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

In the Matter of the Accusation Against: **MEDAUS INC.,** **DBA MEDAUS PHARMACY** **STEVEN L. RUSSELL, PRESIDENT** **6801 Cahaba Balley Road, Suite 116** **Birmingham, AL 35242** **Non-Resident Pharmacy Permit No. NRP 547** **Non-Resident Sterile Compounding No. NSC 99170** Respondent.	Case No. 5859 **FIRST AMENDED ACCUSATION**

Complainant alleges:

PARTIES

1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy ("Board"), Department of Consumer Affairs.

2. On or about September 2, 2003, the Board issued Non-Resident Pharmacy Permit Number NRP 547 to Medaus Inc., doing business as Medaus Pharmacy, Steven L. Russell, President, ("Respondent"). The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2017, unless renewed.

3. On or about November 29, 2014, the Board issued Non-Resident Sterile Compounding License Number NSC 99170 to Respondent. The Non-Resident Sterile Compounding License expired on September 1, 2014. The Board did not permit renewal of the license and it was canceled on November 3, 2014.

4. From on or about September 2, 2003, to on or about August 22, 2014, S. R. was Respondent's designated California Pharmacist-in-Charge ("PIC") within the meaning of Business and Professions Code section 4113.

JURISDICTION

5. This 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.

6. Section 4300 of the Code states, in pertinent part:

(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing [the licensee] upon probation.

(3) Suspending [the licensee's] right to practice for a period not exceeding one year.

(4) Revoking [the licensee's] license.

(5) Taking any other action in relation to disciplining [the licensee] as the board in its discretion may deem proper.

. . .

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

7. Section 4300.1 of the Code 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.

8. Section 4402 of the Code provides, in pertinent part:

. . .

(e) any other license issued by the board may be canceled by the board if the license is not renewed within 60 days after its expiration. Any license canceled under this subdivision may not be reissued. Instead, a new application will be required.

STATUTORY PROVISIONS

9. Section 4301 of the Code states, in pertinent part:

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

. . .

(b) Incompetence.

(c) Gross negligence.

. . .

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

. . .

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this statute.

. . .

(*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.

(p) Actions or conduct that would have warranted denial of a license.

10. Section 4303 of the Code provides, in pertinent part:

. . .

(b) The board may cancel, deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on an of the same grounds upon which such action might be taken against resident pharmacy, provided that the grounds for the action are also rounds for action in the state in which the nonresident pharmacy is permanently located.

11. Section 4022 of the Code provides, in pertinent part:

"Dangerous drug". . .means any drug. . . 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.

. . .

(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.

12. Section 4052 of the Code states, in pertinent part:

(a) Notwithstanding any other law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

. . .

13. Section 4113 of the Code states, in pertinent part:

(a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.

(b) The proposed pharmacist-in-charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved pharmacist-in-charge for the pharmacy.

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

(d) Every pharmacy shall notify the board in writing, on a form designed by the board, within 30 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge, and shall on the same form propose another pharmacist to take over as the pharmacist-in-charge. The proposed replacement pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of the disapproval and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

(e) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead provide on that form the name of any pharmacist who is an employee, officer, or administrator of the pharmacy or the entity that owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis, to act as the interim pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, of the entity that owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with the name of the interim pharmacist-in-charge with documentation of the active involvement of the interim pharmacist-in-charge in the daily management of the pharmacy, and with documentation of the pharmacy's good faith efforts prior to naming the interim pharmacist-in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the identification of the interim pharmacist-in-charge, the pharmacy shall propose to the board the name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

14. Section 4127.2 of the Code states, in pertinent part:

. . .

(c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any

regulations adopted by the board. The nonresident pharmacy shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually pursuant to subdivision (v) of Section 4400.

. . .

(e) A pharmacy licensed pursuant to this section shall do all of the following:

. . .

(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.

15. Code section 4305 provides, in pertinent part:

. . .

(b) Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in-charge shall constitute grounds for disciplinary action.

(c) Any person who has obtained a license to conduct a pharmacy, who willfully fails to timely notify the board that the pharmacist-in-charge of the pharmacy has ceased to act in that capacity, and who continues to permit the compounding or dispensing of prescriptions, or the furnishing of drugs or poisons, in his or her pharmacy, except by a pharmacist subject to the supervision and management of a responsible pharmacist-in-charge, shall be subject to summary suspension or revocation of his or her license to conduct a pharmacy.

REGULATORY PROVISIONS

16. California Code of Regulations ("CCR"), title 16, section 1735.2 provides, in pertinent part:

(a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A "reasonable quantity" as used in Business and Professions Code section 4052(a) (1) means that amount of compounded drug product that:

. . .

(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

. . .

(i) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) That

form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

17. California Code of Regulations, title 16, section 1735.3 provides, in pertinent part:

(a) For each compounded drug product, the pharmacy records shall include:

. . .

(5) The quantity of each component used in compounding the drug product.

. . .

(9) The quantity or amount of drug product compounded.

. . .

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

18. California Code of Regulations, title 16, section 1735.5 states:

(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented. . . .

19. California Code of Regulations, title 16, section 1735.7 states:

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

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20. California Code of Regulations, title 16, section 1735.8 states:

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

21. California Code of Regulations, title 16, section 1751.1 states:

(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.

