DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	3/7/2022-3/10/2022
	FEI NUMBER 3008875046

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kenneth E Shirley, President

FIRM NAME	STREET ADDRESS
BPI Labs	97 S Red Willow Rd
CITY, STATE, ZIP CODE, COUNTRY Evanston, WY 82930-9769	TYPE ESTABLISHMENT INSPECTED Manufacturer

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:
PRODUCTION SYSTEM

OBSERVATION 1

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established and written.

Specifically,
A.) On 03/07/2022, a production employee was observed reaching into a drum of cellulose powder to dispense the material for the production of antifungal foot powder lot #22B28. Powder was observed on the employee's arm, coat, and pants. No protective garments such as smock or disposable sleeves were required to protect the material. The only PPE observed were gloves, hairnet, and dust mask.
B.) During packaging of (b)(4) Lube (personal lubricant) lot #22B26 on 03/07/2022, an employee was observed moving uncapped, filled bottles from the packaging line to a nearby table. The firm's Compliance and Quality Manager indicated that no procedure existed limiting the time that these open bottles may remain on the table before being returned to the packaging line for capping.
C.) During a walk-through of the facility on 03/07/2022, wood pallets were observed being used in the (b)(4) manufacturing area and the (b)(4) packaging area. In addition, a section of wall in the (b)(4) packaging area is composed of (b)(4) wood.

OBSERVATION 2

The batch production and control records are deficient in that they do not include the identity of major equipment used.

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	Alan P Kurtzberg, Investigator	x Alan P Kurtzberg Investigator Signed By: Alan P. Kurtzberg -S Date Signed: 03-10-2022 15:32:24	3/10/2022

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Specifically, the batch record for bulk zinc oxide batch 22A12 does not list the major equipment used in compounding. Although there is only (b)(4) mixing tank the product is currently made in, other information is also missing such as the secondary tank used, the pH meter used, and the balance(s) used.

OBSERVATION 3

Actual yield and percentages of theoretical yield are not determined at the conclusion of each appropriate phase of manufacturing of the drug product.

Specifically, the batch record for zinc oxide cream bulk lot #22A12 does not have a completed calculation for the batch yield. Without a calculated yield, determining if the batch met the specification of (b)(4) yield is not possible.

QUALITY SYSTEM

OBSERVATION 4

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, the following equipment/processes have not been qualified/validated evidenced by lack of a written and approved qualification/validation protocol and report.

A.) The (b)(4) gal stainless steel tank
B.) The (b)(4) water system
C.) Bulk blending of the zinc oxide product
D.) Cleaning procedures used in bulk manufacturing

OBSERVATION 5

The quality control unit lacks responsibility to approve all procedures or specifications impacting on the identity, strength, quality and purity of drug products.

Specifically, none of the firm's SOPs bear an approval signature by a member of the quality unit.

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OBSERVATION 6

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

Specifically, SOP QC001 which provides quality oversight to changes to documentation does not extend to changes in the facility or equipment.

OBSERVATION 7

Employees are not given training in the particular operations they perform as part of their function and current good manufacturing practices.

Specifically, a review of training records for employee (b) (6) who recorded weight checks of zinc oxide finished batch 22A20 and employee (b) (6) who participated in formulating the associated bulk batch 22A12 showed no training specific to the task they were performing, no training given as a new employee, and no training in good manufacturing practice.

OBSERVATION 8

Records are not maintained so that data therein can be reviewed at least (b)(4) to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures.

Specifically, the firm does not create a report of product quality for its OTC products on at least an (b)(4) basis.

MATERIALS SYSTEM

OBSERVATION 9

The number of containers to be sampled is not based upon appropriate criteria.

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Specifically, there are no statistical sampling plans for chemical or packaging components. Raw material and packaging component samples are taken from (b)(4) container no matter how many containers are received in a shipment.

LABORATORY CONTROL SYSTEM

OBSERVATION 10

The establishment of laboratory control mechanisms including any changes thereto, are not drafted by the appropriate organizational unit. Electronic records are used, but they do not meet system access limitation, audit trail, systems documentation control, signature manifestation and signature to record linking requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

Specifically, the (b)(4) software used with the (b)(4) FTIR lacks controls to limit access, retain an audit trail, and associate testing to a specific user.

OBSERVATION 11

The written stability program for drug products does not describe the storage conditions for samples retained for testing.

Specifically, sample storage conditions are not described in SOP GL006. The (b)(4) room has no limits for temperature or humidity. This room contains stability samples of OTC products.

PACKAGING AND LABELING SYSTEM

OBSERVATION 12

Strict control is not exercised over labeling issued for use in drug product labeling operations.

Specifically, amounts of labels issued are not recorded. Label reconciliation is not performed.

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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."