent Nausea====

Special Instructions: - **Allergies:** NO KNOWN ALLERGIES; - **Diagnosis:** ;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: RAMON ADDISON RELYEA PA-C Date: Jul/24/2023 05:12:09 PM (CST)

Signed electronically by: RAMON ADDISON RELYEA PA-C

Strive Pharmacy Arizona
1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy System

Order #88455393

BOISE BIOLOGICS AND REGENERATIVE

3224 N MAPLE GROVE RD, BOISE, ID 83704
Phone: 530-520-7796, Fax: 208-600-0876
Date: Sep/08/2023 11:55:17 AM (CST)

RAMON ADDISON RELYEA PA-C DEA #MR7273965 State Lic. IDPA-1084

RAMON ADDISON RELYEA PA-C

Electronic Prescription Order

Name:	[redacted]	Last Name:	[redacted]	Middle Name:	
Phone:		Cell Phone:		DOB:	[redacted]
Address:	**2710 Inglewood Rd**	Address (Cont):		Email:	
City:	**Boise**	State:	**ID**	Zip:	**83705**
Gender:	**Female**	Pay Type:		Ins. Name:	
Group Name:		Ins. Phone:		Member ID:	
Ins. Control Number:		Ins. BIN:		Delivery Type:	**UPS Ground**
Driver's License Number:		Driver's License State:			

#1 Semaglutide/B12 Inj

Strength: 2.5/1 mg/ml (2ml)====
Quantity: 2 ml (two)====
Refills: 0====
Directions: Week 1-4 Inject 0.1 ML (10 units) subcutaneously weekly. Week 5-8 Inject 0.2 ML (20 units) weekly. Week 9-12 Inject 0.4 ML (40 units) weekly, Week 13-16 Inject 0.68 ML (68 units) weekly, Week 17+ inject 0.96 ML (96 units) weekly====
Dispensation: Therapeutically equivalent generic drug may be substituted====
Days Supply: 70====
Special instructions: NO NEEDLES====
Date Written: 09/08/2023 (Sep 08, 2023)====
Purpose: Add B12 to prevent nausea/vomiting and use compounded vials that offer flexible dosing for patients and lowest effective dose to minimize side effects and increase outcomes.====

Special Instructions: - **Allergies:** NO KNOWN ALLERGIES; - **Diagnosis:** ;

The compounded medications listed are made at the request of the prescribing practitioner whose signature appears above due to the medical need of a specific patient and the preparation is prescribed because the prescriber has determined that the preparation will produce a clinically significant therapeutic response compared to a commercially available product.

Submitted by: RAMON ADDISON RELYEA PA-C Date: Sep/08/2023 11:55:17 AM (CST)

Signed electronically by: RAMON ADDISON RELYEA PA-C

Strive Pharmacy Arizona

1275 E Baseline Rd ste 104, Gilbert, AZ, 85233
Phone: 480-626-4366, Fax: 480-626-4365
LIFE FILE Pharmacy System

Order #89038563