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

In the Matter of the Accusation Against:

CENTRAL ADMIXTURE PHARMACY SERVICES INC., Respondent

Outsourcing Facility Permit No. OSF 103

Agency Case No. 7496

DECISION AND ORDER

The attached Stipulated Surrender of License Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on November 6, 2024.

It is so ORDERED on October 7, 2024.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
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DESIREE I. KELLOGG
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Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **CENTRAL ADMIXTURE PHARMACY SERVICES, INC.** **7935 Dunbrook Road, Suite B-G** **San Diego, CA 92126** **Outsourcing Facility Permit No. OSF 103** Respondent.	Case No. 7496 **STIPULATED SURRENDER OF LICENSE AND ORDER**

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Desiree I. Kellogg, Deputy Attorney General.

2. Respondent Central Admixture Pharmacy Services, Inc. is acting in this proceeding through Jim West, President and Lisa Siegel, Treasurer of Central Admixture Pharmacy Services, Inc., who have been designated and authorized by Central Admixture Pharmacy Services, Inc. to enter into this agreement on its behalf.

3. Central Admixture Pharmacy Services, Inc. (Respondent) is represented in this proceeding by attorney Sweta H. Patel of Potomac Law Group, PLLC, whose address is: 1255 Treat Boulevard, Suite 300, Walnut Creek CA 94597.

4. On or about August 9, 2017, the Board issued Outsourcing Facility Permit No. OSF 103 to Central Admixture Pharmacy Services, Inc. (Respondent). The Outsourcing Facility Permit No. OSF 103 was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 7496 and was cancelled on December 29, 2023.

JURISDICTION

5. First Amended Accusation No. 7496 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on September 14, 2023. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of First Amended Accusation No. 7496 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 7496. Respondent also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of License and Order.

7. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to confront and cross-examine the witnesses against it; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

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CULPABILITY

9. Respondent understands that the charges and allegations in First Amended Accusation No. 7496, if proven at a hearing, constitute cause for imposing discipline upon its Outsourcing Facility Permit No. OSF 103.

10. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the First Amended Accusation and that those charges constitute cause for discipline. Respondent hereby gives up its right to contest that cause for discipline exists based on those charges.

11. Respondent understands that by signing this stipulation, it enables the Board to issue an order accepting the surrender of its Outsourcing Facility Permit No. OSF 103 without further process.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board. Respondent understands and agrees that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and surrender, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Surrender and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Surrender of License and Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

14. This Stipulated Surrender of License and Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions,

negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Order:

ORDER

IT IS HEREBY ORDERED that Outsourcing Facility Permit No. OSF 103, issued to Respondent Central Admixture Pharmacy Services, Inc., is surrendered and accepted by the Board.

1. The surrender of Respondent's Outsourcing Facility Permit No. OSF 103 and the acceptance of the surrendered license by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board. Respondent understands and agrees that this stipulated surrender is the same as and shall be treated as a revocation for all purposes.

2. Respondent shall lose all rights and privileges as an outsourcing facility as it pertains to Outsourcing Facility Permit No. OSF 103 in California as of the effective date of the Board's Decision and Order.

3. If Respondent ever applies for licensure of an outsourcing facility other than the currently existing Permit Nos. NSF 130 and 135 or petitions for reinstatement in the State of California of Outsourcing Facility Permit No. OSF 103, the Board shall treat it as a new application for licensure. Respondent must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in First Amended Accusation No. 7496 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition.

4. Respondent shall pay the agency its costs of investigation and enforcement in the amount of $58,465.00, prior to issuance of a new or reinstated license.

///

5. If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in First Amended Accusation No. 7496 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

6. Respondent shall not apply for an outsourcing facility licensure other than the currently existing Permit Nos. NSF 130 and 135 or petition for reinstatement of Permit No. OSF 103 for three (3) years from the effective date of the Board's Decision and Order.

ACCEPTANCE

We, Jim West, President and Lisa Siegel, Treasurer of Central Admixture Pharmacy Services, Inc. have been authorized to act on Central Admixture Pharmacy Services, Inc.'s behalf in this matter, and have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with its counsel, Sweta Patel. Respondent Central Admixture Pharmacy Services, Inc. understands the stipulation and the effect it will have on its Outsourcing Facility Permit. On behalf of Central Admixture Pharmacy Services, Inc., as its authorized representatives, we enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and Central Admixture Pharmacy Services, Inc. agrees to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

CENTRAL ADMIXTURE PHARMACY SERVICES, INC.
Respondent
Name: Jim West
Title: President
Authorized Representative

DATED: _____

CENTRAL ADMIXTURE PHARMACY SERVICES, INC.
Respondent
Name: Lisa Siegel
Title: Treasurer
Authorized Representative

5. If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in First Amended Accusation No. 7496 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

6. Respondent shall not apply for an outsourcing facility licensure other than the currently existing Permit Nos. NSF 130 and 135 or petition for reinstatement of Permit No. OSF 103 for three (3) years from the effective date of the Board's Decision and Order.

