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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 (c) 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

KAMALA D. HARRIS
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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 **FIRST AMENDED A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about 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 ingestible 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 First Amended Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code 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 (c) 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.

COST RECOVERY

12. 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

13. 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).

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FACTUAL BACKGROUND

14. 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.

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

16. 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.

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

18. RX Unlimited Pharmacy Technician Brian Goldstein informed the Board inspector that Respondents conducted in house pyrogen testing. Respondents failed to produce documentation of the pyrogen testing results upon request.

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

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

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

22. 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.

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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.

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

24. 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.

25. 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.

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

27. 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.

28. 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.

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

FIRST CAUSE FOR DISCIPLINE

30. 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 14 – 29, as if fully set forth herein.

SECOND CAUSE FOR DISCIPLINE

31. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs. 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 14 – 29, as if fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

32. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs. 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 23 – 29, 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: 2/4/15

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

KAMALA D. HARRIS
Attorney General of California
ARMANDO ZAMBRANO
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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: **RX UNLIMITED LLC** **RX UNLIMITED PHARMACY** 6815 Noble Ave. Ste. 107 Van Nuys, CA 91405 Pharmacy Permit No. PHY 50203 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 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about 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, 2014, 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, 2014, 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 ingestible 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, 2014, unless renewed.

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 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.

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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 (c) 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.

COST RECOVERY

12. 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

13. 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).

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FACTUAL BACKGROUND

14. 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.

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

16. 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.

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

18. RX Unlimited Pharmacy Technician Brian Goldstein informed the Board inspector that Respondents conducted in house pyrogen testing. Respondents failed to produce documentation of the pyrogen testing results upon request.

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

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

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

22. 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.

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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. Pyroger 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.

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

24. 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.

25. 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.

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

27. 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.

28. 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.

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

FIRST CAUSE FOR DISCIPLINE

30. 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 14 – 29, as if fully set forth herein.

SECOND CAUSE FOR DISCIPLINE

31. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs. 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 14 – 29, as if fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

32. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs. 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 23 – 29, 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;

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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;

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

DATED: 1/31/14

Virginia Herold

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