(b) In addition to the records required by section 1735.3 and subdivision (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be made and kept by the pharmacy:

(1) The training and competency evaluation of employees in sterile product procedures.

(2) Refrigerator and freezer temperatures.

(3) Certification of the sterile compounding environment.

(4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.

(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

(c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

22. California Code of Regulations, title 16, section 1751.3. provides, in pertinent part:

. . .

(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.

. . .

23. California Code of Regulations, title 16, section 1751.4 provides, in pertinent part:

. . .

(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.

. . .

24. California Code of Regulations, title 16, section 1751.6 provides, in pertinent part:

. . .

(e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

(C) Sterile product compounding documentation.

(D) Quality assurance procedures.

(E) Aseptic preparation procedures.

(F) Proper gowning and gloving technique.

(G) General conduct in the controlled area.

(H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.

(I) Sterilization techniques.

(J) Container, equipment, and closure system selection.

(2) Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

25. California Code of Regulations, title 16, section 1751.7 provides, in pertinent part:

. . .

(b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

. . .

26. California Code of Regulations, title 24, section 1250.4[1] provides, in pertinent part:

The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:

1. In accordance with Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment as approved by the Commission, Federal Supply Service, General Service Administration meet standards for Class 100HEPA (high efficiency particulate air) filtered air such as laminar airflow hood or clean room.

2. Have nonporous and cleanable surfaces, ceilings and ceiling tiles, walls, floors and floor coverings.

3. The pharmacy shall be arranged in such a manner that the laminar-flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral solutions.

There shall be sufficient space, well separated from the laminar-flow hood area for the storage of bulk materials, equipment and waste materials.

. . .

COST RECOVERY

27. Section 125.3 of the Code states, 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

[1] The quoted language was in effect during the August 21, 2014, inspection.

enforcement of the case.

DRUGS

28. **Lipo PF [preservative free] injectable** is a dangerous drug within the meaning of Code section 4022 in that a prescription is required. The drug is used for weight loss.

29. **Cyano B12 PF injectable** is a dangerous drug within the meaning of Code section 4022 in that a prescription is required. The drug is used for weight loss.

FACTUAL BACKGROUND

30. On or about August 21, 2014, a Board inspector conducted an all-day inspection of Respondent located at 6801 Cahaba Balley Road, Suite 116, Birmingham, Alabama. L. S. (male) assisted the inspector during the inspection and conducted a tour of Respondent's pharmacy and operations and explained the services provided by Respondent. The tour included, but was not limited to, the areas where non-sterile[2] and sterile compounding[3] were conducted. The sterile compounding conducted by Respondent was primarily from non-sterile to sterile compounding and described as "high risk". Respondent compounded and dispensed, among other things, Lip PF injectable and Cyano B12 PF injectable. The tour also included Respondent's warehouse where supplies were stored and prescription orders were staged[4] for delivery to out-of-state customers for mailing. The inspection revealed violations of pharmacy law governing, among other things, compounding of drug products, prescription requirements, training of compounding staff, condition of the compounding area, compounding and dispensing without the supervision or management of a PIC, and other violations.

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[2] Non-sterile compounding refers to the practice of preparing a specific medication for use by a patient to swallow in pill form, apply as a topical treatment to the skin, or insert by injection under the skin. The practice is performed in a closely monitored environment and in compliance with very strict rules and professional guidelines. The medications are customized pursuant to legal standards that ensure that each pharmaceutical used in the medication maintains the proper ingredient potency and purity standards.

[3] Sterile compounding refers to the techniques actually used for the administration of the medicine, not how it is compounded. Sterile compounding techniques are used to create customized medications that will either be directly inserted into a patient or directly into the patient's eye(s). The medications carry a high risk of infection or other medical problem(s), thus, requiring compounded pursuant to sterile rules and regulations. Sterile compounding usually takes place in a completely clean environment, that is, a cleanroom.

[4] Staging is the process whereby the produced compounded drug was matched with the customer order.

31. On or about September 4, 2014, the Board's inspector requested that Respondent submit additional documentation including, but not limited to: cleanroom[5] certifications; staff training and performance evaluations; process validation documentation; policies and procedures addressing California regulatory requirements; invoices, master formula, worksheets, end product testifying for sterility and pyrogens records; patient specific prescriptions; and compounding self-assessment for S. R. Respondent's failure to produce the requested records or inadequate records revealed additional violations of the Pharmacy Law ands regulations.

FIRST CAUSE FOR DISCIPLINE

(Incompetence and/or Gross Negligence)

32. Respondent's permit and license are subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (b) and/or (c), from on or about August 2013 to on or about August 21, 2014, Respondent committed acts constituting incompetence and/or gross negligence as follows:

a. Respondent endangered the safety of customers in that Respondent knowingly released high risk compounded drug products before the completion of sterility and endotoxin tests.

b. Respondent allowed pharmacy technicians to conduct compounding of high risk compounded drug products before a pharmacist reviewed the product for accuracy of the proper ingredient potency and purity standards and compliance with pharmaceutical standards for integrity, potency, quality, strength, sterility and absence of endotoxins[6] prior to dispensing to physicians.

[5] A cleanroom is a designated room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Industry standards classify cleanrooms on the relationships between particle size and particle concentration. An ISO 7 is one of the classifications.

