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

In the Matter of the Accusation Against: **INNOVATIVE COMPOUNDING, INC.,** **dba INNOVATIVE COMPOUNDING PHARMACY** **MASOUD RASHIDI, President/Pharmacist-in-Charge/Owner** **ANNA RASHIDI, Vice President/Owner** **820 Wales Drive, Suite 3** **Folsom, CA 95630** **Pharmacy Permit No. PHY 48417** **Sterile Compounding License No. LSC 99600,** **MASOUD RASHIDI** **P.O. Box 1773** **Folsom, CA 95763** **Pharmacist License No. RPH 56324,** **and** **ANNA RASHIDI** **P.O. Box 1773** **Folsom, CA 95763** **Pharmacist License No. RPH 56323** Respondents.	Case No. 5663 **A C C U S A T I O N**

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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 February 7, 2007, the Board issued Pharmacy Permit Number PHY 48417 to Innovative Compounding, Inc. ("Respondent Innovative Compounding"), doing business as Innovative Compounding Pharmacy, with Masoud Rashidi ("Respondent Masoud Rashidi") as president and pharmacist-in-charge ("PIC") and Anna Rashidi ("Respondent Anna Rashidi") as vice president. The pharmacy permit was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2017, unless renewed.

3. On or about April 30, 2010, the Board issued Sterile Compounding License Number LSC 99600 to Respondent Innovative Compounding. The sterile compounding license was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2017, unless renewed.

4. On or about September 24, 2004, the Board issued Pharmacist License Number RPH 56324 to Respondent Masoud Rashidi. The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2016, unless renewed.

5. On or about September 24, 2004, the Board issued Pharmacist License Number RPH 56323 to Respondent Anna Rashidi. The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on April 30, 2016, unless renewed.

JURISDICTION/STATUTORY AND REGULATORY PROVISIONS

6. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code ("Code") unless otherwise indicated.

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7. Code 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. Code section 4300.1 states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

9. Code section 4301 states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct . . . Unprofessional conduct shall include, but is not limited to, any of the following:

. . . .

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency . . . .

10. Code section 4306.5 states, in pertinent part:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board . . .

11. Section 4307(a) of the Code states

> Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:
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> (1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.
>
> (2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

12. Code section 4113, subdivision (c), states that "[t]he pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

13. Code section 4022 states, in pertinent part:

> "Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:
>
> (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
>
> . . . .
>
> (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

14. Code section 4025 states:

> "Drug" means any of the following:
>
> (a) Articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement of any of them.
>
> (b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals.
>
> (c) Articles (other than food) intended to affect the structure or any function of the body of human beings or other animals.

(d) Articles intended for use as a component of any article specified in subdivision (a), (b), or (c).

15. Code section 4342, subdivision (a), states:

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).

16. Health and Safety Code section 110290 states:

In determining whether the labeling or advertisement of a food, drug, device, or cosmetic is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these, shall be taken into account. The extent that the labeling or advertising fails to reveal facts concerning the food, drug, device, or cosmetic or consequences of customary use of the food, drug, device, or cosmetic shall also be considered.

17. Health and Safety Code section 111330 states that "[a]ny drug or device is misbranded if its labeling is false or misleading in any particular".

18. Health and Safety Code section 111400 states:

Any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

19. Health and Safety Code section 111440 states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

20. Health and Safety Code section 111450 states:

It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

21. Health and Safety Code section 111550 provides, in pertinent part:

No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:

(a) It is one of the following:

(1) A new drug, and a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355).

. . . .

(b) The department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended . . .

22. Section 201, subdivision (p), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. section 321, subdivision (p)), states, in pertinent part:

The term "new drug" means--

(1) Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof . . .

(2) Any drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

23. Title 21, United States Code, Section 352 states, in pertinent part:

A drug or device shall be deemed to be misbranded—

(f) Directions for use and warnings on label. Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

24. Section 505, subdivision (a), of the Act (21 U.S.C. section 355, subdivision (a)), states, in pertinent part, that ". . . [n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."

25. California Code of Regulations, title 16, section ("Regulation") 1735.2 states, in pertinent part:

. . . .

(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 . . .

26. Regulation 1735.3 states, in pertinent part:

(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 . . .

27. Regulation 1751.7 states, in pertinent part:

. . . .

(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens . . .

COST RECOVERY

28. Code section 125.3 provides, in pertinent part, that a 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 CLASSIFICATIONS

29. "Domperidone" is an anti-dopaminergic drug that acts as an antiemetic and a prokinetic agent. Domperidone is not currently a legally marketed human drug and is not approved for sale in the United States.

30. "Depo-testosterone", a brand of testosterone cypionate, is a Schedule III controlled substance as designated by Health and Safety Code section 11056, subdivision (f)(30). Depo-

testosterone is indicated for the treatment of low testosterone. Depo-testosterone is a dangerous drug within the meaning of Code section 4022 in that it requires a prescription under federal law.

