UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA	:	**No.**
	:	
v.	:	**Violations: 1:24mj00039**
	:	
MELISSA BANDY	:	**21 U.S.C. § 331(c) and 333(a)(1)**

INFORMATION

INTRODUCTION

The United States Attorney charges and includes in each count of this Information, that at times relevant to this Information:

1. MELISSA BANDY ("BANDY") owned and operated White Orchid Med Spa, LLC ("WOMS"), located at 149 Suffolk Ave, Richlands, Virginia.

2. BANDY is not a licensed healthcare provider, medical practitioner, or licensed pharmacist. Neither BANDY nor WOMS are registered with the FDA as a drug manufacturer or held a wholesale or distribution license.

3. The Federal Food, Drug, and Cosmetic Act (the "FDCA") prohibits the receipt in interstate commerce of misbranded drugs, and the delivery or proffered delivery of them for pay or otherwise. 21 U.S.C. § 331(c).

4. There are a number of ways that a drug may be misbranded, including: (i) its labeling is false and misleading in any particular,[1] (ii) its labeling fails to bear

[1] 21 U.S.C. § 352(a)

required information in the English Language,[2] (iii) it is a drug sold under the name of another drug or as an imitation of another drug,[3] and (iv) its labeling fails to bear adequate directions for the drug's use, as well as any contraindication and warnings.[4] Prescription drugs are misbranded when they are dispensed without a valid prescription from a licensed medical practitioner.[5] Drugs are also misbranded if they are manufactured in a facility that has not been registered with the United States Food and Drug Administration ("FDA").[6]

5. BANDY ordered and received Saxenda, an injectable prescription drug containing liraglutide that is manufactured by Novo Nordisk, online from the Nano Shape of Beauty website. The Saxenda pens traveled in interstate commerce because Nova Nordisk does not have a manufacturing location in the Commonwealth of Virginia. The Saxenda pens BANDY received had the word "Saxenda" on them, but the rest of the writing on the Saxenda pen was Korean.

6. BANDY did not have a valid prescription for Saxenda. Saxenda pens must be temperature controlled. There are also several warnings and precautions related to Saxenda such as, risk of thyroid c-cell tumors, acute pancreatitis, acute

[2] 21 U.S.C. § 352(c), 21 C.F.R. 201.15(c).
[3] 21 U.S.C. § 352(i).
[4] 21 U.S.C. 21 U.S.C. § 352 (f)(1). "Adequate directions for use" is defined in FDA regulations as directions under which the *layman* can use a drug safely and for the purposes for which it is intended. 21 C.F.R. § 201.5.
[5] 21 U.S.C. § 353(b).
[6] 21 U.S.C. § 352(o), 360.

gallbladder disease, hypoglycemia, heart rate increase, renal impairment, hypersensitivity reactions, and suicidal behavior and ideation.

7. BANDY, who was not a licensed healthcare provider, sold multiple Saxenda pens to other individuals. The Saxenda pens BANDY sold were misbranded because, among other things, their labeling failed to bear required information in the English Language and they were dispensed without a valid prescription from a licensed medical practitioner.

8. BANDY also purchased and received SelaTox, a product manufactured in South Korea by Sela Cosmetics that is sometimes marketed as an "alternative to Botox," from the Nano Shape of Beauty website. The main active ingredient of SelaTox is acetyl hexapeptide. Neither SelaTox nor acetyl hexapeptide are FDA approved drugs, and Sela Cosmetics is not registered with FDA as a drug manufacturer. BANDY used SelaTox during derma stamp procedures she administered to other individuals at WOMS.

9. The SelaTox BANDY purchased was misbranded because it was manufactured in a facility that has not been registered with the FDA.

10. BANDY also purchased and received Botulax 200 and Innotox, products that contain botulinum toxin type A, a highly potent and potentially dangerous toxin that can cause the disease botulism when present in human beings in a sufficient amount. Botulinum toxin type A is an active ingredient in Botox®

Cosmetic (Botox), a prescription only injection drug. Both Botulax and Innotox are manufactured in South Korea, and neither are FDA approved drugs. BANDY used Botulax 200 and Innotox during derma stamp procedures she administered to other individuals at WOMS.

11. BANDY also purchased and received Juvéderm Volbella with Lidocaine, an injectable gel/filler manufactured in France, and TheraFill, a collagen filler for soft tissue augmentation manufactured in South Korea. Neither Juvéderm Volbella with Lidocaine nor TheraFill are FDA approved drugs.

12. Botulax 200, Innotox, Juvéderm Volbella with Lidocaine, and TheraFill are all misbranded drugs that BANDY received in interstate commerce and delivered and proffered for delivery for pay or otherwise.

COUNT ONE

The United States Attorney charges that:

13. On or about and between December 2022 and April 2023, in the Western District of Virginia, MELISSA BANDY, received misbranded drugs in interstate commerce and delivered and proffered for delivery the misbranded drugs for pay or otherwise.

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

DATE: May 24, 2024

Christopher Kavanaugh by PDS

CHRISTOPHER KAVANAUGH
United States Attorney