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 RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY 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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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
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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 RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY 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 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 16673 Roscoe Blvd., North Hills, California 91343. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2017, unless renewed.

4. On or about September 28, 2010, the Board of Pharmacy issued Sterile Compounding Permit No. LSC 99642 to RX Unlimited, LLC dba RX Unlimited Pharmacy. The Sterile Compounding Permit 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 June 1, 2017, unless renewed.

JURISDICTION

5. 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.

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

ADVISEMENT AND WAIVERS

7. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in the Second Amended Accusation No. 4567. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order.

8. Respondents are fully aware of its 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 its own expense; 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. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

10. Respondents understand and agree that the charges and allegations in Accusation No. 4567, if proven at a hearing, constitute cause for imposing discipline upon Respondents' pharmacy and sterile compounding licenses.

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 Respondents hereby give up their right to contest those charges.

12. Respondents agree that their pharmacy and sterile compounding licenses are subject to discipline and agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree 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 Respondents or its counsel. By signing the stipulation, Respondents understand and agree 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.

14. 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.

15. 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.

16. 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 Original Pharmacy Permit Number PHY 50302 and Sterile Compounding Permit No. LSC 99642 issued to Respondent RX Unlimited, LLC dba RX Unlimited Pharmacy ("Respondents") are revoked. However, the revocation is stayed and Respondents are placed on probation for five (5) years on the following terms and conditions.

1. **Obey All Laws**

Respondents' owner shall obey all state and federal laws and regulations.

Respondents' owner 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 original pharmacy permit and sterile compounding 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**

Respondents' 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, respondents' 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, respondents' 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**

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

5. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, respondents' owner shall pay to the board its costs of investigation and prosecution in the amount of $11,584.00. Respondents 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 respondents' owner shall not relieve respondents of their responsibility to reimburse the board its costs of investigation and prosecution.

6. **Probation Monitoring Costs**

Respondents' 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**

Respondents' owner shall, at all times while on probation, maintain current licensure with the board. If respondents' 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 respondents' shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondents' 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 respondents' 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 respondents' owner discontinue business, respondents' 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, respondents will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondents' 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. Respondents' owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

Respondents' 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, Respondents' 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.

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

Respondents' 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**

Respondents' 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. Respondents' 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, respondents' 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**

Respondents 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 respondents or respondents' 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**

Respondents' 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.

Respondents' 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 respondents' owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondents' licenses, 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.

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If respondents' owner violates probation in any respect, the board, after giving respondents' 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 respondents 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 all charges and allegations in Accusation No. 4567 shall be deemed true and correct.

13. **Completion of Probation**

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

14. **Suspension**

Original Pharmacy Permit Number PHY 50302 and Sterile Compounding Permit No. LSC 99642 issued to Respondents are suspended, beginning with the effective date of this decision, until the time in which forty (40) hours of in-person remedial education in sterile compounding are completed by Brian Goldstein, Eugene Braddy, Naomi Parvizi and any other licensed employees of the Respondents. 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.

Respondents shall cease all pharmacy operations during the period of suspension. Failure to comply with this suspension shall be considered a violation of probation.

15. **Accreditation by PCAP and NABP**

During the period of probation Respondents shall obtain semi-annual accreditation by the Pharmacy Compounding Accreditation Board (PCAB) and annual accreditation by the National Association of Boards of Pharmacy (NABP).

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Frederick M. Reich. I understand the stipulation and the effect it will have on my Sterile Compounding 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: 12-12-16

RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY
Respondent

I have read and fully discussed with Respondent RX Unlimited, LLC dba RX Unlimited Pharmacy, 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