ACCEPTANCE

We, Jim West, President and Lisa Siegel, Treasurer of Central Admixture Pharmacy Services, Inc. have been authorized to act on Central Admixture Pharmacy Services, Inc.'s behalf in this matter, and have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with its counsel, Sweta Patel. Respondent Central Admixture Pharmacy Services, Inc. understands the stipulation and the effect it will have on its Outsourcing Facility Permit. On behalf of Central Admixture Pharmacy Services, Inc., as its authorized representatives, we enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and Central Admixture Pharmacy Services, Inc. agrees to be bound by the Decision and Order of the Board of Pharmacy.

DATED: Aug 26, 2024

Jim West
Jim West (Aug 26, 2024 15:41 EDT)

CENTRAL ADMIXTURE PHARMACY SERVICES, INC.
Respondent
Name: Jim West
Title: President
Authorized Representative

DATED: Aug 26, 2024

Lisa Sigal
Lisa Sigal (Aug 26, 2024 14:22 PDT)

CENTRAL ADMIXTURE PHARMACY SERVICES, INC.
Respondent
Name: Lisa Sigal
Title: Treasurer
Authorized Representative

I have read and fully discussed with Respondent Central Admixture Pharmacy Services, Inc. the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: _____ _____
SWETA H. PATEL
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General

DESIREE I. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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I have read and fully discussed with Respondent Central Admixture Pharmacy Services, Inc. the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: 8/26/24

SWETA H. PATEL
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _August 27, 2024_____

Respectfully submitted,

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General

DESIREE I. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

First Amended Accusation No. 7496

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GREGORY J. SALUTE
Supervising Deputy Attorney General
DESIREE I. KELLOGG
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Facsimile: (619) 645-2061
Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **CENTRAL ADMIXTURE PHARMACY SERVICES, INC.** **7935 Dunbrook Road, Suite B-G** **San Diego, CA 92126** **Outsourcing Facility Permit No. OSF 103** Respondent.	Case No. 7496 **FIRST AMENDED ACCUSATION**

PARTIES

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

2. On or about August 9, 2017, the Board issued Outsourcing Facility Permit Number OSF 103 to Central Admixture Pharmacy Services, Inc. (Respondent). The Outsourcing Facility Permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2024, unless renewed.

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JURISDICTION

3. This First Amended Accusation 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 (Code, § 4000 *et seq*.) and the Uniform Controlled Substances Act (Health & Safety Code, § 11000 *et seq*.).

5. Code section 4300, subdivision (a) provides that every license issued by the Board may be suspended or revoked.

6. Code section 4300.1 states:

> The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY PROVISIONS

7. 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.

8. Code section 4129.1, subdivisions (b) and (e)(2) state:

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

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

9. Code section 4169, subdivision (a)(2) states:

(a) A person or entity shall not do any of the following:

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

10. Code section 4301, subdivisions (f), (g), (j) and (o) state:

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:

. . .

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

. . .

(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.

11. Health and Safety Code section 111255 states:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

12. Health and Safety Code section 111295 states:

It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated.

REGULATORY PROVISIONS

13. Code of Federal Regulations, title 21, section 210.1, subdivisions (a) and (b) state:

(a) The regulations set forth in this part and in parts 211, 225, and 226 of this chapter contain the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

(b) The failure to comply with any regulation set forth in this part and in parts 211, 225, and 226 of this chapter in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under section 501(a)(2)(B) of the act and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action.

14. Code of Federal Regulations, title 21 section 211.22, subdivisions (a) and (c) state:

(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.

15. Code of Federal Regulations, title 21, section 211.25, subdivisions (a) and (b) state:

(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 procedure 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.

16. Code of Federal Regulations, title 21, section 211.42, subdivisions (a) and (c)(10)(iii) state:

(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.

(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)(iii) Aseptic processing, which includes as appropriate: An air supply filtered through high-efficiency particulate air filters under positive pressure, regardless of whether flow is laminar or nonlaminar.

