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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**:** **VITAE ENIM VITAE SCIENTIFIC INC.** **Resident Outsourcing Facility License Applicant** Respondent.	Case No. 8033 **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, Department of Consumer Affairs.

2. On or about March 7, 2024, the Board of Pharmacy, Department of Consumer Affairs received an application for a Resident Outsourcing Facility License from Vitae Enim Vitae Scientific Inc. (Respondent). The Board denied the application on June 12, 2025.

JURISDICTION

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

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STATUTORY PROVISIONS

4. Code section 4129 states in part:

(a) A facility registered as an outsourcing facility with the federal Food and Drug Administration (FDA) shall be concurrently licensed with the board as an outsourcing facility if it compounds sterile medication or nonsterile medication for nonpatient-specific distribution within or into California.

5. Code section 4129.1 states:

(a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) and with an address in this state shall also be licensed by the board as an outsourcing facility before doing business within this state. The license shall be renewed annually and is not transferable.

(b) An outsourcing facility shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities.

(c) An outsourcing facility license shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(d) An outsourcing facility license shall not be issued or renewed until the board does all of the following:

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

(2) 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 outsourcing facility's premises conducted in the prior 12 months.

(3) Prior to inspection, receives a list of all sterile drugs and nonsterile drugs compounded by the outsourcing facility as reported to the FDA in the last 12 months.

(e) An outsourcing facility licensed pursuant to this section shall provide the board with all of the following:

(1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.

(2) Notice within 24 hours of any recall notice issued by the outsourcing facility.

(3) A copy of any clinically related complaint it receives involving an outsourcing facility's compounded products from or involving any provider, pharmacy, or patient in California within 72 hours of receipt.

(4) Notice within 24 hours after learning of adverse effects reported or potentially attributable to the outsourcing facility's products.

6. Code section 4207, subdivision (c) states:

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

7. Code section 4300, subdivision (c) states:

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….

8. Code section 4301 states:

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 includes, 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.

. . .

9. Code section 4307 states in pertinent part:

(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.

REGULATORY PROVISIONS

10. Title 21, Code of Federal Regulations (CFR) 211.22, states in 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.

(b) Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-process materials, and drug products shall be available to the quality control unit.

(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.

(d) The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed.

11. Title 21, CFR 211.160, subdivision (a) states:

(a) 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.

12. Title 21, CFR 211.198, subdivision (a) states:

(a) Written procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed. Such procedures shall include provisions for review by the quality control unit, of any complaint involving the possible failure of a drug product to meet any of its specifications and, for such drug products, a determination as to the need for an investigation in accordance with § 211.192. Such procedures shall include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration in accordance with §§ 310.305 and 514.80 of this chapter.

13. Title 21, CFR 211.56 states:

(a) Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a clean and sanitary condition, Any such building shall be free of infestation by rodents, birds, insects, and other vermin (other than laboratory animals). Trash and organic waste matter shall be held and disposed of in a timely and sanitary manner.

(b) There shall be written procedures assigning responsibility for sanitation and describing in sufficient detail the cleaning schedules, methods, equipment, and materials to be used in cleaning the buildings and facilities; such written procedures shall be followed.

(c) 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).

(d) Sanitation procedures shall apply to work performed by contractors or temporary employees as well as work performed by full-time employees during the ordinary course of operations.

14. Title 21, CFR 211.113 states:

(a) Appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile, shall be established and followed.

(b) Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and sterilization processes.

15. Title 21, CFR 211.192 states:

All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and follow up.

16. Title 21, CFR 211.166, subdivision (a) states:

(a) 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.

17. Title 21, CFR 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.

18. Title 21, CFR 211.28 states:

(a) Personnel engaged in the manufacture, processing, packing, or holding of a drug product shall wear clean clothing appropriate for the duties they perform. Protective apparel, such as head, face, hand, and arm coverings, shall be worn as necessary to protect drug products from contamination.

(b) Personnel shall practice good sanitation and health habits.

(c) Only personnel authorized by supervisory personnel shall enter those areas of the buildings and facilities designated as limited-access areas.

(d) Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drug products shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of drug products. All personnel shall be instructed to report to supervisory personnel any health conditions that may have an adverse effect on drug products.

