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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Statement of Issues Against:	Case No. 7559
QUALGEN, LLC **SHAUN PATRICK RINEY,** **MEMBER/MANAGER/CEO/OWNER** **CHARLES TIFFIN RINEY, JR.,** **MEMBER/OWNER** **KENNETH ALBERT JOSEPH KOTOWICH,** **MEMBER/OWNER** **WILD WEST GROUP, LLC, OWNER** **JASEN LAVOIE, DIRECTOR** **AMY ENGEL, DIRECTOR** **TARAH LAGALY, MANAGER** **TAMARA LOVE, MANAGER** **STEPHEN ANDERSON,** **PHARMACIST-IN-CHARGE** **Nonresident Outsourcing Facility License Applicant** Respondent.	**STATEMENT OF ISSUES**

PARTIES

1. Anne Sodergren (Complainant) brings this Statement of Issues solely in her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

2. On or about November 30, 2020, the Board received an application for a Nonresident Outsourcing Facility License from Qualgen, LLC (Respondent). On or about and between November 10, 2020, through November 23, 2020, Shaun Riney, Charles Riney, Kenneth Kotowich, and the authorized agent for Wild West Group, LLC, certified under penalty of perjury to the truthfulness of all statements, answers, and representations in the application. The Board denied the application on May 1, 2023.

JURISDICTION

3. This Statement of Issues is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Code section 4011 provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

STATUTORY PROVISIONS

5. Code section 4022 states:

> "Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:
>
> (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
>
> (b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
>
> (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

6. Code section 4129.2 states, in pertinent part:

> …
>
> (b) A nonresident outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities.

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(c) A license for a nonresident outsourcing facility shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident outsourcing facility shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the nonresident outsourcing facility at least once annually pursuant to subdivision (x) of Section 4400.

(d) A license for a nonresident outsourcing facility shall not be issued or renewed until the board:

(1) Prior to inspection, reviews a current copy of the nonresident outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.

(2) (A) Is provided with copies of all federal and state regulatory agency inspection reports, as well as accreditation reports, and certification reports of facilities or equipment of the nonresident outsourcing facility's premises conducted in the prior 12 months.

(B) For purposes of this paragraph, "state" refers to the state in which the nonresident outsourcing facility resides.

(3) Prior to inspection, receives a list of all sterile drug products and nonsterile drug products compounded by the pharmacy as reported to the FDA within the prior 12 months.

7. Code section 4207 states:

(a) Upon receipt of an application for a license and the applicable fee, the board shall make a thorough investigation to determine whether the applicant is qualified for the license being sought. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license that may affect the public welfare.

(b) The board shall not investigate matters connected with the operation of a premises other than those matters solely related to the furnishing of dangerous drugs or dangerous devices that might adversely affect the public welfare.

(c) The board shall deny an application for a license if the applicant does not qualify for the license being sought.

(d) Notwithstanding any other provision of law, the board may request any information it deems necessary to complete the application investigation required by this section, and a request for information that the board deems necessary in carrying out this section in any application or related form devised by the board shall not be required to be adopted by regulation pursuant to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

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8. Code section 4300 states, in pertinent part:

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(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure. The board may issue the license subject to any terms or conditions not contrary to public policy, including, but not limited to, the following:

(1) Medical or psychiatric evaluation.

(2) Continuing medical or psychiatric treatment.

(3) Restriction of type or circumstances of practice.

(4) Continuing participation in a board-approved rehabilitation program.

(5) Abstention from the use of alcohol or drugs.

(6) Random fluid testing for alcohol or drugs.

(7) Compliance with laws and regulations governing the practice of pharmacy.

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9. Code section 4301 states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

…

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

…

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

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10. Code section 4307 states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

CODE OF FEDERAL REGULATIONS

11. Code of Federal Regulations, title 21, (CFR) section 211.22 states, in pertinent part:

(a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

…

(c) The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product.

12. CFR section 211.25 states, in pertinent part:

(a) Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

(b) Each person responsible for supervising the manufacture, processing, packing, or holding of a drug product shall have the education, training, and experience, or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess.

