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8	BEFOI	RETHE	
9	BOARD OF	PHARMACY ONSUMER AFFAIRS	
10		CALIFORNIA	
11	In the Matter of the Accusation Against:	Case No. 4567	
12	RX UNLIMITED LLC		
13	RX UNLIMITED PHARMACY 6815 Noble Ave. Ste. 107	SECOND AMENDED ACCUSATION	
14	Van Nuys, CA 91405		
15	Pharmacy Permit No. PHY 50302	· · · · · · · ·	
16	Sterile Compounding Permit No. LSC 99642		
17	and		
18 19	<b>Clifton Eugene Braddy</b> 18333 Hatteras St. #110 Tarzana, CA 91356		
20			
20	Pharmacist License No. RPH 45546		
21	Respondents.		
22			
24	Complainant alleges:	1	
25	PARTIES		
26	1. Virginia Herold (Complainant) brings this Second Amended Accusation solely in		
27	her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of		
28	Consumer Affairs.		
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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.

On or about June 28, 2010, the Board of Pharmacy issued Original Pharmacy 3. 5 Permit Number PHY 50302 to RX Unlimited LLC, dba RX Unlimited Pharmacy with the address 6 of record of 6815 Noble Ave., Ste. 107, Van Nuys, California 91405 (Respondent RX Unlimited). 7 The Pharmacy Permit was in full force and effect at all times relevant to the charges brought 8 herein and will expire on June 1, 2015, unless renewed. 9

On or about September 28, 2010, the Board issued Sterile Compounding Permit 4. 10 Number LSC 99642 to RX Unlimited LLC, dba RX Unlimited Pharmacy to compound injectable 11 sterile drug products. The Sterile Compounding Permit was in full force and effect at all times 12 relevant to the charges brought herein and will expire on June 1, 2015, unless renewed. 13

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### JURISDICTION

5. This Second Amended Accusation is brought before the Board under the authority 15 of the following laws. All section references are to the Business and Professions Code unless 16 otherwise indicated. 17

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## STATUTORY PROVISIONS

6. Section 118, subdivision (b), provides in pertinent part that the suspension, 19 expiration, or forfeiture by operation of law of a license issued by a board in the department, or its 20suspension, 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 22 renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue 23 a disciplinary proceeding against the licensee upon any ground provided by law or to enter an 24 order suspending or revoking the license or otherwise taking disciplinary action against the 25 licensee on any such ground. 26

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7.

Section 4300 states, in pertinent part:

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

1	(b) The board shall discipline the holder of any license issued by the board, whose default	
2	has been entered or whose case has been heard by the board and found guilty, by any of the	
3	following methods:	
4	(1) Suspending judgment.	
5	(2) Placing him or her upon probation.	
6	(3) Suspending his or her right to practice for a period not exceeding one year.	
7	(4) Revoking his or her license.	
8	(5) Taking any other action in relation to disciplining him or her as the board in its	
9	discretion may deem proper."	
10	8. Section 4169 states, in pertinent part:	
11	"(a) A person or entity may not do any of the following:	
12		
13	(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably	
14	should have known were misbranded, as defined in Section 111335 of the Health and Safety	
15	Code."	
16	9. Section 4342 states, in pertinent part:	
17	"(a) The board may institute any action or actions as may be provided by law and that, in	
18	its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do	
19	not conform to the standard and tests as to quality and strength, provided in the latest edition of	
20	the United States Pharmacopoeia or the National Formulary, or that violate any provision of the	
21	Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division	
22	104 of the Health and Safety Code)."	
23	REGULATORY PROVISIONS	
24	10. California Code of Regulations, title 16, section 1735.3 states:	
25	"(a) For each compounded drug product, the pharmacy records shall include:	
26	1,71	
27	(6) The manufacturer, expiration date and lot number of each component. If the	
28	manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.	
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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) (35<sup>th</sup> 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.

6 11. California Code of Regulations, title 16, section 1751.7, subdivision (c) states in
7 pertinent part that batch-produced sterile injectable drug products compounded from one or more
8 non-sterile ingredients shall be subject to documented end product testing for sterility and
9 pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable
10 levels of pyrogens.