31. "Caverject", a brand of alprostadil, is a dangerous drug within the meaning of Code section 4022 in that it requires a prescription under federal law. Caverject is indicated for the treatment of erectile dysfunction.

32. "Papaverine" is a dangerous drug within the meaning of Code section 4022 in that it requires a prescription under federal law. Papaverine is indicated for the treatment of erectile dysfunction.

33. "Phentolamine" is a dangerous drug within the meaning of Code section 4022 in that it requires a prescription under federal law. Papaverine is indicated for the treatment of erectile dysfunction.

FACTUAL ALLEGATIONS

(Compounding and Dispensing of Unapproved Drug Domperidone)

34. On or about June 7, 2004, the U.S. Food and Drug Administration ("FDA") issued a Talk Paper titled, "FDA Warns Against Women Using Unapproved Drug, Domperidone, to Increase Milk Production", warning breastfeeding women not to use the product because of safety concerns. The FDA stated that although domperidone was approved in several countries outside the U.S. to treat certain gastric disorders, it is not approved in any country, including the U.S., for enhancing breast milk production in lactating women and is also not approved in the U.S. for any indication. The FDA stated that there had been several published reports and case studies of cardiac arrhythmias, cardiac arrest, and sudden death in patients receiving an IV form of domperidone that had been withdrawn from marketing in a number of countries. Further, in several countries where the oral form of domperidone continued to be marketed, labels for the product contained specific warnings against use of domperidone by breastfeeding women. The Talk Paper indicated that the FDA had issued six letters to pharmacies that compound products containing domperidone and firms that supply domperidone for use in compounding, stating that all drug products containing domperidone (whether compounded or not) violated the Federal

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Food, Drug and Cosmetic Act ("the Act") because they are unapproved new drugs and misbranded.

35. On or about June 7, 2004, the FDA issued a warning letter to Spectrum Chemicals & Laboratory Products. The FDA stated that their inspection of the firm revealed they were repacking and distributing bulk API (active pharmaceutical ingredients) domperidone for use in pharmacy compounding in violation of the Act. The FDA also stated that the drug's labeling did not contain adequate directions for use and that domperidone was not an active ingredient contained in any FDA-approved drug product.

36. On or about April 9, 2010, the FDA issued a warning letter to Alexandria Medical Arts Pharmacy & Compounding Laboratory. The FDA found during their inspection of the firm that they had compounded domperidone products for human patients on numerous occasions. The FDA stated that the domperidone products compounded by the firm were new drugs as defined by section 201(p) [21 U.S.C. section 321(p)] of the Act and may not be introduced or delivered into interstate commerce under section 505(a) of the Act [21 U.S.C. section 355(a)] because no approval of an application filed pursuant to section 505 of the Act [21 U.S.C. section 335] is in effect for the products.

37. On or about March 12, 2012, the FDA issued Import Alert 61-07, stating that domperidone was being imported as a bulk API for pharmacy compounding and that importation of the drug presented a public health risk and violated the Act.

38. On or about April 13, 2015, Board Inspectors M. and I. assisted FDA Consumer Safety Officers with an investigation of Innovative Compounding Pharmacy. An investigator of the California Department of Public Health was also present during the inspection. Respondent Masoud Rashidi, the pharmacist-in-charge ("PIC Rashidi"), assisted the investigation team.

39. During the tour of the compounding lab, Inspector M. inspected the finished compounded products and found two expired compounded topical hormone replacement therapy products, Bi-Est 50/50 E3/E2 0.75 mg/0.5 ml and Bi-Est 80/20 0.5 mg/ml, on the inventory shelves. Later, the FDA officers found various expired injectable compounds, including MIC +

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B12 Methylcobalamin injectable solution, Methylcobalamin 20 mg/ml injectable solution, and Cyanocobalamin 1000 mcg/ml, near the pharmacy autoclave.

40. PIC Rashidi was asked if the pharmacy had any domperidone powder in stock. PIC Rashidi checked the pharmacy cabinets and found a 500 gram stock bottle of domperidone bulk powder. Inspector I. told PIC Rashidi that she wanted to review the stock compounded capsules. PIC Rashidi opened the cabinets underneath the autoclave counter. Inspector I. inspected the cabinets and found domperidone capsules in varying strengths. Inspectors M. and I. obtained copies of the pharmacy's compounding log and prescriptions filled report and found that domperidone capsules were compounded multiple times within the previous year.

41. On or about April 28, 2015, Inspector M. conducted a follow-up inspection at the pharmacy and obtain copies of additional documents, including original domperidone prescriptions, compounding logs, dispensing records, and logged formula worksheets.