…

13. CFR section 211.46, subdivision (b), states:

Equipment for adequate control over air pressure, micro-organisms, dust, humidity, and temperature shall be provided when appropriate for the manufacture, processing, packing, or holding of a drug product.

14. CFR section 211.56, subdivision (c), states:

There shall be written procedures for use of suitable rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents. Such written procedures shall be designed to prevent the contamination of equipment, components, drug product containers, closures, packaging, labeling materials, or drug products and shall be followed. Rodenticides, insecticides, and fungicides shall not be used unless registered and used in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135).

15. CFR section 211.58, states:

Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a good state of repair.

16. CFR section 211.67, subdivision (a), states:

Equipment and utensils shall be cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

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17. CFR section 211.84, subdivision (d), states, in pertinent part:

Samples shall be examined and tested as follows:

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(2) Each component shall be tested for conformity with all appropriate written specifications for purity, strength, and quality. In lieu of such testing by the manufacturer, a report of analysis may be accepted from the supplier of a component, provided that at least one specific identity test is conducted on such component by the manufacturer, and provided that the manufacturer establishes the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

18. CFR section 211.103, states:

Actual yields and percentages of theoretical yield shall be determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product. Such calculations shall either be performed by one person and independently verified by a second person, or, if the yield is calculated by automated equipment under § 211.68, be independently verified by one person.

19. CFR section 211.130 states, in pertinent part:

There shall be written procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products; such written procedures shall be followed. These procedures shall incorporate the following features:

…

(e) Inspection of the packaging and labeling facilities immediately before use to assure that all drug products have been removed from previous operations. Inspection shall also be made to assure that packaging and labeling materials not suitable for subsequent operations have been removed. Results of inspection shall be documented in the batch production records.

20. CFR section 211.160, subdivision (a), states:

The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit. The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified.

21. CFR section 211.165, subdivision (e), states:

The accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented. Such validation and documentation may be accomplished in accordance with § 211.194(a)(2).

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22. CFR section 211.166, subdivision (a), states:

There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates. The written program shall be followed and shall include:

(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability;

(2) Storage conditions for samples retained for testing;

(3) Reliable, meaningful, and specific test methods;

(4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed;

(5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted.

23. CFR section 211.167(c), states:

For each batch of controlled-release dosage form, there shall be appropriate laboratory testing to determine conformance to the specifications for the rate of release of each active ingredient. The test procedures shall be in writing and shall be followed.

24. CFR section 211.180, subdivision (e), states:

Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures. Written procedures shall be established and followed for such evaluations and shall include provisions for:

(1) A review of a representative number of batches, whether approved or rejected, and, where applicable, records associated with the batch.

(2) A review of complaints, recalls, returned or salvaged drug products, and investigations conducted under § 211.192 for each drug product.

25. CFR section 211.194, subdivision (a), states, in pertinent part:

Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays, as follows:

…

(2) A statement of each method used in the testing of the sample. The statement shall indicate the location of data that establish that the methods used in the testing of the sample meet proper standards of accuracy and reliability as applied to the product tested. (If the method employed is in the current revision of the United States Pharmacopeia, National Formulary, Association of Official Analytical Chemists,

> Book of Methods, [footnote omitted] or in other recognized standard references, or is detailed in an approved new drug application and the referenced method is not modified, a statement indicating the method and reference will suffice). The suitability of all testing methods used shall be verified under actual conditions of use.

DRUG DEFINITIONS

26. Anastrozole is a type of hormone treatment that works by lowering the levels of oestrogen hormones in the body that is mainly prescribed for women who have been through menopause and have a type of cancer called hormone-dependent breast cancer. Anastrozole is a dangerous drug as defined by Code section 4022.

27. Estradiol is a form of estrogen, a female sex hormone, and is a dangerous drug as defined by Code section 4022.

28. Testosterone is a naturally occurring male sex hormone, and is a dangerous drug as defined by Code section 4022.

FACTUAL BACKGROUND

29. As part of the application process, a Board inspector scheduled an application inspection of Respondent's facility for June 2022, and requested a pre-inspection documentation review prior to the inspection. In June 2022, Respondent requested to postpone its application inspection.

