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	4/6/2026-4/17/2026* FEI NUMBER 3015156709

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jugal K. Taneja, Chairman and Chief Executive Officer (CEO)

FIRM NAME	STREET ADDRESS
BPI Labs, LLC	12393 Belcher Rd S Ste 450
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Largo, FL 33773-3097	Outsourcing 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 I OBSERVED:

OBSERVATION 1

Your outsourcing facility compounds drug products using bulk drug substances that cannot be used in compounding under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) because they (a) are not used to compound drug products that appear on the drug shortage list in effect under section 506E of the Act and (b) do not appear on a list developed by FDA of bulk drug substances for which there is a clinical need.

Specifically,

Your facility compounded human drug products using tirzepatide bulk drug substance.

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A. Your firm failed to conduct a media fill for all worst-case conditions on a (b) (4) basis, including but not limited to, vial size, fill volume, number of vials, and processing run speeds. For example,

i. Your firm failed to assess the processing run speed and fill volume for the (b) (4) (b) (4) (Line (b) (4)) during a (b) (4) media fill to simulate true

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Lisa R Hilliard, Investigator	X Lisa R Hillard Investigator Signed By: Lisa R. Hillard -S Date Signed: 04-17-2026 15:27:28	4/17/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	4/6/2026-4/17/2026* FEI NUMBER 3015156709

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jugal K. Taneja, Chairman and Chief Executive Officer (CEO)	
FIRM NAME BPI Labs, LLC	STREET ADDRESS 12393 Belcher Rd S Ste 450
CITY, STATE, ZIP CODE, COUNTRY Largo, FL 33773-3097	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

production conditions. On Line (b)(4), your firm performed a media fill in April 2025 yielding (b)(4) vials, with a fill volume of (b)(4) in a (b)(4) vial, for a total filling run time of (b)(4) hours and (b)(4) minutes. This does not simulate worst case conditions to represent the released sterile drug product Liraglutide Injection, 18 mg/3 mL (6 mg/mL), Batch I846I002A1 (BUD 08/15/2026) produced on Line (b)(4) on (b)(4), which yielded (b)(4) vials, with a fill volume of 3ml in a 2R vial, for a total filling run time of (b)(4) hours and (b)(4) minutes.

ii. Your firm failed to assess the vial size, production run time, and fill volume for the (b)(4) (b)(4) (Line (b)(4)) during a (b)(4) media fill to simulate true production conditions. On Line (b)(4), your firm performed a media fill in June 2025 using only (b)(4) vials (Total Batch Size of (b)(4) vials with a (b)(4) fill volume) but did not perform any media fills for other vial types and fill volumes for (b)(4) vials or (b)(4) vials. This does not simulate worst case conditions for the larger vial size representing actual sterile drug product produced, for example:

a. For 10R vial size filled with 5ml of Testosterone Cypionate Injection, USP 1000 mg/5 mL (200 mg/mL), Batch I850H001A1 (BUD 10/09/2026, Total Batch Size: (b)(4) vials) produced on Line (b)(4) on (b)(4) with a total filling run time of (b)(4) hours and (b)(4) minutes.

b. For 10R vial size filled with 10ml of Testosterone Cypionate Injection, USP 1000 mg/5 mL (200 mg/mL), Batch I861I001A1 (BUD 10/04/26, Total Batch Size: (b)(4) vials) produced on Line (b)(4) on (b)(4), with a total filling run time of (b)(4) hours and (b)(4) minutes.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Lisa R Hilliard, Investigator	DATE ISSUED 4/17/2026

X Lisa R Hilliard
Investigator
Signed By: Lisa R. Hilliard -S
Date Signed: 04-17-2026
15:27:28

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	4/6/2026-4/17/2026* FEI NUMBER 3015156709

