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

In the Matter of the Accusation Against: **RX UNLIMITED LLC** **RX UNLIMITED PHARMACY** 16673 Roscoe Blvd. North Hills, CA 91343 Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642 and **CLIFTON EUGENE BRADDY** 18333 Hatteras St. #110 Tarzana, CA 91356 Pharmacist License No. RPH 45546 Respondents.	Case No. 4567 OAH No. 2014030526 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO CLIFTON EUGENE BRADDY ONLY**

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary 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 March 13, 2017.

It is so ORDERED on February 10, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

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Attorneys for Complainant

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

In the Matter of the Second Accusation Against: **RX UNLIMITED LLC** **RX UNLIMITED PHARMACY** 16673 Roscoe Blvd., North Hills, CA 91343 Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642 and **CLIFTON EUGENE BRADDY** 18333 Hatteras St. #110 Tarzana, CA 91356 Pharmacist License No. RPH 45546 Respondents.	Case No. 4567 OAH No. 2014030526 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO CLIFTON EUGENE BRADDY ONLY**

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. She brought this action solely in her official capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of California, by Kevin J. Rigley, Deputy Attorney General.

2. Respondent RX Unlimited, LLC dba RX Unlimited Pharmacy is represented in this proceeding by attorney Tony J. Park, whose address is: 2855 Michelle, Ste. 180, Irvine, CA 92606.

3. On or about August 14, 1992, the Board of Pharmacy issued Pharmacist License No. RPH 45546 to Clifton Eugene Braddy (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought in the Second Amended Accusation, No. 4567 and will expire on April 30, 2018, unless renewed.

JURISDICTION

4. The Accusation, First Amended Accusation and Second Amended Accusation No. 4567 were filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and the Second Amended Accusation is currently pending against Respondent. The Second Amended Accusation and all other statutorily required documents were properly served on Respondent on May 4, 2015. Respondent timely filed its Notice of Defense contesting the Second Amended Accusation .

5. A copy of the Second Amended Accusation No. 4567 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in the Second Amended Accusation No. 4567. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

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

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

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in Accusation No. 4567, if proven at a hearing, constitute cause for imposing discipline upon his Pharmacist License No. RPH 45546.

10. 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 his right to contest those charges.

11. Respondent agrees that his Pharmacist License is subject to discipline and he to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

12. 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 his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his 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.

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

14. 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.

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 45546 issued to Respondent Clifton Eugene Braddy (Respondent) 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 shall obey all state and federal laws and regulations.

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

- 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
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

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

2. **Report to the Board**

Respondent 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 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 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 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 his probation. Failure to cooperate shall be considered a violation of probation.

5. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. **Notice to Employers**

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 4567 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 4567, and terms and conditions imposed

thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number 4567 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he has read the decision in case number 4567 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. **No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant**

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

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8. **Reimbursement of Board Costs**

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 $5,792.00. Respondent shall make said payments on a payment plan approved by the Board.

There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

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

9. **Probation Monitoring Costs**

Respondent 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.

10. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

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

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

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his 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. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

12. **Notification of a Change in Name, Residence Address, Mailing Address or Employment**

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. **Tolling of Probation**

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of practice, and

must further notify the board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code section 4000 et seq . "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq."

Respondent is required to practice as a pharmacist in a licensed pharmacy setting that dispenses medication for a minimum of one year prior to the completion of probation. After the first year of probation, the board or its designee may consider a modification of this requirement. If respondent fails to comply with this requirement or a subsequent modification thereto, such failure shall be considered a violation of probation.

14. **Violation of Probation**

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be 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 violates probation in any respect, the board, after giving respondent 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, and charges and allegations in Accusation No. 4567 shall be deemed true and correct.

15. **Completion of Probation**

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

16. **Suspension**

As part of probation, respondent is suspended from the practice of pharmacy up and until forty (40) hours of in-person remedial education in sterile compounding is completed beginning the effective date of this decision. The in-person training may be completed prior to the execution of this stipulation, and Complainant shall render full credit for all satisfactory completion of this requirement that is successfully fulfilled before the effective date of its decision.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

17. **Restricted Practice – No Sterile Compounding**

Respondent shall not prepare, oversee or participate in the preparation of sterile products at any time in which he is licensed, regardless of whether he is on probation. Respondent Pharmacist shall submit proof satisfactory to the board of compliance with this term of probation. Failure to abide by this restriction or to timely submit proof to the board of compliance therewith shall be considered a violation of probation.