11 12. California Code of Regulations, title 16, section 1735.2 subdivisions (c) and (h)
12 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."

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27 "(h) Every compounded drug product shall be given an expiration date representing the
28 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 2 the compounded drug product, unless a longer date is supported by stability studies of finished 3 drugs or compounded drug products using the same components and packaging. Shorter dating 4 than set forth in this subsection may be used if it is deemed appropriate in the professional 5 judgment of the responsible pharmacist." 6

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### COST RECOVERY

13. Section 125.3 states, in pertinent part, that the Board may request the 9 administrative law judge to direct a licentiate found to have committed a violation or violations of 10 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and 11 enforcement of the case. 12

#### 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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<ul> <li>I. <u>May 15, 2012 Inspection</u> <ol> <li>On or about May 15, 2012, the Board conducted an annual licensed sterile</li> <li>compounding inspection (LSC Inspection) at Respondent RX Unlimited, located at 6815 Noble</li> <li>Ave. #107, Van Nuys, CA 91404.</li> <li>18. During the LSC Inspection, the Board inspector reviewed RX Unlimited's end-</li> <li>product test results to determine sterility of compounded products.</li> <li>19. Respondent Braddy stated that RX Unlimited did not conduct in-house testing of</li> <li>the finalized products for sterility, but rather sent the products out to Eagle Analytical Services</li> <li>(Eagle) for testing.</li> <li>20. The Board inspector learned that for some of the compounded product results,</li> </ol></li></ul>	
<ul> <li>compounding inspection (LSC Inspection) at Respondent RX Unlimited, located at 6815 Noble</li> <li>Ave. #107, Van Nuys, CA 91404.</li> <li>18. During the LSC Inspection, the Board inspector reviewed RX Unlimited's end-</li> <li>product test results to determine sterility of compounded products.</li> <li>19. Respondent Braddy stated that RX Unlimited did not conduct in-house testing of</li> <li>the finalized products for sterility, but rather sent the products out to Eagle Analytical Services</li> <li>(Eagle) for testing.</li> <li>20. The Board inspector learned that for some of the compounded product results,</li> </ul>	
<ul> <li>Ave. #107, Van Nuys, CA 91404.</li> <li>18. During the LSC Inspection, the Board inspector reviewed RX Unlimited's end-product test results to determine sterility of compounded products.</li> <li>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.</li> <li>20. The Board inspector learned that for some of the compounded product results,</li> </ul>	
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<ul><li>(Eagle) for testing.</li><li>20. The Board inspector learned that for some of the compounded product results,</li></ul>	
20. The Board inspector learned that for some of the compounded product results,	
sterility and potency testing were completed but not pyrogen testing <sup>1</sup> .	
21. RX Unlimited Pharmacy Technician B.G. <sup>2</sup> 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.	
<sup>1</sup> 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.	
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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.

5 26. On or about September 14, 2012, the Board conducted a follow up inspection and 6 to obtain additional pharmacy records.

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

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.

14 29. The Board inspector also selected a sample of compounding logs for end-product
15 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.

19 31. A sample of compounding worksheet records also revealed that Respondent failed
20 to document the manufacturer of each ingredient used to prepare approximately 15 compounds
21 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.

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# 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

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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.

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

Respondents' compounding logs revealed that they were compounding and 36. 14 dispensing HPC injections outside of the scope of traditional pharmacy compounding practices in 15 that the HPC injections were commercially available in the marketplace and there was no specific 16 17 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, 18 2012, RX No. 100898, dispensed June 19, 2012, RX No. 100907, dispensed June 21, 2012, RX 19 No. 100907, dispensed September 5, 2012, RX No. 101765, dispensed November 27, 2012, and 20RX No. 101765, dispensed December 28, 2012. 21

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## 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