17. Code of Federal Regulations, title 21, section 211.67, subdivisions (a) and (b) state:

(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;

(2) Maintenance and cleaning schedules, including where appropriate, sanitizing schedules;

(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;

(4) Removal or obliteration of previous batch identification;

(5) Protection of clean equipment from contamination prior to use;

(6) Inspection of equipment for cleanliness immediately before use.

18. Code of Federal Regulations, title 21, section 211.68, subdivisions (a) and (b) state:

(a) Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, may be used in the manufacture, processing, packing, and holding of a drug product. If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections shall be maintained.

(b) Appropriate controls shall be exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Input to and output from the computer or related system of formulas or other records or data shall be checked for accuracy. The degree and frequency of input/output verification shall be based on the complexity and reliability of the computer or related system. A backup file of data entered into the computer or related system shall be maintained except where certain data, such as calculations performed in connection with laboratory analysis, are eliminated by computerization or other automated processes. In such instances a written record of the program shall be maintained along with appropriate validation data. Hard copy or alternative systems, such as duplicates, tapes, or microfilm, designed to assure that backup data are exact and complete and that it is secure from alteration, inadvertent erasures, or loss shall be maintained.

19. Code of Federal Regulations, title 21, section 211.166, subdivision (a)(2) 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:

(2) Storage conditions for samples retained for testing.

20. Code of Federal Regulations, title 21, section 211.180, subdivision (e), states:

(e) 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, record associated with the batch.

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

21. Code of Federal Regulations, title 21, section 211.188, subdivisions (a) and (b)(12) state:

> 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:
>
> (a) An accurate reproduction of the appropriate master production or control record, checked for accuracy, dated and signed;
>
> (b) Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including: …
>
> (12) Any investigation made according to § 211.192.

22. Code of Federal Regulations, title 21, section 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 a 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 followup.

COST RECOVERY

23. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

FACTUAL ALLEGATIONS

24. Respondent was an outsourcing facility that compounded non-patient specific, large batches of sterile drug products for dispensing to patients in healthcare facilities or institutions. Pharmacy Law requires outsourcers such as Respondent to compound its sterile drug products in compliance with federal current good manufacturing practices applicable to outsourcing facilities.[1] The Board inspects outsourcing facilities, such as Respondent, annually to determine

[1] Federal current good manufacturing practices require the implementation of systems to

if they are compounding sterile drug products in accordance with federal current good manufacturing practices and investigates complaints filed against them.

June 2022 Annual Renewal Inspection

25. On June 7 through 9, 2022, the Board conducted an annual renewal inspection of Respondent. The Board observed multiple instances of Respondent's non-compliance with federal current good manufacturing practices as follows.

26. Respondent did not adequately educate, train and provide experience to its compounding staff in order to enable them to utilize proper aseptic techniques.[2] For example, during the compounding of sterile products, a member of the compounding staff laid his arms on hood 6 and tightened caps with his hands, failed to wait for alcohol to dry on his gloves and did not adequately sanitize his gloves when entering and exiting the ISO 5 cleanroom space(s). Another staff member failed to adequately disinfect sterile drug product(s) with alcohol, laid his arms on the hood, tightened caps with his hands and rapidly entered and exited hood 3 in the ISO 5 cleanroom space(s) multiple times. Another staff member allowed his bare skin to be exposed between his mask and goggles in hood 9 located in the small core cleanroom. These poor aseptic techniques increased the risk of contamination to sterile products from microorganisms such as bacteria and fungus.

27. For the second consecutive year, viable air sampling in the ISO 5 and 7 cleanroom space(s) showed "exceeded action levels," meaning expected amounts of contaminants in the air were higher than allowed in the ISO 5 and 7 cleanroom space(s).[3] These elevated action levels of air in the cleanroom classified space(s) increased the risk of contamination from microorganisms such as bacteria and fungus, thereby depriving the Quality Control Unit of the ability to properly

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assure proper design, monitoring, and control of manufacturing processes and facilities for the compounding of non-patient specific, large batches of sterile products which are riskier to compound, than small batches of patient-specific sterile products.

[2] Aseptic techniques are those techniques and procedures designed to prevent contamination of drugs, packaging, equipment or supplies by microorganisms during preparation.

[3] Cleanrooms are classified according to the cleanliness level of the air inside the controlled environment of each cleanroom. The cleanroom class refers to the level of cleanliness the room complies with according to the quantity and size of particles per cubic meters of air, ISO 1 cleanrooms possess the "cleanest" air while ISO 9 cleanrooms have the "dirtiest" air.

exercise its responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products.