19. Title 21, CFR 211.170 subdivision (a) states:

(a) An appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained. The reserve sample consists of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except for sterility and pyrogen testing. The retention time is as follows:

(1) For an active ingredient in a drug product other than those described in paragraphs (a) (2) and (3) of this section, the reserve sample shall be retained for 1 year after the expiration date of the last lot of the drug product containing the active ingredient.

(2) For an active ingredient in a radioactive drug product, except for nonradioactive reagent kits, the reserve sample shall be retained for:

(i) Three months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is 30 days or less; or

(ii) Six months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is more than 30 days.

20. Title 21, CFR 211.46 states:

(a) Adequate ventilation shall be provided.

(b) 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.

(c) Air filtration systems, including prefilters and particulate matter air filters, shall be used when appropriate on air supplies to production areas. If air is recirculated to production areas, measures shall be taken to control recirculation of dust from production. In areas where air contamination occurs during production, there shall be adequate exhaust systems or other systems adequate to control contaminants.

(d) Air-handling systems for the manufacture, processing, and packing of penicillin shall be completely separate from those for other drug products for human use.

FACTUAL ALLEGATIONS

21. Vitae Enim Vitae Scientific Inc. (Respondent) is an existing business which engages in the production of Food and Drug Administration (FDA) approved drug products. Respondent's product line consists of human and veterinary products, most of which are sterile. Respondent is registered with the FDA as a commercial drug manufacturer.[1] Respondent applied for a resident outsourcing facility license with the Board. A pre-licensure evaluation and inspection is required for a resident outsourcing facility license. The Board conducted that inspection from January 28, 2025, to January 30, 2025.

[1] On or about March 17, 2022, the FDA issued a Warning Letter to Respondent. An FDA Warning Letter represents a major escalation in the FDA's enforcement process. The Warning Letter is a formal written notice to Respondent that it has violated U.S. law and must take corrective action immediately. The Warning Letter summarized significant violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals following the FDA inspection of Respondent's drug manufacturing facility.

22. The Board's inspection resulted in multiple observations of non-conformance to current good manufacturing practices (cGMP). Respondent did not meet the pre-requisite requirements for licensure.[2]

FIRST CAUSE FOR DENIAL

(Smoke Studies)

23. Respondent is subject to denial under Code sections 4129.1, subdivisions (b) and (c), 4207, subdivision (c), and 4300, subdivision (c), for unprofessional conduct as defined in Code section 4301, subdivision (o), in that Respondent was not in compliance with current good manufacturing practices, specifically, 21 CFR 211.22, subdivision (c). The circumstances are as follows.

24. The Board inspector reviewed a sampling of static / dynamic smoke studies.[3] Some smoke studies were not fully simulated to demonstrate actual conditions observed during filling. Accordingly, the Board inspector concluded that at the time of inspection Respondent did not have adequate smoke simulations to support their intended processes. Although Respondent reperformed smoke studies in portions of the cleanrooms as well as in areas immediately outside the cleanrooms, Respondent failed to demonstrate similar smoke visualization studies for other parts of the cleanroom, and Respondent's cleanroom lacked overall quality due to its design.

SECOND CAUSE FOR DENIAL

(Visual Inspection Program of Finished Vials)

25. Respondent is subject to denial under Code sections 4129.1, subdivisions (b) and (c), 4207, subdivision (c), and 4300, subdivision (c), for unprofessional conduct as defined in Code

[2] Some of the processes viewed at Respondent for the consideration of licensure was a review current and past processes intended to be cGMP processes which were the same or representative of how Respondent planned to produce 503B outsourcing facility products. At the time of the inspection, Respondent remained under Warning Letter status with the FDA as a commercial drug manufacturer.

[3] Airflow visualization studies (smoke studies) are conducted to determine airflow patterns within a facility's cleanroom. Static studies are intended to show that the airflows are unidirectional and cascade out to the zones with lower requirements. Dynamic studies are intended to show that airflow within the cleanroom filling lines is unidirectional and sweeping down and away from sterile equipment surfaces, container/closure systems, and products. Dynamic studies work to confirm that facility and equipment design, equipment operation, and personnel aseptic activities do not interfere with the air exiting the high-efficiency particulate air filters to critical areas where sterile surfaces, materials, and products are exposed.

section 4301, subdivision (o), in that Respondent was not in compliance with current good manufacturing practices, specifically, 21 CFR 211.22, subdivision (c). The circumstances are as follows.

