DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main St., Suite 7000 Dallas. TX 75202 (214) 253-5200	12/02/2025-12/12/2025* FEI NUMBER 3041017461

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Bridgett M. Goddard, Manager

FIRM NAME	STREET ADDRESS
Pure Indulgence Aesthetics	1695 E. Southlake Blvd., Unit 150
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Southlake, Texas, 76092	Dispenser of Prescription Drugs

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM, WE OBSERVED:

OBSERVATION 1

Failure to conduct business only with authorized trading partners as required by section 582(d)(3) of the FD&C Act

Specifically,

During the inspection, it was observed that your firm dispensed significantly more Botox (onabotulinumtoxinA) units than documented purchases from AbbVie (the manufacturer of Botox) would support. During the inspection, your firm's management stated that you only purchase Botox from AbbVie. AbbVie and their subsidiary, Allergan Aesthetics, are the only legitimate suppliers of Botox in the United States.[1]

Purchase records show your firm received (b) (4) vials ((b) (4) units) from AbbVie between December 18, 2024 and December 02, 2025. However, treatment records indicate that your firm administered "Botox" to (b) (4) patients between January 2025 and December 2025, with an estimated (b) (4) units dispensed. This represents a discrepancy of (b) (4) units (approximately (b) (4) vials[2]).

Based on records provided to FDA by both the product manufacturer and your firm, your firm has not purchased enough Botox from AbbVie to supply patients with the quantity of Botox indicated in patient records. This discrepancy strongly suggests that your firm is obtaining product from unauthorized sources and claiming that that product is Botox. Based on the thorough review of your purchasing and patient records, you have been unable to demonstrate compliance with the requirement under 21 U.S.C. 360eee-1(d)(3) to conduct transactions only with authorized trading partners.

Botox Received and Purportedly Dispensed

Lot Information		Amount Purchased		Dispensed "Botox" by Lot per patient records	
Ship Date	Lot; Exp.	Vials	Units	Calculated Vials[2]	Total Units
(b) (4)					

[1] See https://news.allerganaesthetics.com/media/response-to-suspected-counterfeit-botox-reports

[2] Calculated vials represent the theoretical number of whole vials that would be required to dispense the total units documented in patient records, based on standard vial concentrations (typically 100 units per vial for Botox). Numbers are rounded up to the next whole vial, since partial vials cannot be purchased.

	EMPLOYEE(S) SIGNATURE	DATE ISSUED
SEE REVERSE OF THIS PAGE	Shelby N Turner, Investigator Milton J. De Jesus, Investigator Aaron Weisbuch, Regulatory Counsel	X Digitally signed by Shelby N. Turner -S Date: 2025.12.12 09:15:38 -06'00' Shelby N. Turner, Investigator	12/12/2025

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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Southlake, Texas, 76092	Dispenser of Prescription Drugs

Lot Information		Amount Purchased		Dispensed "Botox" by Lot per patient records	
Ship Date	Lot; Exp.	Vials	Units	Calculated Vials[2]	Total Units
(b) (4)					

OBSERVATION 2

Failure to engage in transactions involving only product with a product identifier as required by section 582(d)(2) of the FD&C Act

Specifically,

An unlabeled, clear vial containing a ring of white powder, later confirmed by laboratory analysis to contain botulinum neurotoxin type A (BoNT/A), was found disposed of in your facility's trash on 12/02/2025. BoNT/A for injection intended for human use is a prescription drug and is a "product" as defined by 581(13) of the FD&C Act. The vial found at your facility does not resemble what a legitimate vial of Botox looks like, being taller and more narrow than legitimate Botox vials. The product found at your facility lacked proper labeling and you were unable to provide a label or packaging that contained a product identifier, as required under 21 U.S.C. 360eee-1(d)(2).

***DATES OF INSPECTION**

12/02/2025(Tue), 12/03/2025(Wed), 12/09/2025(Tue), 12/12/2025(Fri)

X MILTON J. DE JESUS-TAVAREZ -S Digitally signed by MILTON J. DE JESUS-TAVAREZ -S Date: 2025.12.12 09:13:09 -06'00'

Milton J. De Jesus, Investigator

X AARON M. WEISBUCH -S Digitally signed by AARON M. WEISBUCH -S Date: 2025.12.12 10:03:05 -05'00'

Aaron Weisbuch, Regulatory Counsel

[2] Calculated vials represent the theoretical number of whole vials that would be required to dispense the total units documented in patient records, based on standard vial concentrations (typically 100 units per vial for Botox). Numbers are rounded up to the next whole vial, since partial vials cannot be purchased.
[3] This order was placed and delivered during the course of the inspection.
[4] Represents patient treatment records where Botox lot number fields were left blank or not documented.
[5] Lot numbers recorded in patient treatment records for Botox do not correspond to lot numbers provided by either the product manufacturer or the firm for the products purportedly dispensed during the documented treatment periods.

	EMPLOYEE(S) SIGNATURE		DATE ISSUED
SEE REVERSE OF THIS PAGE	Shelby N Turner, Investigator Milton J. De Jesus, Investigator Aaron Weisbuch, Regulatory Counsel	X Digitally signed by Shelby N. Turner -S Date: 2025.12.12 09:16:21 -06'00' Shelby N. Turner, Investigator	12/12/2025