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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. 6936
PANTHEON LABS, LLC; SUBASH MEDIRATTA, MANAGING MEMBER	**STATEMENT OF ISSUES**
Outsourcing Facility License Applicant	
Respondent.	

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 April 12, 2019, the Board of Pharmacy, Department of Consumer Affairs received an application for an Outsourcing Facility License from Pantheon Labs, LLC; Subash Mediratta, Managing Member (Respondent). On or about April 9, 2019, Subash Mediratta certified under penalty of perjury to the truthfulness of all statements, answers, and representations in the application. The Board denied the application on January 17, 2020.

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JURISDICTION

3. This Statement of Issues is brought before the Board of Pharmacy (Board), 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.

4. Section 4300, subdivision (c) of the Code provides, in pertinent part, that 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.

STATUTORY PROVISIONS

5. Section 4034 of the Code states:

> "Outsourcing facility" means a facility that meets all of the following:
>
> (a) Is located within the United States of America at one address that is engaged in the compounding of sterile drugs and nonsterile drugs.
>
> (b) Has registered as an outsourcing facility with the federal Food and Drug Administration under Section 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353b).
>
> (c) Is doing business within or into California.
>
> (d) Is licensed with the board as an outsourcing facility pursuant to Article 7.7 (commencing with Section 4129).

6. Section 4129 of the Code states, in pertinent part:

> (a) A facility licensed 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.
>
> (b) A facility premises licensed with the board as a sterile compounding pharmacy shall not be concurrently licensed with the board as an outsourcing facility at the same location.
>
> (c) The board may adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.
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> …

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7. Section 4129.1 of the Code 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.

REGULATORY PROVISIONS

8. Code of Federal Regulations, title 21, section 211.1(a) states:

(a) The regulations in this part contain the minimum current good manufacturing practice for preparation of drug products (excluding positron emission tomography drugs) for administration to humans or animals.

9. Code of Federal Regulations, title 21, section 211.100 states:

(a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

(b) Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified

10. Code of Federal Regulations, title 21, 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.

11. Code of Federal Regulations, title 21, section 211.122(b) states:

(b) Any labeling or packaging materials meeting appropriate written specifications may be approved and released for use. Any labeling or packaging materials that do not meet such specifications shall be rejected to prevent their use in operations for which they are unsuitable.

12. Code of Federal Regulations, title 21, section 211.170(a) states, in pertinent part:

(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….

13. Code of Federal Regulations, title 21, section 211.186 states, in pertinent part:

(a) To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person. The preparation of master production and control records shall be described in a written procedure and such written procedure shall be followed.

(b) Master production and control records shall include:

…

(7) A statement of theoretical yield, including the maximum and minimum percentages of theoretical yield beyond which investigation according to § 211.192 is required;

(8) A description of the drug product containers, closures, and packaging materials, including a specimen or copy of each label and all other labeling

signed and dated by the person or persons responsible for approval of such labeling;

14. Code of Federal Regulations, title 21, section 211.188 states, in pertinent part:

Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include:

…

(b) Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including:

…

(2) Identity of individual major equipment and lines used;

…

15. Code of Federal Regulations, title 21, section 211.42 states, in pertinent part:

(a) Any building or buildings used in the manufacture, processing, packing, or holding of a drug product shall be of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations.

(b) Any such building shall have adequate space for the orderly placement of equipment and materials to prevent mixups between different components, drug product containers, closures, labeling, in-process materials, or drug products, and to prevent contamination. The flow of components, drug product containers, closures, labeling, in-process materials, and drug products through the building or buildings shall be designed to prevent contamination.

(c) Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination or mixups during the course of the following procedures:

(10) Aseptic processing, which includes as appropriate:

…

(ii) Temperature and humidity controls;

…

(v) A system for cleaning and disinfecting the room and equipment to produce aseptic conditions;

…

16. Code of Federal Regulations, title 21, section 211.67 states, in pertinent part:

(a) 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.

(b) Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product. These procedures shall include, but are not necessarily limited to, the following:

(1) Assignment of responsibility for cleaning and maintaining equipment;

…

(3) A description in sufficient detail of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance;

…

17. Code of Federal Regulations, title 21, section 211.84 states, in pertinent part:

(a) Each lot of components, drug product containers, and closures shall be withheld from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit.