1	reasonably known were misbranded, as defined in section 11135 of the Health and Safety Code.
2	Complainant incorporates by reference paragraphs $17 - 32$ , as if fully set forth herein.
3	SECOND CAUSE FOR DISCIPLINE
4	(Sterile Compounding – Quality Assurance)
5	38. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary
6	action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1751.7,
7	subdivision (c) in that an inspection conducted on September 14, 2012, revealed that Respondents
8	did not test for sterility and pyrogen for each sterile injectable batch product prepared from a non-
9	sterile source prior to dispensing the product. Complainant incorporates by reference paragraphs
10	17 – 32, as if fully set forth herein.
11	THIRD CAUSE FOR DISCIPLINE
12	(Records of Compounding Drug Products)
13	39. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary
14	action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.3,
15	subdivision (a) (6) in that inspections conducted on or about May 15, 2012, and September 13,
16	2012, revealed that Respondents failed to identify the name of the manufacturer of each
17	ingredient of a compounded drug prior to dispensing the product. Complainant incorporates by
18	reference paragraphs 26 – 32, as if fully set forth herein.
19	FOURTH CAUSE FOR DISCIPLINE
20	(Compounding Limitations and Requirements; Self Assessment)
21	40. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary
22	action under Section 4300 in conjunction with Cal. Code of Regs., title 16 Section 1735.2,
23	subdivision (h) in that the inspection on February 13, 2013, and the records thereafter provided,
24	revealed that Respondents had compounding worksheets for nandrolone deconoate 200/mg/ml
25	that showed a beyond the use date of 180 days despite a master formula estimated 90 days beyond
26	the use date. In addition, Respondents were unable to provide stability studies that supported the
27	beyond the use date of 180 days. Complainant incorporates by reference paragraphs 33 - 35, as if
28	fully set forth herein.

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1	FIFTH CAUSE FOR DISCIPLINE	
2	(Compounding Limitations)	
3	41. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary	
4	action under Section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.2,	
5	subdivision (c) in that the inspection on February 13, 2013, and the records thereafter provided,	
6	revealed that Respondents were compounding and dispensing HPC injections in a form that is	
7	essentially a copy of a product which is commercially available in the market place. Complainant	
8	incorporates by reference paragraphs 33, 34 & 36, as if fully set forth herein.	
9	PRAYER	
10	WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,	
11	and that following the hearing, the Board of Pharmacy issue a decision:	
12	1. Revoking or suspending Pharmacist License Number RPH 45546 issued to Clifton	
13	Eugene Braddy;	
14	2. Revoking or suspending Sterile Compounding Permit Number LSC 99642 issued	
15	to RX Unlimited LLC;	
16	3. Revoking or suspending Pharmacy Permit Number PHY 50302, issued to RX	
17	Unlimited LLC. dba RX Unlimited Pharmacy;	
18	4. Ordering RX Unlimited LLC and Clifton Eugene Braddy, Pharmacist-in-Charge,	
19	to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this	
20	case, pursuant to Business and Professions Code section 125.3; and	
21	5. Taking such other and further action as deemed necessary and proper.	
22		
23	DATED: 4/3/15 Jugine Herde	
24	VIRGINIA K. HEROLD Executive Officer	
25	Board of Pharmacy Department of Consumer Affairs	
26	State of California Complainant	
27	Соприлин	
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	10	

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2	ARMANDO ZAMBRANO Supervising Deputy Attorney General		
3	LANGSTON EDWARDS Deputy Attorney General		
4	State Bar No. 300 So. Spring Street, Suite 1702		
5	Los Angeles, CA 90013 Telephone: (213) 620-6343 Facsimile: (213) 897-2804		
6	Facsimile: (213) 897-2804 Attorneys for Complainant		
7			
8	BEFORE THE BOARD OF PHARMACY		
9		CONSUMER AFFAIRS CALIFORNIA	
10 11		]	
	In the Matter of the Accusation Against:	Case No. 4567	
12	RX UNLIMITED LLC RX UNLIMITED_PHARMACY		
13	6815 Noble Ave. Ste. 107	FIRST AMENDED A C C U S A T I O N	
14	Van Nuys, CA 91405		
15 16	Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642		
17	and		
18	<b>Clifton Eugene Braddy</b> 18333 Hatteras St. #110		
19 20	Tarzana, CA 91356		
20	Pharmacist License No. RPH 45546		
21	Respondents.		
22 23			
23	Complainant alleges:	<b>.</b>	
25	PARTIES		
26	1. Virginia Herold (Complainant) brings this Accusation solely in her official		
27	capacity as the Executive Officer of the Board o	f Pharmacy (Board), Department of Consumer	
28	Affairs.		
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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.