42. Inspector M. determined, based on the above documents, that on and between September 13, 2014 and April 13, 2015, the pharmacy had compounded 22 batches and 12,418 capsules of various strengths of domperidone. 20 batches and 10,618 capsules had been compounded by PIC Rashidi; 2 batches and 1,800 capsules had been compounded by Respondent Anna Rashidi. The pharmacy had also dispensed approximately 146 prescriptions and 14,141 capsules to patients which were compounded from domperidone. PIC Rashidi had dispensed approximately 143 of the prescriptions and approximately 13,711 of the capsules; Respondent Anna Rashidi had dispensed approximately 3 of the prescriptions and approximately 430 of the capsules.

FIRST CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law and Federal and State Laws and Regulations Governing Pharmacy)

43. Respondent Innovative Compounding's pharmacy permit is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code

§ 4300, et seq.), and federal and state laws and regulations governing pharmacy, as follows:

a. On and between September 13, 2014 and April 13, 2015, Respondent introduced or delivered for introduction into interstate commerce the new drug, domperidone, by compounding and dispensing the drug to patients, as set forth in paragraph 42 above, when, in fact, there was no IND for domperidone approved by the FDA, in violation of 21 U.S.C. section 355, subdivision (a).

b. On and between September 13, 2014 and April 13, 2015, Respondent sold, delivered, or gave away the new drug dromperidone by dispensing the drug to patients, as set forth in paragraph 42 above, when, in fact, there was no IND for domperidone approved by the FDA, in violation of Health and Safety Code section 111550.

c. On or about April 13, 2015, Respondent had its active dispensing inventory compounded drug products that were expired, as set forth in paragraph 39 above, in violation of Code section 4342.

d. Respondent failed to list on the logged formula worksheets for Lot Nos. 04082015@31 (domperidone 20 mg capsules), 03132015@26 (domperidone 10 mg capsules), 03192015@5 (domperidone 10 mg/ml suspension), 03262015@17 (domperidone 40 mg capsules), and 12222014@20 (domperidone 20 mg capsules) the manufacturer of each drug component, in violation of Regulation 1735.3, subdivision (a)(6).

SECOND CAUSE FOR DISCIPLINE

(Sold Misbranded Drugs)

44. Respondent Innovative Compounding's pharmacy permit is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (j), for violating statutes regulating controlled substances and dangerous drugs, in that Respondent sold misbranded drugs, as defined by Health and Safety Code section 111400 and United States Code, title 21, section 352(f), in violation of Health and Safety Code section 111440, as set forth in paragraphs 34 through 38 and 40 through 42, above.

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THIRD CAUSE FOR DISCIPLINE

(Delivered of Proffered for Delivery Misbranded Drugs)

45. Respondent Innovative Compounding's pharmacy permit is subject to disciplinary action pursuant to section 4301, subdivision (j), for unprofessional conduct, for violating statutes regulating controlled substances and dangerous drugs, in that Respondent delivered or proffered for delivery misbranded drugs, as defined by Heath and Safety Code section 111400, in violation of Health and safety Code section 111450, as set forth in paragraphs 34 through 38 and 40 through 42, above.

FOURTH CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law and Federal and State Laws and Regulations Governing Pharmacy)

46. Respondent Innovative Compounding's sterile compounding license is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.), and federal and state laws and regulations governing pharmacy, as follows: On or about April 13, 2015, Respondent had in its active dispensing inventory compounded drug products that were expired, as set forth in paragraph 39 above, in violation of Code section 4342.

FIFTH CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law and Federal and State Laws and Regulations Governing Pharmacy)

47. Respondent Masoud Rashidi's pharmacist license is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.), and federal and state laws and regulations governing pharmacy, as follows:

a. On and between September 13, 2014 and April 13, 2015, Respondent introduced or delivered for introduction into interstate commerce the new drug, domperidone, by compounding

and dispensing the drug to patients, as set forth in paragraph 42 above, when, in fact, there was no IND for domperidone approved by the FDA, in violation of 21 U.S.C. section 355, subdivision (a).

b. On and between September 13, 2014 and April 13, 2015, Respondent sold, delivered, or gave away the new drug dromperidone by dispensing the drug to patients, as set forth in paragraph 42 above, when, in fact, there was no IND for domperidone approved by the FDA, in violation of Health and Safety Code section 111550.

c. On or about April 13, 2015, Respondent, as pharmacist-in-charge of Innovative Compounding Pharmacy, had in the pharmacy's active dispensing inventory compounded drug products that were expired, as set forth in paragraph 39 above, in violation of Code section 4342.

d. Respondent, as pharmacist-in-charge of Innovative Compounding Pharmacy, failed to list on the logged formula worksheets for Lot Nos. 04082015@31 (domperidone 20 mg capsules), 03132015@26 (domperidone 10 mg capsules), 03192015@5 (domperidone 10 mg/ml suspension), 03262015@17 (domperidone 40 mg capsules), and 12222014@20 (domperidone 20 mg capsules) the manufacturer of each drug component, in violation of Regulation 1735.3, subdivision (a)(6).