28. For the second consecutive year, Respondent did not complete adequate annual product reviews on a representative number of sterile drug product batches, records associated with those batches, complaints, recalls, returned or salvaged drug products, and investigations conducted for each drug product (*i.e.*, the quality standards of each drug product) to determine the need for changes in drug product specifications or manufacturing or control procedures.

29. From approximately January through May, 2022, the electronic pressure gauges which measured the positive pressure of air in the large core clean cleanroom malfunctioned and broke. Although staff knew that electronic pressure gauges had malfunctioned, they did not manually measure the air pressure in the large core cleanroom as intended and continued to compound and distribute sterile products in the large core cleanroom.

2022-2023 Complaint Investigation:

30. On November 7, 2022, the Board received a complaint alleging that Respondent was not in compliance with federal current good manufacturing practices when compounding sterile drug products. The Board initiated an investigation of that complaint and conducted inspections of Respondent on February 7 and 8 and May 25 and 26, 2023. Once again, the Board observed multiple instances of Respondent's non-compliance with federal current good manufacturing practices as follows.

31. Respondent maintained equipment and utensils used to compound sterile drug products in such a poor state of repair that there was a risk of malfunctioning equipment and of contamination that would alter the safety, identity, strength, quality or purity of sterile drug products. Respondent also lacked adequate written procedures for cleaning and maintaining equipment and utensils used to compound sterile drug products. For example, Respondent maintained many of its repeater pumps in a rusty condition and its laminar flow hoods and cleaning equipment in a damaged or degraded condition. Multiple screws and bolts were missing from hoods 2, 6, 7, 8, 9 and 11. There was cracked plexiglass on the sides of hoods 3 and 4, a gap in the frame of hood 3 and rust on the metal brackets of hoods 8 and 9, all of which made those

hoods difficult to clean. Indeed, Respondent allowed an unknown brown/black residue of likely contaminated material to build up on the back panel of the ISO-5 in hood 9.

32. During the Board's inspection, the Director of Pharmacy submitted photographs of repeater pumps which did not accurately depict the condition of them (i.e., submitted a photograph of repeater pump #114957 with a sticker concealing the rust).

33. The facility and equipment used in the compounding of sterile drug products were not maintained in a clean and sanitary condition. For example, surfaces were not disinfected properly or equipment was not completely sanitized in the ISO-5 areas. Staff also sprayed flexible IV bags indiscriminately with a solution and then transferred them into the ISO-5 space. Even during the Board's inspection, the likely contaminated back panel of hood 9 was not completely and thoroughly cleaned by staff.

34. Nonetheless, Respondent continued to use malfunctioning, broken, unclean and insanitary equipment located in an unclean and insanitary facility to compound sterile drug products, thereby increasing the risk of contamination to sterile drug products from microorganisms.

35. Respondent's compounding staff continued to lack the necessary education, training and experience in federal current good manufacturing practices, including aseptic techniques. For example, on May 25, 2023, compounding staff in hoods 1, 5 and 6 blocked first air at the critical site during the pooling steps; staff in hood 2 performed incomplete sanitization of equipment into the ISO-5 with 70% IPA; staff in hood 7 performed incomplete sanitization of syringe caps during material transfer; and staff in hood 8 performed incomplete sanitization of the scale plate and diluent bags prior to entry into the ISO-5. Again, these poor aseptic techniques increased the risk of contamination to sterile drug products from microorganisms such as bacteria and fungus.

36. Respondent's Quality Control Unit failed to review, reject and/or approve all procedures or specifications impacting on the identity, strength, quality and purity of sterile drug products and the components, drug product containers, closures, in-process materials, packaging materials, labeling and drug products. The Quality Control Unit also failed to review production and control records to assure that no errors had occurred or, when errors occurred to fully

investigate them. For example, the investigations of NQE-US32-181106-147, lots 17-125264 (failed to review physical condition of repeater pump when microbial growth was found from samples of drug product collected on that repeater pump), 17-125304, 17-125357, 17-212456 (no investigation of discrepancies), 17-212733 (no records discussing if drug products recalled or destroyed) and NQE US32-210514-047 (no records discussing if drug products recalled or destroyed) were either incomplete or non-existent.

37. Respondent's Quality Control Unit also failed to review and approve all sterile drug product production and control records, including those for packaging and labeling to determine compliance with all established, approved written procedures before batches were distributed. The Quality Control Unit also failed to thoroughly investigate all unexplained discrepancies or the failure of batches or any of its components to meet any of its specifications.