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.

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#### 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, 21 expiration, or forfeiture by operation of law of a license issued by a board in the department, or its 22 suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its 23 surrender without the written consent of the board, shall not, during any period in which it may be 24 renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue 25 a disciplinary proceeding against the licensee upon any ground provided by law or to enter an 26order suspending or revoking the license or otherwise taking disciplinary action against the 27 28 licensee on any such ground.

1	7. Section 4300 states, in pertinent part:	
2	(a) Every license issued may be suspended or revoked.	
3	(b) The board shall discipline the holder of any license issued by the board, whose default	
4	has been entered or whose case has been heard by the board and found guilty, by any of the	
5	following methods:	
6	(1) Suspending judgment.	
7	(2) Placing him or her upon probation.	
8	(3) Suspending his or her right to practice for a period not exceeding one year.	
9	(4) Revoking his or her license.	
10	(5) Taking any other action in relation to disciplining him or her as the board in its	
11	discretion may deem proper."	
12	8. Section 4169 states, in pertinent part:	
13	"(a) A person or entity may not do any of the following:	
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15	(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably	
16	should have known were misbranded, as defined in Section 111335 of the Health and Safety	
17	Code."	
18	9. Section 4342 states, in pertinent part:	
19	"(a) The board may institute any action or actions as may be provided by law and that, in	
20	its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do	
21	not conform to the standard and tests as to quality and strength, provided in the latest edition of	
22	the United States Pharmacopoeia or the National Formulary, or that violate any provision of the	
23	Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division	
24	104 of the Health and Safety Code)."	
25	REGULATORY PROVISIONS	
26	10. California Code of Regulations, title 16, section 1735.3 states:	
27	"(a) For each compounded drug product, the pharmacy records shall include:	
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	3	

1	(6) The manufacturer, expiration date and lot number of each component. If the	
2	manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.	
3	Exempt from the requirements in this paragraph are sterile products compounded on a one-time	
4	basis for administration within seventy-two (72) hours and stored in accordance with standards	
5	for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National	
6	Formulary (USP-NF) (35 <sup>th</sup> Revision, Effective May 1, 2012), hereby incorporated by reference,	
7	to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.	
8	11. California Code of Regulations, title 16, section 1751.7, subdivision (c) states in	
9	pertinent part that batch-produced sterile injectable drug products compounded from one or more	
10	non-sterile ingredients shall be subject to documented end product testing for sterility and	
11	pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable	
12	levels of pyrogens.	
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14	COST RECOVERY	
15	12. Section 125.3 states, in pertinent part, that the Board may request the	
16	administrative law judge to direct a licentiate found to have committed a violation or violations of	
17	the licensing act to pay a sum not to exceed the reasonable costs of the investigation and	
18	enforcement of the case.	
19		
20	DRUG DEFINITIONS	
21	13. <u>Tri-Mix</u> , is a sterile injectable compound comprised of three different ingredients:	
22	alprostadil, phentolamine, and papaverine. All three of the products are dangerous drugs pursuant	
23		
24	to Business and Professions Code Section 4022 (c).	
25	1/	
26	//	
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1		FACTUAL BACKGROUND
2	14.	On or about May 15, 2012, the Board conducted an annual licensed sterile
3	compounding	g inspection (LSC Inspection) at Respondent RX Unlimited, located at 6815 Noble
4	Ave. #107, V	an Nuys, CA 91404.
5	15.	During the LSC Inspection, the Board inspector reviewed RX Unlimited's end-
6	product test re	esults to determine sterility of compounded products.
7	16.	Respondent Braddy stated that RX Unlimited did not conduct in-house testing of
8	the finalized p	products for sterility, but rather sent the products out to Eagle Analytical Services
9	(Eagle) for te	sting.
10	17.	The Board inspector learned that for some of the compounded product results,
11	sterility and p	otency testing were completed but not pyrogen testing <sup>1</sup> .
12	18.	RX Unlimited Pharmacy Technician Brian Goldstein informed the Board inspector
13	that Respondents conducted in house pyrogen testing. Respondents failed to produce	
14	documentation of the pyrogen testing results upon request.	
15	19.	The Board inspector subsequently learned that RX Unlimited possessed pyrogen
16	test kits, but r	never used any of them.
17	20.	While reviewing Eagle's testing reports, the Board inspector also observed that the
18	potency result	ts of multiple compounds were outside of the normal range.
19	21.	Respondent Braddy stated that the products outside of normal range were not
20	dispensed to c	consumers.
21	22.	During the inspection, Respondents were unable to produce compounding
22	worksheets for all products identified by the Board inspector, however, Respondent Braddy	
23	admitted that RX Unlimited did not test each and every batch of sterile products to make sure	
24	they were sterile.	
25	$\frac{1}{1}$ A pyrogen is a protein that can induce a fever in a patient by triggering a series of immune reactions. The	
26	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	
27	humans. It deter	b determine if bacterial toxins are present in vaccines and drugs that might cause fever when used on mines if microbes or their metabolites are present in intravenous solutions during the manufacturing
28	process.	
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23. On or about September 14, 2012, the Board conducted a follow up inspection and 2 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. 5