[6] Endotoxins are part of gram negative bacteria which causes fevers and diseases if they get into the body's blood stream. Endotoxin testing ensures that the injectable product is not contaminated.

c. Respondent allowed pharmacy technicians to conduct compounding of high risk compounded drug products under the supervision of untrained pharmacists.

d. Respondent knowingly provided high risk compounded drug products to consumers in preservative-free multi-use vials knowing that the vials would be entered, up to 30 times, with a needle and syringe.

e. Respondent failed to provide precautions to ensure the safety of consumers in relation to paragraph d, above, incorporated herein by reference.

f. Respondent failed to provide original documentation of compounding worksheets at inspection thereby bringing into question the validity of documents provided at a later date.

g. Respondent falsely denied to the Board's inspector the existence of prior recalls of compounded drug products when in fact recalls were conducted on August 21, 2014 and September 4, 2013.

h. Respondent identified S. R. as the PIC for California when S. R. had not been in oversight of the pharmacy for up to two years prior to the August 21, 2014, Board inspection.

SECOND CAUSE FOR DISCIPLINE

(Failed to Comply with Compounding Process Regulation)

33. Respondent's permit and license are subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR, title 16, section 1751.3, subdivision (b), in that on and between July 12, 2013 and August 21, 2014, Respondent produced compounded products without a pharmacist's prior written review of the compounding worksheets (ingredients and compounding process) for those products.

THIRD CAUSE FOR DISCIPLINE

(Failed to Obtain Valid Patient Specific Prescriptions)

34. Respondent's permit and license are subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR , title 16, section 1735.2, subdivision (a), in that on and between July 12, 2013, and August 21, 2014, (a) Respondent failed to obtain valid patient specific prescriptions prior to

compounding drug products, and (b) Respondent dispensed large quantities of sterile compounded drug products to physician prescribers in California without first obtaining valid patient specific prescriptions for those drug products.

FOURTH CAUSE FOR DISCIPLINE

(Failed to Demonstrate Quality of Products Prior to Dispensing)

35. Respondent's permit and license are subject to discipline on the grounds of unprofessional conduct under Code section 4052, subdivision (a)(1), as it relates to CCR section 1735.2, subdivision (c)(3), in that Respondent dispensed sterile preservative-free ("PF") compounded products to prescribers in vial sizes intended to last up to 30 days without demonstrating that the compounded products complied with pharmaceutical standards for integrity, potency, quality, strength, sterility and absence of endotoxins prior to dispensing to physicians. Specifically, Respondent dispensed compounded drug products in 30 ml [millimeters] vials with the usual dosage of 1 ml, thus, causing the vial to be entered more than once, increasing the risk of contamination.

FIFTH CAUSE FOR DISCIPLINE

(Failed to Comply with End Product Testing Prior to Dispensing)

36. Respondent's permit and license are subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR, title 16, section 1751.7, subdivision (c), in that on and between July 12, 2013 and August 21, 2014, Respondent dispensed sterile compounded products to prescribers before the completion of end product testing on the products, resulting in recall of the product. Specifically, Lipo (PF) injectable Lot 140805@43 had been dispensed to 40 prescribing physicians including Dr. A and Dr. M, practitioners in California, prior to completion of end product testing. The drug was recalled on or about August 21, 2014.

SIXTH CAUSE FOR DISCIPLINE

(Failed to Complete Validation Process Representative of Compounded Drugs)

37. Respondent's permit and license are subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with

CCR section 1751.7, subdivision (b), in that on and between 2012 and August 21, 2014, Respondent failed to require all compounding staff to conduct validation process on technique that was representative of all types of manipulations, products, and batch sizes that the staff was expected to prepare. Specifically, although product batch sizes could be as large as 21,000 ml and placed into up to 700 vials of 30 ml, the product was only submitted to a validation process with up to six vials of 10 ml.

SEVENTH CAUSE FOR DISCIPLINE

(Failed to Maintain Compounding Records)

38. Respondent's permit and license are subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR section 1751.1, subdivision (c), in that Respondent failed to maintain and retain compounding records and worksheets in a readily retrievable form for three years from the date the record was created. Specifically, on or about August 21, 2014 and September 4, 2014, Respondent could not produce original records including compounding worksheets for the full three year period prior to the August 21, 2014, inspection date.

EIGHTH CAUSE FOR DISCIPLINE

(Failed to Maintain Compounded Drug Product Records)

39. Respondent's permit and license are subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR section 1735.3, subdivisions (a)(5) and (a)(9), in that Respondent failed to maintain compounded drug product records for each compounded drug stating, among other things, the quantity of each component used in the drug product and the quantity or amount compounded. Specifically, on or about August 21 and September 4, 2014, Respondent failed to produce compounding worksheets which identified the number of vials made from each individual batch of the compounded drug. Further, Respondent admittedly could not produce requested original records including compounding worksheets for the full three year period prior to the inspection date.

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NINTH CAUSE FOR DISCIPLINE

(Failed to Train and Evaluate Compounding Staff)

40. Respondent's permit and license are subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR section 1735.7 as it relates to CCR section 1751.6, subdivision (e), as follows:

a. On or about August 21, 2014, Respondent failed to train all sterile compounding personnel for the period of 2011 to August 21, 2014. Respondent admitted that it had not trained any of the compounding staff for calendar year 2012. Further, Respondent admitted that when training was conducted, it was only for pharmacy technicians.

b. On or about August 21, 2014, Respondent failed to have in place an established written program of training and performance evaluation for the compounding staff addressing the following: aseptic technique; pharmaceutical calculations and terminology; sterile product compounding documentation; quality assurance and aseptic preparation procedures; proper gowning and gloving techniques; general conduct in the controlled area; cleaning, sanitizing and maintaining equipment used in the controlled area; sterilization techniques; and container, equipment, and closure system selection.