38. Respondent failed to adequately calibrate, inspect, or check automatic, mechanical or electronic equipment used in the manufacture of sterile drug products, according to a written program designed to assure proper performance and to maintain written records of the calibration checks and inspections. For example, hood 6 (asset number 101887) was not adequately validated or calibrated prior to resuming commercial batch production commencing with lot 17-254028. Additionally, the factory installed pressure gauge for hood 6 was not calibrated, although it was marked as calibrated. New hood 6 also had an existing patch on the HEPA filter which exceeded the allowable limits for patches set forth in Respondent's standard operating procedures. The change order CCR-4000115 for the replacement of an ISO-5 laminar flow hood was not timely reviewed and its approval could not be justified because the newly installed hood was of a different physical construct for the process validations performed in the legacy laminar flow hood and was not suitable for the process validations performed in the newly installed laminar flow hood.

39. Respondent's electronic batch production and control records for sterile drug products did not contain complete information relating to the production and control of each significant step in the manufacture, processing, packing, or holding of each patch of drug product, including for lots 17-249001, 17-198736, 17-249096, 17-249193 and 17-249230. Records for

investigations of lot 17-227459, lot 17-212456, lot 17-212733, NQE US32-210514-047, and NQE-US32-211008-085 were incomplete or nonexistent.

40. Respondent's electronic batch production and control records for each batch of sterile drug products were also not accurate reproductions of complete information relating to the production of each batch of sterile drug product, including lots 17-212456, 17-224517 and 17-226381 (i.e., the records were inaccurate as to the tamper evident caps used, the times for line clearance and packaging of those batches and the batches were released without a complete list of materials used and documentation of overwrapping).

41. The electronic batch records also lacked integrity and Respondent lacked the capacity to conduct a complete audit trial of the production of sterile drug products. For example, the electronic batch records for lot 17-212456 were changed (i.e., the identity of operators who performed visual inspections and label verifications) without appropriate controls and/or a complete audit trail. Electronic batch records for lot 17-198736 were deleted and the number of units for that batch were changed without an audit trail. For lot 17-198736, original entries documenting the "RC volume" by a pharmacist were deleted and the number of units changed by the Technology Department without an audit trial. For lot 17-212733, the batch was released and then changed to "discontinued" without noting the date and time of discontinuation and who made that decision.

42. Respondent's written records were not maintained so that data could be used for evaluating the quality standards of sterile drug products to determine the need for changes in drug product specifications or manufacturing or control procedures, along with written procedures for such evaluations.

43. On or about May 11, 2021, Respondent failed to notify the Board of the recall of sterile drug products (lot 17-212733) within 24 hours. Respondent also failed to follow its own procedures for the recall of that sterile drug product which resulted in at least three customers receiving recalled drugs. During the 2021 June annual inspection, Respondent falsely represented that there had been no recalls, even though there had been a recall in May 2021.

44. Respondent also failed to institute appropriate controls over computer or related systems to assure that changes in master production and control records were instituted only by authorized personnel. For example, a compounding operator filled a 50mL syringe with a target volume of 31.2mL of a drug product which was contrary to the requirements of Drug Master Formula, DMF 6009-1, which specified a target volume of 31.20 mL. Yet, the electronic batch records incorrectly recorded the target volume in that syringe as 31.20 mL rather than 50mL and a pharmacist did not visually verify the contents of that syringe to determine that the volume was higher than allowed.

June 2023 Annual Renewal Inspection:

45. On June 6 through 8, 2023, the Board conducted an annual renewal inspection of Respondent. Once again, the Board observed multiple instances of Respondent's non-compliance with federal current good manufacturing practices as follows.

46. Respondent continued to provide a lack of training on federal current good manufacturing practices for its compounding staff, including failing to hold annual trainings for its staff to ensure its compounding staff members were aware of federal current good manufacturing practices and followed them. For example, a visual inspection operator was allowed to examine two 30mL syringes simultaneously against black and white backgrounds. Respondent's Quality Control Unit also continued to lack oversight and review over electronic batch records review, environmental monitoring, validating vendor qualifications (out of 42 vendors, 24 were missing validations or qualifications), aseptic techniques and investigations.

47. Respondent's testing program designed to assess the stability characteristics of sterile drug products did not ensure appropriate storage conditions for samples of sterile drug products retained for testing. Namely, Respondent performed stability testing in an environment which lacked the appropriate regulated temperatures which had also been observed during the inspection in 2022. For several months, the temperature never reached the required minimum temperatures and the excursions were longer than 24 hours. Respondent also did not retain samples of sterile drug products to perform testing to confirm that the lack of temperature controls did not negatively impact sterile drug products.

