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 Valley Road, Suite 116** **Birmingham, AL 35242** **Non-Resident Pharmacy Permit No. NRP 547** **Non-Resident Sterile Compounding No. NSC 99170** Respondent.	Case No. 5859 OAH No. 2017010535 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

DECISION AND ORDER

The attached Stipulated Settlement of License and 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 August 10, 2017.

It is so ORDERED on July 11, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

XAVIER BECERRA
Attorney General of California
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BEFORE THE
BOARD OF PHARMACY
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In the Matter of the Accusation Against: **MEDAUS INC., DBA MEDAUS PHARMACY; STEVEN L. RUSSELL, PRESIDENT** **6801 Cahaba Valley Road, Suite 116** **Birmingham, AL 35242** **Non-Resident Pharmacy Permit No. NRP 547** **Non-Resident Sterile Compounding No. NSC 99170** Respondent.	Case No. 5859 OAH No. 2017010535 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Virginia Herold (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 Xavier Becerra, Attorney General of the State of California, by Andrew M. Steinheimer, Deputy Attorney General.

2. Respondent Medaus Inc., dba Medaus Pharmacy; Steven L. Russell, President (Respondent) is represented in this proceeding by attorney Hube Dodd, Esq., whose address is:

2323 Second Avenue, N., Suite 111, Birmingham, AL 35203.

3. On or about September 2, 2003, the Board issued Non-Resident Pharmacy Permit No. NRP 547 to Medaus Inc., dba 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 in Accusation No. 5859, and will expire on September 1, 2017, unless renewed.

4. On or about November 29, 2004, the Board issued Non-Resident Sterile Compounding Permit Number NSC 99170 to Medaus Inc., dba Medaus Pharmacy; Steven L. Russell, President (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.

JURISDICTION

5. Accusation No. 5859 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 December 12, 2016. Respondent timely filed its Notice of Defense contesting the Accusation. An Amended Accusation was filed on April 5, 2017 and was served on Respondent on April 13, 2017

6. A copy of the operative Amended Accusation No. 5859 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

7. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 5859. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

8. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against them; 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.

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

CULPABILITY

10. Respondent understands and agrees that the charges and allegations in Accusation No. 5859, if proven at a hearing, constitute cause for imposing discipline upon its Non-Resident Pharmacy Permit.

11. For the purpose of resolving the 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 Accusation, and that Respondent hereby gives up its right to contest those charges.

12. Respondent agrees that its Non-Resident Pharmacy Permit is subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

RESERVATION

13. The admissions made by Respondent herein are only for the purposes of this proceeding, or any other proceedings in which the Board of Pharmacy or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.

CONTINGENCY

14. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, 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 Settlement 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.

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

16. This Stipulated Settlement and Disciplinary 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 Settlement and Disciplinary 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.

17. 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 Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Respondent voluntarily surrenders Non-Resident Sterile Compounding Permit Number NSC 99170. Non-Resident Pharmacy Permit No. NRP 547 issued to Respondent Medaus Inc., dba Medaus Pharmacy; Steven L. Russell, President is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions:

1. **Obey All Laws**

Respondent owner shall obey all state and federal laws and regulations.

Respondent owner shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

(a) an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws

(b) a plea of guilty or nolo contendre in any state or federal criminal proceeding to

any criminal complaint, information or indictment

(c) a conviction of any crime

(d) discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. **Report to the Board**

Respondent owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board**

Upon receipt of reasonable prior notice, respondent owner shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff**

Respondent owner shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. **Reimbursement of Board Costs and Administrative Penalty**

As a condition precedent to successful completion of probation, respondent shall pay to the

board its costs of investigation and prosecution in the amount of $29,750.00. In addition to these costs, Respondent stipulates and agrees to pay an Administrative Penalty in the amount of $20,000.00. The Board will agree to a reasonable payment plan over the course of probation. Failure to pay costs and penalty by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of their responsibility to reimburse the board its costs of investigation and prosecution.

6. **Probation Monitoring Costs**

Respondent owner shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. **Status of License**

Respondent owner shall, at all times while on probation, maintain current licensure with the board. If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondent owner's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondent owner's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should respondent owner discontinue business, respondent owner may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of

the license, respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent owner may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. **Notice to Employees**

Respondent owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally,

respondent owner shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. **Owners and Officers: Knowledge of the Law**

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. **Posted Notice of Probation**

Respondent owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. **Violation of Probation**

If a respondent owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent license, and probation shall be automatically extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent owner violates probation in any respect, the board, after giving respondent owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

13. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, respondent license will be fully restored.

14. **Semi-Annual Inspections**

Respondent agrees to provide the Board with semi-annual inspection reports of its facility at respondent's costs. The inspections are to be performed by the Alabama Board of Pharmacy or the NABP. The failure to timely provide said inspection reports shall be considered a violation of probation.

15. **Report on Compounded Products to California**

Respondent agrees to provide the Board, on a semi-annual basis, with a list of all compounded products shipped to California. The failure to timely provide said lists of compounded products shall be considered a violation of probation.

16. **Prohibition on Applying for License**

Respondent is prohibited from applying for a sterile compounding license or outsourcing license in California during the probation term. Non-compliance with this provision shall be considered a violation of probation.

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Hube Dodd, Esq.. I understand the stipulation and the effect it will have on my Non-Resident Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: May 14, 2017

By:
On behalf of MEDAUS INC.
Respondent

I have read and fully discussed with Respondent Medaus Inc., dba Medaus Pharmacy; Steven L. Russell, President the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 5/15/17

HUBE DODD, ESQ.
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

Dated:

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
JANICE K. LACHMAN
Supervising Deputy Attorney General

ANDREW M. STEINHEIMER
Deputy Attorney General
Attorneys for Complainant

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ACCEPTANCE

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DATED: _____

By:
On behalf of MEDAUS INC.
Respondent

I have read and fully discussed with Respondent Medaus Inc., dba Medaus Pharmacy; Steven L. Russell, President the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

HUBE DODD, ESQ.
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

Dated: May 19 2017

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
JANICE K. LACHMAN
Supervising Deputy Attorney General

ANDREW M. STEINHEIMER
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 5859

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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: **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.

[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.

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[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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