30. On or about December 1, 2022, a Board inspector re-scheduled the application inspection for January 2023, and sent the previously requested pre-inspection documentation list to Respondent.

31. On or about December 14 and 15, 2022, Respondent requested to postpone the delivery of requested pre-inspection documents, and the Board's inspector requested Respondent to provide any collected records by December 20, 2022.

32. On or about December 20, 2022, the Board's inspector received a press release from the FDA regarding a complaint against and a consent decree with Respondent. On or about December 20, 2022, the Board's inspector requested an unredacted copy of the consent decree agreement from Respondent.

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33. On or about December 20, 2022, the Board's inspector received pre-inspection documents from Respondent. However, Respondent did not produce the following requested documents: unredacted FDA, DEA or accreditation inspections with applicable reports or warning letters and responses; batch records and corresponding protocols for both processes and personnel and the corresponding SOP; and annual product reviews, one for each product family if the active pharmaceutical ingredients (API) is produced in more than one container closure.

34. On or about December 21, 2022, Respondent requested the Board's inspector contact its attorney regarding the FDA consent decree, and the Board's inspector emailed Respondent's attorney requesting the previously requested unredacted FDA complaint and consent decree.

35. On or about December 22, 2022, Respondent provided the Board's inspector with FDA inspection observations, Respondent's response, and the SOP governing annual product reviews. Respondent told the Board's inspector that there had been no process validations completed within the last year, and annual product reviews (APRs) had never been completed.

36. On or about December 29, 2022, the Board's inspector emailed Respondent's attorney regarding the December 22, 2022 request for a copy of the FDA consent decree. Respondent's attorney told the Board's inspector that the December 22, 2022 request was made during a week when the law office was closed for the holidays, and the document would be submitted at the latest by January 3, 2023. On or about December 29, 2022, the Board's inspector contacted the office of Respondent's attorney, and the Board's inspector was informed by a staff member that the law office was only closed on December 26, 2022, in observation of Christmas.

37. On or about January 4, 2023, the Board's inspector emailed Respondent's attorney again requesting a copy of the FDA consent decree. Respondent's attorney respond with a copy of the consent decree.

38. On or about January 5, 2023, the Board's inspector asked Respondent's attorney if Respondent had completed certain actions required by the consent decree and if Respondent had engaged in non-enjoined activities, and requested a response by January 12, 2023.

39. On or about January 17, 2023, the Board's inspector requested consumer complaints, investigations, batch records, and SOPs from Respondent to be provided by January 20, 2023.

40. On or about January 17, 2023, Respondent's attorney send the Board's inspector a letter from the FDA, but Respondent's attorney did not answer the questions asked by the Board's inspector regarding completion of FDA requirements. The Board's inspector replied requesting a response. On or about January 19, 2023, Respondent's attorney refused to provide answers to the Board's inspector's questions based upon confidentiality, lack of authority per Code section 4129.2, and/or FDA supremacy, and he directed the Board's inspector to the U.S. District Court regarding the consent decree.

41. On or about January 20, 2023, Respondent provided two of the requested batch records and told the Board's inspector that the remaining requested documents could not be provided.

42. On or about January 24, 2023, the Board's inspector arrived at Respondent's address on its application to conduct the onsite application inspection, and the Board's inspector was denied access and told to go to an address that was not listed on Respondent's application. The Board's inspector was eventually allowed access after approximately 30 minutes.

43. On or about January 24-26, 2023, the Board's inspector conducted an onsite application inspection at Respondent's address on its application.

44. On or about January 26, 2023, the Board's inspector provided Respondent with an inspection report along with twenty-one (21) inspectional observations of observed non-compliance, as set forth in paragraphs 45 through 61, below.