48. Compounding staff continued to use unacceptable aseptic techniques such as blocking first air when puncturing vials and when using the syringe block. All staff members moved between ISO 7 and ISO 8 areas with no gown changes. Additionally, Andrew improperly sprayed his head and shoulders with alcohol; Catherine sprayed the tops of vials for drug pooling in a manner which did not assure all tops were thoroughly sanitized in hood 7; A.C. used poor cleaning techniques (i.e., no overlaps and missed corners) when cleaning the Primary Engineering Control; Omar moved too fast during first air; Catherine used a plastic block to push vials around and leaned her arm on the block in hood 7; Reina used balance as a table for empty bags and a syringe cup holder; Catherine used balance as a table for the syringe block in hood 7; and L.S. sprayed her hand immediately prior to glove fingertip and sleeve testing.

49. Electronic batch records continued to be inaccurate reproductions of compounding processes and investigations were not documented completely, although Respondent promised to make those enhancements to the electronic batch records during the annual inspection in 2022. Specifically, Respondent promised the Board in writing that it would change its electronic batch records to accurately reflect the time inputs for compounding drug products and to conduct complete audit trails. However, it failed to do so.

50. Equipment continued to be maintained in a poor state of repair, was not calibrated properly and the facility and equipment used to compound sterile drug products were unclean and insanitary and no repairs were initiated. For example, hood 4 had a gap between the plastic shield fastened with Velcro and the top portion of the shield was not cleaned adequately, the speaker cover in the small core clean room was rusty and had chipped paint on it, the doors between the Warehouse Controlled Space and the labeling and packaging area were broken and missing pieces in the flashing and a plastic flap over the conveyor belt was cracked and ripped with old and unsanitary tape securing it. Instruments to measure the viability and non-viability of particulates (i.e., the NVPC and the VAC) in a hood were not configured in accordance with the standard operating procedures.

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July and August 2023 FDA/Board Inspection:

51. On July 10, 17 and 18 and August 25, 2023, the Federal Food and Drug Administration (FDA) and the Board conducted an inspection of Respondent. The FDA observed multiple instances of Respondent's non-compliance with federal current good manufacturing practices, many of which were consistent with the Board's observations of Respondent's non-compliance with federal current good manufacturing practices.

52. The FDA's observations included Respondent's failure to thoroughly review any unexplained discrepancies or the failures of batches to meet any of their specifications, its failure to establish and follow written procedures designed to prevent microbiological contamination of drug products purporting to be sterile, its failure to establish adequate written procedures for production and process controls designed to ensure that drug products have the identity, strength, purity, and quality that they are purported to possess, its failure to maintain complete batch production and control records, and its failure to maintain equipment and buildings used in the manufacture, processing, packing or holding of drug products in a clean and sanitary condition. The aseptic processing areas were also observed to be deficient regarding the system for cleaning and disinfecting the rooms and equipment to produce aseptic conditions and for maintaining any equipment used to control the aseptic conditions. The FDA issued a Form-483 to Respondent setting forth seventeen observations of Respondent's non-compliance with federal current good manufacturing practices.

53. During the FDA's inspection, the Board also continued to observe unsanitary and unclean conditions and the facility and equipment in a poor state of repair. For example, in the area immediately outside the ISO-8 gowning and product introduction rooms, a compounding staff member prepared a bucket of cleaning solution and a mop to clean the compounding rooms. However, the mop and bucket of cleaning solution had copious amounts of dark particulates, contaminates and filth in or on them. That same dark particulate matter was also found in reusable spray bottles intended for use in the cleanrooms. The Board also observed damage to the wall behind hood 1 in the large core room, two damaged ceiling tiles and a wall with exposed

fibrous material above and behind hood 9. Dark particulate matter and stains were located behind hood 9 in the small core room and near the window by hood 2 in the large core room.

FIRST CAUSE FOR DISCIPLINE

(Failure of Quality Control Unit to Approve or Reject, Review Production Records and Fully Investigate)

54. Respondent's License is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivisions (j) and (o) because it violated Code section 4129.1, subdivision (b), by failing to comply with federal current good manufacturing practices set forth in Code of Federal Regulations, section 211.22, subdivisions (a) and (c). Namely, Respondent failed to maintain allowable air cleanliness or "exceeded action levels" in the ISO 5 and ISO 7 classified areas, thereby depriving the Quality Control Unit of its ability to evaluate the quality of sterile products. The Quality Control Unit also failed to exercise its responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging materials, labeling and drug products and all procedures or specifications impacting on the identity, strength, quality and purity of drug products. The Quality Control Unit also failed to review production records to assure that no errors occurred and if they did, to fully investigate them, as described above in paragraphs 24 through 53.

