UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA,

Plaintiff,

v.

Flor Sileing CHAM,

Defendant.

Mag. Case No. **2:23-mj-08652-LR**

COMPLAINT FOR VIOLATION OF

21, U.S.C., Sections 331(a) and 333(a)(1)– Distribution of Misbranded Drugs in Interstate Commerce

The undersigned complainant being duly sworn states:

On or about July 2, 2019, defendant Flor Sileing CHAM, within the Southern District of California, did introduce and cause to be introduced in interstate commerce a drug, to wit, two (2) boxes of one hundred (100) units apiece of "Xeomeen" powder containing botulinum toxin, which was misbranded in violation of Title 21, United States Code, Sections 331(a) and 352(f)(1).

All in violation of Title 21, United States Code, Sections 331(c) and 333(a)(1).

And the complainant states that this complaint is based on the attached statement of facts, which is incorporated herein by reference.

KELLEN A ENZ Digitally signed by KELLEN A ENZ Date: 2023.08.23 17:25:05 -07'00'

Kellen Enz
Special Agent
U.S. Department of Homeland Security
Homeland Security Investigations

Sworn and attested to under oath by telephone, in accordance with Federal Rule of Criminal Procedure 4.1, on August 24, 2023.

HON. LUPE RODRIGUEZ, JR.
UNITED STATES MAGISTRATE JUDGE

STATEMENT OF FACTS

In violation of the aforementioned statutes, the following acts were committed in the Southern District of California and elsewhere:

Background: The Food, Drug and Cosmetic Act

The Food, Drug and Cosmetic Act (FDCA) governs the manner in which drugs can lawfully be marketed and sold in the United States. Drugs that are labeled and distributed outside of this framework violate the FDCA, and such violations can be punished criminally.

The FDCA defines "drugs" as "articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals," and includes "articles intended for use as a component of" a drug. 21 USC § 321(g)(1).

The FDCA states that a drug is deemed to be misbranded if its labeling is false or misleading in any particular. 21 U.S.C. § 352(a). The term "labeling" 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). A drug is deemed to be misbranded unless its labeling bears adequate directions for use. 21 U.S.C. § 352 (f)(1). Unless subject to an exemption, a drug must bear adequate directions for use under which a layperson can administer the drug safely for the purposes for which it is intended. 21 C.F.R. § 201.5. A drug is deemed to be misbranded if any word, statement, or other information required by the FDCA is not prominently placed on the drug in the English language. 21 CFR § 201.15(c)(1). The term "interstate commerce" is defined as "commerce between any State or Territory and any place outside thereof." 21 USC § 312(b)(1).

Under the FDCA, a "new drug" is a drug not generally recognized as "safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling," or any drug that is so recognized "but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions." 21 USC § 312((p)(1). Pursuant to Section 355(a) of Title 21, "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subdivision (b) or (j) is effective with respect to such drug," or unless the drug is the subject of an approved investigational new drug application. The approval process is specific to each manufacturer and each product. 21 CFR § 314.50. Therefore, drugs that are manufactured and distributed in other countries or manufactured in this country for distribution in other countries are not approved pursuant to this statutory framework.

The FDCA prohibits the introduction, or causing the introduction or delivery for introduction, into interstate commerce of any drug that has not been approved pursuant to the process set forth in Section 355. 21 U.S.C. § 331(d).

Xeomeen is the Mexican trade name for a prescription drug (active ingredient botulinum toxin) trademarked by MERZ Pharmaceuticals North America. Xeomeen is not approved for sale or distribution in the United States. Instead, a different prescription drug (trade name Xeomin; active ingredient: botulinum toxin) is approved by the FDA for sale and distribution within the United States.

Transaction Involving Flor Sileing CHAM

On or about November 28, 2018, Flor Sileing CHAM posted an ad to the online marketplace OfferUp advertising the sale of Xeomeen, an unapproved foreign botulinum toxin used to provide cosmetic treatments. CHAM agreed to sell $380 worth of Xeomeen and "filler" to Person 1 using OfferUp's online chat feature, and sent Person 1 CHAM's personal telephone number. In the online chat, CHAM suggested that Person 1 watch videos on YouTube explaining how to inject Xeomeen, because (CHAM said) "if you don't put [it] in the right place it might make you[r] muscle drop." CHAM offered to apply the product herself.