6 25. A review of the compounding logs, laboratory testing results, and dispensing 7 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-8 9 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 10 testing and requested the prescription dispensing history for those specific lots. 11

27.The records revealed that approximately 105 sterile injectable compounded 12 13 prescriptions prepared as batch products from a non-sterile source were dispensed to consumers without first conducting end product sterility and pyrogen testing. 14

28. A sample of compounding worksheet records also revealed that Respondent failed 15 to document the manufacturer of each ingredient used to prepare approximately 15 compounds 16 for Tri-Mix, Nandrolone, Progesterone, Testosterone, Tri-Mix XL and Quad-Mix. 17

29. A written notice of non-compliance was given to Respondents Braddy and RX 18 Unlimited at the end of the inspection. 19

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#### FIRST CAUSE FOR DISCIPLINE

30. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary 22 action under section 4169 subdivision (a)(3) in conjunction with section 4342 in that inspections 23 conducted on or about May 15, 2012, and September 13, 2012, revealed that Respondents 24 purchased, traded, sold or transferred dangerous drugs that Respondents knew or should have 25reasonably known were misbranded, as defined in Section 11135 of the Health and Safety Code. 26 Complainant incorporates by reference paragraphs 14 - 29, as if fully set forth herein. 27

28

1	SECOND CAUSE FOR DISCIPLINE		
2	31. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary		
3	action under Section 4300 in conjunction with Cal. Code of Regs. section 1751.7, subdivision (c)		
4	in that an inspection conducted on September 14, 2012, revealed that Respondents did not test for		
5	sterility and pyrogen for each sterile injectable batch product prepared from a non-sterile source		
6	prior to dispensing the product. Complainant incorporates by reference paragraphs $14 - 29$ , as if		
7	fully set forth herein.		
8			
9	THIRD CAUSE FOR DISCIPLINE		
10	32. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary		
11	action under Section 4300 in conjunction with Cal. Code of Regs. section 1735.3, subdivision (a)		
12	(6) in that inspections conducted on or about May 15, 2012, and September 13, 2012, revealed		
13	that Respondents failed to identify the name of the manufacturer of each ingredient of a		
14	compounded drug prior to dispensing the product. Complainant incorporates by reference		
15	paragraphs $23 - 29$ , as if fully set forth herein.		
16			
17	PRAYER		
18	WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,		
19	and that following the hearing, the Board of Pharmacy issue a decision:		
20	1. Revoking or suspending Pharmacist License Number RPH 45546 issued to Clifton		
21	Eugene Braddy;		
22	2. Revoking or suspending Sterile Compounding Permit Number LSC 99642 issued		
23	to RX Unlimited LLC;		
24	3. Revoking or suspending Pharmacy Permit Number PHY 50302, issued to RX		
25	Unlimited LLC. dba RX Unlimited Pharmacy;		
26	4. Ordering RX Unlimited LLC and Clifton Eugene Braddy, Pharmacist-in-Charge,		
27	to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this		
28	case, pursuant to Business and Professions Code section 125.3; and		
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Taking such other and further action as deemed necessary and proper. 5. 2/4/15 DATED: VIRGINIA HEROLD Executive Officer Board of Pharmacy Department of Consumer Affairs State of California Complainant 