FIRST CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Current Good Manufacturing Practices – Testing Requirements)

45. Respondent's application is subject to denial under Code sections 4300, subdivision (c), 4301, subdivisions (j) and (o), and 4207, subdivision (c), in that Respondent failed to comply with laws, regulations, and rules governing pharmacy, as defined by Code section 4129.2, subdivision (b), by failing to comply with current good manufacturing practices (CGMP) as set forth in CFR section 211.167, subdivision (c), in that Respondent failed to complete dissolution

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studies or testing of equivalent meaning for all formulations of implantable pellets during the pre-licensure inspection. Specifically, there were no studies to support consistent product quality.

SECOND CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Current Good Manufacturing Practices – Quality Control Unit)

46. Respondent's application is subject to denial under Code sections 4301, subdivisions (j) and (o), 4300, subdivision (c), and 4207, subdivision (c), in that Respondent failed to comply with laws, regulations, and rules governing pharmacy, as defined by 4129.2, subdivision (b), by failing to comply with CGMP as set forth in CFR section 211.22, subdivision (c), as follows:

a. Respondent failed to justify specifications for yield at significant steps in the production process. Specifically, the final granulation yield of testosterone/cholesterol BR-021 rev 5 lacked justification for the difference from the expected value.

b. Respondent utilized an unvalidated and unmonitored refrigerator labeled for non-CGMP use was utilized to hold and store endotoxin challenge vials labeled as approved for use as well as retained microbial plates exhibiting growth.

c. Respondent failed to justify specifications for acceptable quality limit (AQL) sampling plans for visual inspection for a sterile implantable pellet. Additionally, Respondent failed to justify light source requirements of 3862.5 lux for inspections of amber vials or difficult to visualize containers.

d. Respondent failed to have an adequate change control process for retiring documents which are in conflict with permissible activities of a 503B outsourcing facility or for processes which are no longer representative of the current process. Specifically, hand sanitizer batch record BR-0100 rev 1 was an active document in the quality system and eligible for issuance, yet the FDA withdrew the authorization to compound hand sanitizers effective December 31, 2021. Additionally, BR-0032 along with supporting activity procedures for aseptically processed testosterone oil injection is an active document for which there is a current injunction by the FDA from producing this for commercial sale.

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THIRD CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Current Good Manufacturing Practices – Laboratory Controls)

47. Respondent's application is subject to denial under Code sections 4301, subdivisions (j) and (o), 4300, subdivision (c), and 4207, subdivision (c), in that Respondent failed to comply with laws, regulations, and rules governing pharmacy, as defined by 4129.2, subdivision (b), by failing to comply with CGMP as set forth in CFR section 211.160, subdivision (a), in that Respondent did not have a written procedure for isolating and gram staining environmental isolates recovered. Specifically, Respondent did not have an approved procedure or training plan for operators who gram stain and/or streak plates for isolation when responding to colony enumeration events exceeding action and/or alert.

FOURTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Current Good Manufacturing Practices – Personnel Qualifications)

48. Respondent's application is subject to denial under Code sections 4301, subdivisions (j) and (o), 4300, subdivision (c), and 4207, subdivision (c), in that Respondent failed to comply with laws, regulations, and rules governing pharmacy, as defined by 4129.2, subdivision (b), by failing to comply with CGMP as set forth in CFR section 211.25, subdivision (a), in that Respondent failed to have adequate visual inspection training requirements and execution of visual inspections activities; inadequate control of the training program, defect challenge kit, and adherence to the visual inspection program. Specifically, the qualification defect kit was not representative of all defects that operators may and have encountered in the past; requalification criteria for an operator's competency was not evaluated on a regular or defined basis; the integrity of the challenge kit and contents was not assured; and visual inspection start time, end time, and optional breaks were not documented.

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FIFTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Current Good Manufacturing Practices – Records and Reports)

49. Respondent's application is subject to denial under Code sections 4301, subdivisions (j) and (o), 4300, subdivision (c), and 4207, subdivision (c), in that Respondent failed to comply with laws, regulations, and rules governing pharmacy, as defined by 4129.2, subdivision (b), by failing to comply with CGMP as set forth in CFR section 211.180, subdivision (e), in that Respondent failed to conduct required annual product reviews on all products compounded and distributed.

SIXTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Current Good Manufacturing Practices – Ventilation, Air Filtration, Air Heating and Cooling)

50. Respondent's application is subject to denial under Code sections 4301, subdivisions (j) and (o), 4300, subdivision (c), and 4207, subdivision (c), in that Respondent failed to comply with laws, regulations, and rules governing pharmacy, as defined by 4129.2, subdivision (b), by failing to comply with CGMP as set forth in CFR section 211.46, subdivision (b), in that Respondent failed to have sufficient systems for monitoring environmental conditions for applicable temperature, humidity, and differential pressure. Specifically, differential pressure was taken three (3) times daily and temperature was taken one (1) times daily only during business days.

SEVENTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Current Good Manufacturing Practices – Equipment Cleaning and Maintenance)

51. Respondent's application is subject to denial under Code sections 4301, subdivisions (j) and (o), 4300, subdivision (c), and 4207, subdivision (c), in that Respondent failed to comply with laws, regulations, and rules governing pharmacy, as defined by 4129.2, subdivision (b), by failing to comply with CGMP as set forth in CFR section 211.67, subdivision (a), as follows:

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a. Respondent had a metallic pellet press tooling materials and other compounding equipment were found to be in a poor state of repair exhibiting damage, degradation, and/or discoloration. Specifically, punch and dye sets had visible degradation of apparent rust and/or odor producing lubricant as well as visible wear on the pellet punch; the protective plastic shield affixed to the testosterone/steric acid press was cracked and appeared discolored or degraded; and the hot plate in the estradiol room was visibly worn and/or degraded.

b. Respondent failed to produce sufficient evidence to support there was no cross-contamination or product carryover among batches of different APIs. Specifically, cleaning validation provided by Respondent's chemical disinfectant vendor failed to provide evidence the

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cleaning methods utilized is effective in removing API anastrozole from shared equipment or materials used in pellet production, processing, and packaging.

EIGHTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Current Good Manufacturing Practices – Testing and Release for Distribution)

52. Respondent's application is subject to denial under Code sections 4301, subdivisions (j) and (o), 4300, subdivision (c), and 4207, subdivision (c), in that Respondent failed to comply with laws, regulations, and rules governing pharmacy, as defined by 4129.2, subdivision (b), by failing to comply with CGMP as set forth in CFR section 211.165, subdivision (e), in that Respondent's analytical methods utilized for release of batches were not stability indicating and inconsistent with the previously validated method(s). Specifically, Respondent utilized a UV-Vis method for testing and subsequent release of testosterone/steric acid pellets and estradiol pellets which is not stability indicating and sufficient to identify and/or quantify degradants in that Respondent has not performed a related forced degradation or equivalent on their UV-Vis process to consider their complete drug matrix.

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NINTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Current Good Manufacturing Practices – Sanitation)

53. Respondent's application is subject to denial under Code sections 4301, subdivisions (j) and (o), 4300, subdivision (c), and 4207, subdivision (c), in that Respondent failed to comply with laws, regulations, and rules governing pharmacy, as defined by 4129.2, subdivision (b), by failing to comply with CGMP as set forth in CFR section 211.56, subdivision (c), in that Respondent failed to have an adequate pest control program and supervision to ensure drug product, components, or container closures were not contaminated during routine application of pesticides. Specifically, Respondent's pest control service included spray application of insecticide in the common areas throughout the facility with the vendor being under indirect supervision.

TENTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Current Good Manufacturing Practices – Stability Testing)

54. Respondent's application is subject to denial under Code sections 4301, subdivisions (j) and (o), 4300, subdivision (c), and 4207, subdivision (c), in that Respondent failed to comply with laws, regulations, and rules governing pharmacy, as defined by 4129.2, subdivision (b), by failing to comply with CGMP as set forth in CFR section 211.166, subdivision (a)(3), in that Respondent's stability studies failed to support the label claims of the current product(s) and Respondent's stability study reports were approved without explanation of findings which did not confirm to the pre-determined specifications of the study protocol. Specifically, stability reports for estradiol describe pellets as both circular, relevant to 2 dimensions (sphere = 3 dimensions) and cylindrical (3 dimensions), and the stability study reported the pellet inconsistently changed its physical color and/or shape without adequate justification or explanation.

