AO 91 (Rev. 11/11) Criminal Complaint

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

United States of America
v.
Rodrigo de Medeiros Siqueira

Case No. 25-mj-8522-PGL

Defendant(s)

CRIMINAL COMPLAINT

I, the complainant in this case, state that the following is true to the best of my knowledge and belief.

On or about the date(s) of May - June 2025 in the county of Norfolk in the _____ District of Massachusetts, the defendant(s) violated:

Code Section	*Offense Description*
21 U.S.C. § 331(k)	Misbranding of a drug after shipment in interstate commerce

This criminal complaint is based on these facts:

☑ Continued on the attached sheet.

Complainant's signature

William Hughes, FDA Special Agent
Printed name and title

Sworn via telephone in accordance with Fed. R. Crim. P. 4.1.

Date: October 10, 2025

Judge's signature

City and state: Boston, Massachusetts

Hon. Paul G. Levenson, U.S. Magistrate Judge
Printed name and title

AFFIDAVIT OF SPECIAL AGENT WILLIAM HUGHES IN SUPPORT OF APPLICATION FOR CRIMINAL COMPLAINT AND ARREST WARRANT

I, William Hughes, state:

AGENT BACKGROUND

1. I have been a Special Agent with the United States Food and Drug Administration's Office of Criminal Investigations ("FDA-OCI") since 2012 and am currently assigned to the Boston Resident Office. Before joining FDA-OCI, I served in the United States Army for approximately 20 years, first as a Military Police Officer and then as a Special Agent with the Criminal Investigation Command.

2. As a Special Agent with FDA-OCI, I am responsible for conducting criminal investigations involving violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and other federal statutes enforced by the United States Food and Drug Administration ("FDA"). During my employment in federal law enforcement, I have completed numerous training courses in criminal investigative techniques and have learned various means and methods by which illegal prescription drug traffickers obtain, possess, transport, divert, and distribute counterfeit prescription drugs, misbranded prescription drugs, unapproved new drugs, controlled substances, and the equipment used to manufacture them.

PURPOSE OF AFFIDAVIT

3. I am investigating Rodrigo de Medeiros Siqueira ("MEDEIROS SIQUEIRA") for violations of 21 U.S.C. § 331(k) (prohibiting the doing of an act that results in a drug being misbranded while held for sale after shipment in interstate commerce) (the "TARGET OFFENSE"), among other offenses.

4. As set forth below, there is probable cause to believe that MEDEIROS SIQUEIRA caused botulinum toxin[1] purchased from outside Massachusetts to become misbranded while held for sale when he dispensed it without a valid prescription and administered it via injection to clients of his business, Rodrigo Beauty Spa ("Rodrigo Beauty"), resulting in numerous cases of botulism.[2]

5. I make this affidavit in support of an application for a criminal complaint charging MEDEIROS SIQUEIRA with the TARGET OFFENSE, and for a warrant for his arrest.

6. This affidavit is based on my personal knowledge and observations, my training and experience, information provided by other FDA employees, evidence obtained from open-source data, business records, and information provided by witnesses and other law enforcement officers. This affidavit is not intended to set forth all of the information I have learned during this investigation but includes only the information necessary to establish probable cause for the requested complaint and warrant.

RELEVANT LAW

The Federal Food, Drug, and Cosmetic Act

7. The FDA is the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the FDCA. The FDA regulates the manufacture, labeling, and distribution of all prescription drugs shipped or received in interstate commerce.

[1] Botulinum toxin is widely used for the temporary improvement of facial wrinkles. As set forth below, when used for this purpose, botulinum toxin is regulated as a prescription drug by the FDA.

[2] As discussed further below, botulism is a rare and dangerous disease that can result from, among other things, the injection of botulinum toxin.

8. A "drug" is defined by the FDCA as, among other things, any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and any article (other than food) intended to affect the structure or any function of the human body. 21 U.S.C. § 321(g)(1).

9. Under the FDCA, a prescription drug is one that, because of its toxicity, other potential harmful effects, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer the prescription drug. 21 U.S.C. § 353(b)(1)(A). A drug is also a prescription drug under the FDCA if the FDA, when it approved the drug, limited the drug to use under the supervision of a licensed practitioner. 21 U.S.C. § 353(b)(1)(B).

10. A prescription drug may be dispensed only upon the prescription of a practitioner licensed by law to administer prescription drugs. 21 U.S.C. § 353(b)(1).