TENTH CAUSE FOR DISCIPLINE

(Failed to Ensure Sterility of Cleanroom)

41. Respondent's permit and license are subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR section 1751.1, subdivision (b)(1), as it relates to CCR title 24, section 1250.4, subdivisions (2) and (3), in that on or about August 21, 2014, (a) Respondent had porous, easily removable paint on the walls of the designated preparation area for sterile products dispensing, and (b) Respondent stored bulk supplies within a few feet of the laminar flow hoods.

ELEVENTH CAUSE FOR DISCIPLINE

(Failed to Timely Notify Board of Product Recall)

42. Respondent's permit and license are subject to discipline on the grounds it violated Code section 4127.2, subdivision (e)(3), in that on or about August 21, 2014, Respondent

initiated a recall of Lip L(PF) injectable Lot 140805@43 but notified the Board of the recall on October 1, 2014, which was more than 12 hours after initiating the recall as required by law.

TWELFTH CAUSE FOR DISCIPLINE

(Failed to Ensure PIC's Annual Review of Policies and Procedures)

43. Respondent's permit and license are subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR section 1735.5, subdivision (b), in that as of on or about August 21, 2014, (a) PIC S. R had not had completed an annual review of Respondent's compounding policies and procedures as required by regulation, and (b) Respondent could not produce S. R.'s annual review of the compounding policies and procedures.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failed to Ensure PIC Completed Compounding Self-Assessment)

44. Respondent's permit and license are subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR section 1735.2, subdivision (j), in that as of on or about August 21, 2014, (a) PIC S. R. failed to complete a compounding self-assessment form which is required to be completed by the PIC prior to allowing any drug product to be compounded by Respondent, and (b) Respondent could not produce S. R.'s completed form.

FOURTEENTH CAUSE FOR DISCIPLINE

(Operated Pharmacy and Compounded Drugs without PIC; Willful Failure to Notify Board of no PIC)

45. Respondent's permit and license are subject to discipline on the grounds of unprofessional conduct under Code section 4305, subdivisions (b) and (c), in that as of on or about August 21, 2014, Respondent continued to operate the pharmacy and permitted the compounding and dispensing of products without the supervision and management of a PIC in that Respondent admitted that S. R. had not been acting in that capacity since at least 2012. Further, Respondent willfully failed to notify the Board that it was operating and compounding drugs without a PIC.

FIFTEENTH CAUSE FOR DISCIPLINE

(Failed to Ensure Quality Assurance)

46. Respondent's permit and license are subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR section 1735.8, subdivision (c), in that as of on or about August 21, 2014, Respondent failed to maintain a quality assurance plan including written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. Specifically, on or about August 21, 2014, Respondent could not produce compounding records which identified its qualitative and quantitative analysis reports for compounded drug products which, by law, were required to be collated with the compounding records.

SIXTEENTH CAUSE FOR DISCIPLINE

(Failed to Disinfect Compounding Area Each Week)

47. Respondent's permit and license are subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR title 16, section 1751.4, subdivision (d), in that on or about August 21, 2016, Respondent admitted that it cleaned the compounding area on a monthly basis, not on a weekly basis as required by regulation.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Out of State Discipline)

48. Respondent's permit and license are subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivision (n), in that on or about March 15, 2016, "In the Matter of: Medaus, Inc., d/b/a Medaus Pharmacy," Permit No. 111215, Alabama Board of Pharmacy ("Alabama Board") Case No. 16-0033, the Board issued a Notice of Emergency Suspension of Permit to continue to operate in the State of Alabama. The action was based upon Respondent's numerous alleged violations of Alabama statutes and regulations and failure to comply with USP 797 . The suspension was effective on March 15, 2016, for a period not to exceed 120 days or until a final order was issued by the Alabama Board.

49. On or about July 1, 2016, the Alabama Board issued its Final Order in Case No. 16-0033. Pursuant to the Final Order, Respondent may not engage in sterile compounding or dispensing any sterile drug products for a minimum of two years. Further, Respondent is required to pay an administrative fine to the Alabama Board of $240,000. Pursuant to the agreement, Respondent acknowledged that it violated Code of Alabama (1975) section 34-23-33 (13) in that it violated Board Rule 688-X-2-.22 (2) (a) (d) and (f) based upon the failure to comply with Section 503 (a) of the Federal Food, Drug and Cosmetic Act as Amended as it relates to sterility and endotoxin testing, assignment of beyond use dates and Respondent's failure to comply with environmental standards and quality control standards.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Actions or Conduct Warranting Denial of License)

50. Respondent's permit and license are subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivision (p), as alleged in paragraphs 30 through 49, and all of their subparts, above, incorporated herein by reference.