1	KAMALA D. HARRIS Attorney General of California ARMANDO ZAMBRANO		
3	Supervising Deputy Attorney General LANGSTON EDWARDS		
4	Deputy Attorney General State Bar No.		
5	300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 620-6343		
6	Facsimile: (213) 897-2804 Attorneys for Complainant		
7			
8		RE THE PHARMACY	
9		CONSUMER AFFAIRS CALIFORNIA	
10 11		]	
12	In the Matter of the Accusation Against:	Case No. 4567	
12	RX UNLIMITED LLC RX UNLIMITED PHARMACY		
14	6815 Noble Ave. Ste. 107 Van Nuys, CA 91405	ACCUSATION	
15	Pharmacy Permit No. PHY 50203		
16	Sterile Compounding Permit No. LSC 99642		
17	and		
18	<b>Clifton Eugene Braddy</b> 18333 Hatteras St. #110		
19	Tarzana, CA 91356		
20	Pharmacist License No. RPH 45546		
21	Respondents.		
22			
23			
24	Complainant alleges:	איזדק	
25	PARTIES 1. Virginia Herold (Complainant) brings this Accusation solely in her official		
26 27	capacity as the Executive Officer of the Board of		
27	Affairs.		
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2, On or about August 14, 1992, the Board issued Pharmacist License Number RPH 1 45546 to Clifton Eugene Braddy (Respondent Braddy). The Pharmacist License was in full force 2 and effect at all times relevant to the charges herein and will expire on April 30, 2014, unless 3 renewed. 4 3. On or about June 28, 2010, the Board of Pharmacy issued Original Pharmacy 5 Permit Number PHY 50302 to RX Unlimited LLC, dba RX Unlimited Pharmacy with the address 6 of record of 6815 Noble Ave., Ste. 107, Van Nuys, California 91405 (Respondent RX Unlimited). 7 The Pharmacy Permit was in full force and effect at all times relevant to the charges brought 8 herein and will expire on June 1, 2014, unless renewed. 9 On or about September 28, 2010, the Board issued Sterile Compounding Permit 4. 10 Number LSC 99642 to RX Unlimited LLC, dba RX Unlimited Pharmacy to compound ingestible 11 sterile drug products. The Sterile Compounding Permit was in full force and effect at all times 12 relevant to the charges brought herein and will expire on June 1, 2014, unless renewed. 13 14 JURISDICTION 15 5. This Accusation is brought before the Board under the authority of the following 16 laws. All section references are to the Business and Professions Code unless otherwise indicated. 17 18 STATUTORY PROVISIONS 19 6. Section 118, subdivision (b), provides in pertinent part that the suspension, 20 21 expiration, or forfeiture by operation of law of a license issued by a board in the department, or its 22 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 23 renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue 24

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

27 licensee on any such ground.