26. The Board inspector determined that Respondent's visual inspection program of finished vials was inadequate.[4] For example, upon review of the qualifications of operators, the Board inspector discovered that Respondent's program did not include a validated test kit which represented all defect types an operator was expected to identify.[5] Additionally, the categorization of defects was not justified. The inspector reviewed retained samples of crimped vials (secure container designed for the storage and transport of liquid/powder samples) that were previously visually inspected and accepted. However, those vials had leaked and contained residue in and around the neck of the vials. In response to that observation, Respondent made some changes to its visual inspection program. While those updates did provide some improvements to their current processes, Respondent's procedure remained inadequate.

THIRD CAUSE FOR DENIAL

(Laboratory Procedures)

27. Respondent is subject to denial under Code sections 4129.1, subdivisions (b) and (c), 4207, subdivision (c), and 4300, subdivision (c), for unprofessional conduct as defined in Code section 4301, subdivision (o), in that Respondent was not in compliance with current good manufacturing practices, specifically, 21 CFR 211.169, subdivision (a). The circumstances are as follows.

28. During inspection, the Board inspector observed laboratory procedures that were inadequate. For example, growth promotion testing[6] to verify growth capabilities of tryptic soy

[4] The visual inspection program of finished vials is a critical quality control process involving the examination of finished drug products for visible defects (i.e. particulate matter), container closure integrity, and other defects. The program is essential for ensuring the safety, efficacy, and quality of injectable and other sterile pharmaceutical products.

[5] A validated test kit is a set of containers that are used to ensure the accuracy and reliability of visual inspection processes and contain a range of known defect standards.

[6] Growth promotion testing is a critical quality control procedure that verifies the ability of culture media to support the growth of specific microorganisms.

agar (TSA) media[7] plates was inadequate for its intended use. The growth promotion for TSA was evaluated by a contract lab over an incubation of "not more than 3 days for bacteria…". The Certificate of Analysis (COA) for Respondent's lot P1863 for TSA was incubated on 7/9/24 and removed on 7/12/24, which exceeds the minimum incubation time of TSA utilized for viable air sampling. The incubation procedure used by the contract lab did not comply to the requirements described in 24-MVP-005-FR, which requires incubation for 48-72 hours. Similar growth promotion testing was conducted by Respondent in-house for a 69 hour incubation period, which also did not demonstrate growth for the worst case incubation period of 48 hours for TSA. In response to that observation, Respondent also modified their relevant procedure to ensure TSA was evaluated following 48 hours for their future qualifications. Respondent also challenged two (2) lots of TSA by performing growth promotion with the technique of "Obtain one plate and touch with at least one ungloved finger; label and incubate at 30-35C for 48 hours." The two (2) lots tested by Respondent demonstrated growth in the 48 hour incubation period. However, the "growth promotion" performed by Respondent did not have appropriate laboratory controls or adequate procedures. Specifically, the test performed was largely uncontrolled and was not consistent with a cGMP or repeatable process. Amongst other requirements, growth promotion is conducted with a specified number of organisms and Respondent's test methods did not conform to scientifically appropriate procedures or principles.

FOURTH CAUSE FOR DENIAL

(Investigations into Complaints)

29. Respondent is subject to denial under Code sections 4129.1, subdivisions (b) and (c), 4207, subdivision (c), and 4300, subdivision (c), for unprofessional conduct as defined in Code section 4301, subdivision (o), in that Respondent was not in compliance with current good manufacturing practices, specifically, 21 CFR 211.198, subdivision (a). The circumstances are as follows.

[7] TSA is a routine laboratory media that supports the growth of a wide variety of microorganisms.

