UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA

v.

ISIS NAVARRO REYES, a/k/a "Beraly Navarro,"

Defendant.

SOUTHERN DISTRICT OF NEW YORK, ss.:

SEALED COMPLAINT

Violations of 21 U.S.C. §§ 353(b); 331(a); 331(c); 331(k); 18 U.S.C. §§ 371; 545

COUNTY OF OFFENSE: NEW YORK

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JASON FERNANDES, being duly sworn, deposes and says that he is a Special Agent with the U.S. Food and Drug Administration ("FDA"), and charges as follows:

<u>COUNT ONE</u> (Receipt of Misbranded Drugs in Interstate Commerce)

1. In or about January 2024 in the Southern District of New York and elsewhere, ISIS NAVARRO REYES, the defendant, did receive and cause the receipt in interstate commerce of a misbranded drug (an article labeled as "Ozempic") and did deliver and proffer delivery of such drug for pay and otherwise, such drug being misbranded in the following ways:

a. All words, statements, and other information required by and under the authority of the Federal Food, Drug, and Cosmetic Act ("FDCA") to appear on the label and labeling were not prominently placed thereon in the English language and with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use pursuant to 21 U.S.C. § 352(c); and

b. The labeling did not bear requisite adequate directions for use pursuant to 21 U.S.C. § 352(f)(1); and

c. The labeling did not bear adequate warnings against use in those pathological conditions and by children where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration and application, in such manner and form, as were necessary for the protection of users pursuant to 21 U.S.C. § 352(f)(2); and

d. It was manufactured, prepared, propagated, compounded, and processed in an establishment, within any foreign country, not duly registered with FDA. 21 U.S.C. §§ 352(o) and 360(i).

(Title 21, United States Code, Sections 331(c) and 333(a)(1))

COUNT TWO (Dispensing of a Misbranded Drug While Held for Sale)

2. In or about January 2024 in the Southern District of New York and elsewhere, ISIS NAVARRO REYES, the defendant, did dispense and cause the dispensing of an article labeled as "Ozempic," a prescription drug as defined at 21 U.S.C. § 353(b)(1), without a prescription of a practitioner licensed by law to administer such drug, an act which resulted in the drug becoming misbranded while held for sale after its shipment in interstate commerce.

(Title 21, United States Code, Sections 331(k) and 333(a)(1))

COUNT THREE

(Conspiracy to Introduce and Deliver for Introduction a Misbranded Drug in Interstate Commerce)

3. From in or about December 2023 through at least in or about January 2024, in the Southern District of New York and elsewhere, ISIS NAVARRO REYES, the defendant, did knowingly and willfully combine, conspire, confederate, and agree with others, known and unknown, to introduce and deliver for introduction into interstate commerce a drug (an article labeled as "Ozempic"), such drug being misbranded in the following ways:

a. All words, statements, and other information required by and under the authority of the FDCA to appear on the label and labeling were not prominently placed thereon in the English language and with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use pursuant to 21 U.S.C. § 352(c); and

b. The labeling did not bear requisite adequate directions for use pursuant to 21 U.S.C. § 352(f)(1); and

c. The labeling did not bear adequate warnings against use in those pathological conditions and by children where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration and application, in such manner and form, as were necessary for the protection of users pursuant to 21 U.S.C. § 352(f)(2); and

d. Prior to dispensing, the drug, being a prescription drug, had a label that failed to bear the symbol "Rx only" pursuant to 21 U.S.C. § 353(b)(4)(A).

(Title 21, United States Code, Sections 331(a) and 333(a)(1), Title 18, United States Code, Section 371)

<u>COUNT FOUR</u> (Dispensing of a Misbranded Drug While Held for Sale)

4. In or about February 2023, in the Southern District of New York and elsewhere, ISIS NAVARRO REYES, the defendant, did dispense and cause the dispensing of an article labeled as "Mesofrance," a prescription drug as defined at 21 U.S.C. § 353(b)(1), without a

prescription of a practitioner licensed by law to administer such drug, an act which resulted in the drug becoming misbranded while held for sale after its shipment in interstate commerce.