January 25, 2019 Sale

On January 25, 2019, CHAM met with Person 1 at a restaurant in Calexico, California and sold Person 1 one (1) box of one hundred (100) units of Xeomeen botulinum toxin powder, along with a syringe containing what CHAM described as filler. The Xeomeen was contained in a bottle and box labeled in Spanish and did not contain English-language directions for use.

According to border crossing records, CHAM had entered the United States at approximately 8:34 p.m. the prior evening. CHAM told Person 1 that she applies products like these for a living and offered to teach Person 1 how to do it him or herself. CHAM cautioned, however, that such training would not be "legal" and she could not supply any "papers" in connection with the training because she was not a licensed instructor herself.

March 6, 2019 Sale

On March 3, 2019, CHAM agreed by text message to sell Person 1 four (4) boxes of one hundred (100) units of Xeomeen, along with five (5) sets of fifty (50) units of cosmetic fillers; four (4) sets of one hundred (100) units of cosmetic fillers; four (4) packages of elastin; five (5) packages of collagen; and one hundred and fifty (150) 100mg pills represented to be Viagra; all in exchange for $4,000. CHAM instructed

Person 1 to pay for this merchandise by wire transfer and agreed to ship the merchandise to a P.O. Box that Person 1 identified in Arizona.

Person 1 paid $4,000 to CHAM via money transfer on March 6, 2019. Agents observed CHAM retrieve part of the funds at one location and drive south to Mexico via the Calexico West Port of Entry. Shortly thereafter, CHAM returned to the United States via the Calexico West Port of Entry and traveled to a second location to pick up the rest of the funds from Person 1. CHAM then went to a U.S. Post Office in Calexico, California and labeled, sealed, paid for and mailed a single express package.

The package arrived bearing CHAM's name on the return address label and containing the pharmaceutical products ordered by Person 1. Preliminary analysis by the U.S. Food and Drug Administration indicated that the "Viagra" was counterfeit, based on inconsistencies with its labeling and the fact that it was missing a lot or batch code. The laboratory also determined that the "Viagra" tablets contained only about 3% of the amount of sildenafil ordinarily present in genuine Viagra. The tablets also contained dipyrone—an active ingredient not present in genuine Viagra, which is banned in the United States due to its risk of severe side effects. The Xeomeen was contained in a bottle and box labeled in Spanish and did not contain English-language directions for use.

July 2, 2019 Sale

On July 1, 2019, CHAM agreed by text message to sell a third bundle of merchandise to Person 1 and Person 2 in exchange for $3,245. Altogether, CHAM agreed to sell two (2) boxes of one hundred (100) units of Xeomeen; ten (10) baggies of pills CHAM represented to be "female Viagra"; six (6) syringes of cosmetic filler; nine (9) syringes of collagen; and ninety (90) 100mg pills represented to be Viagra. CHAM instructed Person 1 to make an advance payment of $2,035 to her bank account and sent her checking account number to Person 1 to facilitate the transfer.

CHAM met with Person 1 and Person 2 on July 2, 2019, at a restaurant in Banning, California. CHAM explained that the Xeomeen was so expensive because "you have to have a license" to buy it. She said that while she did not have a license, she had a doctor who works with her, whose papers she used to obtain the product. CHAM explained that one of the services she provided was drawing a customer's blood and then putting it back into the customer's face. CHAM claimed that she did not need to perform such a procedure at a clinic, saying "It doesn't have to be at a sterile place." She added that she doesn't "do the surgeries, but I do everything else."

Person 2 asked CHAM whether or not it was "a big deal" for her to bring these products across the border from Mexico. CHAM explained that "if you are not licensed," you can "get in trouble" or "get cited . . . unless you can say they're for your personal use. But you're not gonna use ten toxins." CHAM agreed with Person 2 when she said, "Ohhh, so you have to break it up," meaning that CHAM would bring smaller quantities of the merchandise across the border in installments to avoid suspicion. Border crossing records indicate that CHAM had entered the United States via the Calexico West Port of Entry at approximately 8:13 a.m. on July 2, 2019, prior to her meeting with Person 1 and Person 2.

When the merchandise purchased from CHAM on July 2, 2019, was analyzed by the FDA laboratory, it again confirmed that the Xeomeen contained the neurotoxin botulinum toxin. The tablets represented to be "Viagra" contained only 48% of the active ingredient (sildenafil) present in legitimate Viagra tablets, indicating that they were counterfeit. The unmarked "female Viagra" pills contained a much smaller amount of sildenafil. Once again, the Xeomeen was contained in a bottle and box labeled in Spanish and did not contain English-language directions for use.