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jugal K. Taneja, Chairman and Chief Executive Officer (CEO)	
FIRM NAME BPI Labs, LLC	STREET ADDRESS 12393 Belcher Rd S Ste 450
CITY, STATE, ZIP CODE, COUNTRY Largo, FL 33773-3097	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

c. For 4R vial size filled with 5ml of Tirzepatide Batch I848I001A1 (BUD 11/01/2026, Total Batch Size: (b) (4) vials) produced on Line (b) (4) on (b) (4), with a total filling run time of (b) (4) hours and (b) (4) minutes.

iii. Your firm failed to assess the number of vials run for (b) (4) (b) (4) (Line (b) (4)) during a (b) (4) media fill. On Line (b) (4), your firm performed (b) (4) initial media fills using approximately (b) (4) vials in August 2025. These media fills did not simulate true production conditions for a batch size of (b) (4) vials, as produced on (b) (4) for the sterile drug product produced on Line (b) (4) using 2R vials with a fill volume of 3ml, Tirzepatide and Pyridoxine Hydrochloride Injection, 60 mg/3 ml (20 mg/ml) and 30 mg/3 ml (10 mg/ml), Batch I842I002A1 (BUD 02/17/2027).

iv. Additionally, all media fills representing the worst-case scenario for vials types produced on each (b) (4) line were not performed on a (b) (4) basis. Since May 2024, your firm produced sterile drug without having had a media fill performed within a (b) (4) (b) (4) time frame. For example, for Line (b) (4), Liraglutide Injection, 18 mg/3 mL (6 mg/mL), Batch I846I002A1 (BUD 08/15/2026) was produced on (b) (4) and the last media fill was performed in April 2025; For Line (b) (4), Testosterone Cypionate Injection, USP 1000 mg/5 mL (200 mg/mL), Batch I861I001A1 (BUD 10/04/26) was produced on (b) (4) and the last media fill was performed in June 2025; For Line (b) (4), Tirzepatide and Pyridoxine Hydrochloride Injection, 60 mg/3 ml (20 mg/ml) and 30 mg/3 ml (10 mg/ml), Batch I842I002A1 (BUD 02/17/2027), was produced on (b) (4) and the last media fill was performed in June 2025.

There is no assurance that your firm can aseptically produce sterile drug products within your

facility.

B. Your firm's visual inspection process governed by SOP IPD-026 *Visual Inspection of Injections Using* (b) (4) *Visual Inspection* (b) (4) (Revision No. 9, effective 03 October 2025) is silent on the requirement of the identification of any critical and major particulates found during the (b) (4) visual inspection process, which could lead to inadequate root cause investigations.

C. Your firm performed visual inspection using (b) (4) visual inspection (b) (4) for sterile drug products produced and packaged in clear vials and accepted inspection results with false rejects or ejects rate of (b) (4) %. However, your firm failed to provide scientific justification for this reject rate for sterile drug products, such as Tirzepatide and Pyridoxine Hydrochloride Injection, 60 mg/3 ml (20 mg/ml) and 30 mg/3 ml (10 mg/ml) Batch I842I002A1 (BUD 02/12/2027, Batch Size: (b) (4) vials). Your firm accepted false rejection vials (ejected by the (b) (4) but found acceptable through 200% visual inspection) for further processing without adequate verification and approval by Quality that these units meet established defect specifications. For Tirzepatide and Pyridoxine Hydrochloride Injection, 60 mg/3 ml (20 mg/ml) and 30 mg/3 ml (10 mg/ml) Batch I842I002A1 (BUD 02/12/2027) approximately (b) (4) false reject vials were placed with accepted vials for further processing. This practice compromises the integrity of your visual inspection process and provides no assurance that finished drug products are free from defects.