(Title 21, United States Code, Sections 331(k) and 333(a)(1))

<u>COUNT FIVE</u> (Dispensing of a Misbranded Drug While Held for Sale)

5. In or about July 2023 in the Southern District of New York and elsewhere, ISIS NAVARRO REYES, the defendant, did dispense and cause the dispensing of an article labeled as "Axcion," a prescription drug as defined at 21 U.S.C. § 353(b)(1), without a prescription of a practitioner licensed by law to administer such drug, an act which resulted in the drug becoming misbranded while held for sale after its shipment in interstate commerce.

(Title 21, United States Code, Sections 331(k) and 333(a)(1))

COUNT SIX (Smuggling)

6. From in or about June 2023 through at least in or about July 2023 in the Southern District of New York, ISIS NAVARRO REYES, the defendant, fraudulently and knowingly received, concealed, bought, sold and in any manner facilitated the transportation, concealment, and sale of merchandise contrary to law, that is, "Axcion," a prescription drug as defined at 21 U.S.C. § 353(b)(1), after the importation thereof, REYES then knowing that said merchandise had been imported and brought into the United States contrary to law, in that the Axcion was a misbranded drug that was introduced into interstate commerce, in violation of Title 18, United States Code, Section 545.

(Title 18, United States Code, Section 545)

APPLICABLE LAW

7. The United States Food and Drug Administration ("FDA"), is the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the FDCA, 21 U.S.C. § 301 *et seq*. Among the purposes of the FDCA is to ensure that drugs intended for human use are safe, effective, and bear labeling containing accurate information. Based on my understanding of the FDCA and, in particular, the proposed charges, I am aware, among other things, that:

a. The FDCA defines interstate commerce as "(1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other territory not organized with a legislative body." 21 U.S.C. § 321(b).

b. Under the FDCA, a "drug" is, among other things, any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans; or any article (other than food) intended to affect the structure or any function of the body of a human. 21 U.S.C. \S 321(g).

c. A "prescription drug" is any drug intended for use by a human which:

i. because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

ii. is limited by an approved new drug application to use under the professional supervision of a practitioner licensed by law to administer such drug. 21 U.S.C. \S 353(b)(1).

d. Under the FDCA, "label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k). The term "labeling," is broader and is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

e. Generally, all words, statements, and other information required by or under authority of the FDCA to appear on drug labels or labeling are required to appear thereon in the English language.¹ 21 C.F.R. § 201.15(c)(1).

f. Among other things, a prescription drug label is required to bear a statement of the recommended or usual dosage, or alternatively in some circumstances, a statement such as "see package insert for dosage information," where the detailed dosage information was contained in such insert. 21 C.F.R. §§ 201.100(b)(2) and 201.55.

g. "Adequate directions for use" means directions under which a layman could use a drug safely for the purposes for which it was intended. 21 C.F.R. § 201.5.

h. Because a prescription drug, by definition, is safe for use only under the supervision of a licensed practitioner, there are no directions that could enable a layman to use a prescription drug safely absent that supervision. Therefore, adequate directions for use could not be written for a prescription drug.

i. A drug is misbranded if, among other things:

i. any word, statement, or other information required by or under the authority of the FDCA to appear on the label or labeling was not prominently placed thereon in the English language and with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. 21 U.S.C. § 352(c),² 21 C.F.R. § 201.15(c)(1); or

¹ In an exemption not applicable here, drugs distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English.

² Drugs dispensed by prescription from a practitioner licensed by law were exempt from the requirements of 21 U.S.C. § 352(c) if the drug contained a label containing the name and address of the dispenser, the serial number and date of the prescription and its filling, the name of the

ii. if its labeling failed to bear requisite "adequate directions for use." 21 U.S.C. § $352(f)(1)^3$; or

iii. if its labeling failed to bear such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. 21 U.S.C. § 352(f)(2).

j. A drug is misbranded while held for sale if, among other things, it is a prescription drug and is dispensed without a prescription of a practitioner licensed by law to administer such drug. 21 U.S.C. \S 353(b)(1).

k. A drug is adulterated if it contains in whole or in part any filthy, putrid, or decomposed substance; or 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. 21 U.S.C. § 351(a)(1).

<u>REYES SELLS WEIGHT LOSS DRUGS ON TIKTOK AND POSTS</u> <u>INSTRUCTIONAL VIDEOS ON HOW THE DRUGS SHOULD BE USED</u>

8. Based on my participation in this investigation, my conversations with law enforcement special agents and officers, my conversations with victims, my review of social media, accounts, my review of communications, my review of documents and records, my review of shipping records, and my review of physical evidence, I know, among other things, the following:

prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription.

