DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	2/10/2025-2/21/2025* FEI NUMBER 3015156709

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jugal K. Taneja, CEO/President

FIRM NAME	STREET ADDRESS
BPI Labs LLC	12393 Belcher Rd S Ste 450
CITY, STATE, ZIP CODE, COUNTRY Largo, FL 33773-3097	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility / Sterile Drug Manufacturing Facility

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

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically,

1. the following information is not found on your drug product labels:

- The statement "Office Use Only."

Examples of your drug product labels that do not contain this information, include but are not limited to:

- Semaglutide Injection 1mg/mL, 1mL vial
- Semaglutide Injection 5mg/2mL, 2mL vial
- Semaglutide Injection 12.5mg/2.5mL, 2.5mL vial
- Semaglutide Injection 2.5mg/mL, 1mL vial
- Semaglutide Injection, 30mg/6mL, 6mL vial
- Tirzepatide Injection, 30mg/3mL, 3mL vial
- Tirzepatide Injection, 10mg/mL, 1mL vial
- Tirzepatide Injection, 60mg/3mL, 3mL vial

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Logan T Williams, Investigator Nicole E Knowlton, Investigator	Nicole E Knowlton Investigator	2/21/2025

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*DATES OF INSPECTION

2/10/2025(Mon), 2/11/2025(Tue), 2/12/2025(Wed), 2/13/2025(Thu), 2/14/2025(Fri), 2/18/2025(Tue), 2/19/2025(Wed), 2/20/2025(Thu), 2/21/2025(Fri)

X Logan T Williams
Investigator
Signed By: 2002955055
Date Signed: 02-21-2025 10:38:47

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Logan T Williams, Investigator
Nicole E Knowlton, Investigator

X Nicole E Knowlton
Investigator
Signed By: NICOLE E. KNOWLTON -S
Date Signed: 02-21-2025 10:38:09

DATE ISSUED
2/21/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."