SIXTH CAUSE FOR DISCIPLINE

(Sold Misbranded Drugs)

48. Respondent Masoud Rashidi's pharmacist license is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (j), for violating statutes regulating controlled substances and dangerous drugs, in that Respondent, as pharmacist-in-charge of Innovative Compounding Pharmacy, sold misbranded drugs, as defined by Health and Safety Code section 111400 and United States Code, title 21, section 352(f), in violation of Health and Safety Code section 111440, as set forth in paragraphs 34 through 38 and 40 through 42, above.

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SEVENTH CAUSE FOR DISCIPLINE

(Delivered of Proffered for Delivery Misbranded Drugs)

49. Respondent Masoud Rashidi's pharmacist license is subject to disciplinary action pursuant to section 4301, subdivision (j), for unprofessional conduct, for violating statutes regulating controlled substances and dangerous drugs, in that Respondent, as pharmacist-in-charge of Innovative Compounding Pharmacy, delivered or proffered for delivery misbranded drugs, as defined by Heath and Safety Code section 111400, in violation of Health and safety Code section 111450, as set forth in paragraphs 34 through 38 and 40 through 42, above.

EIGHTH CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law and

Federal and State Laws Governing Pharmacy)

50. Respondent Anna Rashidi's pharmacist license is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.), and federal and state laws governing pharmacy, as follows:

a. On and between September 13, 2014 and April 13, 2015, Respondent introduced or delivered for introduction into interstate commerce the new drug domperidone by compounding and dispensing the drug to patients, as set forth in paragraph 42 above, when, in fact, there was no IND for domperidone approved by the FDA, in violation of 21 U.S.C. section 355, subdivision (a).

b. On and between September 13, 2014 and April 13, 2015, Respondent sold, delivered, or gave away the new drug dromperidone by dispensing the drug to patients, as set forth in paragraph 42 above, when, in fact, there was no IND for domperidone approved by the FDA, in violation of Health and Safety Code section 111550.

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NINTH CAUSE FOR DISCIPLINE

(Sold Misbranded Drugs)

51. Respondent Anna Rashidi's pharmacist license is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (j), for violating statutes regulating controlled substances and dangerous drugs, in that Respondent sold misbranded drugs, as defined by Health and Safety Code section 111400 and United States Code, title 21, section 352(f), in violation of Health and Safety Code section 111440, as set forth in paragraphs 34 through 38 and 40 through 42, above.

TENTH CAUSE FOR DISCIPLINE

(Delivered of Proffered for Delivery Misbranded Drugs)

52. Respondent Anna Rashidi's pharmacist license is subject to disciplinary action pursuant to section 4301, subdivision (j), for unprofessional conduct, for violating statutes regulating controlled substances and dangerous drugs, in that Respondent delivered or proffered for delivery misbranded drugs, as defined by Heath and Safety Code section 111400, in violation of Health and safety Code section 111450, as set forth in paragraphs 34 through 38 and 40 through 42, above.

FACTUAL ALLEGATIONS

(Violations of the Pharmacy Law Pertaining to Sterile Injectable Compounding)

53. On and between April 13, 2015 and April 17, 2015, the Food and Drug Administration ("FDA") inspected Innovative Compounding Pharmacy. On or about April 17, 2015, the FDA issued a Form 483 Inspection Report to the pharmacy listing a number of observations made by FDA representatives during the inspection. The FDA found that "[e]ach batch of drug product purporting to be sterile is not laboratory tested to determine conformance to such requirements", and that sterility and endotoxin testing is not consistently performed on compounded sterile products, including testosterone cypionate 200 mg/ml injectable solution and bi-mix papaverine/phentolamine 30 mg/2 mg/ml injectable solution.

54. On or about June 11, 2015, a Board Inspector contacted the pharmacy and spoke with Respondent Masoud Rashidi ("PIC Rashidi"). The inspector requested the pharmacy's

compounding logs along with testing information from December 1, 2014 to June 11, 2015. On or about July 3, 2015, the Board received compounding logs together with testing results from PIC Rashidi.

55. The inspector found based on the above records that the pharmacy dispensed batch-produced compounds without completing the appropriate sterility and endotoxin tests and that compounds made without the appropriate tests were used to compound individual patient-specific compounds. The inspector also found that the pharmacy used components in multiple formulations which were past the indicated beyond use date (expiration date), and would label the compounds with a beyond use date greater than the shortest beyond use date of some of the components used.