³ A prescription drug is misbranded if it did not comply with FDA regulations that exempted certain prescription drugs from the adequate directions for use requirement. In an exemption not applicable to the drugs marketed and sold by ISIS NAVARRO REYES, the defendant, FDAapproved prescription drugs were exempted from the requirement of bearing labeling with adequate directions for use when they complied with regulations related to who possessed the drug and the contents of the drug's label and labeling. 21 C.F.R. § 201.100. For that exemption to apply, the drug's labeling requirements included that the label bore the statement "Rx only," the usual dosage, the route of administration, the quantity and proportion of each active ingredient and the names of all inactive ingredients for drugs not for oral use. 21 C.F.R. § 201.100; 21 C.F.R. § 201.15(c)(1). Additionally, for that exemption to apply, the drugs must be in the possession of (1) a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; or (2) a retail, hospital, or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs; or (3) a practitioner licensed by law to administer or prescribe such drugs. Unapproved prescription drugs and prescription drugs that did not meet all of the conditions listed in 21 C.F.R. § 201.100 were misbranded for failing to bear adequate directions for use.

a. From at least in or about November 2022 through at least on or about November 2023, ISIS NAVARRO REYES, the defendant, using the TikTok username "beralyreyes88" posted dozens of videos pertaining to weight loss drugs including, but not limited to, Ozempic, Axcion, and Mesotherapy.

b. **Ozempic.** Ozempic is the brand name for an FDA-approved prescription drug manufactured by Novo Nordisk A/S. The active pharmaceutical ingredient in Ozempic is semaglutide. Ozempic is administered by subcutaneous injection. Ozempic was indicated for use as "an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; and to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease."4 Ozempic bears a boxed warning, commonly referred to as a "black box warning," which is the strongest warning FDA requires, indicating that the drug carries a significant risk of serious or even life-threatening adverse effects. The boxed warning addresses the risk of thyroid C-cell tumors. Generally, foreign-market versions of Ozempic that are not approved by FDA could not lawfully be commercially distributed in the United States.⁵ Injectable products purporting to be Ozempic and intended to be used for weight loss or to treat type 2 diabetes are prescription drugs. Over the past few years, the public has learned that semaglutide, one of the active ingredients in Ozempic, can assist in weight loss.⁶ Ozempic has quickly become popular as a weight-loss drug. Ozempic and other drugs with the same active ingredient—semaglutide—have been on the FDA's drug shortage list since in or about March 31, 2022.

c. Axcion. Axcion is a brand of weight loss pills that are sold in Mexico. See "Axcion: The Mexican Brand of Phentermine," available: https://www.phentermine.com/brands/acxion/ (last accessed December 3, 2023). The active ingredient in Axcion, phentermine, is an appetite suppressant that is used to accelerate weight loss. See "Phentermine," available: https://www.drugs.com/phentermine.html (last accessed December 3, 2023). Axcion is not approved in the United States and may only be obtained in Mexico when prescribed by a doctor.

d. **Mesofrance.** Mesoterapia, or mesotherapy in English, refers to a technique in which individuals inject microinjections of conventional homeopathic medication and/or vitamins into the mesoderm or middle layer of the skin to promote healing or corrective treatment

⁴ See Ozempic package insert. <u>https://www.accessdata.fda.gov/</u> <u>drugsatfda_docs/label/2023/209637s020s0211bl.pdf</u>. (last accessed February 2, 2024).

⁵ In very limited circumstances not applicable here, the FDCA may permit certain pharmacists and wholesalers to import specific prescription drugs from Canada. 21 U.S.C. § 384.