11. The FDA has approved several botulinum toxin prescription drugs, including, but not limited to, Botox, Daxxify, Dysport, and Xeomin. These and similar drugs containing botulinum toxin intended to be injected for the prevention of wrinkles are prescription drugs under the FDCA because, due to their potential for harmful effects and the method of their use, they are not safe for use except under the supervision of a licensed practitioner.

12. Under the FDCA, dispensing a prescription drug without the valid prescription of a licensed practitioner is deemed to be an act which results in the drug being misbranded while held for sale. 21 U.S.C. § 353(b)(1).

13. The FDCA prohibits, among other things, the doing of any act that results in a drug being misbranded if the act is done while the drug is held for sale and after the drug was shipped in interstate commerce. 21 U.S.C. § 331(k). Any individual who commits a violation of 21 U.S.C. § 331(k) with the intent to defraud or mislead is subject to imprisonment for up to three years and

a fine of not more than $250,000 or twice the gross gain or loss from the offense (whichever is greater). 21 U.S.C. § 333(a)(2);18 U.S.C. § 3571.

14. The FDCA establishes a presumption that the "interstate commerce" requirement is met for jurisdictional purposes. *See* 21 U.S.C. § 379a ("In any action to enforce the requirements of this chapter respecting a device, tobacco product, food, drug, or cosmetic the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist.").

BACKGROUND ON BOTULISM

15. Botulism is a rare and sometimes fatal illness classically acquired by ingestion of pre-formed toxin, often from improperly canned foods or less commonly from ingestion of spores of Clostridium botulinum.

16. Botulism cases occur annually in the United States and are broken down into six different types: infant botulism (most common), food-borne, wound-associated, adult intestinal toxemia, inhalation, and iatrogenic.

17. Iatrogenic botulism is a rare but potentially serious adverse event resulting from the administration of botulinum toxin products. It is caused by botulinum toxin circulating in the blood and producing effects remotely from the injection site. When botulinum toxin spreads beyond the injection site, it can lead to life-threatening symptoms, including: blurred or double vision, drooping eyelids, slurred speech, and/or difficulty swallowing or breathing.

18. While botulinum toxin is generally safe when administered by trained medical professionals, improper dosing, administration technique, or use of non-FDA-approved products may increase the risk of systemic botulism symptoms.

19. The U.S. Centers for Disease Control and Prevention ("CDC") has reported adverse effects, including iatrogenic botulism, resulting from injections of counterfeit/unapproved

botulinum toxin and/or from injections administered by unlicensed or untrained individuals or in non-healthcare settings, such as homes or spas.

PROBABLE CAUSE TO BELIEVE A FEDERAL CRIME WAS COMMITTED

Investigation Background

20. On or about June 6, 2025, the Massachusetts Department of Public Health ("DPH") notified FDA-OCI that DPH had identified injections performed at Rodrigo Beauty, located at 464 Granite Avenue in Milton, Massachusetts, as the source of multiple cases of botulism. Specifically, on or about June 1, 2025, DPH received a report from an attending physician of a patient diagnosed with botulism who had received botulinum toxin injections at Rodrigo Beauty in May 2025 with symptom onset approximately two days later. This individual was reportedly hospitalized in the intensive care unit ("ICU"). Thereafter, DPH received multiple additional reports of individuals exhibiting botulism symptoms after receiving botulinum toxin injections at Rodrigo Beauty in May 2025, with several hospitalized under ICU care.

21. On June 7, 2025, DPH issued a press release "warning the public about a growing cluster of botulism cases linked to cosmetic botulinum toxin . . . injections administered at Rodrigo Beauty[.]"[3] The press release stated that, at that time, ten cases of suspected iatrogenic botulism were under investigation, "all associated with procedures performed at this spa." The press release further advised that anyone who received botulinum toxin injections at Rodrigo Beauty between May 1st and June 4th should contact DPH or their local board of health and that anyone experiencing symptoms should go to the nearest hospital emergency room.

[3] *See* https://www.mass.gov/news/dph-alerts-public-to-botox-related-botulism-cases-linked-to-rodrigo-beauty-in-milton.

22. In response to this information, FDA-OCI began investigating MEDEIROS SIQUEIRA, in coordination with DPH.

Source of Botulinum Toxin Resulting in Botulism Outbreak

23. Several of the individuals diagnosed with botulism reported to DPH that MEDEIROS SIQUEIRA had informed them that the product he injected was Daxxify, specifically, a Daxxify vial with lot number R1006283 and expiration date August 2025. According to MEDEIROS SIQUEIRA, he had obtained the product from a licensed nurse practitioner ("NP 1").