ELEVENTH CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law and State Laws and Regulations Governing Pharmacy)

56. Respondent Innovative Compounding's pharmacy permit and sterile compounding license are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.) and state laws and regulations governing pharmacy, as follows:

a. On and between December 1, 2014 and June 1, 2015, Respondent Innovative Compounding's pharmacist-in-charge, Respondent Masoud Rashidi, failed to test batch-produced sterile injectable drug products for sterility and pyrogens, specifically, papaverine/phentolamine (bi-mix) injectable solution 30 mg/5 mg/ml (on three occasions between December 2, 2014 and June 1, 2015), papaverine/phentolamine (bi-mix) injectable solution 30 mg/2 mg/ml (on six occasions between December 10, 2014 and May 14, 2015), papaverine/phentolamine (bi-mix) injectable solution 30 mg/1 mg/ml (on three occasions between December 30, 2014 and May 21, 2015), papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/1 mg/30 mcg/ml (on December 1, 2014), and testosterone cypionate injectable solution 200 mg/ml (on seven

occasions between March 30, 2015 and June 1, 2015), in violation of Regulation 1751.7, subdivision (c).

b. On and between December 5, 2014 and June 8 , 2015, Respondent Innovative Compounding's pharmacist-in-charge, Respondent Masoud Rashidi, used compounds which were made without appropriate sterility and endotoxin tests to compound individual patient-specific compounds, in violation of Regulation 1751.7, subdivision (c), specifically:

1. Papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/1 mg/10 mcg/ml, using the untested compound bi-mix 30 mg/1 mg/ml, Lot #12302014@23, on 11 occasions between January 2, 2015 and February 9, 2015; the untested compound bi-mix 30 mg/1 mg/ml, Lot #05212015@4, on seven occasions between May 18, 2015 and June 5, 2015, and the untested compound bi-mix 30 mg/1 mg/ml, Lot #05072015@9, on three occasions between May 5, 2015 and May 11, 2015;

2. Papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/5 mg/10 mcg/ml, using the untested compound bi-mix 30 mg/5 mg/ml, Lot #12022014@8, on December 5, 2014 and December 12, 2014; the untested compound bi-mix 30 mg/5 mg/ml, Lot #05182015@4, on May 15, 18, and 19, 2015; and the untested compound bi-mix 30 mg/5 mg/ml, Lot #06012015@26, on June 5 and 8, 2015; and

3. Papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/5 mg/20 mcg/ml, using the untested compound bi-mix 30 mg/5 mg/ml, Lot #12022014@8, on December 5 and 12, 2014.

c. On and between December 1, 2014 and June 11, 2015, Respondent Innovative Compounding's pharmacist-in-charge, Respondent Masoud Rashidi, and pharmacist Anna Rashidi, documented beyond use dates on finished compounds that exceeded the shortest beyond use date of the components in the compounded drug product; i.e., wrongfully extended beyond use dates that were recorded for the following compounds, in violation of Regulation 1735.2, subdivision (h):

1. Respondent Masoud Rashidi recorded beyond use dates for papaverine/phentolamine (bi-mix) injectable solution 30 mg/5 mg/ml, compounded on December

2, 2014, January 12, 2015, and February 12, 2015, that exceeded the shortest beyond use date of the components used in the compounded drug product, specifically, the ingredient edetate disodium aliquot 1 mg/ml.

2. Respondent Masoud Rashidi recorded beyond use dates for papaverine/phentolamine (bi-mix) injectable solution 30 mg/1 mg/ml, compounded on January 20, 2015 (two different lots), April 28, 2015, and June 9, 2015, that exceeded the shortest beyond use date of the components used in the compounded drug product, specifically, the ingredients edetate disodium aliquot 1 mg/ml and benzyl alcohol NF.

3. Respondent Masoud Rashidi recorded a beyond use date for papaverine/phentolamine (bi-mix) injectable solution 30 mg/7 mg/ml, compounded on March 27, 2105, that exceeded the shortest beyond use date of the components used in the compounded drug product, specifically, the ingredient edetate disodium aliquot 1 mg/ml.

4. Respondent Masoud Rashidi recorded beyond use dates for papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/1 mg/10 mcg/ml, compounded on 29 occasions between December 4, 2014 and June 2, 2015, that exceeded the shortest beyond use date of the components used in the compounded drug product, specifically, the ingredient bi-mix 30 mg/1 mg/ml.

5. Respondent Anna Rashidi recorded beyond use dates for papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/1 mg/10 mcg/ml, compounded on May 11, 2015, May 26, 2105, June 5, 2015, and June 10, 2015, that exceeded the shortest beyond use date of the components used in the compounded drug product, specifically, the ingredient bi-mix 30 mg/1 mg/ml.