⁶ See "Ozempic for weight loss: Does it work and what do experts recommend?" Available: https://health.ucdavis.edu/blog/cultivating-health/ozempic-for-weight-loss-does-it-work-and-what-do-experts-

recommend/2023/07#:~:text=What%20is%20Ozempic%3F,the%20pancreas%20make%20more %20insulin. (last accessed December 3, 2023); *see also* "What Is Ozempic and Why Is It Getting So Much Attention?" N.Y. Times November 22, 2022, updated November 13, 2023, https://www.nytimes.com/2022/11/22/well/ozempic-diabetes-weight-loss.html (last accessed December 4, 2023).

to a specific area of the body.⁷ Mesotherapy is a popular weight loss strategy. Mesofrance, a Mexican pharmaceutical company, offers its own prescription drug for use as Mesoterapia— Triac—intended to, among other things, assist users in losing unwanted body fat. Triac, when intended to be injected for the purposes of weight loss or losing unwanted body fat, is a prescription drug and does not have a requisite drug approval from the FDA. Mesofrance has a directory of approved distributors on its website.⁸

e. In her videos,⁹ REYES showcases the weight loss drugs, instructs viewers how frequently they should be used, describes how they should be taken or injected, and claims to describe her personal experiences—for example, side effects and effectiveness in causing weight loss—in detail. In several of these videos, REYES tells viewers that they can contact her via an encrypted messaging application using a number ending in -4416 (the "Cellphone") if they would like to order the weight loss drugs that she is selling. The paragraphs below offer a representative sample of the videos REYES posted and a sample of certain messages REYES sent to viewers via an encrypted messaging application.

f. In or about November 2022, a woman who had viewed content posted to REYES's TikTok account ("Victim-1") called the call number assigned to the Cellphone for the purpose of ordering weight loss drugs. The individual who answered Victim-1's call identified herself as "Isis Navarro Reyes."

g. On or about March 3, 2023, REYES sent a video of a tutorial pertaining to burning localized fat using Mesofrance to a group chat consisting of individuals who had expressed interest in purchasing her products via an encrypted messaging application. The text at the bottom of the video directs viewers to place orders via the call number assigned to the Cellphone. A screenshot from this TikTok post is below.

⁷ See "Mesotherapy," available:

https://pubmed.ncbi.nlm.nih.gov/17314456/#:~:text=Mesotherapy%20is%20a%20technique%20 which,specific%20area%20of%20the%20body. (last accessed December 3, 2023).

⁸ See "Dealers," available https://mesofrance.com/distribuidores/ (last accessed December 3, 2023).

⁹ ISIS NAVARRO REYES, the defendant, posts primarily in Spanish. To the extent posts or messages were originally in the Spanish language, I have been assisted in reviewing this content by an investigator with the United States Attorney's Office for the Southern District of New York who is fluent in the Spanish language. The Spanish language translations included in this Complaint are drafts and subject to change.



h. On or about April 15, 2023, the call number assigned to the Cellphone sent a message via an encrypted messaging application to Victim-1 in which the sender identifies herself as "Isis Navarro."

i. On or about October 11, 2023, REYES posted a video pertaining to Ozempic. In this video, REYES demonstrates how to inject oneself with the medication and shares her experience using the drug. Toward the end of the video, REYES instructs viewers to contact her on an encrypted messaging application via the call number assigned to the Cellphone if they are interested in having her obtain Ozempic for them. A screenshot from this TikTok post is below.



j. On or about October 12, 2023, REYES posted a video in which she can be seen placing boxes of Axcion into shipping envelopes. A screenshot from this TikTok post is below.



k. On or about November 28, 2023, REYES posted a video about Mesofrance. In the video, REYES instructs viewers where the injections can be injected and that the drugs are used for burning fat. A screenshot from this TikTok post is below.



1. In or about November 2023, the United States Department of Homeland Security, Homeland Security Investigations provided a photo from a 2019 United States Visa application associated with the name "Isis Navarro Reyes" (the "Visa Application"). The photo from the Visa Application closely resembles REYES.

VICTIM-1 DEVELOPS MULTIPLE MYCOBACTERIUM ABSCESSUS AFTER USING MESOTHERAPY PURCHASED FROM REYES

9. Based on my participation in this investigation, my conversations with law enforcement special agents and officers, my review of electronic devices, my conversations with witnesses, my review of communications, my review of documents and records, my review of shipping records, and my review of physical evidence, I know, among other things, the following:

a. In or about February 2023, Victim-1 purchased 30 injections of Mesofrance from ISIS NAVARRO REYES, the defendant. REYES mailed the Mesofrance to Victim-1's residence, which is in White Plains, New York. REYES did not ask Victim-1 to provide a prescription and Victim-1 did not provide one.

b. Between in or about February 2023 and in or about June 2023, Victim-1 self-administered 28 injections. In an audio message that she recorded and transmitted through an encrypted messaging application, REYES provided Victim-1 with instructions on how to administer the drug; REYES told Victim-1, among other things, to inject herself every three days.

