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	7/7/2025-7/16/2025* FEI NUMBER 3011976853

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Robert J. Kilgore, Chief Executive Officer	
FIRM NAME BSO LLC	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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the sterilization process.

Specifically,

a. **Lack of Potency Data at Maximum Sterilizing Dose Range**: Under RAM 24008, dated 08/14/2024, your firm changed the container-closure system for all doses less than 87.5 mg of Anastrozole, Estradiol, Testosterone, and Testosterone with Cholesterol pellets from (b) (4) Amber Vials to (b) (4) Clear Vials. You performed a (b) (4) (BSO04, dated 05/06/2024) showing that the sterilizing dose increased from (b) (4) to (b) (4). However, your firm did not assess the impact of this sterilization range on product quality in the revised container-closure system. Specifically, you were unable to provide pre- and post-sterilization potency data for Anastrozole and Estradiol products packaged in clear vials. Instead, in BSO.ST.034.1, Potency/Sterilization Study Results (signed 11/14/2024), your firm used products packaged in amber glass vials, which does not reflect the current distributed configuration.

   Without data demonstrating that the increased sterilization dose does not degrade potency in the clear vial configuration, there is no assurance that the distributed product retains its labeled strength and therapeutic effectiveness after sterilization.

b. **Inadequate Sterility Method used in Method Suitability**: Your firm utilizes (b) (4) as the

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basis for sterility method suitability during (b) (4) sterilization validation studies and (b) (4) Dose Audits, while applying the compendial USP <71> sterility test to stability study samples. The method suitability under (b) (4) does not include *Clostridium sporogenes* as a challenge microorganism. The current method, a new sterility test method involving crushing pellet since the original validation, uses *S. aureus, B. subtilis, P. aeruginosa, C. albicans, and A. brasiliensis*. In contrast, the method validated in the 2015 sterilization study demonstrated the ability to recover *C. sporogenes.*

Your current method fails to demonstrate equivalency or superiority to the compendial method in sensitivity, specificity, and reproducibility because it omits *C. sporogenes,* an anaerobic spore-forming organism critical for sterility assurance. Additionally, your method validation did not demonstrate reproducibility, as there was no evidence of consistent detection of all six specified challenge organisms across replicates or reliable recovery of low levels of spores.

Without appropriate sterility method suitability including all compendial challenge microorganisms, there is no assurance that the sterility testing methods used for validation and routine monitoring can detect contamination reliably. This deficiency compromises sterility assurance for distributed (b) (4) sterilized pellets.

c. **Failure to demonstrate bioburden method suitability in current container**. Your firm implemented a new container-closure system for multiple pellet products, with a new contract testing lab, but did not reconduct bioburden method suitability studies to assess microbial recovery efficiency in the revised container configuration.

Under RAM 24008, dated 08/14/2024, the container-closure system for all doses less than 87.5 mg including Anastrozole and Estradiol pellets was changed from amber to clear vials. Instead of performing bioburden method suitability using product-filled vials in the new configuration, your firm performed bioburden and endotoxin testing using empty clear vials.

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REPEAT OBSERVATION

OBSERVATION 2

Employees engaged in the manufacture and processing of a drug product lack the training required to perform their assigned functions.

Specifically,

The (b) (4) used to train and evaluate personnel performing the visual inspection of liquid injectable products is incomplete. Review of Form 190-02, *Liquid Injectables* (b) (4) *Inventory (BSO Lakewood and Golden*) found that the (b) (4) does not contain examples of all critical defects, including: "*Improper crimp (not gripping the lip of the vial)*" and "*Stopper on vial crooked or compromised*".

This (b) (4) is intended to serve as the reference library of vials from which the (b) (4) are created to assess the proficiency of visual inspectors. The absence of representative examples of all critical container-closure integrity defects prevents adequate demonstration that personnel can consistently identify defects which pose a risk to product sterility.

Liquid Injectable products include Testosterone Cypionate/Anastrozole 200mg/0.5 mg; Testosterone Cypionate/Anastrozole 200mg/1mg; Testosterone Cypionate/DHEA 200mg/10mg.