24. During an interview conducted by DPH investigators, NP 1 and her business partner ("NP 2"), who together own/operate a med spa in Rockland, Massachusetts ("Med Spa 1"), denied providing Daxxify to MEDEIROS SIQUEIRA.[4]

25. During a later interview conducted by FDA-OCI, NP 2 stated, in part, that NP 1 told her (NP 2) that she (NP 1) had taken a picture of an expired vial of Daxxify that Med Spa 1 used as a "display" vial and sent the picture to MEDEIROS SIQUEIRA to "help" him when some of his clients began experiencing adverse medical events.

26. Based in part on information provided by the manufacturer of Daxxify, Revance, I believe the representation MEDEIROS SIQUEIRA made to his clients, referenced in paragraph 23 above, to be false. Specifically, a representative of Revance reported that there is no record of MEDEIROS SIQUEIRA or Rodrigo Beauty ever having purchased Daxxify. The Revance representative also stated that the lot number MEDEIROS SIQUEIRA provided to his clients—R1006283—is a valid Daxxify lot number, but that lot had an expiration date of August 2024 (not

[4] FDA-OCI is investigating NP 1 and NP 2. The investigation remains ongoing.

August 2025 as represented by MEDEIROS SIQUEIRA). Further, Revance did not sell that lot number to Med Spa 1 or to NP 1.[5]

27. Manufacturers of other commonly used FDA-approved botulinum toxin products likewise reported that there is no record of MEDEIROS SIQUEIRA or Rodrigo Beauty ever having purchased their products. For example:

a. A representative of AbbVie Inc., the parent company of Allergan, which is the manufacturer of Botox, reported that there is no record of Rodrigo Beauty or MEDEIROS SIQUEIRA ever having purchased legitimate Botox.

b. A representative of Galderma, the manufacturer of Dysport, reported that there is no record of Rodrigo Beauty or MEDEIROS SIQUEIRA ever having purchased legitimate Dysport.

c. A representative of Merz Aesthetics, the manufacturer of Xeomin, reported that there is no record of Rodrigo Beauty or MEDEIROS SIQUEIRA ever having purchased legitimate Xeomin.[6]

28. Based on the information set forth above, it appears that MEDEIROS SIQUEIRA did not obtain the botulinum toxin that caused the botulism outbreak directly from an FDA-approved manufacturer.

29. Based on my training and experience, I am aware that owners/operators of med spas—particularly those that operate without the requisite licenses/certifications—frequently

[5] Revance did sell 25 vials of Daxxify to Med Spa 1 in or around March 2025, but those vials had a different lot number and expiration date than that MEDEIROS SIQUEIRA provided to his clients.

[6] Merz Aesthetics does have a record of Xeomin purchases by Med Spa 1, including purchases in May, June, and July of 2025.

purchase botulinum toxin online from various websites that offer prescription drugs sourced from countries outside the United States, including, but not limited to, China and South Korea. The primary reasons for this are, one, such products are typically significantly less expensive than FDA-approved botulinum toxin products, and, two, unlicensed/uncertified individuals cannot purchase directly from the FDA-approved manufacturers.

30. One such website is Alibaba, a Chinese-owned online marketplace that connects businesses with suppliers, manufacturers, and wholesalers. Bank records for a joint account held by MEDEIROS SIQUEIRA and another individual at Bank of America reflect multiple purchases from Alibaba, including purchases in November 2024, December 2024, and May 2025.[7]

31. Because, as discussed further below, MEDEIROS SIQUEIRA is not a licensed medical professional and was therefore unable to purchase botulinum toxin directly from FDA-approved manufacturers, I believe he likely obtained the botulinum toxin he administered to clients of Rodrigo Beauty from illegitimate/unapproved sources outside the United States.

32. However, even if that were not the case and MEDEIROS SIQUEIRA indirectly obtained an FDA-approved botulinum toxin product, such product necessarily came from outside Massachusetts and was therefore shipped in interstate commerce. This is because there are no FDA-approved botulinum toxin manufacturers located in Massachusetts.

MEDEIROS SIQUEIRA's Licenses/Certifications

33. Regardless of where MEDEIROS SIQUEIRA obtained the botulinum toxin that resulted in the botulism outbreak described herein, he was not licensed/certified to prescribe, dispense, or administer prescription drugs or perform injections.