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1	7. Section 4300 states, in pertinent part:	
2	(a) Every license issued may be suspended or revoked.	
3	(b) The board shall discipline the holder of any license issued by the board, whose default	
4	has been entered or whose case has been heard by the board and found guilty, by any of the	
5	following methods:	
6	(1) Suspending judgment.	
7	(2) Placing him or her upon probation.	
8	(3) Suspending his or her right to practice for a period not exceeding one year.	
9	(4) Revoking his or her license.	
10	(5) Taking any other action in relation to disciplining him or her as the board in its	
11	discretion may deem proper."	
12	8. Section 4169 states, in pertinent part:	
13	"(a) A person or entity may not do any of the following:	
14		
15	(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably	
16	should have known were misbranded, as defined in Section 111335 of the Health and Safety	
17	Code."	
18	9. Section 4342 states, in pertinent part:	
19	"(a) The board may institute any action or actions as may be provided by law and that, in	
20	its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do	
21	not conform to the standard and tests as to quality and strength, provided in the latest edition of	
22	the United States Pharmacopoeia or the National Formulary, or that violate any provision of the	
23	Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division	
24	104 of the Health and Safety Code)."	
25		
26	REGULATORY PROVISIONS	
27	10. California Code of Regulations, title 16, section 1735.3 states:	
28	"(a) For each compounded drug product, the pharmacy records shall include:	
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2	(6) The manufacturer, expiration date and lot number of each component. If the	
3	manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.	
4	Exempt from the requirements in this paragraph are sterile products compounded on a one-time	
5	basis for administration within seventy-two (72) hours and stored in accordance with standards	
6	for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National	
7	Formulary (USP-NF) (35 <sup>th</sup> Revision, Effective May 1, 2012), hereby incorporated by reference,	
8	to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.	
9	11. California Code of Regulations, title 16, section 1751.7, subdivision (c) states in	
10	pertinent part that batch-produced sterile injectable drug products compounded from one or more	
11	non-sterile ingredients shall be subject to documented end product testing for sterility and	
12	pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable	
13	levels of pyrogens.	
14		
15	<u>COST RECOVERY</u>	
16	12. Section 125.3 states, in pertinent part, that the Board may request the	
17	administrative law judge to direct a licentiate found to have committed a violation or violations of	
18	the licensing act to pay a sum not to exceed the reasonable costs of the investigation and	
19	enforcement of the case.	
20		
21	DRUG DEFINITIONS	
22	13. <u>Tri-Mix</u> , is a sterile injectable compound comprised of three different ingredients:	
23	alprostadil, phentolamine, and papaverine. All three of the products are dangerous drugs pursuant	
24		
25	to Business and Professions Code Section 4022 (c).	
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1	FACTUAL BACKGROUND	
2	14. On or about May 15, 2012, the Board conducted an annual licensed sterile	
3	compounding inspection (LSC Inspection) at Respondent RX Unlimited, located at 6815 Noble	
4	Ave. #107, Van Nuys, CA 91404.	
5	15. During the LSC Inspection, the Board inspector reviewed RX Unlimited's end-	
6	product test results to determine sterility of compounded products.	
7	16. Respondent Braddy stated that RX Unlimited did not conduct in-house testing of	
8	the finalized products for sterility, but rather sent the products out to Eagle Analytical Services	
9	(Eagle) for testing.	
10	17. The Board inspector learned that for some of the compounded product results,	
11	sterility and potency testing were completed but not pyrogen testing <sup>1</sup> .	
12	18. RX Unlimited Pharmacy Technician Brian Goldstein informed the Board inspector	
13	that Respondents conducted in house pyrogen testing. Respondents failed to produce	
14	documentation of the pyrogen testing results upon request.	
15	19. The Board inspector subsequently learned that RX Unlimited possessed pyrogen	
16	test kits, but never used any of them.	
17	20. While reviewing Eagle's testing reports, the Board inspector also observed that the	
18	potency results of multiple compounds were outside of the normal range.	
19	21. Respondent Braddy stated that the products outside of normal range were not	
20	dispensed to consumers.	
21	22. During the inspection, Respondents were unable to produce compounding	
22	worksheets for all products identified by the Board inspector, however, Respondent Braddy	
23	admitted that RX Unlimited did not test each and every batch of sterile products to make sure	
24	they were sterile.	
25	<sup>1</sup> A pyrogen is a protein that can induce a fever in a patient by triggering a series of immune reactions. The	
26	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.	Pyrc
27	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	
28	process.	
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1 23. On or about September 14, 2012, the Board conducted a follow up inspection and 2 to obtain additional pharmacy records.

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

6 25. A review of the compounding logs, laboratory testing results, and dispensing
7 reports for Tri-Mix (alprostadil-10mcg/papaverine-30mg/phentolamine-0.5mg) revealed
8 approximately 44 compounded prescriptions which were prepared as batch products from a non9 sterile source and found to be outside of expected potency ranges were dispensed to consumers.

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

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

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

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

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#### 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
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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.

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25	Unlimited LLC. dba RX Unlimited Pharmacy;
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Ordering RX Unlimited LLC and Clifton Eugene Braddy, Pharmacist-in-Charge, 4. 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; Taking such other and further action as deemed necessary and proper. 5. DATED: ₩ſRGIN Executive Officer Board of Pharmacy Department of Consumer Affairs State of California Complainant