18. **Remedial Education**

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to sterile compounding. The program of remedial education shall consist of at least forty (40) hours, which shall be completed at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at his own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

19. **No Ownership of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written

proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

20. **Ethics Course**

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.

21. **Supervised Practice**

During the period of probation, respondent shall practice only under the supervision of a licensed pharmacist not on probation with the board. Upon and after the effective date of this decision, respondent shall not practice pharmacy and his license shall be automatically suspended until a supervisor is approved by the board or its designee.

The supervision shall be, as required by the board or its designee, set as:

Daily Review - Supervisor's review of probationer's daily activities within 24 hours. "Daily review" as this term is used herein shall not require that the supervising pharmacist be engaged in physical supervision of respondent's activities in real time, but shall require that the supervising pharmacist, by no later than close of business on each day following, review all transactions

performed by respondent and records associated with those transactions to ensure compliance with state and federal statutes and regulations and with the requirements of this decision.

If respondent violates probation in any respect, the board or its designee shall have to power to impose any of the following supervision restrictions:

Continuous – At least 75% of a work week

Substantial - At least 50% of a work week

Partial - At least 25% of a work week

Within thirty (30) days of the effective date of this decision, respondent shall have his supervisor submit notification to the board in writing stating that the supervisor has read the decision in case number 4567 and is familiar with the required level of supervision as determined by the board or its designee. It shall be the respondent's responsibility to ensure that his employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

If respondent changes employment, it shall be the respondent's responsibility to ensure that his employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Respondent shall have his new supervisor, within fifteen (15) days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number 4567, and is familiar with the level of supervision as determined by the board. Respondent shall not practice pharmacy and his license shall be automatically suspended until the board or its designee approves a new supervisor. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

Within ten (10) days of leaving employment, respondent shall notify the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act

involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Failure to comply with this suspension shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Tony J. Park. I understand the stipulation and the effect it will have on my Pharmacist License. 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: 12/13/16

Clifton Eugene Braddy

CLIFTON EUGENE BRADDY
Respondent

I have read and fully discussed with Respondent Clifton Eugene Braddy the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 12/16/2016

TONY J. PARK
Attorney for Respondent

ENDORSEMENT

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

Dated: 12/19/16

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
LINDA L. SUN
Supervising Deputy Attorney General

KEVIN J. RIGLEY
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Second Amended Accusation No. 4567

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

In the Matter of the Accusation Against: **RX UNLIMITED LLC** **RX UNLIMITED PHARMACY** 6815 Noble Ave. Ste. 107 Van Nuys, CA 91405 Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642 and **Clifton Eugene Braddy** 18333 Hatteras St. #110 Tarzana, CA 91356 Pharmacist License No. RPH 45546 Respondents.	Case No. 4567 **SECOND AMENDED ACCUSATION**

Complainant alleges:

PARTIES

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

2. On or about August 14, 1992, the Board issued Pharmacist License Number RPH 45546 to Clifton Eugene Braddy (Respondent Braddy). The Pharmacist License was in full force and effect at all times relevant to the charges herein and will expire on April 30, 2016, unless renewed.

3. On or about June 28, 2010, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 50302 to RX Unlimited LLC, dba RX Unlimited Pharmacy with the address of record of 6815 Noble Ave., Ste. 107, Van Nuys, California 91405 (Respondent RX Unlimited). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2015, unless renewed.

4. On or about September 28, 2010, the Board issued Sterile Compounding Permit Number LSC 99642 to RX Unlimited LLC, dba RX Unlimited Pharmacy to compound injectable sterile drug products. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2015, unless renewed.

JURISDICTION

5. This Second Amended Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

STATUTORY PROVISIONS

6. Section 118, subdivision (b), provides in pertinent part that the suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground.

7. Section 4300 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 him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper."

8. Section 4169 states, in pertinent part:

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

...

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code."

9. Section 4342 states, in pertinent part:

"(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

REGULATORY PROVISIONS

10. California Code of Regulations, title 16, section 1735.3 states:

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

...

(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted,

Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

11. California Code of Regulations, title 16, section 1751.7, subdivision (o) states in pertinent part that 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.

