UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NORTH CAROLINA WESTERN DIVISION

NO.: 5:25-CR-34-FL

UNITED STATES OF AMERICA) v.) ADAM SCOTT MELAND)

CRIMINAL INFORMATION

FILED

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The United States Attorney charges that at all relevant times:

Regulatory Framework

1. 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.

2. The FDCA defined a "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," "articles (other than food) intended to affect the structure or any function of the body of man," and "articles intended for use as a component of" a drug. 21 U.S.C. § 321(g)(1)(B) and (C) and (D).

3. Under the FDCA, upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug, every person was required to immediately register with the FDA such person's name, places of business, all establishments owned or operated by such person, the unique facility identifier of each establishment, and a point of contact email address. 21 U.S.C. § 360(b)(1) & (c).

4. 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).

5. The FDCA prohibited, among other things, the introduction or delivery for introduction into interstate commerce, or the causing thereof, of any drug that is misbranded.

6. Under the FDCA, a drug was misbranded if, among other things, it was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered with FDA, or if it was not included in a list of drugs manufactured by a facility registered with the FDA. 21 U.S.C. § 352(o).

Website Sales

7. In or around 2018, the e-commerce website <u>www.madisonjamesresearchchems.com</u> ("MJR website") was launched by coconspirator Mark James Meland out of an office in Rockingham, North Carolina. The MRJ website offered a variety of FDA-regulated products for sale.

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8. Starting in or around September 2021, and continuing through September 2023, ADAM SCOTT MELAND (MELAND) aided and abetted his brother, Mark James Meland, in the business of manufacturing and distributing drugs to customers in the Eastern District of North Carolina and elsewhere through the online sales of products from the MJR website.

9. Many products sold on the MJR website fell under the FDCA definition of "drug," including, "Tadalafil/Sildenafil Capsules," and "GLP-1 Semaglutide."

10. Tadalafil and Sildenafil were active pharmaceutical ingredients ("APIs") in FDA-approved drugs used for the treatment of erectile dysfunction, and included drugs marketed under the proprietary names Cialis and Viagra. FDAapproved drugs containing Tadalafil and Sildenafil were prescription drugs.

11. Semaglutide was an API in FDA-approved drugs indicated to lower blood sugar for adults with type 2 diabetes, and to help adults and children with obesity and chronic weight management. These drugs were marketed under the proprietary names Ozempic, Rybelsus, and Woegovy. FDA-approved drugs containing Semaglutide were prescription drugs.

12. Products sold on the MRJ website were manufactured in an office suite in Rockingham, North Carolina. MELAND engaged in and aided and abetted in mixing the APIs with other products and cutting agents and then repacking the products in new capsules, bottles, and vials. MELAND also engaged in and aided

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and abetted in the creation of new labels to be affixed to the products. The products were then shipped to website customers nationwide.

13. For example, on or about February 7, 2023, an order was placed through the MJR website for GLP-1 Semaglutide 10mg and Tadalafil/Sildenafil capsules. The products were manufactured in the office suite in Rockingham, N.C., and then shipped in interstate commerce to a customer in Miami, Florida.

14. Neither the MJR website, business, or office location were registered with the FDA as a drug facility engaged in the manufacturing, preparation, propagation, compounding, or processing of drugs. Various drugs marketed on the MRJ website, including, GLP-1 Semaglutide, and Tadalafil/Sildenafil capsules, lacked requisite approval from the FDA to be lawfully marketed in the United States.

THE CHARGE

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

16. On or about February 8, 2023, in the Eastern District of North Carolina and elsewhere, the defendant, ADAM SCOTT MELAND, did and caused, with the intent to defraud and mislead, the introduction and delivery for introduction into interstate commerce drugs, namely "GLP-1 Semaglutide" and "Tadalafil/Sildenafil capsules," that were misbranded in that the drugs were not manufactured, prepared, propagated, compounded, and processed in an

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establishment duly registered under 21 U.S.C. § 360 in violation of 21 U.S.C. § 352(o), and did aid and abet others known and unknown to do the same.

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2), and Title 18, United States Code, Section 2.

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BY:

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