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	8/25/2016-9/2/2016* FEI NUMBER 3011976853

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Anne M. Szilagyi , Quality Head and General Manager

FIRM NAME	STREET ADDRESS
BSO LLC	12860 W Cedar Dr Ste 211
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lakewood, CO 80228-1971	Sterile 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:

OBSERVATION 1

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically, hold time studies have not been performed for (b) (4) in-process stages of testosterone pellets and estradiol pellets.

1. (b) (4) material is (b) (4) for (b) (4) (b) (4).

2. Pellets are stored in (b) (4) for (b) (4) (b) (4) (b) (4) (b) (4) atches have been held for longer than (b) (4) Estradiol 6mg lot 20160112@1 sterilization date (b) (4) and Testosterone 200mg lot 20160310@3 sterilization date (b) (4) were stored for longer than (b) (4) (b) (4)

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,

1. Process validation has not been performed for the any of the four unique hormone pellets drug products manufactured on site. No procedures are established for the ongoing periodic monitoring of the drug manufacturing process.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Zachary L Stamm, Investigator Zachary A Bogorad, Investigator 9/2/2016 X Zachary A Bogorad Zachary A Bogorad Investigator Signed by: Zachary A. Bogorad -S	9/2/2016

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Drug Name	Concentrations in mg
Testosterone	12.5, 25, 37.5, 50, 62.5, 70, 80, 87.5, 100, 112.5, 200
Estradiol	6, 10, 12.5, 15, 18, 20, 22, 25, 37.5, 50, 75
Progesterone	25, 35, 50, 75
Anastrozole	6

2. Equipment qualifications have not been assessed for the (b) (4)
The (b) (4) (b) (4) testosterone as well as estradiol active pharmaceutical ingredients. No end point to the (b) (4) has been identified. You have not collected data in support of the efficacy and reproducibility of the (b) (4) There are no defined criteria for the end point of the (b) (4)

3. Equipment qualifications have not been assessed for (b) (4) incubators model (b) (4) Incubators are used to store environmental monitoring plates. No procedures are established for the ongoing periodic monitoring of laboratory equipment.

***DATES OF INSPECTION**

8/25/2016(Thu),8/26/2016(Fri),8/29/2016(Mon),8/30/2016(Tue),8/31/2016(Wed),9/02/2016(Fri)

9/2/2016

X Zachary L Stamm

Zachary L Stamm
Investigator
Signed by: Zachary L Stamm-S

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Zachary L Stamm, Investigator
Zachary A Bogorad, Investigator

9/2/2016

X Zachary A Bogorad

Zachary A Bogorad
Investigator
Signed by: Zachary A. Bogorad -S

DATE ISSUED
9/2/2016