DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	2/6/2024-3/19/2024* FEI NUMBER 3011286349

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stephen K. Anderson, PharmD, Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
Qualgen, LLC	14844 Bristol Park Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Edmond, OK 73013-1891	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

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

a) Your firm is not documenting all reports of product complaints in your complaint handling system to ensure they are being documented, investigated, tracked, and trended by Quality Assurance. Please refer to **OBSERVATION 2** for details.

b) Your firm is not always identifying all root causes of deviations and/or documenting the root cause for investigations. In addition, your firm does not always document within the investigation all issues/deficiencies/deviations related to the problem being investigated. Please refer to **OBSERVATION 3** for details.

c) CAPA 22-0017 was created after the last inspection to address a 483 observation related to Work Orders not containing sufficient information regarding the activities/tasks performed. One action item listed is to perform an effectiveness check for 6 months to verify compliance with SOP QG-1158 Generating Work Orders. The results of the checks were to be attached to the CAPA. The checks were to be completed in May 2023. No documentation of the effectiveness checks was included in the CAPA and the

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CAPA was closed November 11, 2022.

The system for documenting Work Orders continues to be deficient in that Work Orders do not always contain sufficient information regarding the activities/tasks actually performed including documentation related to repairs and maintenance that have been performed on all equipment, including the pellet presses. For example,

i. Work Order 23-026 states under Description of Activities Performed on Testosterone Press (b)(4): "investigation for recent (b)(4) damage causes. Disassembled and checked various failing points. Cleaned parts and reassembled". The Work Order does not indicate what "failing points" were checked and if any other maintenance was performed.

ii. Work Order 382 states under Full Description of Work Required: "move Testosterone Pellet Press, (b)(4) , from T-Room into warehouse for maintenance. Trouble shoot and perform maintenance." Work Order 381 states "move Estradiol Pellet Press (b)(4) from E-Room into warehouse for maintenance. Trouble shoot Perform maintenance". These two Work Orders were attached to Change Request #CR-23-0017 which states: "recently several (b)(4) have been bend on both Presses, therefore trouble shooting and maintenance is required to prevent further bent (b)(4) There is no documentation of what specific maintenance was performed or if a root cause for the bent (b)(4) was identified to assess any changes made to the preventive maintenance program.

This is a repeat observation from the 09/13-30/2022 inspection.

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d) Your firm does not have a written procedure that defines when manufacturing equipment needs to be re-qualified. Please refer to **OBSERVATION 4** for details.

e) Changes were made to equipment and raw materials that were implemented without following proper change control procedures. Please refer to **OBSERVATION 4** for details.

This is a repeat observation from the 08/2018-09/13/2018, 04/29/2021-06/15/2021, and 09/13-30/2022 inspections.

f) Your firm performed investigational environmental monitoring in February-April 2023 in the ISO 8 Prep Room. The sampling was to determine if residue and scratches on the (b)(4) walls contributed to overall bioburden in the room. Your firm could not find an approved protocol for the sampling to include location and frequency of sampling. The sampling was not referenced in Change Request CR-23-0013 which governed the replacement of the windows in the ISO 8 Prep Room. In addition, CR-23-0013 required a smoke study be performed prior to releasing the room for production after replacement of the windows. There was no documentation of a smoke study being performed in the change request and QA was unaware that a smoke study had been performed until requested by FDA during the current inspection.

OBSERVATION 2

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

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Specifically,

a) Your firm is not documenting and investigating all complaints received. For example, since the previous inspection in September 2022, your firm has received at least 23 reports of broken pellets that were not documented in your complaint handling system and investigated.

This is a repeat observation from the 09/13-30/2022 inspection.

b) Complaint #CIN-22-055 - A report was received on October 27, 2022 of 12 broken pellets from lot #(b)(4). Quality Assurance did not document review and approval (signature) of the decision to not investigate this complaint.

This is a repeat observation from the 09/13-30/2022 inspection.

c) SOP QG-1069 Handling of Complaints, revision 10 effective November 7, 2023, requires complaints related to broken pellets be tracked and trended to detect any negative trends. Your firm is not tracking and trending all complaints per this SOP. Complaints reported in your Customer Complaint Log/Customer Complaint Logbook are the only complaints that are tracked and trended. In addition, when you are trending complaints of broken pellets, your firm is only looking at the number of complaints received and is not tracking and trending the number of broken pellets reported for a specific lot.