6. Respondent Masoud Rashidi recorded beyond use dates for papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/5 mg/10 mcg/ml, compounded on 24 occasions between December 5, 2014 and June 8, 2015, that exceeded the shortest beyond use date of the components used in the compounded drug product, specifically, the ingredient bi-mix 30 mg/5 mg/ml.

7. Respondent Masoud Rashidi recorded beyond use dates for

papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/5 mg/20 mcg/ml, compounded on eight occasions between December 1, 2014 and May 14, 2015, that exceeded the shortest beyond use date of the components used in the compounded drug product, specifically, the ingredient bi-mix 30 mg/5 mg/ml.

d. On and between December 1, 2014 and June 11, 2015, Respondent Innovative Compounding's pharmacist-in-charge, Respondent Masoud Rashidi, and pharmacist Anna Rashidi, documented beyond use dates on finished compounds that exceeded the shortest beyond use dates of the components in the compounded drug product, as set forth in subparagraph (c) above. As such, the beyond use dates on the finished compounds were false or misleading and the finished compounds were misbranded.

TWELFTH CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law and State Laws and Regulations Governing Pharmacy)

57. Respondent Masoud Rashidi's pharmacist license is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (o), in that Respondent violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.) and state laws and regulations governing pharmacy, as follows:

a. On and between December 1, 2014 and June 1, 2015, Respondent failed to test batch-produced sterile injectable drug products for sterility and pyrogens, specifically, papaverine/phentolamine (bi-mix) injectable solution 30 mg/5 mg/ml (on three occasions between December 2, 2014 and June 1, 2015), papaverine/phentolamine (bi-mix) injectable solution 30 mg/2 mg/ml (on six occasions between December 10, 2014 and May 14, 2015), papaverine/phentolamine (bi-mix) injectable solution 30 mg/1 mg/ml (on three occasions between December 30, 2014 and May 21, 2015), papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/1 mg/30 mcg/ml (on December 1, 2014), and testosterone cypionate injectable solution 200 mg/ml (on seven occasions between March 30, 2015 and June 1, 2015), in violation of Regulation 1751.7, subdivision (c).

b. On and between December 5, 2014 and June 8 , 2015, Respondent used compounds which were made without appropriate sterility and endotoxin tests to compound individual patient-specific compounds, in violation of Regulation 1751.7, subdivision (c), specifically:

1. Papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/1 mg/10 mcg/ml, using the untested compound bi-mix 30 mg/1 mg/ml, Lot #12302014@23, on 11 occasions between January 2, 2015 and February 9, 2015; the untested compound bi-mix 30 mg/1 mg/ml, Lot #05212015@4, on seven occasions between May 18, 2015 and June 5, 2015, and the untested compound bi-mix 30 mg/1 mg/ml, Lot #05072015@9, on three occasions between May 5, 2015 and May 11, 2015;

2. Papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/5 mg/10 mcg/ml, using the untested compound bi-mix 30 mg/5 mg/ml, Lot #12022014@8, on December 5, 2014 and December 12, 2014; the untested compound bi-mix 30 mg/5 mg/ml, Lot #05182015@4, on May 15, 18, and 19, 2015; and the untested compound bi-mix 30 mg/5 mg/ml, Lot #06012015@26, on June 5 and 8, 2015; and

3. Papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/5 mg/20 mcg/ml, using the untested compound bi-mix 30 mg/5 mg/ml, Lot #12022014@8, on December 5 and 12, 2014.

c. On and between December 1, 2014 and June 11, 2015, Respondent documented beyond use dates on finished compounds that exceeded the shortest beyond use date of the components in the compounded drug product; i.e., wrongfully extended beyond use dates that were recorded for the following compounds, in violation of Regulation 1735.2, subdivision (h):

1. Respondent recorded beyond use dates for papaverine/phentolamine (bi-mix) injectable solution 30 mg/5 mg/ml, compounded on December 2, 2014, January 12, 2015, and February 12, 2015, that exceeded the shortest beyond use date of the components used in the compounded drug product, specifically, the ingredient edetate disodium aliquot 1 mg/ml.

2. Respondent recorded beyond use dates for papaverine/phentolamine (bi-mix) injectable solution 30 mg/1 mg/ml, compounded on January 20, 2015 (two different lots), April 28, 2015, and June 9, 2015, that exceeded the shortest beyond use date of the components used in

the compounded drug product, specifically, the ingredients edetate disodium aliquot 1 mg/ml and benzyl alcohol NF.

3. Respondent recorded a beyond use date for papaverine/phentolamine (bi-mix) injectable solution 30 mg/7 mg/ml, compounded on March 27, 2105, that exceeded the shortest beyond use date of the components used in the compounded drug product, specifically, the ingredient edetate disodium aliquot 1 mg/ml.

