

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax: (303)236-3100	DATE(S) OF INSPECTION 9/9/2019-9/20/2019*
	FEI NUMBER 3011976853

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Anne Szilagyi, General Manager/VP of Quality

FIRM NAME BSO LLC DBA Belmar Select Outsourcing	STREET ADDRESS 12860 W Cedar Dr Ste 211
CITY, STATE, ZIP CODE, COUNTRY Lakewood, CO 80228-1971	TYPE ESTABLISHMENT INSPECTED 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 I OBSERVED:**

**OBSERVATION 1**

Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, validation/verification of the cleaning methods for tools and equipment used in the manufacture of pellet drug products has not been proven. Data examined for the cleaning from testosterone/cholesterol pellets and from progesterone pellets have inappropriate acceptance criteria.

**OBSERVATION 2**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically,

A.) An employee in the blending/granulation room (ISO 8) of cleanroom (b) (4) was observed on 09/09/2019 with a beard cover that did not completely cover the beard.

B.) On the same day, an umbrella was observed inverted on a plastic tray. Both the umbrella and tray were located in an unclassified area reserved for temporary storage of quarantine non-ingredient materials such as caps and vials.

**\*DATES OF INSPECTION**

9/09/2019(Mon), 9/10/2019(Tue), 9/11/2019(Wed), 9/12/2019(Thu), 9/13/2019(Fri), 9/19/2019(Thu), 9/20/2019(Fri)

**AMENDMENT 1**

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Alan P Kurtzberg, Investigator	Alan P Kurtzberg Investigator Signed by Alan P. Kurtzberg -S Date Signed 09-20-2019 13:08:54 X	DATE ISSUED 9/20/2019