c. All of the label and labeling of the vials that contained the Mesofrance that Victim-1 purchased from REYES were in a language other than English.

d. On or about July 13, 2023, Victim-1 began developing lesions from administering the Mesofrance. Victim-1 sent Spanish-language messages to REYES about her injuries and sent photos.

e. In or about October 2023, Victim-1's physician diagnosed her with a mycobacterium abscessus infection, which is frequently caused by the contamination of medications, medical products, and medical devices with the mycobacterium abscessus bacterium.

f. In or about November 2023, the New York Department of Health tested one of the vials of Mesofrance that Victim-1 purchased from REYES. The substance tested positive for mycobacterium abscessus, a species of rapidly growing, multidrug-resistant, nontuberculous mycobacteria.

U.S. CUSTOMS AND BORDER PROTECTION SEIZES A PACKAGE CONTAINING FOREIGN WEIGHT LOSS DRUGS AND NOTIFIES REYES OF THE SEIZURE

10. Based on my participation in this investigation, my conversations with law enforcement special agents and officers, my review of electronic devices, and my review of documents and records, I know, among other things, the following:

a. On or about January 27, 2023, agents with U.S. Customs and Border Protection ("CBP") seized a parcel sent from Mexico with "Beraly Navarro" listed as the recipient (the "Intercepted Package").¹⁰

b. The Intercepted Package contained weight loss drugs, including dozens of boxes of Axcion. A photo depicting some of the contents of the Intercepted Package is below:

¹⁰ Based on my participation in this investigation, I know that ISIS NAVARRO REYES, the defendant, also used the name "Beraly." For example, REYES had a TikTok account with a handle that used the name "Beraly" and, in addition, the email address listed in the subscriber information for this TikTok account also used the name "Beraly."



c. On or about March 22, 2023, CBP sent ISIS NAVARRO REYES, the defendant¹¹, a letter (the "CBP Letter") informing her that, on or about January 27, 2023, agents seized the Intercepted Package, that it contained Phentermine¹² and D-norpseudoephedrine, and that importation of these substances into the United States violated provisions of the United States Code prohibiting the importation of Schedule IV controlled substances and adulterated or misbranded products.

VICTIM-2 PURCHASES FOREIGN DIET MEDICATION NOT APPROVED BY THE FDA FROM REYES

11. Based on my participation in this investigation, my conversations with law enforcement special agents and officers, my review of communications, my review of documents and records, my review of shipping records, and my review of physical evidence, I know, among other things, the following:

¹¹ The letter is addressed to "Beraly Navarro." As explained in footnote 8, *supra*, based on my participation in this investigation, I understand that ISIS NAVARRO REYES, the defendant, also went by the name "Beraly Navarro."

¹² Based on my participation in this investigation, I know that Axcion boxes have the word "fentermina," which based on my consultation with individuals fluent in the Spanish language, means "phentermine."

a. In or about June 2023, an individual ("Victim-2") contacted ISIS NAVARRO REYES, the defendant, via an encrypted messaging application at the number assigned to the Cellphone to inquire about purchasing weight-loss drugs. Victim-2 asked REYES to sell her Axcion.

b. On or about July 10, 2023, Victim-2 sent REYES money to purchase Axcion. REYES did not ask Victim-2 to provide a prescription and Victim-2 did not provide one.

c. On or about July 12, 2023, REYES mailed Victim-2 a substance labeled as Axcion from Center Moriches, New York to Victim-2's residence in North Brunswick, New Jersey via United States Postal Service ground advantage. Based on my conversations with inspectors from United States Postal Service ("USPS"), I understand that the package was transported via motor vehicle and that, based on the path USPS typically takes to transport packages by motor vehicle from this original to this destination, the motor vehicle passed through the Southern District of New York. A photo of the Axcion that REYES mailed Victim-2 is below:



d. All of the label and labeling of the substance labeled as Axcion that Victim-2 purchased from REYES was in the Spanish language.