REPEAT OBSERVATION

OBSERVATION 3

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

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Specifically,

Your firm's procedure, SOP 12, Visual Inspection of Pellets (BSO-Lakewood & Golden), Version 26, Effective 03/19/2025, is deficient in that it does not contain several critical elements necessary to ensure the consistent detection and classification of defects in sterile pellet products:

a. The SOP does not classify defects into Critical, Major, and Minor categories. Instead, defects are categorized only as container-closure, physical, or packaging defects, without linkage to severity.
b. The procedure does not include definitions of Critical, Major, and Minor defect categories, preventing consistent interpretation by personnel conducting inspections.
c. The SOP does not establish acceptance criteria linked to defect severity. While the procedure states that a (b) (4) overall defect rate will trigger a deviation investigation, it does not define numerical acceptance criteria for critical defects (e.g., zero tolerance) or specify Acceptable Quality Levels (AQLs) per defect class, as expected under a scientifically justified sampling plan.
d. The procedure does not specify that inspections must be performed under adequate lighting using contrasting (white and black) backgrounds or a calibrated light source with magnification, to ensure reliable detection of particulates and defects.

These deficiencies significantly reduce assurance that visible contamination, pellet defects, or container-closure integrity issues will be reliably detected and classified during production. Failure to implement adequate inspection procedures increases the risk that defective units may be released to patients, potentially resulting in serious health consequences.

OBSERVATION 4

The written stability program does not assure testing of the drug product in the same container-closure system as that in which the drug product is marketed.

Specifically,

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Your firm has not conducted stability studies in the packaging system currently used for distribution to demonstrate that assigned expiration date is appropriate for the following products. Without container-specific stability data, there is no assurance that product quality is maintained for the duration of the labeled shelf life. Your firm was unable to provide data to support the (b) (4) expiry period for the products listed below in their current clear vials container-closure system:

a. Anastrozole (6 mg) pellets
b. Estradiol (6 mg, 10 mg, 12.5 mg, 15 mg, 18 mg, 20 mg, 25 mg, 37.5 mg, 50 mg) pellets
c. Progesterone (50 mg, 75 mg) pellets

OBSERVATION 5

The written stability program for drug products does not include specific test methods.

Specifically,

Drug products are not tested for critical quality attributes to ensure they maintain their identity, strength, quality, and purity throughout the expiry period.

a. **Lack of Photostability Studies for drug products stored in clear containers that may be light sensitive**: Your firm manufactures the following light-sensitive products, and are packaged and released in clear, non-light-resistant containers. Your stability studies (PQ003.1.VP/PQ003.1.VR and BSO.SS.008.1P-RT.TC_A_DHEALiquidInjectables-(b) (4)Summary) do not contain any data to demonstrate that the packaging protects the drug from photodegradation. No photostability studies have been performed on the drug product in its container-closure system to demonstrate its protection from light. Failure to demonstrate photostability increases the risk of degradation and reduced potency or altered safety profile during distribution and storage.

   - Estradiol (6 mg, 10 mg, 12.5 mg, 15 mg, 18 mg, 20 mg, 25 mg, 37.5 mg, 50 mg) pellets

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- Progesterone (50 mg, 75 mg) pellets
- Testosterone Cypionate/DHEA (200 mg/10 mg/ml) liquid injectable vials
- Testosterone Cypionate/Anastrozole (200 mg/0.5 mg/ml and 200 mg/1 mg/ml) liquid injectable vials

Moreover,

- On 07/01/2022, under RAM 22013 and Change Control #22048, your firm changed the container closure for Progesterone (50 mg & 75 mg) from (b) (4) Amber Vials to (b) (4) Clear Vials and performed a photolytic forced degradation study (FR-0319).
- Under RAM 24008, dated 08/14/2024, your firm changed the container closure for Estradiol pellets (doses less than 87.5 mg) from (b) (4) Amber Vials to (b) (4) Clear Vials and performed a photolytic forced degradation study (FR-0317).

These studies are inadequate because they did not contain negative (protected) controls and measured assay (potency) without evaluating functionality such as dissolution.

b. **Lack of Dissolution testing: in Stability Studies:** Stability studies for the following products do not include dissolution testing to evaluate the drug release characteristics over time (PQ003.1.VP/PQ003.1.VR and PRO-1307-V1). Dissolution testing is a critical quality attribute for pellets and the lack of performance testing, there is no assurance that the products will deliver the intended dose at the expected rate throughout their shelf life.