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ELEVENTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Current Good Manufacturing Practices – Responsibilities of Quality Control Unit)

55. Respondent's application is subject to denial under Code sections 4301, subdivisions (j) and (o), 4300, subdivision (c), and 4207, subdivision (c), in that Respondent failed to comply with laws, regulations, and rules governing pharmacy, as defined by 4129.2, subdivision (b), by failing to comply with CGMP as set forth in CFR section 211.22, subdivision (a), in that Respondent failed to have adequate quality oversight and review of CGMP systems. Specifically, daily cleaning logs for August 2022 and September 2022 were not reviewed by Operations and Quality until November 9, 2022, and November 11, 2022, respectively. Batches produced during this timeframe and prior to complete review of cleaning logs were released for sale.

TWELFTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Current Good Manufacturing Practices – Stability Testing)

56. Respondent's application is subject to denial under Code sections 4301, subdivisions (j) and (o), 4300, subdivision (c), and 4207, subdivision (c), in that Respondent failed to comply with laws, regulations, and rules governing pharmacy, as defined by 4129.2, subdivision (b), by failing to comply with CGMP as set forth in CFR section 211.166, subdivision (a), in that Respondent's stability program failed to conform with CGMP requirements, including requirements for bracketing were not appropriately applied and procedures were inconsistent with current FDA guidance. Specifically, no intermediate strength(s) were tested where the testosterone/steric acid is offered in 7 different strengths, and the estradiol is offered in 8 different strengths.

THIRTEENTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Current Good Manufacturing Practices – Calculation of Yield)

57. Respondent's application is subject to denial under Code sections 4301, subdivisions (j) and (o), 4300, subdivision (c), and 4207, subdivision (c), in that Respondent failed to comply

with laws, regulations, and rules governing pharmacy, as defined by 4129.2, subdivision (b), by failing to comply with CGMP as set forth in CFR section 211.103, in that Respondent failed to properly justify and appropriately evaluate specifications and evaluation of production yields at each appropriate step. Specifically, testosterone granulation batch record BR-0029 rev 2 fails to evaluate the actual yield of the granulations process to a pre-defined specification.

FOURTEENTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Current Good Manufacturing Practices – Maintenance of Buildings and Facilities)

58. Respondent's application is subject to denial under Code sections 4301, subdivisions (j) and (o), 4300, subdivision (c), and 4207, subdivision (c), in that Respondent failed to comply with laws, regulations, and rules governing pharmacy, as defined by 4129.2, subdivision (b), by failing to comply with CGMP as set forth in CFR section 211.58, in that Respondent's facility had damaged wall panels creating potentially difficult to clean surfaces. Specifically, one room had at least two wall panels with scratches and the cleanroom inspection forms made no mention of scratches on the walls from October 2022 through December 2022.

FIFTEENTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Current Good Manufacturing Practices – Packaging and Labeling Operations)

59. Respondent's application is subject to denial under Code sections 4301, subdivisions (j) and (o), 4300, subdivision (c), and 4207, subdivision (c), in that Respondent failed to comply with laws, regulations, and rules governing pharmacy, as defined by 4129.2, subdivision (b), by failing to comply with CGMP as set forth in CFR section 211.130, subdivision (e), in that Respondent failed to adequately remove and destroy previous labels used for batch production prior to initiation of a new batch. Specifically, testosterone 87.5 mg Lot 1022 compounded on January 13, 2023, was packaged in secondary packaging intended for terminal sterilization with in-process batch labeling and irradiation indicators for at least testosterone 100 mg Lot H394 and testosterone 50 mg Lot H259 comingled with the testosterone 87.5 mg batch.