NINETEENTH CAUSE FOR DISCIPLINE

(Cause for Non-Renewal of License)

51. Respondent's permit and license are subject to non-renewal under Code section 4127.2 in that the August 21, 2014, inspection of Respondent found that Respondent was not in compliance with numerous provisions of the Pharmacy Law and regulations, as alleged in paragraphs 30 through 49, and all of their subparts, above, incorporated herein by reference.

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 Non-Resident Pharmacy Permit Number NRP 547, issued to Medaus Inc., doing business as Medaus Pharmacy, Steven L. Russell, President;

2. Revoking or suspending Non-Resident Sterile Compounding License Number NSC 99170 issued to Medaus Inc., doing business as Medaus Pharmacy, Steven L. Russell, President;

3. Ordering Medaus Inc., doing business as Medaus Pharmacy, Steven L. Russell, President, 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: 4/5/17

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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

In the Matter of the Accusation Against: **MEDAUS INC.,** **DBA MEDAUS PHARMACY** **STEVEN L. RUSSELL, PRESIDENT** **6801 Cahaba Balley Road, Suite 116** **Birmingham, AL 35242** **Non-Resident Pharmacy Permit No. NRP 547** Respondent.	Case No. 5859 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy ("Board"), Department of Consumer Affairs.

2. On or about September 2, 2003, the Board issued Non-Resident Pharmacy Permit Number NRP 547 to Medaus Inc., doing business as Medaus Pharmacy, Steven L. Russell, President, ("Respondent"). The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2017, unless renewed.

3. From on or about September 2, 2003, to on or about August 22, 2014, S. R. was Respondent's designated California Pharmacist-in-Charge ("PIC") within the meaning of Business and Professions Code section 4113.

JURISDICTION

4. This 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.

5. Section 4300 of the Code states, in pertinent part:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing [the licensee] upon probation.
>
> (3) Suspending [the licensee's] right to practice for a period not exceeding one year.
>
> (4) Revoking [the licensee's] license.
>
> (5) Taking any other action in relation to disciplining [the licensee] as the board in its discretion may deem proper.
>
> . . .
>
> (e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

6. Section 4300.1 of the Code 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.

7. Section 4402 of the Code provides, in pertinent part:

> . . .
>
> (e) any other license issued by the board may be canceled by the board if the license is not renewed within 60 days after its expiration. Any license canceled under this subdivision may not be reissued. Instead, a new application will be required.

STATUTORY PROVISIONS

8. Section 4301 of the Code states, in pertinent part:

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

. . .

(b) Incompetence.

(c) Gross negligence.

. . .

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

. . .

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this statute.

. . .

(*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.

(p) Actions or conduct that would have warranted denial of a license.

9. Section 4303 of the Code provides, in pertinent part:

. . .

(b) The board may cancel, deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on an of the same grounds upon which such action might be taken against resident pharmacy, provided that the grounds for the action are also rounds for action in the state in which the nonresident pharmacy is permanently located.

10. Section 4022 of the Code provides, in pertinent part:

"Dangerous drug". . .means any drug. . . 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.

. . .

(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.

11. Section 4052 of the Code states, in pertinent part:

(a) Notwithstanding any other law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

. . .

12. Section 4113 of the Code states, in pertinent part:

(a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.

(b) The proposed pharmacist-in-charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved pharmacist-in-charge for the pharmacy.

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

(d) Every pharmacy shall notify the board in writing, on a form designed by the board, within 30 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge, and shall on the same form propose another pharmacist to take over as the pharmacist-in-charge. The proposed replacement pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of the disapproval and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

(e) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead provide on that form the name of any pharmacist who is an employee, officer, or administrator of the pharmacy or the entity that owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis, to act as the interim pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, of the entity that owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with the name of the interim pharmacist-in-charge with documentation of the active involvement of the interim pharmacist-in-charge in the daily management of the pharmacy, and with documentation of the pharmacy's good faith efforts prior to naming the interim pharmacist-in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the identification of the interim pharmacist-in-charge, the pharmacy shall propose to the board the name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

13. Section 4127.2 of the Code states, in pertinent part:

. . .

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

. . .

(e) A pharmacy licensed pursuant to this section shall do all of the following:

. . .

(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.

14. Code section 4305 provides, in pertinent part:

. . .

(b) Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in-charge shall constitute grounds for disciplinary action.

(c) Any person who has obtained a license to conduct a pharmacy, who willfully fails to timely notify the board that the pharmacist-in-charge of the pharmacy has ceased to act in that capacity, and who continues to permit the compounding or dispensing of prescriptions, or the furnishing of drugs or poisons, in his or her pharmacy, except by a pharmacist subject to the supervision and management of a responsible pharmacist-in-charge, shall be subject to summary suspension or revocation of his or her license to conduct a pharmacy.

REGULATORY PROVISIONS

15. California Code of Regulations ("CCR"), title 16, section 1735.2 provides, in pertinent part:

(a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A "reasonable quantity" as used in Business and Professions Code section 4052(a) (1) means that amount of compounded drug product that:

. . .

(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

. . .

(i) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the

issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

16. California Code of Regulations, title 16, section 1735.3 provides, in pertinent part:

(a) For each compounded drug product, the pharmacy records shall include:

. . .

(5) The quantity of each component used in compounding the drug product.

. . .

(9) The quantity or amount of drug product compounded.

. . .

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

17. California Code of Regulations, title 16, section 1735.5 states:

(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented. . . .