OBSERVATION 3

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There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, your firm is not always identifying all root causes of deviations and/or documenting the root cause for investigations. In addition, your firm does not always document within the investigation all issues/deficiencies/deviations related to the problem being investigated. For example,

a) General Investigation GI-23-050 initiated on June 8, 2023, was related to the use of a lot of Testosterone (b)(4) ((b)(4) to make several lots of pellets before it had been approved/released by QA. The investigation noted the need to re-train (b)(4) production employees on the procedure related to proceeding at risk with production as well as good documentation practices for batch records. The investigation does not address how a lot of (b)(4) was dispensed to production for pelleting before it had been released by QA or how the production technicians were to verify if the lot had been approved for use before beginning pellet production as there is no procedure that addresses dispensing of (b)(4) to production. Lot (b)(4) was under investigation (GI-23-049) due to a failure to perform line clearance properly and had not been released by QA at the time it was used to manufacture several lots of Testosterone pellets.

b) Your firm received a complaint (CIN-23-002) in January 2023 regarding a mislabeled box of pellets. The vials contained Testosterone 50mg pellets however, the label placed on the secondary box stated they were Testosterone/Anastrozole pellets. General Investigation GI-23-004 failed to note that personnel fulfilling orders were using an unapproved label that had not been reviewed and approved by QA prior to use. The

investigation also failed to note there is no documentation of the use of the label, including printing, approval before use, or label reconciliation performed. No corrective actions were identified with respect to these deficiencies to prevent recurrence. GI-23-004 stated that QA notified Logistics of the issue and GI-23-001 was assigned to Logistics to investigate the issue on their end. There is no documentation of an investigation being performed by Logistics with respect to this issue. GI-23-001 is unrelated to this issue.

This is a repeat observation from the 04/17/2017-05/10/2017 and 08/08/2018-09/13/2018 inspections.

OBSERVATION 4

Your firm failed to establish 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.

Specifically,

a) Your firm does not have a written procedure that defines when manufacturing equipment needs to be re-qualified. Since the previous inspection in September 2022, your firm has work orders and/or change controls related to replacement of parts such as the (b) (4) removing the (b)(4) " from one press and installing on another, switching out and replacing a (b) (4) from one press to another, and switching out the (b) (4) from one press to another and replacing it on one. Other maintenance and repairs performed were not fully documented. Most of this work required the removal of the pellet presses from the cleanrooms. Your firm has no documented evaluation of the maintenance, repairs

and/or other work performed on the pellet presses to determine if a re-qualification and/or verification of the functioning of the pellet press needed to be performed after the maintenance and/or repairs.

b) Change Request #CR-23-0016 was created for a change to the tooling for the Testosterone/Cholesterol pellets (b) (4) . The change control was released and closed by QA on February 9, 2024 however, the change was implemented in July 2023 and the process validation lots ((b)(4) and (b)(4) released and distributed. Approximately (b)(4) lots have been made since July 2023.

c) Sometime in 2022, your firm changed manufacturers of the Anastrozole USP used to make Testosterone 200mg/Anastrozole 20mg pellets. There is no documentation of a change control or performance of an assessment/evaluation to determine the change's potential to impact product quality, including test methods for assay, bioburden, and sterility, and product stability.

OBSERVATION 5

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

Specifically, on February 13, 2024, I observed trays containing vials that had been (b) (4) sterilized uncovered and sitting inside one of the Biological Safety Cabinets (BSC) located in the Testosterone ISO 7 cleanroom. Per your Production Manager, the BSC was unplugged on January 26, 2024. No HEPA filtered air is supplied to the area within the BSC where the uncovered vials were stored before being used to vial lot #(b)(4) of (b) (4) mg Testosterone pellets.

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OBSERVATION 6

There is a lack of written procedures providing cleaning schedules and describing in sufficient detail the methods, equipment and materials to be used for sanitation.

Specifically, your firm has no written procedure governing the entry of 3rd party personnel who perform activities such as room/hood certification and equipment calibration and qualification to enter the ISO 7/ISO 8 cleanrooms without being gown qualified. Your firm is not performing non-routine cleaning such as a (b)(4) clean after work is performed by these 3rd party personnel.

OBSERVATION 7

Routine calibration of automatic, mechanical and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

Your firm is not bracketing the range of use when calibrating all equipment used in the manufacture of hormone pellets. For example,

a) Asset #220 - a balance used to weigh (b)(4) and pellet samples in the Estradiol cleanroom. For the E6mg Estradiol pellets, the required quantity of (b)(4) used weighs (b)(4) grams. For the calibrations performed on 07/15/2022 & 05/09/2023, the first test point is (b)(4) grams.
b) Asset #115 - balance used to weigh individual pellet weights in the Estradiol cleanroom. For E6mg Estradiol pellets, the specification for individual pellet weights is (b)(4) grams. For the calibration performed on 01/06/2023, the first

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test point was (b)(4) grams. For the calibration performed on 01/09/2024, the test points are (b)(4) and (b)(4) grams.

c) Asset #046 - (b) (4) used to measure thickness of all Estradiol pellets. The first test point for the calibrations performed on 01/05/2022, 01/06/2023, and 01/09/2024 is (b)(4) inches. For E6mg Estradiol pellets, the specification for pellet thickness is (b)(4)).

d) Asset #221 - balance used to weigh (b)(4) and pellet samples in the Testosterone cleanroom. For the T12.5mg Testosterone pellets, the required quantity of (b)(4) used weighs (b)(4) grams. For the calibrations performed on 07/15/2022 & 05/09/2023, the first test point is (b)(4) grams.

e) Asset #147 - balance used to weigh individual pellet weights in the Testosterone cleanroom. For T12.5mg Testosterone pellets, the specification for individual pellet weights is (b)(4) grams. For the calibrations performed on 05/16/2022 & 01/06/2023, the first test point was (b)(4) grams. For the calibration performed on 01/09/2024, the test points are (b)(4) and (b)(4) grams.

f) Asset #092 - (b) (4) used to measure thickness of all Testosterone pellets. The first test point for the calibrations performed on 05/16/2022, 01/06/2023, and 01/09/2024 is (b)(4) inches. For T12.5mg Testosterone pellets, the specification for pellet thickness is (b)(4)).