30. The Board inspector reviewed Respondent's internal investigation following a complaint about product quality. The inspector concluded that Respondent's investigation was inadequate. Specifically, the standard operating procedures (SOP-SC-QA-017 rev 00 and previous legacy SOP) required an investigation to be completed within 45 days of the complaint, and if the investigation was not completed on time, the complainant would be notified. However, Respondent's investigation (23-PC-003) was not completed pursuant to the SOP. In fact, the complaint was received on or about 5/23/23 and completed 10/4/23 without notification of delay to the complainant. The time to complete the investigation was also not commensurate to the rigor and scope of the investigation that Respondent performed. Respondent's conclusions were not justified, as there was no probabilistic testing or deterministic testing to support Respondent's conclusions. Additionally, the verification of the crimps by the regulatory compliance associate EMS was not documented and there were incomplete assurances that EMS was adequately trained to perform such inspections.

31. In response to the observation, Respondent acknowledged the investigation lacked the necessary documentation and rigor, explained there were additional communications not included within the investigation and that there were limitations preventing the evaluation of the product in question at the time of complaint as well as retrospectively, and committed to updating their investigative processes and procedures. In addition, Respondent made a modification to SOP-SC-QA-024 to require operators to be trained on visual inspection procedures when inspecting articles such as retained products. However, Respondent provided limited information to evaluate the proposed investigation requirements for scenarios of similar concern. Although they committed to requiring equivalent training to those inspecting retained products, there remains durable concerns with the visual inspection process itself. In addition, Respondent's description of additional "communications" to have taken place during the complaint investigation was concerning given Respondent's failure to retain complete records in the complaint file or reproduce records for review. Regardless, at the time of the Board inspection, Respondent's investigation into customer complaints was inadequate, untimely, and failed to prevent reoccurrence.

FIFTH CAUSE FOR DENIAL

(Environmental Monitoring Program)

32. Respondent is subject to denial under Code sections 4129.1, subdivisions (b) and (c), 4207, subdivision (c), and 4300, subdivision (c), for unprofessional conduct as defined in Code section 4301, subdivision (o), in that Respondent was not in compliance with current good manufacturing practices, specifically, 21 CFR 211.113, subdivision (b). The circumstances are as follows:

33. The Board inspector reviewed Respondent's environmental monitoring program and determined that it was inadequate. Some examples include, but are not limited to, personal monitoring and deferential pressure. In response to the observation, Respondent enhanced their gowning evaluation process. However, Respondent did not adequately address how they intended to evaluate microbial recoveries on personnel who routinely participate in the ISO-5 areas and their proposed procedure did not ensure all microbial contamination from the ISO-5 or potentially attributable to the ISO-5 would be adequately investigated. With regard to the differential pressures, Respondent provided a change control record to procure and install a continuous differential pressure monitoring system, with plans for installation and qualification by the end of March 2025. However, the Board inspector could not determine the adequacy of this correction since the correction was ongoing.

SIXTH CAUSE FOR DENIAL

(Incubation Practices and Procedures)

34. Respondent is subject to denial under Code sections 4129.1, subdivisions (b) and (c), 4207, subdivision (c), and 4300, subdivision (c), for unprofessional conduct as defined in Code section 4301, subdivision (o), in that Respondent was not in compliance with current good manufacturing practices, specifically, 21 CFR 211.169, subdivision (a). The circumstances are as follows.

35. The Board inspector reviewed Respondent's incubation practices and procedures, and determined that incubation requirements of media plates were not fully followed. For example, the Board inspector observed media plates that were not in an incubator and instead, in the open

area of room 205 being "incubated" for environmental monitoring. The room temperature at the time of inspection was 18.1C, which does not conform to the incubation requirements of 20-25C. In addition, the gowning qualification samples for operator FG were incubated from 11/28/24 at 5:35am to 12/2/24 at 11:15am, without a deviation / investigation, where media is required to be incubated for 48-72 hours at 30-35C. In response to the observation, Respondent committed to purchasing an additional incubator to support the 20-25C incubation cycle and explained that the samples observed during the inspection were invalidated because the operator FG was found to be not properly trained at the time of sampling. Respondent further provided updated training records. However, Respondent failed to fully address the observation. Specifically, Respondent failed to provide their investigative reports as well as description of the impact to the lot or other lots potentially affected by the operator(s) inadequate qualification. Respondent did not adequately identify the root cause of the deficiency and how similar occurrences would be prevented in the future. The failure to train operators has broad based implications beyond incubation of media plates which warrant investigation and an assessment of risk which was not provided. Regardless, at the time of inspection, procedures were not followed, operators were not adequately trained and qualified, and control over microbial contamination was insufficient.