12. California Code of Regulations, title 16, section 1735.2 subdivisions (c) and (h) state as follows:

"..."

"(c) Pursuant to Business and Professions Code section 4052 (a)(1), a "reasonable quantity" of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is that amount of compounded drug product that:

(1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and

(2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and

(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."

"..."

"(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the

compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

"...."

COST RECOVERY

13. Section 125.3 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.

DRUG DEFINITIONS

14. Tri-Mix, is a sterile injectable compound comprised of three different ingredients: alprostadil, phentolamine, and papaverine. All three of the products are dangerous drugs pursuant to Business and Professions Code Section 4022 (c).

15. Nandrolone Deconoate 200mg/ml injection, brand name "Androlone", is used to treat anemia in patients with kidney failure, is classified as a Schedule III controlled substance under the Anabolic Steroids Control Act of 1990 as designated by Health and Safety Code section 11056 and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

16. Hydroxyprogesterone Caproate, brand name "Makena", is a synthetic, steroidal progestin that is used in pregnancy to prevent preterm labor in women, and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

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FACTUAL BACKGROUND

I. May 15, 2012 Inspection

17. On or about May 15, 2012, the Board conducted an annual licensed sterile compounding inspection (LSC Inspection) at Respondent RX Unlimited, located at 6815 Noble Ave. #107, Van Nuys, CA 91404.

18. During the LSC Inspection, the Board inspector reviewed RX Unlimited's end-product test results to determine sterility of compounded products.

19. Respondent Braddy stated that RX Unlimited did not conduct in-house testing of the finalized products for sterility, but rather sent the products out to Eagle Analytical Services (Eagle) for testing.

20. The Board inspector learned that for some of the compounded product results, sterility and potency testing were completed but not pyrogen testing[1].

21. RX Unlimited Pharmacy Technician B.G.[2] informed the Board inspector that Respondents conducted in house pyrogen testing. Respondents failed to produce documentation of the pyrogen testing results upon request.

22. The Board inspector subsequently learned that RX Unlimited possessed pyrogen test kits, but never used any of them.

23. While reviewing Eagle's testing reports, the Board inspector also observed that the potency results of multiple compounds were outside of the normal range.

24. Respondent Braddy stated that the products outside of normal range were not dispensed to consumers.

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[1] A pyrogen is a protein that can induce a fever in a patient by triggering a series of immune reactions. The guaranteed absence of pyrogens is a critical safety precaution for all drugs administered parenterally, since these contaminants can pose a life-threatening risk of shock to the patient. Pyrogen testing defines a process used by drug manufacturers to determine if bacterial toxins are present in vaccines and drugs that might cause fever when used on humans. It determines if microbes or their metabolites are present in intravenous solutions during the manufacturing process.

[2] For potential witnesses and/or patients, initials are used in lieu of names in order to protect the privacy rights of these individuals.

25. During the inspection, Respondents were unable to produce compounding worksheets for all products identified by the Board inspector, however, Respondent Braddy admitted that RX Unlimited did not test each and every batch of sterile products to make sure they were sterile.

26. On or about September 14, 2012, the Board conducted a follow up inspection and to obtain additional pharmacy records.

27. The inspector requested the dispensing reports of compounds identified during the May 15, 2012 inspection which were found to have potency results outside acceptable potency ranges for the compound.

28. A review of the compounding logs, laboratory testing results, and dispensing reports for Tri-Mix (alprostadil-10mcg/papaverine-30mg/phentolamine-0.5mg) revealed approximately 44 compounded prescriptions which were prepared as batch products from a non-sterile source and found to be outside of expected potency ranges were dispensed to consumers.

29. The Board inspector also selected a sample of compounding logs for end-product testing and requested the prescription dispensing history for those specific lots.

30. The records revealed that approximately 105 sterile injectable compounded prescriptions prepared as batch products from a non-sterile source were dispensed to consumers without first conducting end product sterility and pyrogen testing.

31. A sample of compounding worksheet records also revealed that Respondent failed to document the manufacturer of each ingredient used to prepare approximately 15 compounds for Tri-Mix, Nandrolone, Progesterone, Testosterone, Tri-Mix XL and Quad-Mix.