18. California Code of Regulations, title 16, section 1735.7 states:

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

19. California Code of Regulations, title 16, section 1735.8 states:

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

20. California Code of Regulations, title 16, section 1751.1 states:

(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.

(b) In addition to the records required by section 1735.3 and subdivision (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be made and kept by the pharmacy:

(1) The training and competency evaluation of employees in sterile product procedures.

(2) Refrigerator and freezer temperatures.

(3) Certification of the sterile compounding environment.

(4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.

(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

(c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

21. California Code of Regulations, title 16, section 1751.3. provides, in pertinent part:

. . .

(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.

. . .

22. California Code of Regulations, title 16, section 1751.4 provides, in pertinent part:

. . .

(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.

. . .

23. California Code of Regulations, title 16, section 1751.6 provides, in pertinent part:

. . .

(e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

(C) Sterile product compounding documentation.

(D) Quality assurance procedures.

(E) Aseptic preparation procedures.

(F) Proper gowning and gloving technique.

(G) General conduct in the controlled area.

(H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.

(I) Sterilization techniques.

(J) Container, equipment, and closure system selection.

(2) Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

24. California Code of Regulations, title 16, section 1751.7 provides, in pertinent part:

. . .

(b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective

action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

. . .

25. California Code of Regulations, title 24, section 1250.4[1] provides, in pertinent part:

The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:

1. In accordance with Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment as approved by the Commission, Federal Supply Service, General Service Administration meet standards for Class 100HEPA (high efficiency particulate air) filtered air such as laminar airflow hood or clean room.

2. Have nonporous and cleanable surfaces, ceilings and ceiling tiles, walls, floors and floor coverings.

3. The pharmacy shall be arranged in such a manner that the laminar-flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral solutions.

There shall be sufficient space, well separated from the laminar-flow hood area for the storage of bulk materials, equipment and waste materials.

. . .

COST RECOVERY

26. Section 125.3 of the Code states, 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.

DRUGS

27. **Lipo PF [preservative free] injectable** is a dangerous drug within the meaning of Code section 4022 in that a prescription is required. The drug is used for weight loss.

[1] The quoted language was in effect during the August 21, 2014, inspection.

28. **Cyano B12 PF injectable** is a dangerous drug within the meaning of Code section 4022 in that a prescription is required. The drug is used for weight loss.

FACTUAL BACKGROUND

29. On or about August 21, 2014, a Board inspector conducted an all-day inspection of Respondent located at 6801 Cahaba Balley Road, Suite 116, Birmingham, Alabama. L. S. (male) assisted the inspector during the inspection and conducted a tour of Respondent's pharmacy and operations and explained the services provided by Respondent. The tour included, but was not limited to, the areas where non-sterile[2] and sterile compounding[3] were conducted. The sterile compounding conducted by Respondent was primarily from non-sterile to sterile compounding and described as "high risk". Respondent compounded and dispensed, among other things, Lip PF injectable and Cyano B12 PF injectable. The tour also included Respondent's warehouse where supplies were stored and prescription orders were staged[4] for delivery to out-of-state customers for mailing. The inspection revealed violations of pharmacy law governing, among other things, compounding of drug products, prescription requirements, training of compounding staff, condition of the compounding area, compounding and dispensing without the supervision or management of a PIC, and other violations.

30. On or about September 4, 2014, the Board's inspector requested that Respondent submit additional documentation including, but not limited to: cleanroom[5] certifications; staff

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[2] Non-sterile compounding refers to the practice of preparing a specific medication for use by a patient to swallow in pill form, apply as a topical treatment to the skin, or insert by injection under the skin. The practice is performed in a closely monitored environment and in compliance with very strict rules and professional guidelines. The medications are customized pursuant to legal standards that ensure that each pharmaceutical used in the medication maintains the proper ingredient potency and purity standards.

[3] Sterile compounding refers to the techniques actually used for the administration of the medicine, not how it is compounded. Sterile compounding techniques are used to create customized medications that will either be directly inserted into a patient or directly into the patient's eye(s). The medications carry a high risk of infection or other medical problem(s), thus, requiring compounded pursuant to sterile rules and regulations. Sterile compounding usually takes place in a completely clean environment, that is, a cleanroom.

[4] Staging is the process whereby the produced compounded drug was matched with the customer order.

[5] A cleanroom is a designated room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Industry standards classify cleanrooms on the relationships between particle size and particle concentration. An ISO 7 is one of the classifications.

training and performance evaluations; process validation documentation; policies and procedures addressing California regulatory requirements; invoices, master formula, worksheets, end product testifying for sterility and pyrogens records; patient specific prescriptions; and compounding self-assessment for S. R. Respondent's failure to produce the requested records or inadequate records revealed additional violations of the Pharmacy Law and regulations.

FIRST CAUSE FOR DISCIPLINE

(Incompetence and/or Gross Negligence)

31. Respondent's license is subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (b) and/or (c), from on or about August 2013 to on or about August 21, 2014, Respondent committed acts constituting incompetence and/or gross negligence as follows:

a. Respondent endangered the safety of customers in that Respondent knowingly released high risk compounded drug products before the completion of sterility and endotoxin tests.

b. Respondent allowed pharmacy technicians to conduct compounding of high risk compounded drug products before a pharmacist reviewed the product for accuracy of the proper ingredient potency and purity standards and compliance with pharmaceutical standards for integrity, potency, quality, strength, sterility and absence of endotoxins[6] prior to dispensing to physicians.

c. Respondent allowed pharmacy technicians to conduct compounding of high risk compounded drug products under the supervision of untrained pharmacists.

d. Respondent knowingly provided high risk compounded drug products to consumers in preservative-free multi-use vials knowing that the vials would be entered, up to 30 times, with a needle and syringe.