SEVENTH CAUSE FOR DENIAL

(Pest Control Program)

36. Respondent is subject to denial under Code sections 4129.1, subdivisions (b) and (c), 4207, subdivision (c), and 4300, subdivision (c), for unprofessional conduct as defined in Code section 4301, subdivision (o), in that Respondent was not in compliance with current good manufacturing practices, specifically, 21 CFR 211.56. The circumstances are as follows.

37. During inspection, the Board inspector observed the pest control program and determined it was inadequate. Specifically, the contracted vendor did not document the areas or methods in which pesticides are sprayed and there was no reliable procedure to prevent the contamination of equipment, components, drug product containers and closures, packaging, labeling materials or items from pesticides utilized within the interior suites. Additionally, the service contract only covered suites 203, 205, 216 and does not include suite 218 where drug

product was processed, labeled, and stored. In response to this operation, Respondent provided an updated service contract to include suite 218, and updated their relevant pest control procedure (SOP-QA-021) to include restrictions and guidelines for pest control operators when conducting pest abatement activities such as spraying of chemicals. Respondent also committed to training the pest control personnel. However, Respondent's proposed pest control procedure did not have any requirement for training. Therefore in the event the personnel changes from the outside vendor, the procedure places no requirement for training. Additionally, the procedure did not require verification or oversight of high risk activities such as spraying of chemicals. Respondent's procedure did not require pest control vendors to be supervised. Indeed, Respondent's Quality Unit was only required to review reports, with no requirement for direct supervision.

EIGHTH CAUSE FOR DENIAL

(Investigations of Out of Specification Test Results)

38. Respondent is subject to denial under Code sections 4129.1, subdivisions (b) and (c), 4207, subdivision (c), and 4300, subdivision (c), for unprofessional conduct as defined in Code section 4301, subdivision (o), in that Respondent was not in compliance with current good manufacturing practices, specifically, 21 CFR 211.192. The circumstances are as follows.

39. The Board inspector reviewed Respondent's internal investigations for out-of-specification (OOS)[8] test results, and determined that they were unperformed, untimely, and/or incomplete. Investigation procedures were also found to be inadequate. For example, Respondent's investigation (- 24-OOS-019 – the NVP action limit[9]) was determined to be due to static electricity. However, the data provided in the investigation did not reasonably justify the hypothesis of static electricity. Additionally, the investigation was not timely and the required procedure was not followed. In fact, the action limit for NVP was exceeded on or about 8/13/24 and an investigation was not initiated until 11/22/24. There were no defined timeframes for which

[8] OOS refers to test results that fall outside the specifications or acceptance criteria. The term also applies to all in-process laboratory tests that are outside of established specifications.

[9] The NVP action limit refers to the regulatory threshold for non-viable particles during aseptic processing. This limit is crucial for contamination risk management and ensures that the aseptic environment remains uncontaminated during the production of products.

Quality Assurance (QA) was required to be notified of an OOS. The requirement described in Respondent's policy (SOP-SC-MF-004) "…. manufacturing must cease until the excursion has been resolved and the manufacturing suite has been released for manufacturing by the approval of QA." could not have been reasonably followed due to the delay in initiation of the OOS investigation.

40. In response to this observation, Respondent reiterated their conclusions about the investigation and agreed to update their procedure to revise their investigational procedure requirements and to modify their environmental monitoring SOP. However, the Board inspector found that the conclusions in the investigation 24-OOS-019 were without support or reasonable application of the scientific method or investigative process.

NINTH CAUSE FOR DENIAL

(Policies and Procedures)

41. Respondent is subject to denial under Code sections 4129.1, subdivisions (b) and (c), 4207, subdivision (c), and 4300, subdivision (c), for unprofessional conduct as defined in Code section 4301, subdivision (o), in that Respondent was not in compliance with current good manufacturing practices, specifically, 21 CFR 211.22, subdivision (a). The circumstances are as follows.

