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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

UNITED STATES OF AMERICA	**)**	
	)	**Case No.**
v.	**)**	
	)	**21 U.S.C. §§ 331(c),**
NABIL CHAGRI	**)**	**333(a)(2), 352(a)**

INFORMATION

The United States Attorney for the Northern District of Alabama, charges that, at all times relevant to this Information, in the Northern District of Alabama:

GENERAL ALLEGATIONS

I. THE FEDERAL FOOD, DRUG AND COSMETIC ACT ("FDCA")

1. The United States Food and Drug Administration ("FDA") was the federal agency responsible for protecting the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA"), by ensuring that drugs intended for use in humans were safe and effective for their intended uses, and by ensuring that the labeling of such drugs bore true and accurate information.

2. The FDCA defines a "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," and "articles

(other than food) intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(B) and (C).

3. Under the FDCA, "prescription drugs" are drugs that, because of their toxicity and other potential for harmful effects, or the collateral measures necessary to their use, are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(l)(A). A drug is also a prescription drug if the FDA requires it to be administered under the supervision of a practitioner licensed by law to administer such drug as a condition of the FDA's approval of the drug. 21 U.S.C. § 353(b)(l)(B).

4. 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," in turn, 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).

5. Under the FDCA, a drug is deemed to be "misbranded" if its labeling is false or misleading in any particular. 21 U.S.C. § 352(a).

6. Under the FDCA, it was illegal to receive in interstate commerce a misbranded drug, and to deliver or proffer delivery of such drug for pay or otherwise. 21 U.S.C. § 331(c).

7. 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).

II. SILDENAFIL CITRATE

8. Viagra is a branded, prescription drug product containing the active pharmaceutical ingredient sildenafil citrate ("sildenafil"). Viagra is FDA-approved for the treatment of erectile dysfunction.

9. Other products containing sildenafil that are intended to treat a disease in man and/or affect the structure or function of the body of man are "drugs" within the meaning of the FDCA. 21 U.S.C. § 321(g)(1)(B) and (C).

10. Due to toxicity and other potential for harmful effects, and the collateral measures necessary to use, drugs containing sildenafil are also "prescription drugs" within the meaning of 21 U.S.C. § 353(b)(1), and therefore are not safe for use except under the supervision of a practitioner licensed by law to administer them.

11. In addition to various side effects, sildenafil-containing drugs can be particularly harmful to persons taking medications containing nitrates, such as nitroglycerin, because sildenafil can interact with the nitrates and lower blood

pressure to dangerous levels. Men with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates.

III. PRODUCTS RECEIVED AND SOLD BY CHAGRI

12. From April 14, 2015, to March 22, 2016, **CHAGRI** received in Alabama numerous "male enhancement" products shipped from China, including "Zhen Gong Fu."

13. **CHAGRI** would then deliver and sell the male enhancement products to various gas stations and wholesale distributors (who would, in turn, sell the products to retail outlets such as gas stations or convenience stores), for sale to final consumers.

14. Laboratory analysis of the Zhen Gong Fu revealed the presence of sildenafil, which was not listed as an ingredient on the labeling of Zhen Gong Fu.

15. The labeling for Zhen Gong Fu included the following false and misleading statement:

> This product is the substitute for American Viagra successfully developed by Hong Kong Hongwei Biological Research Center in 2007 after years of clinical trials and the best challenger of Xilishi. It can quickly elongate, thicken and enlarge the penis to effectively rescue you from short sexual intercourse time, take good therapeutic effect on preventing impotence and premature ejaculation, ... It does not affect heart diseases [sic], hypertension or diabetes. It is of good therapeutic effect on prostate disease. Alcohol does not interfere with its therapeutic effect.

COUNT ONE
[21 U.S.C. §§ 331(c), 333(a)(2), 352(a)]

16. On or about March 22, 2016, in the Northern District of Alabama and elsewhere, the defendant,

NABIL CHAGRI,

with intent to defraud and mislead, received in interstate commerce drugs, namely Zhen Gong Fu, a "male enhancement product" containing the undeclared ingredient sildenafil citrate, that were misbranded within the meaning of Title 21, United States Code, Section 352(a), in that their labeling was false or misleading in a particular, and delivered or proffered delivery of such misbranded drugs for pay or otherwise.

All in violation of Title 21 United States Code, Sections 33l(c), 333(a)(2) and 352(a).

JOYCE WHITE VANCE
United States Attorney

/s/_____
CHINELO DIKÉ-MINOR
Assistant United States Attorney