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	10/31/2022-11/4/2022
	FEI NUMBER 1000526113

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

FIRM NAME	STREET ADDRESS
Belcher Pharmaceuticals, LLC	6911 Bryan Dairy Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Largo, FL 33777	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:
(b) (4)
ANDA(b) (4)

OBSERVATION 1

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components conform to appropriate standards of identity, strength, quality and purity.

Specifically, you do not prevent the possibility of contamination of *Burkholderia cepacia*, an opportunistic gram-negative organism commonly identified in (b) (4) systems. You purchase (b) (4) (b) (4) which is used as an ingredient for the production of (b) (4) (b) (4) under review for application ANDA(b) (4). Although you test your finished products for the presence of this organism, your finished product testing is only an examination of a small sample size of products that are expected to represent the entire batch produced. There is no indication this organism is monitored in the purchased (b) (4) at any frequency by either your quality unit or the (b) (4) manufacturer prior to its use as an ingredient in drug products.

OBSERVATION 2

Written records of investigations into the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically, you received four (4) out of specification results for assay content during various stages of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Saundrea A Munroe, Investigator Harshal J Desai, Investigator Brittny C Cargo, Investigator	X Saundrea A Munroe Investigator Signed By: Saundrea A. Munroe - S Date Signed: 11-0 -2022 11:10:58	11/4/2022

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	10/31/2022-11/4/2022
	FEI NUMBER 1000526113

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jugal K. Taneja, CEO	
FIRM NAME Belcher Pharmaceuticals, LLC	STREET ADDRESS 6911 Bryan Dairy Rd
CITY, STATE, ZIP CODE, COUNTRY Largo, FL 33777	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

stability analysis for (b) (4)
under review for application ANDA(b) (4) . Each of these investigations were invalidated attributing the root cause to sample prep error, however, the root cause triggering the sample prep errors was never determined. Although your quality unit created a CAPA to monitor this issue with the outsourced testing laboratory responsible for performing this testing, there is concern of the reliability of the data due to the frequency of this error type.

X Brittny C Cargo
Investigator
Signed By: Brittny C. Cargo -S
Date Signed: 11-04-2022 11:11:32

X Harshal J Desai
Investigator
Signed By: Harshal J. Desai -S
Date Signed: 11-04-2022 11:12:10

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Saundrea A Munroe, Investigator
Harshal J Desai, Investigator
Brittny C Cargo, Investigator

X Saundrea A Munroe
Investigator
Signed By: Saundrea A. Munroe -S
Date Signed: 11-0 -2022 11:10:58

DATE ISSUED
11/4/2022

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."