- Anastrozole (6 mg) pellets
- Estradiol (6 mg, 10 mg, 12.5 mg, 15 mg, 18 mg, 20 mg, 25 mg, 37.5 mg, 50 mg) pellets
- Progesterone (50 mg, 75 mg) pellets

Testosterone (12.5 mg, 25 mg, 37.5 mg, 50 mg, 62.5 mg, 70 mg, 80 mg, 87.5 mg, 100 mg,

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200 mg BLNT) pellets
Testosterone/< 2 % Cholesterol (100 mg, 200mg, 200 mg BLNT) pellets
Testosterone/< 4 % Cholesterol (12.5 mg, 25 mg, 37.5 mg, 50 mg, 62.5 mg, 70 mg, 80 mg, 87.5 mg, 100 mg, 200 mg, 200 mg BLNT) pellets

c. **Lack of Impurities and Degradants in Stability Studies:** Stability studies for the following products omit testing to detect and quantify impurities and degradants, such as related substances and known degradation products (PQ003.1.VP/PQ003.1.VR, PRO-1307-V1 and BSO.SS.008.1P-RT.TC_A_DHEALiquidInjectables-(b) (4)Summary) The omission of impurities testing prevents the evaluation of changes in the product's purity over time.

Anastrozole (6 mg) pellets
Estradiol (6 mg, 10 mg, 12.5 mg, 15 mg, 18 mg, 20 mg, 25 mg, 37.5 mg, 50 mg) pellets
Progesterone (50 mg, 75 mg) pellets
Testosterone (12.5 mg, 25 mg, 37.5 mg, 50 mg, 62.5 mg, 70 mg, 80 mg, 87.5 mg, 100 mg, 200 mg BLNT) pellets
Testosterone/< 2 % Cholesterol (100 mg, 200mg, 200 mg BLNT) pellets
Testosterone/< 4 % Cholesterol (12.5 mg, 25 mg, 37.5 mg, 50 mg, 62.5 mg, 70 mg, 80 mg, 87.5 mg, 100 mg, 200 mg, 200 mg BLNT) pellets
Testosterone Cypionate/DHEA (200 mg/10 mg/ml) liquid injectable vials
Testosterone Cypionate/Anastrozole (200 mg/0.5 mg/ml and 200 mg/1 mg/ml) liquid injectable vials

d. **Inadequate Sterility Method used during Stability**: During sterility method suitability testing conducted to support the stability studies of your hormone pellet products, your firm did not appropriately prepare the dosage form prior to inoculation into the growth media. The pellets were introduced into the sterility media intact without crushing, disintegration, or other suitable procedures to ensure that any microorganisms potentially present within or on the surface of the pellet were exposed to the media for detection.

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This approach does not adequately demonstrate the ability of the sterility test method to detect viable microorganisms that may be entrapped within the solid dosage form.

OBSERVATION 6

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,

a. **Lack of Dissolution testing:** Your firm does not perform dissolution testing to evaluate the drug release characteristics of the following products. Without dissolution testing, there is no assurance that these products will release the active ingredient at the intended rate and extent, which may result in sub-therapeutic dosing or drug toxicity.
   - Anastrozole (6 mg) pellets
   - Estradiol (6 mg, 10 mg, 12.5 mg, 15 mg, 18 mg, 20 mg, 25 mg, 37.5 mg, 50 mg) pellets
   - Progesterone (50 mg, 75 mg) pellets
   - Testosterone (12.5 mg, 25 mg, 37.5 mg, 50 mg, 62.5 mg, 70 mg, 80 mg, 87.5 mg, 100 mg, 200 mg BLNT) pellets
   - Testosterone/< 2 % Cholesterol (100 mg, 200mg, 200 mg BLNT) pellets
   - Testosterone/< 4 % Cholesterol (12.5 mg, 25 mg, 37.5 mg, 50 mg, 62.5 mg, 70 mg, 80 mg, 87.5 mg, 100 mg, 200 mg, 200 mg BLNT) pellet

b. **Lack of Impurities and Degradation testing:** Your firm does not conduct testing for impurities and degradants in the following products prior to release. Without testing for impurities and degradation products, there is insufficient evidence that released lots conform to applicable purity standards, increasing the risk of compromised product safety and efficacy.
   - Progesterone (50 mg, 75 mg) pellets