SECOND CAUSE FOR DISCIPLINE

(Failure to Educate, Train and Provide Experience to Staff and Supervisors)

55. Respondent's License is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivisions (j) and (o), because it violated Code section 4129.1, subdivision (b), by failing to comply with federal current good manufacturing practices set forth in Federal Code of Regulations, section 211.25, subdivisions (a) and (b). Namely, Respondent failed to adequately educate and train staff and supervisors and to provide them the experience necessary for them to compound sterile drug products employing federal current good manufacturing practices, including aseptic techniques, as described above in paragraphs 24 through 53.

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THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Facility in Clean and Sanitary Condition, Including Verifying Positive Air Pressure in Large Core Clean Room)

56. Respondent's License is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivisions (j) and (o) because it violated Code section 4129.1, subdivision (b) by failing to comply with federal current good manufacturing practices set forth in Federal Code of Regulations, section 211.42, subdivisions (a) and (c)(10)(iii). Namely, Respondent failed to verify the positive air pressure in the large core clean room when producing and releasing batches of sterile drug products. It also failed to maintain the facility used for the manufacture of sterile drug products in a clean and sanitary condition, as described above in paragraphs 24 through 53.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Clean, Maintain and Sanitize or Sterilize Equipment and Utensils and Establish Written Procedures for Cleaning and Maintaining Equipment and Utensils)

57. Respondent's License is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivisions (j) and (o) because it violated Code section 4129.1, subdivision (b) by failing to comply with federal current good manufacturing practices set forth in Federal Code of Regulations, section 211.67, subdivisions (a) and (b). Namely, Respondent did not clean, maintain, sanitize or sterile equipment and utensils to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of sterile drug products and establish written procedures for cleaning and maintaining equipment used to compound sterile drug products, as described above in paragraphs 24 through 53.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Routinely Calibrate, Inspect or Check Automatic, Mechanical, or Electronic Equipment, Maintain Calibration Records and Exercise Appropriate Controls over Computer or Related Systems)

58. Respondent's License is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivisions (j) and (o) because it violated Code section 4129.1,

subdivision (b) by failing to comply with federal current good manufacturing practices set forth in Federal Code of Regulations, section 211.68, subdivisions (a) and (b). Namely, Respondent failed to routinely calibrate, inspect or check automatic, mechanical or electronic equipment, maintain calibration records and to exercise appropriate controls over computer or related systems to assure that changes in master production and control records are instituted only by authorized personnel and to check those systems for accuracy, as described above in paragraphs 24 through 53.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Conduct Proper Stability Testing of Sterile Drug Products)

59. Respondent's License is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivisions (j) and (o) because it violated Code section 4129.1, subdivision (b) by failing to comply with federal current good manufacturing practices set forth in Federal Code of Regulations, section 211.166, subdivision (a)(2). Namely, Respondent failed to maintain samples of sterile drug products in properly regulated temperatures when conducting stability testing in the Warehouse Control Area, as described above in paragraphs 24 through 53.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Review Representative Number of Sterile Drug Product Batches and Corresponding Records and Complaints, Recalls, Returned or Salvaged Drug Products and Investigations Conducted)

60. Respondent's License is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivisions (j) and (o) because it violated Code section 4129.1, subdivision (b), by failing to comply with federal current good manufacturing practices set forth in Federal Code of Regulations, section 211.180, subdivision (e). Namely, Respondent failed to review a representative number of sterile drug product batches, the records associated with those batches, complaints, recalls, returned or salvaged products, and any investigations conducted under Federal Code of Regulations section 211.192 for each drug product, as described above in paragraphs 24 through 53.

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EIGHTH CAUSE FOR DISCIPLINE

(Failure to Maintain Complete Electronic Batch Production and Control Records, Including an Accurate Reproduction of the Master Production or Control Records and Investigations Conducted)

61. Respondent's License is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivisions (j) and (o) because it violated Code section 4129.1, subdivision (b), by failing to comply with federal current good manufacturing practices set forth in Federal Code of Regulations, section 211.188, subdivisions (a) and (b)(12). Namely, Respondent failed to maintain batch production and control records that included an accurate reproduction of the appropriate master production or control records, checked for accuracy, dated and signed and documentation that each significant step in the manufacture, processing, packing or holding of the batch was accomplished, including any investigations conducted, as described above in paragraphs 24 through 53.

