UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

NO.: 5:24-CR-283-BO

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| UNITED STATES OF AMERICA | ) | |
| | ) | |
| v. | ) | **CRIMINAL INFORMATION** |
| | ) | |
| LEONDAS PAUL III | ) | |

The United States Attorney charges that at all relevant times:

Introduction

1. Defendant Leondas Paul III (Paul) was an individual living in North Carolina who owned and operated the Internet-based business LP3 Health.

2. Paul used the LP3 Health website, www.lp3health.com, to advertise and sell a variety of FDA-regulated products to customers nationwide.

3. One of the products sold by Paul on the LP3 Health website was Clenbuterol, a drug that was not approved by the FDA for any human use.[1]

4. Clenbuterol was marketed on Paul's LP3 Health website as a "powerful and effective weight loss supplement that helps to burn fat and increase muscle mass." The website also stated that Clenbuterol would boost metabolism and suppress appetite and was described as "easy to use" and "convenient" for "those looking to lose weight quickly and effectively."

[1] The FDA has approved other drugs containing Clenbuterol for veterinary uses.

Manufacturing

5. In addition to operating LP3 Health, Paul was also employed as a graphic designer at Copy Proz, a printing/copying business in Rockingham, North Carolina. Paul used Copy Proz to operate his e-commerce website, including to process orders, create and print labels for products, and prepare orders for shipment.

6. Paul used the United States Postal Service (USPS) to ship his products to customers across the country, including to individuals residing in the Eastern District of North Carolina. Paul also shipped products through the Eastern District of North Carolina to out-of-state customers.

7. Paul's employer at Copy Proz owned a second business, Madison James Research (MJR), which operated from the office suite next to Copy Proz. This suite was used to manufacture a variety of FDA-regulated products sold on the MJR website, www.madisonjamesresearchchems.com. MJR supplied Paul with inventory for his website, while Paul designed and created the labels used in the products' packaging. All of the products sold on the LP3 Health website were mixed, bottled, labeled, and packaged at the MJR office suite.

8. The MJR officers where the products, including LP3 Health's Clenbuterol, were manufactured were not registered with the FDA as an establishment engaged in the manufacturing, preparation, propagation, compounding, or processing of drugs.

FDA Regulatory Framework

9. The United States Food and Drug Administration (FDA) was the federal agency charged with the responsibility of protecting the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., (FDCA). Among other responsibilities, the FDA enforced laws and regulations regarding the manufacture and distribution of drugs, including prescription drugs, shipped or received in interstate commerce, as well as the labeling of such drugs.

10. Under the FDCA, the term "drug" included any article and component of any article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," or an "article (other than food) intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(B), (C) and (D).

11. Under the FDCA, every person who engaged in the manufacture, preparation, propagation, compounding, or processing of a drug, was required to immediately register with the FDA. 21 U.S.C. § 360(b)(1) & (c).

12. The terms "manufacture, preparation, propagation, compounding, or processing" included repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user. 21 U.S.C. § 360(a)(1).

13. The term "label" was 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, was 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).

14. The FDCA prohibited the introduction or delivery for introduction into interstate commerce, or the causing thereof, of any drug that is misbranded. 21 U.S.C. § 331(a). Under the FDCA, a drug was misbranded if, among other things:

a. it was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered with FDA. 21 U.S.C. § 352(o); or

b. it is in package form and does not bear a label containing the name and place of business of the manufacturer, packer, or distributor. 21 U.S.C. § 352(b) and 21 C.F.R. § 201.1(i); or

c. its labeling fails to bear adequate directions for use, under which a layman can use a drug safely for the purposes for which it was intended. 21 U.S.C. § 352(f)(1) and 21 C.F.R. § 201.5; or

d. its labeling is false or misleading in any particular. 21 U.S.C. § 352(a)(1).

Website Sales

15. Beginning in or around October 2020 and continuing through September 2023, Paul used the LP3 Health website to offer a variety of products for sale that fall under the FDCA definition of "drug," including Clenbuterol.

16. On or about August 9, 2023, an order was placed through the LP3 Health website for "Clenbuterol 250mcg x 30ml tincture." On or about August 10, 2023, the product was shipped via USPS from Rockingham, North Carolina, processed through a USPS distribution center in Fayetteville, North Carolina, and mailed in interstate commerce to an address in Miami, Florida.

17. The "Clenbuterol 250mcg x 30ml tincture" purchased from the LP3 Health website was received by the customer on or about August 18, 2023. The Clenbuterol was in a small glass bottle, with a label branding the product as "MJR Laboratories." The labeled stated that the bottle contained "30ML" of liquid Clenbuterol, with a dosing "Amount: 1ML." The label did not include the name and place of business of the manufacturer, packer, or distributor.

18. Despite being marketed on the LP3 Health website as a "weight loss supplement" for "those looking to lose weight quickly and effectively," the labeling affixed to the Clenbuterol bottle read: "This is not a dietary supplement. For research purposes only" and "For research use only. Not for human consumption." None of the labeling for the Clenbuterol contained any directions for use.

## THE CHARGE

19. The preceding paragraphs of this Criminal Information are re-alleged and incorporated herein by reference as factual allegations.

20. On or about August 10, 2023, in the Eastern District of North Carolina and elsewhere, the defendant, LEONDAS PAUL III, with the intent to defraud and

mislead, did deliver for introduction, and caused the introduction and delivery for introduction, into interstate commerce, a drug, namely Clenbuterol, that was misbranded in at least one of the following ways:

a. The labeling was false or misleading in any particular. 21 U.S.C. § 352(a)(1);

b. The labeling failed to bear adequate directions for use. 21 U.S.C. § 352(f)(1);

c. The drugs were in package form and did not bear a label containing the name and place of business, including the city and state and country, of the manufacturer, packer, and distributor. 21 U.S.C. §352(b); 21 C.F.R. § 201.1(i); and

d. The drug was not manufactured, prepared, propagated, compounded, and processed in an establishment duly registered with the FDA as required by 21 U.S.C. § 360. 21 U.S.C. §352(o).

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).

## ***FORFEITURE NOTICE***

Notice is hereby given that all right, title and interest in the property described herein is subject to forfeiture.

Upon conviction of the offense charged in Count One, the defendant shall forfeit to the United States, pursuant to 21 U.S.C. § 334, and 28 U.S.C. § 2461, any and all drugs that were misbranded when introduced into or while in interstate

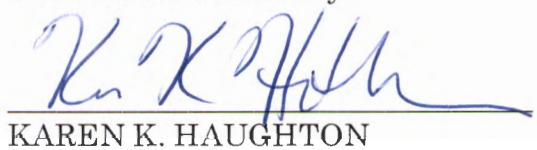
commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of 21 U.S.C. §§ 331, 352, or 355, have been introduced into interstate commerce, including but not limited to the following:

Forfeiture Money Judgment:

a) A sum of money representing the value of the adulterated or misbranded drugs involved in the offense(s) charged herein against LEONDAS PAUL III, in the amount of at least $12,600.00.

If any of the above-described forfeitable property, as a result of any act or omission of a defendant: cannot be located upon the exercise of due diligence; has been transferred or sold to, or deposited with, a third party; has been placed beyond the jurisdiction of the court; has been substantially diminished in value; or has been commingled with other property which cannot be divided without difficulty; it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of said defendant up to the value of the forfeitable property described above.

MICHAEL F. EASLEY, JR
United States Attorney

BY: 
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