42. Upon inspection, the Board inspector determined that Respondent's policies and procedures were inadequate. Respondent lacked a state of control required for a cGMP facility, and it was not clear the status of all materials found within the cGMP spaces. There was co-mingling of cGMP items and "non-cGMP" items with no discernable way to differentiate the two.

TENTH CAUSE FOR DENIAL

(Stability Program)

43. Respondent is subject to denial under Code sections 4129.1, subdivisions (b) and (c), 4207, subdivision (c), and 4300, subdivision (c), for unprofessional conduct as defined in Code section 4301, subdivision (o), in that Respondent was not in compliance with current good manufacturing practices, specifically, 21 CFR 211.166, subdivision (a). The circumstances are as follows.

44. During inspection, the Board inspector observed an inadequate stability program. For example, Respondent's stability studies for multi-dose vials (MDV) did not include evaluation of anti-microbial effectiveness testing beyond the initial timepoint T0 (baseline or condition at the exact moment the test material is introduced). In response to the finding, Respondent modified their stability protocol for their drug product to include the inclusion of the anti-microbial effectiveness testing (AET) at the desired beyond use date (BUD) along with some additional analytical tests. However, the changes Respondent made, addressed the specific formulation only and did not explicitly address the stability program to prevent reoccurrence of inadequate testing designs. Regardless, at the time of inspection Respondent's stability study(s) and stability program and stability protocol were non-compliant.

ELEVENTH CAUSE FOR DENIAL

(Equipment and Facility Fixtures)

45. Respondent is subject to denial under Code sections 4129.1, subdivisions (b) and (c), 4207, subdivision (c), and 4300, subdivision (c), for unprofessional conduct as defined in Code section 4301, subdivision (o), in that Respondent was not in compliance with current good manufacturing practices, specifically, 21 CFR 211.58. The circumstances are as follows.

46. During inspection, the Board inspector observed several pieces of equipment and facility fixtures that were in a poor state of repair. Some examples include, but are not limited to:

Suite 203

47. In the ISO-8 cleanroom area, the laminate tile flooring had cracks/crevices throughout. The inspector also observed dirty windows/window tracks with hanging blinds. He also observed industrial ceiling with pipes/infrastructure that was not smooth/easily cleanable. The pass through connecting suite 203 to 205 was found to be partially open on both sides of the passthrough.

48. In the ISO-7 cleanroom area, there were multiple gaps between where the walls met the ceiling (including a blue cord running between these) and where the walls met the floor (able to pass a plastic bag underneath). The floor had a hole within it (missing piece was lying on the floor next to the hole). Balance within the room had visible residue white on it. The HEPA filter

ducting / fixtures in the ISO-7 buffer were sealed with what appeared to be clear packaging tape which was incomplete and peeling in areas creating difficult to clean surfaces. The pass through from the ISO-7 buffer to the ISO-8 area was found to be partially open on both sides of the pass through.

49. In the ISO-5 cleanroom area, the Flexicon aseptic filling machine had visible residue on the underside of the plate where empty vials were loaded into the fill sequence and visible residue on the left hand side of the machine. There was also visible residue on the plastic flaps hanging at the bottom of the ISO 5 area walls.

Suite 205

50. In suite 205, the Board inspector observed a machine for washing vials that had broken glass on the in feed, out feed, as well as in the washing chamber where vials were washed. The sink where waste water is drained from the vial washer also had visible glass in the particulate trap of the sink drain. The ISO-7 area (room 4A) had balances with white powder residue and rust on them and tables with rust / degradation or filth on them.

Suite 216

51. The Board inspector observed trays of unlabeled white powder on the counter and there was white powder residue on the counters, floors, and other common areas of the room.

Suite 218

52. The Board inspector observed that suite 218 had multiple rooms The initial room (where retain samples are stored) did not have temperature monitoring. The Board inspector also observed the interior of the autoclave as dirty, with visible black and rust colored residue was observed when the interior surface was wiped.

53. In response to these findings, Respondent took some corrective actions. However, even after these actions, many elements remained non-compliant and inconsistent with a cGMP operation in a state of control.