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- Testosterone Cypionate/DHEA (200 mg/10 mg/ml) liquid injectable vials
- Testosterone Cypionate/Anastrozole (200 mg/0.5 mg/ml and 200 mg/1 mg/ml) liquid injectable vials

OBSERVATION 7

Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration.

Specifically,

a. Your firm's procedure SOP 35, (b) (4) Sterilization Testing Samples and Finished Drug Test Samples and Retains (BSO- Lakewood, & Golden), Version 13.0, Effective 04/30/2025, does not provide instructions for the annual visual examination of reserve samples (pellets and liquid injectable products). There is no defined requirement or trigger for initiating investigations or recall assessments if critical defects are identified during the review of reserve samples.

b. SOP 35 does not require review of retained samples as part of complaint investigations for sterile pellet products, including when critical defects are reported. This omission may prevent the firm from identifying systemic quality issues related to manufacturing, packaging, or handling. Nor is this process included in SOP 12, Visual Inspection of Pellets (BSO-Lakewood & Golden), Version 26, Effective 03/19/2025. For example: the review of retain samples were not included in the evaluation of 3 batches of pellet products involved in Complaint # 25091 and INV # 25269 One of three batches, Testosterone with Cholesterol 200mg/<2% Lot# (b) (4) was involved in Recall #96792, initiated on 04/25/2025.

Failure to incorporate retained sample review into the complaint handling and investigation process undermines the firm's ability to detect, confirm, and trend product quality issues.

OBSERVATION 8

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Aseptic processing areas are deficient in that floors and walls are not smooth and/or hard surfaces that are easily cleanable.

Specifically,

a. On 07/09/2025, I observed multiple locations of hard-to-clean wall and floor surfaces in ISO-8 Cleanroom 1, the Inspection Room, and the Pellet Press Room. There are numerous locations of peeling paint and holes on the walls exposing drywall and crumbling drywall along the seam of the air return vent, Chipped sections on the air vent return screen, and several locations on the floor marked with red tape that exhibited residue or powder buildup. These conditions were observed while the following operations were occurring:

- Pellet Pressing, Cleanroom 1- Estradiol 6 mg Lot # (b) (4)
- Vial and Capping - Cleanroom 1 Inspection Room, Estradiol 12.5 mg (b) (4)
- 100% Pellet Weighing, Cleanroom 1 Inspection Room, Estradiol 6 mg (b) (4)
- 100% Pellet Weighing, Cleanroom 1 Inspection Room, Estradiol 25 mg (b) (4)

b. On 07/07/2025, during the mixing and filling of Testosterone Cypionate/Anastrozole (200 mg/1 mg/ml) Lot # (b) (4), in the ISO-8 (b) (4) room in Cleanroom 2, I observed visible discoloration and apparent residue buildup on the air return vent. The presence of discoloration and residue on air handling system surfaces in a classified area increases the risk of contamination of in-process materials and drug products.

The observed poor facility conditions and residue accumulation create hard-to-clean surfaces and increase the risk of contamination of components, in-process materials, and finished drug products, compromising product quality.

OBSERVATION 9

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Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

The vacuum oven used in the production of Estradiol, Testosterone, Testosterone/Cholesterol ≤2%, and Testosterone/Cholesterol ≤4% (b) (4) has not been qualified for its current operating temperature range.

The oven is qualified for operation at (b) (4); however, your firm is routinely operating the oven at (b) (4) during the (b) (4) drying process. There is no documented qualification or performance data to demonstrate that the oven maintains uniform and controlled conditions at this higher temperature range.

***DATES OF INSPECTION**

7/07/2025(Mon), 7/08/2025(Tue), 7/09/2025(Wed), 7/10/2025(Thu), 7/11/2025(Fri), 7/14/2025(Mon), 7/15/2025(Tue), 7/16/2025(Wed)

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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."