UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. FLOR SILEING CHAM, Defendant.	Case No. 23-cr-1926-JLS I N F O R M A T I O N Title 21, U.S.C., Sections 331(a) and 333(a)(1)- Introduction of Misbranded Drugs in Interstate Commerce

The Acting United States Attorney charges:

INTRODUCTORY ALLEGATIONS

Xeomin® and Xeomeen

1. Botulinum Toxin Type A was a highly potent toxin which can cause the disease botulism when present in human beings in a sufficient amount.

2. The United States Food and Drug Administration (FDA) approved a biological products license for Xeomin®, the brand name of a drug derived from Botulinum Toxin Type A and manufactured by MERZ Pharmaceuticals North America. The FDA approved a biological products license for Botox®, the brand name of a drug derived from Botulinum Toxin Type A and manufactured by Allergan, Inc. The FDA-approved

NWP:San Diego
9/20/23

licenses limited them to use pursuant to a prescription by a licensed practitioner.

3. Injectable botulinum toxins used in these ways also met the definition of a "drug" under the FDCA, and any such products that were not the subject of an approved biological license would require approval. Such products also met the definition of a prescription drug under the FDCA.

4. Xeomeen was the trade name for a prescription drug (active ingredient: botulinum toxin) that was marketed in Mexico and elsewhere by MERZ Pharmaceuticals North America. Although a different product, trade name Xeomin, was approved by the FDA for sale and distribution in the United States, Xeomeen was not approved by the FDA for sale or distribution in the United States.

COUNT 1

Introduction in Interstate Commerce of a Misbranded Drug

21 U.S.C. §§ 331(a) & 333(a)(1)

(Misdemeanor)

5. The allegations set forth in the foregoing paragraphs are realleged and incorporated by reference as if fully set forth herein.

6. On or about July 2, 2019, defendant FLOR SILEING CHAM, within the Southern District of California, and elsewhere, 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 drugs were misbranded within the meaning of Title 21, United States Code, Section 352(a) and (f), in that their labeling was false and misleading and lacked adequate directions for use.

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

DATED: September 21, 2023

ANDREW R. HADEN
Acting United States Attorney

By: NICHOLAS W. PILCHAK
Assistant U.S. Attorney