[7] I have requested but not yet obtained records from Alibaba relating to these purchases.

34. The Bureau of Health Professions Licensure, a component of DPH that is responsible for the licensing of health care professionals in Massachusetts, has no record of any license or certification for MEDEIROS SIQUEIRA that would permit him to prescribe, dispense, or administer prescription drugs or perform injections.[8]

35. Per records maintained by the Board of Registration of Cosmetology and Barbering, which is responsible for regulating cosmetology (among other industries) in Massachusetts, MEDEIROS SIQUEIRA was a registered aesthetician during the relevant time period.[9] Aestheticians are not permitted to prescribe, dispense, or administer prescription drugs or perform injections.

Witness Interviews

36. During an interview conducted by FDA-OCI, MEDEIROS SIQUEIRA's former assistant at Rodrigo Beauty ("Assistant 1"), provided the following information:

a. Assistant 1 worked at Rodrigo Beauty beginning in or around February 2025 until MEDEIROS SIQUEIRA closed the business after several of his clients were diagnosed with botulism.

b. When Assistant 1 interviewed for the job, MEDEIROS SIQUEIRA told her that he was a nurse and was certified to perform injection procedures. MEDEIROS SIQUEIRA also told clients that he was a certified nurse.

[8] MEDEIROS SIQUEIRA did previously hold a nurse aid certification, which expired on or about March 17, 2025. Certified nurse aides ("CNAs") work under the supervision of a registered/licensed nurse and are typically responsible for, among other things, assisting patients with activities of daily living (*e.g.*, bathing, dressing, eating) and monitoring/recording patients' vital signs. CNAs are not permitted to prescribe, dispense, or administer prescription drugs or perform injections.

[9] MEDEIROS SIQUEIRA's aesthetician license is currently suspended.

c. Assistant 1 did not know what products MEDEIROS SIQUEIRA used because she did not order, receive, or stock the products and did not participate in the procedures.

d. After the first client reported an adverse event in late May/early June 2025, MEDEIROS SIQUEIRA instructed Assistant 1 to take her work computer and phone home and to tell any clients who called asking to speak with MEDEIROS SIQUEIRA that he was on vacation. The next day, MEDEIROS SIQUEIRA told Assistant 1 not to come in to work anymore.

e. On her last day of work at Rodrigo Beauty, Assistant 1 saw MEDEIROS SIQUEIRA packing products and documents into bags and boxes and removing them from the office. MEDEIROS SIQUEIRA told Assistant 1 that he was moving the items because he was going on vacation.

37. FDA-OCI has also conducted interviews of several of the individuals who were diagnosed with botulism after receiving injections from MEDEIROS SIQUEIRA at Rodrigo Beauty. These individuals generally reported that they received what they believed to be Botox injections from MEDEIROS SIQUEIRA, who they believed to be a licensed medical professional, in late May 2025 and began experiencing symptoms consistent with botulism several days later.

38. For example, one of MEDEIROS SIQUEIRA's clients ("Client 1") provided the following information:

a. Client 1 received what she believed to be Botox injections from MEDEIROS SIQUEIRA on May 28 or 29, 2025. Approximately five days later, Client 1 began experiencing heaviness and drooping around the injection sites. She also experienced a lack of energy and memory problems. Client 1 made several trips to

the hospital and was ultimately treated for botulism, which her doctor reported was caused by a botulinum toxin overdose.

b. When Client 1 contacted MEDEIROS SIQUEIRA to inform him of the symptoms she was experiencing and inquire whether it could be "a reaction to the Botox," MEDEIROS SIQUEIRA told Client 1 that the symptoms she was describing were not typical and recommended that she seek immediate medical attention.

c. Client 1 later followed up with MEDEIROS SIQUEIRA "to ask for some details about the Botox treatment [she] received" because her doctor had requested certain information (*e.g.*, how many units were injected) in light of the symptoms she was experiencing. MEDEIROS SIQUEIRA responded with the following message, telling Client 1, "[s]how this for [sic] your doctor":

To Whom It May Concern,

This message is being provided on behalf of Rodrigo Beauty in response to a recent medical concern reported by the patient.