32. A written notice of non-compliance was given to Respondents Braddy and RX Unlimited at the end of the inspection.

II. <u>February 13, 2013 Inspection</u>

33. On or about February 13, 2013, the Board conducted an inspection at Respondent RX Unlimited, located at 6815 Noble Ave. #107, Van Nuys, CA 91404 after a complaint was made by T.Corp. alleging that Respondents continued to compound large quantities of

hydroxyprogesterone caproate (HPC) injection outside the scope of traditional pharmacy compounding.

34. Respondent Clifton Braddy was not present during the inspection. Pharmacist N.P. was present and provided the documents requested during the inspection. At the conclusion of the inspection, Respondent Braddy was notified that he was required to supplement the documents collected during the inspection within 14 days. After review of all documents provided at the inspection site, as well as those provided thereafter by Respondents, the following findings were made.

35. Respondents' sterile compounding worksheets were reviewed and revealed that the Respondents were compounding nandrolone deconoate 200mg/ml injection with a beyond the use date of 180 days despite the Master Formula's estimated 90 days beyond the use date. Respondents were unable to provide stability studies that supported the 180 days beyond the use date for the nandrolone deconoate 200mg/ml.

36. Respondents' compounding logs revealed that they were compounding and dispensing HPC injections outside of the scope of traditional pharmacy compounding practices in that the HPC injections were commercially available in the marketplace and there was no specific need for said drug. The records revealed that a total of six (6) prescriptions were filled from January 1, 2012 through February 13, 2013 as follows: RX No. 100897, dispensed June 19, 2012, RX No. 100898, dispensed June 19, 2012, RX No. 100907, dispensed June 21, 2012, RX No. 100907, dispensed September 5, 2012, RX No. 101765, dispensed November 27, 2012, and RX No. 101765, dispensed December 28, 2012.

FIRST CAUSE FOR DISCIPLINE

(Misbranded Drugs)

37. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4169 subdivision (a)(3) in conjunction with section 4342 in that inspections conducted on or about May 15, 2012, and September 13, 2012, revealed that Respondents purchased, traded, sold or transferred dangerous drugs that Respondents knew or should have

reasonably known were misbranded, as defined in section 11135 of the Health and Safety Code. Complainant incorporates by reference paragraphs 17 – 32, as if fully set forth herein.

SECOND CAUSE FOR DISCIPLINE

(Sterile Compounding – Quality Assurance)

38. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1751.7, subdivision (c) in that an inspection conducted on September 14, 2012, revealed that Respondents did not test for sterility and pyrogen for each sterile injectable batch product prepared from a non-sterile source prior to dispensing the product. Complainant incorporates by reference paragraphs 17 – 32, as if fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

(Records of Compounding Drug Products)

39. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.3, subdivision (a) (6) in that inspections conducted on or about May 15, 2012, and September 13, 2012, revealed that Respondents failed to identify the name of the manufacturer of each ingredient of a compounded drug prior to dispensing the product. Complainant incorporates by reference paragraphs 26 – 32, as if fully set forth herein.

FOURTH CAUSE FOR DISCIPLINE

(Compounding Limitations and Requirements; Self Assessment)

40. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs., title 16 Section 1735.2, subdivision (h) in that the inspection on February 13, 2013, and the records thereafter provided, revealed that Respondents had compounding worksheets for nandrolone deconoate 200/mg/ml that showed a beyond the use date of 180 days despite a master formula estimated 90 days beyond the use date. In addition, Respondents were unable to provide stability studies that supported the beyond the use date of 180 days. Complainant incorporates by reference paragraphs 33 - 35, as if fully set forth herein.

FIFTH CAUSE FOR DISCIPLINE

(Compounding Limitations)

41. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.2, subdivision (c) in that the inspection on February 13, 2013, and the records thereafter provided, revealed that Respondents were compounding and dispensing HPC injections in a form that is essentially a copy of a product which is commercially available in the market place. Complainant incorporates by reference paragraphs 33, 34 & 36, as if fully set forth herein.

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 Pharmacist License Number RPH 45546 issued to Clifton Eugene Braddy;

2. Revoking or suspending Sterile Compounding Permit Number LSC 99642 issued to RX Unlimited LLC;

3. Revoking or suspending Pharmacy Permit Number PHY 50302, issued to RX Unlimited LLC. dba RX Unlimited Pharmacy;

4. Ordering RX Unlimited LLC and Clifton Eugene Braddy, Pharmacist-in-Charge, 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

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

DATED: 4/3/15

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