4. Respondent recorded beyond use dates for papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/1 mg/10 mcg/ml, compounded on 29 occasions between December 4, 2014 and June 2, 2015, that exceeded the shortest beyond use date of the components used in the compounded drug product, specifically, the ingredient bi-mix 30 mg/1 mg/ml.

5. Respondent recorded beyond use dates for papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/5 mg/10 mcg/ml, compounded on 24 occasions between December 5, 2014 and June 8, 2015, that exceeded the shortest beyond use date of the components used in the compounded drug product, specifically, the ingredient bi-mix 30 mg/5 mg/ml.

6. Respondent Masoud Rashidi recorded beyond use dates for papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/5 mg/20 mcg/ml, compounded on eight occasions between December 1, 2014 and May 14, 2015, that exceeded the shortest beyond use date of the components used in the compounded drug product, specifically, the ingredient bi-mix 30 mg/5 mg/ml.

d. On and between December 1, 2014 and June 11, 2015, Respondent documented beyond use dates on finished compounds that exceeded the shortest beyond use dates of the components in the compounded drug product, as set forth in subparagraph (c) above. As such, the beyond use dates on the finished compounds were false or misleading and the finished compounds were misbranded.

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THIRTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

58. Respondent Masoud Rashidi's pharmacist license is subject to disciplinary action for unprofessional conduct pursuant to Code sections 4301 and 4306.5, subdivision (a), in that on and between December 1, 2014 and June 11, 2015, Respondent failed to appropriately exercise his education, training, or experience as a pharmacist, as set forth in paragraphs 57 (a) and (b) above.

FOURTEENTH CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law and State Laws and Regulations Governing Pharmacy)

59. Respondent Anna Rashidi's pharmacist license is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (o), in that Respondent, while acting as vice president of Innovative Compounding Pharmacy, violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.) and state laws and regulations governing pharmacy, as follows:

a. On and between December 1, 2014 and June 1, 2015, Respondent Innovative Compounding's pharmacist-in-charge, Respondent Masoud Rashidi, failed to test batch-produced sterile injectable drug products for sterility and pyrogens, specifically, papaverine/phentolamine (bi-mix) injectable solution 30 mg/5 mg/ml (on three occasions between December 2, 2014 and June 1, 2015), papaverine/phentolamine (bi-mix) injectable solution 30 mg/2 mg/ml (on six occasions between December 10, 2014 and May 14, 2015), papaverine/phentolamine (bi-mix) injectable solution 30 mg/1 mg/ml (on three occasions between December 30, 2014 and May 21, 2015), papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/1 mg/30 mcg/ml (on December 1, 2014), and testosterone cypionate injectable solution 200 mg/ml (on seven occasions between March 30, 2015 and June 1, 2015), in violation of Regulation 1751.7, subdivision (c).

b. On and between December 5, 2014 and June 8 , 2015, Respondent Innovative Compounding's pharmacist-in-charge, Respondent Masoud Rashidi, used compounds which were

made without appropriate sterility and endotoxin tests to compound individual patient-specific compounds, in violation of Regulation 1751.7, subdivision (c), specifically:

1. Papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/1 mg/10 mcg/ml, using the untested compound bi-mix 30 mg/1 mg/ml, Lot #12302014@23, on 11 occasions between January 2, 2015 and February 9, 2015; the untested compound bi-mix 30 mg/1 mg/ml, Lot #05212015@4, on seven occasions between May 18, 2015 and June 5, 2015, and the untested compound bi-mix 30 mg/1 mg/ml, Lot #05072015@9, on three occasions between May 5, 2015 and May 11, 2015;

2. Papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/5 mg/10 mcg/ml, using the untested compound bi-mix 30 mg/5 mg/ml, Lot #12022014@8, on December 5, 2014 and December 12, 2014; the untested compound bi-mix 30 mg/5 mg/ml, Lot #05182015@4, on May 15, 18, and 19, 2015; and the untested compound bi-mix 30 mg/5 mg/ml, Lot #06012015@26, on June 5 and 8, 2015; and

3. Papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/5 mg/20 mcg/ml, using the untested compound bi-mix 30 mg/5 mg/ml, Lot #12022014@8, on December 5 and 12, 2014.

c. On and between May 11, 2015 and June 10, 2015, Respondent documented beyond use dates on a finished compound that exceeded the shortest beyond use date of the components in the compounded drug product; i.e., wrongfully extended beyond use dates that were recorded for the compound, in violation of Regulation 1735.2, subdivision (h). Specifically, Respondent recorded beyond use dates for papaverine/phentolamine/alprostadil (tri-mix) injectable solution 30 mg/1 mg/10 mcg/ml, compounded on May 11, 2015, May 26, 2105, June 5, 2015, and June 10, 2015, that exceeded the shortest beyond use date of the components used in the compounded drug product, specifically, the ingredient bi-mix 30 mg/1 mg/ml.

d. On and between May 11, 2015 and June 10, 2015, Respondent documented beyond use dates on a finished compound that exceeded the shortest beyond use dates of the components in the compounded drug product, as set forth in subparagraph (c) above. As such, the beyond use

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dates on the finished compounds were false or misleading and the finished compounds were misbranded.

