

**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 3/1/2021-3/11/2021*
	FEI NUMBER 3011976853

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David W. Hill, CEO

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

Written records of investigations into unexplained discrepancies do not always include the conclusions and follow-up.

For example:

Non Conformance Investigation INV20018 covered EM excursions on 7/14/20 and 7/28/20. Excursions occurring 7/14/20 and 7/28/20 at the gowning room computer area (Clean Room (b)(4) ISO 8, where compounded drugs, such as Testosterone Pellets, are made) concerned surface viable monitoring excursion exceeding the action limit (b)(4) cfu). Counts were 30 and 32 cfu respectively. Viable air limits were also exceeded on 7/14/20 in the area by the hanging gowns at TNTC (too numerous to count); the action limit is (b)(4) cfu. Various organisms were found in the surface and air monitoring samples indicating origins from human skin ((b)(4) %), with plants, soil and water accounting for (b)(4) % of results. Root cause was determined to be failure to follow procedures, but what actually was the cause specifically lacked thorough investigation. No documented data supported the conclusion that procedures weren't followed. For example, observation of routine actions conducted by Technicians in the controlled areas were not documented as part of the investigation, nor were there any documented investigations of air patterns (e.g., turbulence and/or dead air in the clean rooms) that may have lead to the excursions. Contact times of disinfectant used for gloved hands and surfaces were also not documented as reviewed (contact times for use of (b)(4) as a disinfectant for hands and surfaces does not have an established time in procedures). The investigation concluded that adequate procedures for gowning and sanitization were in place but employees were not following them. Which elements of the procedures that were not followed were not documented as

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investigated. Other EM investigations were conducted in similar fashion. INV20025 found a fingertip excursion on 11/4/20 at 10 cfu (action limit ^{(b)(4)} cfu in production area) on a Technician processing Testosterone/Cholesterol Pellets in Clean Room ^{(b)(4)}. The root cause again was deemed that the Technician did not follow procedures but the specific actual element that was not followed was not fully investigated. Five other EM investigations (INV20008, INV2009, INV20011, INV20012 and INV 20022) in the year 2020 also concluded the general cause of excursion to be a failure to follow procedures. Comprehensive searches to determine root cause are not undertaken to resolve unexplained discrepancies.

OBSERVATION 2

Procedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance.

For example:

a) Manual cleaning procedures for (shared) drug processing equipment do not always include details such as precise parameters, e.g., time required for cleaning, equipment used and volume of cleaning solvent to be utilized. Technician subjectivity, not actual delivery of cleaning process parameters, sometimes determines whether equipment is adequately cleaned in a process where cleaning validation was performed. Reproducible and consistent results are therefore not assured. For example, cleaning procedures (SOP-Cleaning/Sanitization of BSO Facility/Cleanroom) read in part, "9.5 Bottles, Dishes used Utensils Cleaning Requirements" in section 9.5.2 "Wipe dishes, Utensils and bottles with ^{(b)(4)}" but procedures do not indicate how much ^{(b)(4)} to use, how many wipes should be utilized, or how much time for wiping a particular dish, utensil or bottle is required to adequately remove drug substances. 9.5.3 states, "Bring dishes, utensils and bottles out and rinse (soak if needed)" but the procedure does not state what to rinse with, what volume of rinse is required, how to rinse precisely, and then gives the Technician the option to soak, which is subjective. 9.5.4 states, "Wash with ^{(b)(4)} ^{(b)(4)} solution" but does not state how much solution (volume) is needed or how precisely to wash and

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what equipment may be needed. 9.5.5 states “Rinse with (b) (4)” but does not indicate how much (b) (4) 9.5.6 states “Rinse with (b) (4)” but does not indicate volume.

The SOP at 9.9 “Pellet Pressing Tool Cleaning” in 9.9.1 states “Remove bulk residue in (b) (4) room and wipe with (b) (4)” but how many wipes, volume of (b) (4) or other pertinent details are missing as are subsequent steps in Pressing Tool Cleaning.

b) Cleaning validation performed to provide evidence that the cleaning methods utilized are effective in removing API (such as Testosterone) residue from shared tools used in pellet production incorporated (b) (4) rinse sampling followed by analysis (BSO Cleaning Validation Results Interpretation and Calculations Assessment performed in 2020). Rinse instead of swab sampling was utilized for surfaces not easily swabbed, such as pressing tools. Your firm does not have data, such as a rinse recovery study, to show that residues on surfaces sampled by rinsing are recovered, and at what level.

OBSERVATION 3

The labels of your outsourcing facility’s drug products do not include information required by section 503B(a)(10)(A).

Per 503B(a)(10)(B)(i), if there is not space on the product label for information described under subparagraph (A)(iii)(X), this information should be included on the container label.

Specifically, the following information is not found on your drug product label or container label:

- a) A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

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Examples of your drug product labels that do not contain this information:

- Testosterone 100 mg Pellet

OBSERVATION 4

You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2).

Specifically, you compound drug products that are not identical or nearly identical to an approved drug, but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Examples of compounded drug products that are essentially a copy of one or more approved drugs include:

- Testosterone 50 mg Pellet
- Testosterone 80 mg Pellet
- Testosterone 100 mg Pellet
- Estradiol 10 mg Pellet
- Estradiol 20 mg Pellet
- Progesterone 50 mg Pellet
- Anastrozole 6 mg Pellet

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***DATES OF INSPECTION**

3/01/2021(Mon), 3/02/2021(Tue), 3/03/2021(Wed), 3/04/2021(Thu), 3/10/2021(Wed), 3/11/2021(Thu)

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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."