[6] Endotoxins are part of gram negative bacteria which causes fevers and diseases if they get into the body's blood stream. Endotoxin testing ensures that the injectable product is not contaminated.

e. Respondent failed to provide precautions to ensure the safety of consumers in relation to paragraph d, above, incorporated herein by reference.

f. Respondent failed to provide original documentation of compounding worksheets at inspection thereby bringing into question the validity of documents provided at a later date.

g. Respondent falsely denied to the Board's inspector the existence of prior recalls of compounded drug products when in fact recalls were conducted on August 21, 2014 and September 4, 2013.

h. Respondent identified S. R. as the PIC for California when S. R. had not been in oversight of the pharmacy for up to two years prior to the August 21, 2014, Board inspection.

SECOND CAUSE FOR DISCIPLINE

(Failed to Comply with Compounding Process Regulation)

32. Respondent's license is subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR, title 16, section 1751.3, subdivision (b), in that on and between July 12, 2013 and August 21, 2014, Respondent produced compounded products without a pharmacist's prior written review of the compounding worksheets (ingredients and compounding process) for those products.

THIRD CAUSE FOR DISCIPLINE

(Failed to Obtain Valid Patient Specific Prescriptions)

33. Respondent's license is subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR , title 16, section 1735.2, subdivision (a), in that on and between July 12, 2013, and August 21, 2014, (a) Respondent failed to obtain valid patient specific prescriptions prior to compounding drug products, and (b) Respondent dispensed large quantities of sterile compounded drug products to physician prescribers in California without first obtaining valid patient specific prescriptions for those drug products.

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FOURTH CAUSE FOR DISCIPLINE

(Failed to Demonstrate Quality of Products Prior to Dispensing)

34. Respondent's license is subject to discipline on the grounds of unprofessional conduct under Code section 4052, subdivision (a)(1), as it relates to CCR section 1735.2, subdivision (c)(3), in that Respondent dispensed sterile preservative-free ("PF") compounded products to prescribers in vial sizes intended to last up to 30 days without demonstrating that the compounded products complied with pharmaceutical standards for integrity, potency, quality, strength, sterility and absence of endotoxins prior to dispensing to physicians. Specifically, Respondent dispensed compounded drug products in 30 ml [millimeters] vials with the usual dosage of 1 ml, thus, causing the vial to be entered more than once, increasing the risk of contamination.

FIFTH CAUSE FOR DISCIPLINE

(Failed to Comply with End Product Testing Prior to Dispensing)

35. Respondent's license is subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR, title 16, section 1751.7, subdivision (c), in that on and between July 12, 2013 and August 21, 2014, Respondent dispensed sterile compounded products to prescribers before the completion of end product testing on the products, resulting in recall of the product. Specifically, Lipo (PF) injectable Lot 140805@43 had been dispensed to 40 prescribing physicians including Dr. A and Dr. M, practitioners in California, prior to completion of end product testing. The drug was recalled on or about August 21, 2014.

SIXTH CAUSE FOR DISCIPLINE

(Failed to Complete Validation Process Representative of Compounded Drugs)

36. Respondent's license is subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR section 1751.7, subdivision (b), in that on and between 2012 and August 21, 2014, Respondent failed to require all compounding staff to conduct validation process on technique that was representative of all types of manipulations, products, and batch sizes that the staff was expected to prepare.

Specifically, although product batch sizes could be as large as 21,000 ml and placed into up to 700 vials of 30 ml, the product was only submitted to a validation process with up to six vials of 10 ml.

SEVENTH CAUSE FOR DISCIPLINE

(Failed to Maintain Compounding Records)

37. Respondent's license is subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR section 1751.1, subdivision (c), in that Respondent failed to maintain and retain compounding records and worksheets in a readily retrievable form for three years from the date the record was created. Specifically, on or about August 21, 2014 and September 4, 2014, Respondent could not produce original records including compounding worksheets for the full three year period prior to the August 21, 2014, inspection date.

EIGHTH CAUSE FOR DISCIPLINE

(Failed to Maintain Compounded Drug Product Records)

38. Respondent's license is subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR section 1735.3, subdivisions (a)(5) and (a)(9), in that Respondent failed to maintain compounded drug product records for each compounded drug stating, among other things, the quantity of each component used in the drug product and the quantity or amount compounded. Specifically, on or about August 21 and September 4, 2014, Respondent failed to produce compounding worksheets which identified the number of vials made from each individual batch of the compounded drug. Further, Respondent admittedly could not produce requested original records including compounding worksheets for the full three year period prior to the inspection date.