(b) Representative samples of each shipment of each lot shall be collected for testing or examination. The number of containers to be sampled, and the amount of material to be taken from each container, shall be based upon appropriate criteria such as statistical criteria for component variability, confidence levels, and degree of precision desired, the past quality history of the supplier, and the quantity needed for analysis and reserve where required by § 211.170.

…

(d) Samples shall be examined and tested as follows:

…

(3) Containers and closures shall be tested for conformity with all appropriate written specifications. In lieu of such testing by the manufacturer, a certificate of testing may be accepted from the supplier, provided that at least a visual identification is conducted on such containers/closures by the manufacturer and provided that the manufacturer establishes the reliability of the supplier's test results through appropriate validation of the supplier's test results at appropriate intervals.

…

18. Code of Federal Regulations, title 21, 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.

19. Code of Federal Regulations, title 21, 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.

…

(c) There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product.

20. Code of Federal Regulations, title 21, section 211.28(a) 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.

21. Code of Federal Regulations, title 21, section 211.56 states, in pertinent part:

(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.

…

(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).

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FIRST CAUSE FOR DENIAL OF APPLICATION

(Failure to Demonstrate Compliance at Inspection with Federal Current Good Manufacturing Practices Applicable to Outsourcing Facilities)

22. Respondent's application is subject to denial under section 4129.1 in that it failed to demonstrate compliance with current good manufacturing practices (cGMPs) applicable to outsourcing facilities under subdivision (b) of that section, at the time of the inspection conducted by the Board pursuant to section 4129.1, subdivisions (c) and (d). The circumstances are as follows:

a. On or about April 12, 2019, the Board received an Outsourcing Facility License application from Respondent listing a facility address in Rancho Santa Margarita.

b. On or about and between October 22, 2019 to October 24, 2019, the Board conducted a pre-licensure inspection consistent with section 4129.1, subdivision (c) and (d) at the subject facility in the city of Rancho Santa Margarita. Respondent provided no plans to produce controlled substance products and no production was completed during inspection.

c. Respondent failed to demonstrate compliance with cGMPs applicable to outsourcing facilities at the time of the inspection conducted by the Board.

d. Among the circumstances of non-compliance noted in the inspection process were the findings or observations that the dimensions of the office failed to permit sufficient space for the proper garbing, hand hygiene, and the change to facility shoes.

e. Also among the circumstances of non-compliance noted were the findings or observations that there was no designated area for the cleaning of equipment and the storage of cleaning supplies, that there was no area for the quarantine and release of product, that there was no area designated to receive and store active pharmaceutical ingredients, and that there was no area for packing and shipping, nor the storage of shipping supplies.

f. Also among the circumstances of non-compliance noted were findings or observations concerning the absence or otherwise non-compliant nature of cGMP required written procedures for production, process control, and record keeping, and the failure to implement or evidence the implementation and maintenance of those required procedures.

g. Following the inspection, the Board provided a report to Respondent containing remarks and descriptions related to observed deficiencies under subparts C through G, and I through J of Part 211, title 21 of the Code of Federal Regulations. These observed deficiencies included the instances of cGMP non-compliance referenced in the subparagraphs above.

h. On or about November 26, 2019, the Board received a written response from Respondent to the report. The written response provided by Respondent failed to demonstrate and adequately evidence Respondent's compliance with cGMP, and in some instances demonstrated a misapprehension of cGMP. The Board denied Respondent's application on or about January 17, 2020.

SECOND CAUSE FOR DENIAL OF APPLICATION

(Failure to Demonstrate Compliance with Federal Current Good Manufacturing Practices Applicable to Outsourcing Facilities)

23. Respondent's application is subject to denial under section 4129.1 in that it has failed to demonstrate compliance with current good manufacturing practices (cGMPs) applicable to outsourcing facilities under subdivision (b) of that section. The circumstances are described in paragraph 22, above, which is incorporated here by reference as set forth in full.

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 Pantheon Labs, LLC; Subash Mediratta, Managing Member for an Outsourcing Facility License;

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

DATED: 10/30/2020

Signature on File

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

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