REYES SOLD VICTIM-2 AXCION AFTER RECEIVING THE CBP LETTER

12. Based on my participation in this investigation, my conversations with law enforcement special agents and officers, my review of communications, my review of documents and records, and my review of physical and electronic evidence I know, among other things, the following:

a. On or about February 15, 2024, law enforcement officers and special agents executed a search warrant for two residences associated with ISIS NAVARRO REYES, the defendant.

b. Law enforcement officers and special agents seized, among other things, multiple boxes of different weight loss drugs, syringes, antibiotics, and multiple electronic devices, including an iPhone that REYES identified as belonging to her ("REYES's Phone").

c. Law enforcement officers and special agents searched REYES's Phone pursuant to the search warrant. The search of REYES's Phone revealed, among other things, that on or about March 4, 2023, REYES took a photo of the first page of the CBP Letter.

<u>REYES SELLS MISBRANDED OZEMPIC TO AN UNDERCOVER LAW</u> <u>ENFORCEMENT OFFICER</u>

13. Based on my participation in this investigation, my conversations with law enforcement special agents and officers, my review of communications, my review of documents and records, my review of shipping records, and my review of physical evidence, I know, among other things, the following:

a. In or about December 2023, a law enforcement officer acting in an undercover capacity (the "UC") began messaging ISIS NAVARRO REYES, the defendant, via an encrypted messaging application at the call number assigned to the Cellphone.

b. From in or about December 2023 through in or about January 2024, the UC and REYES exchanged several messages via an encrypted messaging application concerning REYES's supply of Ozempic and the UC's interest in purchasing Ozempic from REYES.

c. On or about January 7, 2024, pursuant to instructions from REYES, the UC sent \$375 to a Zelle account in the name of "Isis Reyes Navarro." REYES did not ask the UC to provide a prescription and the UC did not provide one.

d. On or about January 9, 2024, REYES dropped off a package intended for the UC at a post office located in or around Shirley, New York.

e. On or about January 12, 2024, law enforcement received a package addressed to the UC from REYES (the "UC Parcel") in Manhattan. The UC Parcel contained a box containing what purported to be Ozempic.¹³ Photos of packaging containing the purported Ozempic that REYES mailed the UC are below:

¹³ To date, there is no evidence that the Ozempic that REYES sold the UC is not genuine.



f. All of the label and labeling accompanying the Ozempic in the UC Parcel was in the Spanish language.

U.S. CUSTOMS AND BORDER PROTECTION INTERCEPTS AN INTERNATIONAL PARCEL INTENDED FOR REYES AND CONTAINING PURPORTED OZEMPIC

14. Based on my participation in this investigation, my conversations with other law enforcement special agents and officers, and my review of documents and records, I know that on or about January 30, 2024, U.S. Customs and Border Protection officers located in or around Miami, Florida intercepted a parcel that was shipped from an individual in El Salvador ("CC-1") and addressed to ISIS NAVARRO REYES, the defendant (the "Salvadorian Parcel").

15. The Salvadorian Parcel contained, among other things, five boxes of purported Ozempic.¹⁴ All of the label and labeling accompanying the purported Ozempic was in the Spanish language.

¹⁴ Law enforcement has not yet determined whether the purported Ozempic is counterfeit.

REYES ACKNOWLEDGES SELLING WEIGHT LOSS DRUGS ON TIKTOK

16. Based on my participation in this investigation and my conversations with other law enforcement special agents and officers, I know that on or about February 15, 2024, ISIS NAVARRO REYES, the defendant, participated in a consensual, non-custodial interview with law enforcement special agents and officers (the "Interview"). During the Interview, REYES stated, in sum and substance, among other things, the following:

a. She had been selling products on TikTok for one year;

b. She has sold Ozempic five times in the past;

c. She sends money to another individual, who ships Ozempic to her from El

Salvador;

d. She purchased Mesofrance on Facebook;

e. She stopped selling Mesofrance because she knew it was illegal and did not want any problems; and

f. She knew that it was illegal to sell medication to others unless she was a doctor, nurse practitioner, or member of the medical field.

WHEREFORE, I respectfully request that a warrant be issued for the arrest of ISIS NAVARRO REYES, the defendant, and that she be arrested, and imprisoned or bailed, as the case may be.

JASON FERNANDES SPECIAL AGENT U.S. FOOD AND DRUG ADMINISTRATION – OFFICE OF CRIMINAL INVESTIGATIONS

Sworn to before me this ²⁹day of April 2024.

THE HONORABLE BARBARA MOSES United States Magistrate Judge Southern District of New York