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NINTH CAUSE FOR DISCIPLINE

(Failed to Train and Evaluate Compounding Staff)

39. Respondent's license is subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR section 1735.7 as it relates to CCR section 1751.6, subdivision (e), as follows:

a. On or about August 21, 2014, Respondent failed to train all sterile compounding personnel for the period of 2011 to August 21, 2014. Respondent admitted that it had not trained any of the compounding staff for calendar year 2012. Further, Respondent admitted that when training was conducted, it was only for pharmacy technicians.

b. On or about August 21, 2014, Respondent failed to have in place an established written program of training and performance evaluation for the compounding staff addressing the following: aseptic technique; pharmaceutical calculations and terminology; sterile product compounding documentation; quality assurance and aseptic preparation procedures; proper gowning and gloving techniques; general conduct in the controlled area; cleaning, sanitizing and maintaining equipment used in the controlled area; sterilization techniques; and container, equipment, and closure system selection.

TENTH CAUSE FOR DISCIPLINE

(Failed to Ensure Sterility of Cleanroom)

40. Respondent's license is subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR section 1751.1, subdivision (b)(1), as it relates to CCR title 24, section 1250.4, subdivisions (2) and (3), in that on or about August 21, 2014, (a) Respondent had porous, easily removable paint on the walls of the designated preparation area for sterile products dispensing, and (b) Respondent stored bulk supplies within a few feet of the laminar flow hoods.

ELEVENTH CAUSE FOR DISCIPLINE

(Failed to Timely Notify Board of Product Recall)

41. Respondent's license is subject to discipline on the grounds it violated Code section 4127.2, subdivision (e)(3), in that on or about August 21, 2014, Respondent initiated a

recall of Lip L(PF) injectable Lot 140805@43 but notified the Board of the recall on October 1, 2014, which was more than 12 hours after initiating the recall as required by law.

TWELFTH CAUSE FOR DISCIPLINE

(Failed to Ensure PIC's Annual Review of Policies and Procedures)

42. Respondent's license is subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR section 1735.5, subdivision (b), in that as of on or about August 21, 2014, (a) PIC S. R had not had completed an annual review of Respondent's compounding policies and procedures as required by regulation, and (b) Respondent could not produce S. R.'s annual review of the compounding policies and procedures.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failed to Ensure PIC Completed Compounding Self-Assessment)

43. Respondent's license is subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR section 1735.2, subdivision (j), in that as of on or about August 21, 2014, (a) PIC S. R. failed to complete a compounding self-assessment form which is required to be completed by the PIC prior to allowing any drug product to be compounded by Respondent, and (b) Respondent could not produce S. R.'s completed form.

FOURTEENTH CAUSE FOR DISCIPLINE

(Operated Pharmacy and Compounded Drugs without PIC; Willful Failure to Notify Board of no PIC)

44. Respondent's license is subject to discipline on the grounds of unprofessional conduct under Code section 4305, subdivisions (b) and (c), in that as of on or about August 21, 2014, Respondent continued to operate the pharmacy and permitted the compounding and dispensing of products without the supervision and management of a PIC in that Respondent admitted that S. R. had not been acting in that capacity since at least 2012. Further, Respondent willfully failed to notify the Board that it was operating and compounding drugs without a PIC.

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FIFTEENTH CAUSE FOR DISCIPLINE

(Failed to Ensure Quality Assurance)

45. Respondent's license is subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR section 1735.8, subdivision (c), in that as of on or about August 21, 2014, Respondent failed to maintain a quality assurance plan including written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. Specifically, on or about August 21, 2014, Respondent could not produce compounding records which identified its qualitative and quantitative analysis reports for compounded drug products which, by law, were required to be collated with the compounding records.

SIXTEENTH CAUSE FOR DISCIPLINE

(Failed to Disinfect Compounding Area Each Week)

46. Respondent's license is subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivisions (j) and (*o*) in conjunction with CCR title 16, section 1751.4, subdivision (d), in that on or about August 21, 2016, Respondent admitted that it cleaned the compounding area on a monthly basis, not on a weekly basis as required by regulation.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Out of State Discipline)

47. Respondent's license is subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivision (n), in that on or about March 15, 2016, "In the Matter of: Medaus, Inc., d/b/a Medaus Pharmacy," Permit No. 111215, Alabama Board of Pharmacy ("Alabama Board") Case No. 16-0033, the Board issued a Notice of Emergency Suspension of Permit to continue to operate in the State of Alabama. The action was based upon Respondent's numerous alleged violations of Alabama statutes and regulations and failure to comply with USP 797. The suspension was effective on March 15, 2016, for a period not to exceed 120 days or until a final order was issued by the Alabama Board.

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EIGHTEENTH CAUSE FOR DISCIPLINE

(Actions or Conduct Warranting Denial of License)

48. Respondent's license is subject to discipline on the grounds of unprofessional conduct under Code section 4301, subdivision (p), alleged in paragraphs 29 through 47, and all of their subparts, above, incorporated herein by reference.

NINETEENTH CAUSE FOR DISCIPLINE

(Cause for Non-Renewal of License)

49. Respondent's license is subject to non-renewal under Code section 4127.2 in that the August 21, 2014, inspection of Respondent found that Respondent was not in compliance with numerous provisions of the Pharmacy Law and regulations alleged in paragraphs 29 through 47, and all of their subparts, above, incorporated herein by reference.

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 Non-Resident Pharmacy Permit Number NRP 547, issued to Medaus Inc., doing business as Medaus Pharmacy, Steven L. Russell, President;

2. Ordering Medaus Inc., doing business as Medaus Pharmacy, Steven L. Russell, President, 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

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

DATED: 11/30/16

Virginia Herold

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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