UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

BILL OF INFORMATION FOR INTRODUCTION OF UNAPPROVED NEW DRUG INTO INTERSTATE COMMERCE

UNITED STATES OF AMERICA	*	**CRIMINAL NO.** 16-124
v.	*	**SECTION:** SECT. N MAG. 5
GUY LYMAN	*	**VIOLATION: 21 U.S.C. § 333(a)(1)**
	*	

* * *

The United States Attorney charges that:

COUNT 1
(Introduction of unapproved new drug into interstate commerce)

A. AT ALL MATERIAL TIMES HEREIN:

1. **GUY LYMAN** ("**LYMAN**") was a resident of New Orleans, Louisiana, and the owner and operator of Flor Nutraceuticals, LLC ("Flor"), a Texas corporation with its principal place of business in New Orleans, Louisiana. Flor sold Herpaflor, a product purported to be a Herpes treatment. Herpaflor was marketed to the public through herpaflor.com and through a Canadian company that operated a website at herpaflor.ca.

2. Under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. ("the Act"), a product is a drug if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. § 321(g)(1)(B). Because a product's intended use determines whether it is a drug, a dietary supplement may also meet the Act's drug definition if it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. See 21 U.S.C. § 321(ff).

3. The intended use of a product may be determined from any relevant source, including statements of persons responsible for distributing the product, labeling, and other promotional materials. See 21 C.F.R. § 201.128. The Act defines labeling 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).

4. **LYMAN** marketed and sold Herpaflor as a liquid, as tablets, and in various combinations. The Herpaflor products are drugs within the meaning of the Act because they are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." 21 U.S.C. § 321(g)(1)(B).

5. On April 28, 2011, the Food and Drug Administration ("FDA") and the Federal Trade Commission ("FTC") sent a joint warning letter (the "Warning Letter") to **LYMAN** concerning the Herpaflor products marketed at herpaflor.com.

6. The Warning Letter stated that statements on Flor's websites established that the Herpaflor products were drugs because they were "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body of man." The letter further stated that "these products are 'new drugs,' as defined [in the Act], because they are not generally recognized as safe and effective for their labeled uses" and "a new

drug may not be introduced into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for it."

7. The Warning Letter quoted statements on herpaflor.com that established that the Herpaflor products were drugs, because they were intended for use in the cure, mitigation, treatment, or prevention of disease.

8. On May 6, 2011, **LYMAN** sent a letter on behalf of Flor to FDA acknowledging receipt of the warning letter and stating that he is providing "information regarding the corrective actions undertaken to date, as well as our planned corrections" so that they can be in "full compliance with all federal laws and regulations." The letter stated that "we have stopped the marketing of Herpaflor products and have removed the products and associated labeling statements from the company's website." The letter further stated that they had retained a "professional regulatory compliance advisor" and "do not intend to sell or reintroduce any of the products until such time as, if ever, the company can verify, with the support from its advisors, that they are in full compliance with all applicable federal laws and regulations."

9. Despite **LYMAN**'s statements in response to the Warning Letter, **LYMAN** continued to ship Herpaflor in interstate commerce. Each Herpaflor product was a "new drug" as defined by 21 U.S.C. § 321(p)(1), because it was not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling. Herpaflor lacked substantial evidence of safety and effectiveness. There were no published adequate and well-controlled investigations demonstrating that the drug was generally recognized as safe and effective for any use and, therefore, qualified experts cannot come to a consensus of opinion concerning the effectiveness of the product.

10. Herpaflor products were not the subject of an approved new drug application or abbreviated new drug application, nor an effective investigational new drug application. Neither **LYMAN** nor Flor had such approvals on file from FDA. As a result, each Herpaflor product was an unapproved new drug.

11. A Canadian company that sold Herpaflor obtained from **LYMAN** expressly marketed Herpaflor products as a herpes treatment making the following claims, among others:

"Only Herpaflör contains all of these 16 proven herpes-killing compounds."

"Works great for attacking the Herpes Virus on contact and sends it back into remission."

"Herpaflor is an all natural, formula used by those who suffer from the herpes virus and is guaranteed to work 100%."

13. From issuance of the Warning Letter to in or about November 2015, **LYMAN** caused the shipment of Herpaflor in interstate commerce directly from the Eastern District of Louisiana to consumer purchasers. Further, **LYMAN** caused Herpaflor to be shipped from Louisiana to British Columbia, Canada, to be sold by a Canadian company associated with **LYMAN**. The Canadian company stated on its website that it shipped Herpaflor into other countries, including the United States, and it did so. On or about July 10, 2015, the Canadian company caused a Herpaflor Combo Pack to be sent via Canada Post and U.S. mail to Washington, D.C. from British Columbia, Canada.

14. In furtherance of the above-described scheme, on or about November 6, 2015, **LYMAN** caused a Herpaflor Combo Pack (consisting of one bottle of Herpaflor Outbreak

Response Tablets and one bottle of Herpaflor Topical Outbreak Formula) to be shipped from New Orleans, Louisiana, to Washington, D.C. via U.S. Mail.

All in violation of Title 21, United States Code, Sections 355, 331(d) and 333(a)(1).

KENNETH ALLEN POLITE, JR.
UNITED STATES ATTORNEY

Ann F. Entwistle
Trial Attorney
U.S. Department of Justice
Consumer Protection Branch

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