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SIXTEENTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Current Good Manufacturing Practices – Testing and Approval/Rejection of Components, Drug Product Containers, and Closures)

60. Respondent's application is subject to denial under Code sections 4301, subdivisions (j) and (o), 4300, subdivision (c), and 4207, subdivision (c), in that Respondent failed to comply with laws, regulations, and rules governing pharmacy, as defined by 4129.2, subdivision (b), by failing to comply with CGMP as set forth in CFR section 211.84, subdivision (d)(2), in that Respondent failed to adequately qualify vendors and verify the suppliers' certificate of analysis at appropriate intervals for at least drug product components and growth media as follows:

a. Vendor qualifications for API supplier Fagron does not include a Quality Agreement and the reliability of the supplier's analysis has not been established at appropriate intervals and through appropriate steps to confirm that the ingredient meets the applicable USP or NF monograph, if one exists.

b. Testing records indicated Anastrozole, USP was last verified on or about September 5, 2017.

c. Vendor qualification for other components such as growth media utilized for personnel and environmental monitoring has not had the reliability of the validity of the medium, including its growth potential verified at appropriate intervals. Specifically, vendor Biomerieux did not have an active quality agreement with Respondent and the TSA agar plates did not have confirmatory growth promotion performed.

SEVENTEENTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Current Good Manufacturing Practices – Personnel Qualifications)

61. Respondent's application is subject to denial under Code sections 4301, subdivisions (j) and (o), 4300, subdivision (c), and 4207, subdivision (c), in that Respondent failed to comply with laws, regulations, and rules governing pharmacy, as defined by 4129.2, subdivision (b), by failing to comply with CGMP as set forth in CFR section 211.25, subdivision (b), in that Respondent failed to have annual CGMP training for all personnel involved in the drug

manufacturing process. Specifically, CEO Shaun Riney did not have documentation of CGMP training.

EIGHTEENTH CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with an Investigation by the Board)

62. Respondent's application is subject to denial under Code sections 4301, subdivision (q), 4300, subdivision (c), and 4207, subdivisions (a) and (d), in that Respondent failed to provide information related to a consent decree agreement with the FDA that included subject matter related to Respondent's operations as an outsourcing facility that was requested by the Board's investigator as part of the Board's pre-licensing inspection of Respondent and the Board's inspector was denied access to Respondent's facility for the onsite application inspection, as set forth above in paragraphs 29 through 43, above.

MATTER IN AGGRAVATION

63. On or about April 4, 2017, the Board of Pharmacy, Department of Consumer Affairs received an application for a Nonresident Outsourcing Facility License from Respondent. The Board denied the application on November 27, 2018, pursuant to Code section 4207, subdivision (c), in that Respondent failed to comply with CGMP as required by Code section 4129.2, subdivision (b). The circumstances are that from February 12 through 14, 2018, Board Inspectors D.D. and J.W. conducted a pre-licensure inspection at Respondent's facilities in Oklahoma, and observed many failures to comply with CGMP.

OTHER MATTERS

64. Pursuant to Code section 4307, if discipline is imposed on Qualgen, LLC, or the application is denied, then any person who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust firm, or association which received this discipline or denial, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control, had knowledge of or knowingly participated in any conduct leading to discipline or denial, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with

management or control of a licensee until the application for Qualgen, LLC is issued if it is denied.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Denying the Nonresident Outsourcing Facility License application of Qualgen, LLC;

2. Prohibiting Qualgen, LLC from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee until the application for Qualgen, LLC is issued;

3. Prohibiting Shaun Patrick Riney from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee until the application for Qualgen, LLC is issued;

4. Prohibiting Jasen Lavoie from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee until the application for Qualgen, LLC is issued;

5. Prohibiting Amy Engel from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee until the application for Qualgen, LLC is issued;

6. Prohibiting Tarah Lagaly from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee until the application for Qualgen, LLC is issued;

7. Prohibiting Tamara Love from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee until the application for Qualgen, LLC is issued;

8. Prohibiting Stephen Anderson from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee until the application for Qualgen, LLC is issued;

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9. Taking such other and further action as deemed necessary and proper.

DATED: 8/16/2024

Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2024.08.16 10:45:38 -07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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