TWELTH CAUSE FOR DENIAL

(Cleaner Training)

54. Respondent is subject to denial under Code sections 4129.1, subdivisions (b) and (c), 4207, subdivision (c), and 4300, subdivision (c), for unprofessional conduct as defined in Code section 4301, subdivision (o), in that Respondent was not in compliance with current good manufacturing practices, specifically, 21 CFR 211.28, subdivision (c). The circumstances are as follows.

55. After inspection, the Board inspector determined that Respondent's contract cleaner who cleaned Respondent's ISO classified spaces including the ISO-5 spaces, was not adequately trained to perform their required tasks. At the time of inspection, Respondent utilized the cleaner B.S. for cleaning, sanitization, and fogging of the sterile compounding areas in Suites 203 and 205 (including the ISO 5 environment in STE 203). Per Respondent's SOP-SC-MF-002, only trained and qualified personnel are allowed in the controlled GMP Suite 203 or must be escorted by trained personnel. Per Respondent's SOP-SC-MF-024, all personnel that enter the ISO 7 space must be gowning qualified by successfully completing the Personnel Monitoring Testing (PMT - which includes gloved fingertip and thumb sampling of both hands and sampling of the chest, head and both sleeves) after sterile gowning procedure, no fewer than 3 consecutive times. In addition, the SOP required ongoing monitoring to be completed at least once a year. However, Michael H., who is listed as a service agent, has not completed any personnel monitoring testing since he began servicing Respondent in 2018.

THIRTEENTH CAUSE FOR DENIAL

(Retention Sample Inspections)

56. Respondent is subject to denial under Code sections 4129.1, subdivisions (b) and (c), 4207, subdivision (c), and 4300, subdivision (c), for unprofessional conduct as defined in Code section 4301, subdivision (o), in that Respondent was not in compliance with current good manufacturing practices, specifically, 21 CFR 211.170, subdivision (b). The circumstances are as follows.

57. At the time of inspection, the frequency of retention sample inspections was not justified, and leaks were observed in multiple samples of multiple products still within its expiry. In response, Respondent revised their relevant retention sample SOP. The key change made to the SOP included a requirement to inspect the samples once per calendar year or sooner based on a risk assessment for each product. In addition, a risk assessment was estimated to be completed by the end of March 2025. However, a risk assessment was not provided by the end of March to the Board inspector. Moreover, Respondent provided no additional information to suggest their product will maintain its quality attributes through its labeled expiration date.

FOURTEENTH CAUSE FOR DENIAL

(HEPA filter)

58. Respondent is subject to denial under Code sections 4129.1, subdivisions (b) and (c), 4207, subdivision (c), and 4300, subdivision (c), for unprofessional conduct as defined in Code section 4301, subdivision (o), in that Respondent was not in compliance with current good manufacturing practices, specifically, 21 CFR 211.46, subdivision (c). The circumstances are as follows.

59. During inspection it was observed there was a failure to investigate a leak in a HEPA filter during the certification activities in 8/2024. The certifier patched a leaking HEPA filter and no related investigation was conducted by Respondent. Only the "as left" values were documented and it is unclear the exact condition of the HEPA filter at time of testing. Additionally, there was no policy or procedure describing the patching of HEPA filters or documentation of the size / dimension of the HEPA filter patch. Accordingly, the Board inspector concluded that Respondent failed to have proper quality oversight of critical air filtration units and adequate investigation was not performed at the time of the HEPA filter failure.

OTHER MATTERS

60. Pursuant to Code section 4307, if Vitae Enim Vitae Scientific Inc. is denied a license, it 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 for five years if it is placed on probation or until it is issued.

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 application of Vitae Enim Vitae Scientific Inc. for a Resident Outsourcing Facility License;

2. Prohibiting the owners and managers of Respondent Vitae Enim Vitae Scientific Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Vitae Enim Vitae Scientific Inc. is placed on probation or until a license is issued if denied;

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

DATED: 11/3/2025

Sodergren, Anne@DCA Digitally signed by Sodergren, Anne@DCA Date: 2025.11.03 20:13:55 -08'00'

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

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