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	8/7/2024-8/16/2024* FEI NUMBER 1000526113

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Supriya S. Taneja, Vice President and General Counsel, Partial Owner

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	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:

OBSERVATION 1

Each batch of controlled-release dosage form drug product is not laboratory tested to determine conformance to the specifications for the rate of release for each active ingredient.

Specifically, your firm failed to conduct dissolution testing as part of your finished product specification requirements prior to batch release for all strengths of Testosterone pellets (12.5mg, 37.5mg, 50mg, 100mg and 225mg) therefore your firm is unable to ensure the pellets do not dissolve immediately, remain integral (does not crumble or break into pieces) and release API at a rate that is reproducible.

The following batches were released for distribution: Testosterone Pellets 100mg, lot #(b) (4), CPD:9/6/23, BUD: 9/4/24 (QTY:(b) (4) blister packs/(b) (4) pellets), Testosterone Pellets 37.5mg, lot #(b) (4), CPD: 2/19/24, BUD: 2/12/25 ((b) (4) blister packs/(b) (4) pellets), Testosterone Pellets, 50mg lot #(b) (4), CPD: 2/19/24, BUD: 2/12/25 ((b) (4) blister packs/(b) (4) pellets) and Testosterone Pellets, 100mg lot #(b) (4), CPD: 2/19/24, BUD: 2/12/25 ((b) (4) blister packs/(b) (4) pellets).

OBSERVATION 2

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, your firm's control testing lab utilizes the Sterility Testing Method (STM No. M109) which is inadequate as it only accounts for the testing of the exterior portion of the pellets by direct inoculation rather than crushing the pellets or requiring them to dissolve prior to testing. In addition, your control testing labs, Assistance Microbiology Manager, stated that the pellets do not dissolve completely during

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jessica P Mcalister, Investigator Kayla V Sprague, Investigator	X Jessica P Mcalister Investigator Signed By: Jessica L. Mcalister -S Date Signed: 08-16-2024 13:23:58	8/16/2024

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	8/7/2024-8/16/2024* FEI NUMBER 1000526113

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Supriya S. Taneja, Vice President and General Counsel, Partial Owner	
FIRM NAME Belcher Pharmaceuticals, LLC	STREET ADDRESS 12393 Belcher Rd S Ste 420
CITY, STATE, ZIP CODE, COUNTRY Largo, FL 33773-3097	TYPE ESTABLISHMENT INSPECTED 503B Outsourcing Facility

testing and are still observed at the 14-day inspection for growth therefore illustrating the interior portion of the pellet is not being tested.

The following batches were released for distribution: Testosterone Pellets 100mg, lot #(b) (4), CPD:9/6/23, BUD: 9/4/24 (QTY:(b) (4) blister packs/(b) (4)pellets), Testosterone Pellets 37.5mg, lot #(b) (4), CPD: 2/19/24, BUD: 2/12/25 ((b) (4) blister packs/(b) (4) pellets), Testosterone Pellets, 50mg lot #(b) (4), CPD: 2/19/24, BUD: 2/12/25 ((b) (4)blister packs/(b) (4) pellets) and Testosterone Pellets, 100mg lot #(b) (4), CPD: 2/19/24, BUD: 2/12/25 ((b) (4) blister packs/(b) (4) pellets).

OBSERVATION 3

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

Specifically, your firm failed to conduct testing for impurities as part of your finished product specification requirements prior to batch release for all strengths of Testosterone pellets (12.5mg, 37.5mg, 50mg, 100mg and 225mg) therefore your firm is unable to ensure degradants such as Androstenedione (Androst-4-ene-3,17-dione), unknown and unspecified related substances can be detected.

The following batches were released for distribution: Testosterone Pellets 100mg, lot #(b) (4), CPD:9/6/23, BUD: 9/4/24 (QTY:(b) (4) blister packs/(b) (4) pellets), Testosterone Pellets 37.5mg, lot #(b) (4), CPD: 2/19/24, BUD: 2/12/25 ((b) (4)blister packs/(b) (4) pellets), Testosterone Pellets, 50mg lot #(b) (4), CPD: 2/19/24, BUD: 2/12/25 ((b) (4) blister packs/(b) (4) pellets) and Testosterone Pellets, 100mg lot #(b) (4), CPD: 2/19/24, BUD: 2/12/25 ((b) (4) blister packs/(b) (4) pellets).

OBSERVATION 4

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jessica P Mcalister, Investigator Kayla V Sprague, Investigator	X Jessica P Mcalister Investigator Signed By: Jessica L. Mcalister -S Date Signed: 08-16-2024 13:23:58	DATE ISSUED 8/16/2024

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	8/7/2024-8/16/2024* FEI NUMBER 1000526113

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Supriya S. Taneja, Vice President and General Counsel, Partial Owner	
FIRM NAME Belcher Pharmaceuticals, LLC	STREET ADDRESS 12393 Belcher Rd S Ste 420
CITY, STATE, ZIP CODE, COUNTRY Largo, FL 33773-3097	TYPE ESTABLISHMENT INSPECTED 503B Outsourcing Facility

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically, your firm failed to certify the following production rooms: Room (b) (4) ((b) (4) , Room (b) (4) ((b) (4)), Room (b) (4) ((b) (4)), Room (b) (4) ((b) (4)) and Room (b) (4) ((b) (4)) where (b) (4) sterilized (via (b) (4)) Testosterone Pellets (12.5mg, 37.5mg, 50mg, 100mg and 225mg) are produced under ISO-8 or better air quality as determined under dynamic conditions. In addition, air exchanges conducted (b) (4) for the production rooms do not meet ISO 8 specifications, non-viable particle counts and HEPA filter integrity testing are only performed every (b) (4) , rather than bi-annually.

OBSERVATION 5

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically, the following information is not found on your drug product labels:

a)The statement "This is a compounded drug";

b)The phone number of the outsourcing facility;

c)The storage and handling instructions;

Examples of your drug product labels that do not contain this information:
Testosterone Pellets 37.5mg
Testosterone Pellets 50mg
Testosterone Pellets 100mg
Testosterone Pellets 225mg

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jessica P Mcalister, Investigator Kayla V Sprague, Investigator	X Jessica P Mcalister Investigator Signed By: Jessica L. Mcalister -S Date Signed: 08-16-2024 13:23:58	8/16/2024

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	8/7/2024-8/16/2024* FEI NUMBER 1000526113

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Supriya S. Taneja, Vice President and General Counsel, Partial Owner

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	503B Outsourcing Facility

OBSERVATION 6
Your outsourcing facility has not submitted a report to FDA identifying a product compounded during the previous six months as required by section 503B(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically, the following product was compounded and not identified on your report dated December 2023 (2023-2).
Testosterone Pellets, 100mg

***DATES OF INSPECTION**
8/07/2024(Wed), 8/08/2024(Thu), 8/09/2024(Fri), 8/12/2024(Mon), 8/13/2024(Tue), 8/14/2024(Wed), 8/15/2024(Thu), 8/16/2024(Fri)

X Kayla V Sprague
Investigator
Signed By: Kayla V. Sprague -S
Date Signed: 08-16-2024 13:24:55

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Jessica P Mcalister, Investigator
Kayla V Sprague, Investigator

X Jessica P Mcalister
Investigator
Signed By: Jessica L. Mcalister -S
Date Signed: 08-16-2024 13:23:58

DATE ISSUED
8/16/2024

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."