The following information was initially shared with me by Nurse Practitioner [redacted] a licensed medical provider (License No. [redacted], who supplied the product used during the patient's cosmetic treatment:

- Product Name: Daxxify
- Lot Number: R1006283
- Expiration Date: August 2025
- Provided by: Nurse Practitioner [redacted]

Based on the initial information I received, the following units were used on the patient:

- Frontalis muscle (forehead): 30 units
- Glabellar complex (procerus and corrugator supercilii muscles): 16 units
- Nasalis muscle (bunny lines on the nose): 10 units
- Orbicularis oculi (around the eyes): 10 units per eye, totaling 20 units

Please note: While this was the information originally given to me, I have since been informed by the provider that the details may not be fully accurate, and at this time, she is unable to confirm the exact product that was used.

For this reason, I am sharing the above information out of caution, so that the medical team evaluating the patient can make informed decisions regarding treatment. I highly recommend that the patient be thoroughly evaluated and monitored by a licensed physician to ensure proper medical care is provided.

If further documentation or clarification is needed, I will be happy to assist.

39. Another one of MEDEIROS SIQUEIRA's clients ("Client 2") provided the following information:

a. In May 2025, Client 2 received botulinum toxin injections from MEDEIROS SIQUEIRA. When Client 2 asked MEDEIROS SIQUEIRA what type of botulinum toxin he was using, he told her that he normally used Dysport but had switched to Daxxify because it was "better." MEDEIROS SIQUEIRA showed Client 2 a vial of Daxxify, but Client 2 did not see MEDEIROS SIQUEIRA draw the product from the vial.

b. MEDEIROS SIQUEIRA told Client 2 that he was a nurse.

c. Approximately an hour after the injection procedure, Client 2 called MEDEIROS SIQUEIRA because she was experiencing stinging pain at the injection sites. MEDEIROS SIQUEIRA told her that the stinging was due to the strength of the botulinum toxin used.

d. Client 2 later experienced blurry vision and reported this to MEDEIROS SIQUEIRA, who attributed it to Client 2 having consumed alcohol after her appointment.

e. A few days later, Client 2 returned to Rodrigo Beauty because she continued to experience blurry vision. MEDEIROS SIQUEIRA gave Client 2 a "cold face" treatment in an attempt to treat the blurry vision. The treatment did not relieve Client 2's symptoms, which worsened over the next several days.

f. Client 2 made two trips to the hospital. The first time, she reported having a headache, blurry vision, and heaviness in her forehead (one of the injection sites). The second time, Client 2 reported experiencing dizziness (the "spins") and difficulty moving and swallowing. The hospital immediately transferred Client 2 to

the ICU. After the medical staff determined that Client 2 had botulism, she received an anti-toxin treatment. A doctor later told Client 2 that she could have died.

40. Another one of MEDEIROS SIQUEIRA's clients ("Client 3") provided the following information:

a. Client 3 began going to Rodrigo Beauty for botulinum toxin injections in or around mid-2024.

b. MEDEIROS SIQUEIRA told Client 3 that he was a licensed medical assistant.

c. MEDEIROS SIQUEIRA never showed Client 3 the vials of drugs he was using but referred to the product generally as Botox.

d. Client 3 received botulinum toxin injections from MEDEIROS SIQUEIRA on or about May 23, 2025. The next day, Client 3 began experiencing a heavy feeling in her face. She contacted MEDEIROS SIQUEIRA but did not receive a response. She then went to the Rodrigo Beauty office but found it closed. At that time, her symptoms had worsened to include blurry vision and trouble swallowing.

e. Client 3 went to a dermatologist who told her that she had received an overdose of botulinum toxin. Client 3 later went to the hospital, where the medical staff diagnosed her with botulism.

CONCLUSION

41. Based on the information described above, I have probable cause to believe that MEDEIROS SIQUEIRA violated 21 U.S.C. § 331(k) (prohibiting the doing of an act that results in a drug being misbranded while held for sale after shipment in interstate commerce) with the intent to defraud or mislead. Specifically, I have probable cause to believe that MEDEIROS SIQUEIRA obtained some form of botulinum toxin from a source outside Massachusetts and

dispensed it to clients of Rodrigo Beauty without a valid prescription, while falsely holding himself out as a licensed medical professional qualified to perform injections.

Subscribed and sworn to,

_____
William Hughes
Special Agent
U.S. Food and Drug Administration

Attested to by the applicant in accordance with the requirements of Fed. R. Crim. P. 4.1 by telephone on October ___, 2025

_____
HONORABLE PAUL G. LEVENSON
UNITED STATES MAGISTRATE JUDGE
DISTRICT OF MASSACHUSETTS