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 OAH No. 2017020577 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RESPONDENT INNOVATIVE COMPOUNDING INC., dba INNOVATIVE COMPOUNDING PHARMACY ONLY**

DECISION AND ORDER

The attached Stipulated Settlement of License and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on August 10, 2017.

It is so ORDERED on July 11, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

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IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy ("Board"). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by Malissa N. Siemantel, Deputy Attorney General.

2. Respondent Innovative Compounding Pharmacy, Inc., doing business as Innovative Compounding Pharmacy, ("Respondent Innovative Compounding") is represented in this proceeding by attorney Ivan Petrzelka, whose address is: 2855 Michelle Drive, Suite 180, Irvine, CA 92606-1027.

3. On or about February 7, 2007, the Board issued Pharmacy Permit Number PHY 48417 to Respondent Innovative Compounding, Inc., 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, 2018, unless renewed.

1. 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, 2018, unless renewed.

2. 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, 2018, unless renewed.

3. 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, 2018, unless renewed.

JURISDICTION

4. Accusation No. 5663 was filed before the Board, and is currently pending against Respondents. The Accusation and all other statutorily required documents were properly served on Respondents on August 30, 2016. Respondents timely filed their Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 5663 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent Innovative Compounding has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 5663. Respondent Innovative Compounding has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

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

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

CULPABILITY

9. Respondent Innovative Compounding understands and agrees that the charges and allegations in Accusation No. 5663, if proven at hearing, constitute cause for imposing discipline upon its Pharmacy Permit and Sterile Compounding License.

10. For the purpose of resolving Accusation No. 5663 without the expense and uncertainty of further proceedings, Respondent Innovative Compounding agrees that, at hearing,

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Complainant could establish a factual basis for the charges against it in Accusation No. 5663, and that Respondent Innovative Compounding hereby gives up its right to contest those charges.

11. Respondent Innovative Compounding agrees that in any future disciplinary proceeding before the Board the allegations set forth in Accusation No. 5663 shall be deemed admitted.

12. Respondent Innovative Compounding agrees that its Pharmacy Permit and Sterile Compounding License are subject to discipline and it agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent Innovative Compounding understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent Innovative Compounding or its counsel. By signing the stipulation, Respondent Innovative Compounding understands and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

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

15. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 48417 and Sterile Compounding License No. LSC 99600 issued to Respondent Innovative Compounding, Inc., doing business as Innovative Compounding Pharmacy, are revoked. However, the revocations are stayed and Respondent Innovative Compounding's permit and license are placed on probation for five (5) years on the following terms and conditions.

1. **Obey All Laws**

Respondent Innovative Compounding shall obey all state and federal laws and regulations.

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

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves Respondent Innovative Compounding's pharmacy permit, sterile compounding license, or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

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

2. **Report to the Board**

Respondent Innovative Compounding shall report to the Board quarterly, on a schedule as directed by the Board or its designee. The report shall be made either in person or in writing, as

directed. Among other requirements, Respondent Innovative Compounding shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board.

3. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent Innovative Compounding shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff**

Respondent Innovative Compounding shall cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent Innovative Compounding's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondent Innovative Compounding shall pay to the Board its costs of investigation and prosecution in the amount of $12,000. Respondent Innovative Compounding shall be jointly and severally liable with Respondent Masoud Rashidi and Respondent Anna Rashidi for payment of those costs. Respondent Innovative Compounding shall be permitted to make payments on a plan approved by the Board or its designee, with payments to be completed no later than six (6) months prior to the end of the probation term. There shall be no deviation from this schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be

considered a violation of probation.

The filing of bankruptcy by Respondent Innovative Compounding shall not relieve Respondent Innovative Compounding of its responsibility to reimburse the Board its costs of investigation and prosecution.