This is a repeat observation from the 04/29/2021-06/15/2021 inspection.

OBSERVATION 8

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Buildings used in the manufacturing, processing and packing of a drug product are not maintained in a good state of repair.

Specifically, there are areas of the flooring where the trim is not completely sealed in the ISO 7 Testosterone Room and ISO 7 Estradiol Room. This is where the flooring meets the window ledges. Repairs that have been made to the trim where the floor meets the window ledges do not always leave a smooth surface for cleaning. Black smudges were also seen on the floor or the ISO 7 Estradiol Room that may have originated from the wheels of the chairs in the cleanroom. There is also some chipped paint on one of the legs of the BSC in the ISO 7 Estradiol Room.

OBSERVATION 9

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

Specifically,

a) On February 13, 2024, we observed rust on the backside of the (b)(4) located in the ISO 8 Prep Room. There are (b)(4) that are (b)(4) and scratches on the top of the (b)(4) and some debris (b) (4) could be seen. The (b)(4) are used to sterilize (b) (4) glass vials and to sterilize rubber stoppers.

b) Scratches and dents could be seen in the metal surface of the base used to hold the small (b) (4) blender (area just below the blender) used for the mixing of the Testosterone (b)(4) Anastrozole, and stearic acid to make Testosterone 200mg/Anastrozole 20mg pellets.

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OBSERVATION 10

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

Specifically, your firm is not including the Testosterone/Cholesterol pellet in your (b)(4) (b) (4) audits. Your firm has no documentation of an assessment conducted to determine the product family for this pellet which was introduced in 2020. Your Testosterone/Cholesterol Sterilization and Sterility Validation performed in 2020 states under the Scope of the protocol that the (b) (4) sterilization process is to be validated for the Testosterone/Cholesterol Drug Pellet Family. There is no further documentation of a determination of the product family for this product.

Your firm has no procedure requiring a product family assessment be performed for each new product to be (b) (4) sterilized. Criteria for defining a product family and assessment against the criteria are not defined and documented.

OBSERVATION 11

The batch production and control records are deficient in that they do not include complete labeling control records, specimen and copy of labeling.

Specifically,

a) Your firm does not include in the batch record an example/copy of the secondary packaging labeling (box).

This is a repeat observation from the 09/13-30/2022 inspection.

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b) SOP QG-1273 Post Batch Release Splitting or Combining Of 6, 12, and 30 Packs including Secondary Labeling Requirements within a Single lot, revision 0 effective January 23, 2024 describes the "steps to be performed when a released batch requires splitting or combining of 6, 12, or 30 packs, including issuance of new secondary labeling, in order to follow the (b)(4) method of inventory control or when Operations/Logistics determines it is necessary to fulfill an order". Your firm is not maintaining a copy of the new secondary labeling generated as a result of this procedure. Lot number #(b)(4) of T87.5mg Testosterone pellets released on January 10, 2024 is an example (packs split on January 25, 2024).

OBSERVATION 12

Procedures describing in sufficient detail the controls employed for the issuance of labeling are not written and followed.

Specifically, your firm does not have a written procedure for the receipt, approval, issuance, use and reconciliation of the secondary packaging containers (boxes) used for all hormone pellets.

OBSERVATION 13

Master production and control records lack a description of the drug product containers, closures and packaging materials.

Specifically, your firm is using a (b)(4) insert for T87.5mg and T100mg Testosterone pellets packed into 30 count boxes. Batch record BR-0020 Pellet Packaging Record does not reference the use of the (b)(4) inserts. During packaging operations, the production technician

refers to an uncontrolled document that instructs them to use the (b)(4) inserts for these specific pellet strengths and quantities.

OBSERVATION 14

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

Specifically,

a) Your firm has no written procedures that require personnel who perform visual inspection to be periodically re-qualified.

Production Technician (b) (5), (D) was initially qualified for visual inspection on August 3, 2021. He continued to perform visual inspection activities, including training of new employees, until July 31, 2023. Production Technician (b) (6), (b) (7)(C) was initially qualified for visual inspection on August 12, 2021. He continued to perform visual inspection activities until July 14, 2023. At no time during the nearly two (2) years these two (2) employees performed visual inspection were they re-qualified.

b) Your firm has (b)(4) that is used for the qualification of personnel to perform visual inspection. The (b)(4) does not contain examples of all types of defects currently identified such as loose caps, glass inside vial, and pellet not well compressed (looks like(b) (4)).

Your procedures do not include a requirement for adding new defect types to the (b) (4) and/or refreshing the defect (b) (4) and performing (b) (4) (b)(4) assessment.

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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."