NINTH CAUSE FOR DISCIPLINE

(Quality Control Unit's Failure to Review and Approve Drug Production and Control Records to Determine Compliance with Established, Approved Procedures and to Thoroughly Investigate Discrepancies or Batch Failures to Meet Specifications)

62. Respondent's License is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivisions (j) and (o) because it violated Code section 4129.1, subdivision (b) by failing to comply with federal current good manufacturing practices set forth in Federal Code of Regulations, section 211.192. Namely, Respondent's records for drug productions, including those for lot 17-212733 and NQE US32-210514-047 were not reviewed and approved by the Quality Control Unit to determine compliance with all established, approved, procedures before those lots or batches were released and any unexplained discrepancies or failures of any batch to meet any specifications were not thoroughly investigated, as described above in paragraphs 24 through 53.

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TENTH CAUSE FOR DISCIPLINE

(Producing and Furnishing of Adulterated Sterile Products)

63. Respondent's License is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivisions (j) and (o) because it violated Code section 4129.1, subdivision (b) and Federal Code of Regulations, section 210.1, when it failed to follow federal current good manufacturing practices, thereby causing sterile drug products produced at its facility to be adulterated, as described above in paragraphs 24 through 53.

ELEVENTH CAUSE FOR DISCIPLINE

(Held or Offered for Sale Adulterated Drugs)

64. Respondent's License is subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Health and Safety Code section 111295 and Code section 4169, subdivision (a)(2), in that it held or offered for sale dangerous drugs that were adulterated within the meaning of Health and Safety Code section 111255, as described above in paragraphs 24 through 53.

TWELFTH CAUSE FOR DISCIPLINE

(Sold or Delivered Adulterated Drugs)

65. Respondent's License is subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Health and Safety Code section 111295 and Code section 4169, subdivision (a)(2), in that it sold or delivered dangerous drugs that were adulterated within the meaning of Health and Safety Code section 111255, as described above in paragraphs 24 through 53.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Provide Board with Recall Notice)

66. Respondent's License is subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Business and Professions Code section 4129.1, subdivision (e)(2), in that it failed to notify the Board of the recall of drug product (lot 17-212733) with twenty four hours, as described above in paragraphs 24 through 53.

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FOURTEENTH CAUSE FOR DISCIPLINE

(Commission of Dishonest Acts)

67. Respondent's License is subject to disciplinary action under Code section 4301, subdivision (f) for committing dishonest acts, as described above in paragraphs 24 through 53.

FIFTEENTH CAUSE FOR DISCIPLINE

(Knowingly Making or Signing Documents that Falsely Represent Facts)

68. Respondent's License is subject to disciplinary action under Code section 4301, subdivision (g) for knowingly making or signing any certificates or other documents that falsely represents the existence or nonexistence of a state of facts, as described above in paragraphs 24 through 53.

SIXTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

69. Respondent's License is subject to disciplinary action under Code section 4301 for unprofessional conduct because it engaged in the activities described above in paragraphs 24 through 53.

DISCIPLINE CONSIDERATIONS

70. To determine the degree of discipline, if any, to be imposed on Respondent, Complainant alleges that on or about June 30, 2022, in a prior action, the Board of Pharmacy issued Citation and Fine Number 2021 94700 because Respondent committed dishonest acts and made misrepresentations about its compliance with federal current good manufacturing practices after the annual inspection in 2021. That Citation is now final.

OTHER MATTERS

71. Pursuant to Code section 4307, if discipline is imposed on Outsourcing Facility Permit No. OSF 103 issued to Central Admixture Pharmacy Services, Inc., it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Outsourcing Facility Permit Number OSF 103 is placed on probation or until the Pharmacy Permit is reinstated if it is revoked.

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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. Revoking or suspending Outsourcing Facility Permit Number OSF 103, issued to Central Admixture Pharmacy Services, Inc.;

2. Prohibiting Central Admixture Pharmacy Services, Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Outsourcing Facility Permit Number OSF 103 is placed on probation or until the Outsourcing Facility Permit is reinstated, if it is revoked;

3. Ordering Central Admixture Pharmacy Services, Inc. to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 12/13/2023

Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2023.12.13 21:10:32 -08'00'

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

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