6. **Probation Monitoring Costs**

Respondent Innovative Compounding shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. **Status of License**

Respondent Innovative Compounding shall, at all times while on probation, maintain current licensure with the Board. If Respondent Innovative Compounding submits an application to the Board, and the application is approved, for a change of location, change of permit or change of ownership, the Board shall retain continuing jurisdiction over the license, and Respondent Innovative Compounding shall remain on probation as determined by the Board. Failure to maintain current licensure shall be considered a violation of probation.

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

8. **License Surrender While on Probation**

Following the effective date of this decision, should Respondent Innovative Compounding discontinue business, Respondent Innovative Compounding may tender the premises license to the Board for surrender. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent Innovative Compounding will no longer be subject to the terms and conditions of probation.

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Upon acceptance of the surrender, Respondent Innovative Compounding shall relinquish the premises wall and renewal license to the Board within ten (10) days of notification by the Board that the surrender is accepted. Respondent Innovative Compounding shall further submit a completed Discontinuance of Business form according to Board guidelines and shall notify the Board of the records inventory transfer.

Respondent Innovative Compounding shall also, by the effective date of the decision accepting the surrender, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent Innovative Compounding shall provide a copy of the written notice to the Board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

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

Respondent Innovative Compounding further stipulates that it shall reimburse the Board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. **Notice to Employees**

Respondent Innovative Compounding shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent Innovative Compounding shall ensure that any employees hired or used after the effective date of this

decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, Respondent Innovative Compounding shall submit written notification to the Board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the Board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. **Owners and Officers: Knowledge of the Law**

Respondent Innovative Compounding shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in Respondent Innovative Compounding or Respondent Innovative Compounding's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. **Posted Notice of Probation**

Respondent Innovative Compounding shall prominently post a probation notice provided by the Board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent Innovative Compounding shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. **Violation of Probation**

If Respondent Innovative Compounding has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent Innovative

Compounding's license, and probation shall be automatically extended until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If Respondent Innovative Compounding violates probation in any respect, the Board, after giving Respondent Innovative Compounding notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against Respondent Innovative Compounding during probation, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

13. **Completion of Probation**

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent Innovative Compounding's license will be fully restored.

14. **Consultant Pharmacist Review**

During the period of probation, Respondent Innovative Compounding shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by Respondent Innovative Compounding with state and federal laws and regulations governing the practice of pharmacy and for compliance by Respondent Innovative Compounding with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by, and not on probation with, the Board and whose name shall be submitted to the Board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. The consultant shall report to the Board or its designee any non-compliance with state and federal laws and regulations governing the practice of pharmacy and non-compliance with the obligations of a pharmacist-in-charge within forty-eight (48) hours of discovery of the non-compliance. During the period of probation, the Board or its designee retains the discretion to reduce the frequency of the consultant's review of Respondent Innovative

Compounding's operations. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

ACCEPTANCE

I, Masoud Rashidi, as president of Innovative Compounding, Inc., doing business as Innovative Compounding Pharmacy, have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Ivan Petrzelka. I, on behalf of Innovative Compounding, Inc., doing business as Innovative Compounding Pharmacy, understand the stipulation and the effect it will have on the Pharmacy Permit and Sterile Compounding License. I am authorized to enter into this Stipulated Settlement and Disciplinary Order on behalf of Innovative Compounding, Inc., doing business as Innovative Compounding Pharmacy. Innovative Compounding, Inc., doing business as Innovative Compounding Pharmacy, enters into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agrees to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 5/24/17

INNOVATIVE COMPOUNDING , INC., DBA
INNOVATIVE COMPOUNDING PHARMACY,
MASOUD RASHIDI, PRESIDENT
Respondent

I have read and fully discussed with Masoud Rashidi as an authorized representative of Innovative Compounding, Inc., doing business as Innovative Compounding Pharmacy, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: May 25, 2017

IVAN PETRZELKA
Attorney for Respondent

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ENDORSEMENT

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

Dated: 5/26/17

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
JANICE K. LACHMAN
Supervising Deputy Attorney General

MALISSA N. SIEMANTEL
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 5663

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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:
>
> (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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