D. From January to November 2025, nine incidents were investigated for false reject rates for (b) (4) visual inspection exceeding the limit of (b) (4) %. Your firm did not initiate re-validation of the (b) (4) visual inspection process. Since January 2025, approximately (b) (4) batches have

been released based on inspection results using (b) (4) visual inspection (b) (4)

E. Your firm classified extrinsic particles such as glass as a major defect.

F. Your firm failed to document the review of the results for the continuous monitoring of non-viable particles (NVP) during the active production of your sterile drug products as part of batch release. For example, this was not performed for the following drug products: Liraglutide Injection, 18 mg/3 mL (6 mg/mL), Batch I846I002A1 (BUD 08/15/2026), Testosterone Cypionate Injection, USP 2000 mg/10 mL Batch I861I001A (I150H001A), and Tirzepatide and Pyridoxine Hydrochloride Injection, 60 mg/3 ml (20 mg/ml) and 30 mg/3 ml (10 mg/ml), Batch I842I002A1 (BUD 02/17/2027) . In addition, non-viable particles counts are not evaluated by Quality in (b) (4) Environmental Monitoring Trend Reports.

OBSERVATION 3

The written stability program for drug products does not include reliable, meaningful and specific test methods.

Specifically,

Your firm failed to establish and follow an adequate written testing program designed to assess impurities profiles for Pyridoxine Hydrochloride used in the Tirzepatide and Pyridoxine Hydrochloride Injection, as outlined in SOP IQC-002 *Stability Program* (Revision No. 5, effective 29 March 2023).

The drug strengths for Tirzepatide and Pyridoxine Hydrochloride Injection produced and released by your firm include the following:

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	4/6/2026-4/17/2026* FEI NUMBER 3015156709

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jugal K. Taneja, Chairman and Chief Executive Officer (CEO)

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

Product Code	Drug Product Strength	Batches Released
(b) (4)	30 mg/3 ml and 30 mg/3 ml	(b) (4)
	10 mg/mL and 10 mg/mL	
	60 mg/3 ml and 30 mg/3 ml	
	40 mg/4 mL and 40 mg/4 mL	
	40 mg/2 mL and 20 mg/2mL	
	20 mg/2mL and 20 mg/2 mL	
	68 mg/4 mL and 40 mg/4 mL	

OBSERVATION 4

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

Your firm's major cleaning performed (b) (4) and (b) (4) the production of Testosterone Cypionate Injection, USP, drug products failed to include swabbing analysis to verify that the cleaning was adequate prior to the start of subsequent production. For example, the (b) (4) (b) (4) (Line (b) (4)) was used to produce Testosterone Cypionate Injection, USP 2000 mg/10 mL Batch I861I001A (I150H001A) on 10/20/2025 and then underwent major cleaning on 10/23/2025, but no

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lisa R Hilliard, Investigator X Lisa R Hilliard Investigator Signed By: Lisa R. Hilliard -S Date Signed: 04-17-2026 15:27:28	4/17/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	4/6/2026-4/17/2026*
	FEI NUMBER 3015156709

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Jugal K. Taneja, Chairman and Chief Executive Officer (CEO)

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

swab samples were collected and analyzed to verify removal of Testosterone residues before Line (b)(4) was released for use in the production of Tirzepatide and Pyridoxine Hydrochloride Injection, 60 mg/3 ml (20 mg/ml) and 30 mg/3 ml (10 mg/ml) Batch I842H007B on 10/24/2025. Without analytical verification of cleaning effectiveness, there is no assurance that residues from Testosterone Cypionate Injection, USP has been adequately removed to prevent cross-contamination of subsequent batches.

***DATES OF INSPECTION**

4/06/2026(Mon), 4/07/2026(Tue), 4/08/2026(Wed), 4/09/2026(Thu), 4/10/2026(Fri), 4/13/2026(Mon), 4/14/2026(Tue), 4/15/2026(Wed), 4/16/2026(Thu), 4/17/2026(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lisa R Hilliard, Investigator X Lisa R Hilliard Investigator Signed By: Lisa R. Hilliard -S Date Signed: 04-17-2026 15:27:28	4/17/2026

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."