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 ORAPHARM2_RESPONSES@fda.hhs.gov	4/19/2021-4/30/2021* FEI NUMBER 3015156709

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jugal K. Taneja, Managing Member	
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 Sterile Drug Manufacturer and 503B 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 WE OBSERVED:
Pre-Approval, NDA #205029 Supplement 10: Epinephrine, USP Pre-Filled Syringes 1mg/mL

OBSERVATION 1

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, during inspection, it was observed that the equipment (b) (4) and Labelling Machine type (b) (4) " intended for labeling the pre-filled epinephrine syringes referenced in your NDA application has not been installed and qualified for use.

OBSERVATION 2

Potential suppliers were not evaluated and selected based on their ability to meet specified requirements.

Specifically, your firm was not evaluating suppliers based upon their ability to meet requirements established in your *Vendor Management System* procedure (SOP IGN-034) and *Purchasing System* procedure (SOP IPC-001). Your firm's initial qualification (signed 02/26/2019) of your supplier of sterile 1 mL syringes indicates that a "review of collected data shows that the company has a vigorous quality system and capable of meeting customer expectations," but the approved supplier did not provide the information required per your firm's procedures and the questionnaire provided. For example, the initial *Questionnaire for Customers* provided by your supplier as a self-audit indicated that their Site Master File, manufacturing equipment, site maps and

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	Saundrea A Munroe, Investigator Emma R Schaefer, Investigator Jessica L Pressley, Investigator	4/30/21 Saundrea A Munroe Investigator Signed By: Saundrea A. Munroe - S Date Signed: 04-30-2021 10:43:20 X	4/30/2021

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drawings, an explanation of how product is protected from the manufacturing environment, deviation handling procedures, previous deviations and OOS syringes, and an explanation of rejected batches of syringes within the last year were not provided. The supplier indicated that this information could be provided at the next on-site audit. There has not been an on-site audit conducted since this initial qualification nor is one scheduled by the firm. Additionally, this self-assessment indicated that the supplier has not been inspected by a regulating body and doesn't confirm the supplier's understanding of FDA's regulations, which is a requirement of the firm's *Purchasing System* procedure.

OBSERVATION 3

Risk analysis is inadequate.

Specifically, your firm's risk analysis conducted as part of the *Combination Product Compliance 21 CFR Part 4 Drug and Device Constituent Parts* document you identified as the design history file for your firm's 1 mL epinephrine syringe does not adequately identify the hazards, estimated risks, and mitigations associated with the use of your finished combination product.

For example, your firm identifies the glass syringe and rubber plunger components of your finished 1 mL epinephrine syringe as high risk for particulate matter, bacterial endotoxin, and lack of sterility in the *Product Development Report for Epinephrine Injection, USP 1 mG/mL* under section 2.1.3. In your firm's design history file your risk analysis conducted for the finished 1 mL epinephrine syringe device does not evaluate the risk levels for the eight risks identified by your firm. Additionally, one of the mitigations listed for risk of particulates is "incoming materials controls". Your firm's supplier control's do not adequately evaluate your supplier's capabilities of meeting the supplier requirements established by your firm, including technical and regulatory requirements. Your firm's supplier of syringes for this combination product was not subject to a quality

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agreement and did not provide evidence to support their abilities to meet your firm's established supplier requirements during their initial self-audit approved on 02/26/2019.

OBSERVATION 4

Procedures for design transfer have not been adequately established.

Specifically, your firm's design history file for your 1 mL epinephrine syringe combination product did not contain a documented design transfer that supported the device's design was correctly translated into production specifications. Under design transfer your firm documented "there is no transfer involved."

OBSERVATION 5

The type and extent of control to be exercised over the product and suppliers was not clearly defined.

Specifically, your firm did not establish a quality agreement with your supplier that defined the type and extent of control to be exercised over the sterile 1 mL syringe that is a component of your firm's sterile 1 mL epinephrine syringe combination product until 04/22/2021. This is required per SOP IGN-034 Section 6.3.6 upon vendor approval. Your firm's supplier of sterile 1 mL syringes was approved on 02/26/2019.

*DATES OF INSPECTION

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4/19/2021(Mon), 4/20/2021(Tue), 4/21/2021(Wed), 4/22/2021(Thu), 4/23/2021(Fri), 4/26/2021(Mon), 4/27/2021(Tue), 4/28/2021(Wed), 4/30/2021(Fri)

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

Observation 5: Not annotated

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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."