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	11/1/2021-11/15/2021* FEI NUMBER 1000526113

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Jugal K. Taneja, Managing Member

FIRM NAME	STREET ADDRESS
Belcher Pharmaceuticals, LLC	12393 Belcher Rd S Ste 420
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Largo, FL 33773-3097	Drug 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 WE OBSERVED:

LABORATORY

OBSERVATION 1

The suitability of all testing methods is not verified under actual conditions of use.

Specifically, no studies have been performed demonstrating your validated analytical methods can adequately recover residues from the different equipment surfaces including but not limited to: CDA-875, (b) (4).

Protocol PD-IOQ-R-3A-PD-TP10-01-2 Installation and Operational Qualification Protocol for the (b) (4) Tablet Press (Model # (b) (4)) [Requalification Due to Equipment Transfer] R. 01 for the (b) (4) Tablet Press ((Model # (b) (4) ID #3A-PD-TP10-01) lists the materials of the product contact surfaces of the feed frame as (b) (4) and the die table as (b) (4). Swab Location Diagram for (b) (4) Tablet Press includes the (b) (4) and (b) (4) as required swab locations of the (b) (4) Tablet Press.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Nicole E Knowlton, Investigator Steven A Brettler, Investigator	X Nicole E Knowlton Investigator Signed By: Nicole E. Knowlton -S Date Signed: 11-15-2021 17:21:1	11/15/2021

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Protocol PD-IOQ-T-4-PK-PL02-01 Installation and Operational Qualification Protocol for the Packaging Line at Belcher 6911 Facility R. 01 (which includes (b) (4) Tablet/Capsule Counter (Model SPC (b) (4)) ID #4-PD-TC07-01) lists the upper and lower counting blocks of the Tablet/Capsule Counter as a product contact surface made of (b) (4). Swab Location Diagram for Tablet/Counter ((b) (4)) includes the (b) (4) as a required swab location of the tablet counter.

The production equipment, including the (b) (4) Tablet Press and (b) (4) Tablet/Capsule Counter, is not dedicated. The above mentioned (b) (4) Tablet Press and (b) (4) Tablet/Capsule Counter were used to manufacture exhibit batches (b) (4) and (b) ((b) (4) in support of ANDA (b) (4) (b) (4) and are intended for use in commercial production of (b) (4). Additionally, the (b) (4) Tablet Press and (b) (4) Tablet/Capsule Counter are used to manufacture (b) (4) Capsules and (b) (4) Tablets.

PRODUCTION

OBSERVATION 2

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 (b) (4) performance of the bottle weight verification using a scale post fill is inadequate in that:

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A. No written procedure has been established providing instructions to perform the (b) (4) weight verification process observed on 11/01/2021 during the filling of (b) (4) Caplets Batch (b) (4)

B. This (b) (4) check weigh process is not documented in the batch records or any other records.

C. There is no documentation to show how the calculation of the target weight is performed or if the calculation is verified.

D. The target weight itself is not documented in the batch record, or otherwise, and the production supervisors and operators have no value which to refer to ensure they are verifying the correct target weight, especially when production personnel return from breaks, lunch and after the weekend.

E. There is no bottle weight range established that would permit bottles to pass if they are not the actual target weight.

F. Management stated the (b) (4) weight check is not part of the validated process.

G. Additionally, no data is collected that would permit trending of this in-process verification.

This post fill bottle weight verification is currently performed for (b) (4) Caplets and is intended to be performed during commercial production of ANDA (b) (4) .

OBSERVATION 3

Batch production and control records do not include complete information relating to the production and control of each batch.

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Specifically, there is no documentation demonstrating the set (b) (4)) of (b) (4) (b) (4) Blender Model (b) (4) during the production of the (b) (4) and (b) (4) . The qualification performed in 2020, as reported in Summary Report Document PD-IOPQ-R-4-PD-BL19-01 R. 01, shows the blender has a variable frequency drive.

These blend batches were used to manufacture exhibit batches (b) (4) submitted in support of (b) (4) .

QUALITY

OBSERVATION 4

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

Specifically, no updates have been made to Maintenance Form (b) (4) Blender (Model No (b) (4)) PD-BL12-3-F1 R. 02 Effective 07/02/2012 after at least (b) (4) review periods (every (b) (4)) for its corresponding procedure, Maintenance of the (b) (4) (b) (4) Blender (Model No (b) (4)) PD-BL12-3 R. 03 Effective 01/27/2016. There are tasks listed in the form that are considered non-applicable to this blender including but not limited to the inspection of the (b) (4) . This procedure was revised in 2016 to clarify and

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remove the calibration of the (b) (4). Form PD-BL12-3-F1 R. 02 is used to document the preventative maintenance performed each (b) (4), (b) (4) and (b) (4)

The (b) (4) Blender PD-BL12-3 is intended for use in commercial production of (b) (4)

FACILITIES AND EQUIPMENT

OBSERVATION 5

Washing and toilet facilities lack hot and cold water.

Specifically, during the inspectional walk through on 11/01/2021, we observed there was no running hot water in the men's and women's restrooms used by the firm's employees. The Chief Operating Officer confirmed these are the only restrooms used by the production personnel.

*DATES OF INSPECTION

11/01/2021(Mon), 11/02/2021(Tue), 11/03/2021(Wed), 11/04/2021(Thu), 11/05/2021(Fri), 11/08/2021(Mon), 11/09/2021(Tue), 11/10/2021(Wed), 11/12/2021(Fri), 11/15/2021(Mon)

X Steven A Brettler
Investigator
Signed By: Steven A. Brettler -S
Date Signed: 11-15-2021 17:24:30

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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."