MATTERS IN AGGRAVATION

60. To determine the degree of discipline to be assessed against Respondents Innovative Compounding, Masoud Rashidi, and Anna Rashidi, if any, Complainant alleges as follows:

a. On or about September 23, 2015, the Board issued Citation No. CI 2013 59993 against Respondent Innovative Compounding for violating Regulations 1707.3 and 1707.2, subdivision (c)(2) (duty to review drug therapy/duty to consult – precautions and relevant warnings including common severe side or adverse effects or interactions that may be encountered). On or about July 18, 2013 and August 24, 2013, while working at Innovative Compounding Pharmacy, pharmacists Anna Rashidi and Masoud Rashidi allegedly failed to properly review a patient's drug therapy and medication record, and then relay significant warning(s) of the prescribed drug to the patient and/or prescriber. The patient's profile documented a penicillin allergy and the issuance of a prescription to the patient for hydrochlorothiazide 25 mg. The drug's safety labeling addresses a risk factor for developing an idiosyncratic reaction resulting in acute angle-closure glaucoma in patients with a history of sulfonamide or penicillin allergy. Respondents Innovative Compounding and pharmacists Masoud Rashidi and Anna Rashidi also allegedly furnished the hydrochlorothiazide prescription to the patient without precautions or relevant warnings, such as the severe side or adverse effects that may be encountered.

b. On or about September 23, 2015, the Board issued Citation and Fine No. CI 2015 67104 against Respondent Masoud Rashidi for violating Regulations 1707.3 and 1707.2, subdivision (c)(2) (duty to review drug therapy/duty to consult – precautions and relevant warnings including common severe side or adverse effects or interactions that may be encountered). The Board ordered Respondent to pay a fine of $500 by October 23, 2015. Respondent has complied with the citation. The factual allegations pertaining to the citation are set forth in subparagraph (a) above.

c. On or about September 23, 2015, the Board issued Citation and Fine No. CI 2015

67106 against Respondent Anna Rashidi for violating Regulations 1707.3 and 1707.2, subdivision (c)(2) (duty to review drug therapy/duty to consult – precautions and relevant warnings including common severe side or adverse effects or interactions that may be encountered). The Board ordered Respondent to pay a fine of $500 by October 23, 2015. Respondent has failed to comply with the citation. The factual allegations pertaining to the citation are set forth in subparagraph (a) above.

OTHER MATTERS

61. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 48417 issued to Innovative Compounding, Inc., doing business as Innovative Compounding Pharmacy, Innovative Compounding Inc. shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 48417 is placed on probation or until Pharmacy Permit Number PHY 48417 is reinstated if it is revoked.

62. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 48417 issued to Innovative Compounding, Inc., doing business as Innovative Compounding Pharmacy, while Masoud Rashidi and/or Anna Rashidi have been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Masoud Rashidi and Anna Rashidi shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 48417 is placed on probation or until Pharmacy Permit Number PHY 48417 is reinstated if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this Accusation, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacy Permit Number PHY 48417, issued to Innovative Compounding, Inc., doing business as Innovative Compounding Pharmacy;

2. Revoking or suspending Sterile Compounding License Number LSC 99600, issued to Innovative Compounding, Inc., doing business as Innovative Compounding Pharmacy;

3. Revoking or suspending Pharmacist License Number RPH 56324, issued to Masoud Rashidi;

4. Revoking or suspending Pharmacist License Number RPH 56323, issued to Anna Rashidi;

5. Prohibiting Innovative Compounding Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 48417 is placed on probation or until Pharmacy Permit Number PHY 48417 is reinstated if Pharmacy Permit Number 48417, issued to Innovative Compounding, Inc., doing business as Innovative Compounding Pharmacy, is revoked;

6. Prohibiting Masoud Rashidi from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 48417 is placed on probation or until Pharmacy Permit Number PHY 48417 is reinstated if Pharmacy Permit Number 48417, issued to Innovative Compounding, Inc., doing business as Innovative Compounding Pharmacy, is revoked;

7. Prohibiting Anna Rashidi from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 48417 is placed on probation or until Pharmacy Permit Number PHY 48417 is reinstated if Pharmacy Permit Number 48417, issued to Innovative Compounding, Inc., doing business as Innovative Compounding Pharmacy, is revoked;

8. Ordering Innovative Compounding, Inc., doing business as Innovative Compounding Pharmacy, Masoud Rashidi, and Anna Rashidi 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

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

DATED: 8/16/16

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

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