In the Matter of the Accusation Against:

RIVER CITY PHARMACY INC.
5491 Carlson Dr.
Sacramento, CA 95819
Pharmacy Permit PHY 51249
Sterile Compounding Permit No. LSC 100527

MICHELLE DAWN HAVERLOCK,
1724 Van Damme Dr.
Davis, CA 95616
Pharmacist License No. RPH 50759

Respondents.

Complainant alleges:

PARTIES

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

2. On or about January 22, 2013, the Board of Pharmacy issued Pharmacy Permit (PHY) Number 51249 to Option Care Enterprises Inc., Walgreens Infusion Services Inc., Walgreen Co.
to do Business as River City Pharmacy Inc.; (Respondent River City Pharmacy). Michelle Dawn Haverlock was the Pharmacist-in Charge from January 22, 2013 to January 26, 2015. The Pharmacy Permit (PHY) was cancelled on January 6, 2015.

3. On or about January 22, 2013, the Board of Pharmacy issued Original Sterile Compounding Permit Number (LSC) Number 100527 issued to Option Care Enterprises Inc., Walgreens Infusion Services Inc., Walgreen Co. to do business as River City Pharmacy Inc.; (Respondent River City Pharmacy). The Original Sterile Compounding Permit Pharmacy Permit was cancelled on January 6, 2015.

4. On or about March 30, 1999, the Board of Pharmacy issued Pharmacist License No. RPH 50759 to Michelle Haverlock (Respondent Haverlock). The Pharmacist license will expire September 30, 2018, unless renewed.

JURISDICTION

5. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

6. Section 4300 of the Code 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.

7. Section 4300.1 of the Code provides:

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.

8. Section 4301 of the Code states in pertinent part:

"The board shall take action against any holder of a license who is guilty of
unprofessional conduct or whose license has been issued by mistake. Unprofessional
conduct shall include, but is not limited to, any of the following:

..."(f) The commission of any act involving moral turpitude, dishonesty, fraud,
deceit, or corruption, whether the act is committed in the course of relations as a
licensee or otherwise, and whether the act is a felony or misdemeanor or not.

..."(j) The violation of any of the statutes of this state, of any other state, or of the
United States regulating controlled substances and dangerous drugs.

..."(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.

9. Section 4342 of the Code states in pertinent part:

(a) The board may institute any action or actions as may be provided by law and that,
in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and
drugs that do not conform to the standard and tests as to quality and strength,
provided in the latest edition of the United States Pharmacopeia 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

10. Health and Safety Code Section 111295 provides:

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

11. Health and Safety Code Section 111255 provides:

Any drug or device is adulterated if it has been produced, prepared,
packed, or held under conditions whereby it may have been contaminated with filth,
when it may have been rendered injurious to health.

REGULATIONS

12. Title 16, California Code of Regulation section 1714 provides in pertinent part:

(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures,
and equipment so that drugs are safely and properly prepared, maintained, secured
and distributed. The pharmacy shall be of sufficient size and unobstructed area to
accommodate the safe practice of pharmacy.

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and
orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and
insects, and properly lighted. The pharmacy shall be equipped with a sink with hot
and cold running water for pharmaceutical purposes....
13. California Code of Regulations Section 1751 provides in pertinent part:

"(a) Any pharmacy engaged in compounding sterile drug preparations shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.

(b) Any pharmacy compounding sterile injectable drug products shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:

(1) Clean Room and Work Station Requirements shall be in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.

(2) Walls ceilings and floors shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.

(3) Be ventilated in a manner in accordance with section 505.12 of Title 24, Chapter 5 of the California Code of Regulations.

(4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar flow hoods and clean room requirements in accordance with standards adopted by the United States General Services Administration, Certification records must be retained for at least 3 years.

(5) The Pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment....

14. California Code of Regulation section 1751.4 provides in pertinent part:

(a) No sterile injectable product shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy’s written policies and procedures for the safe compounding of sterile injectable drug products.

(b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.

(c) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.

(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.....

COST RECOVERY

15. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
enforcement of the case, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

BACKGROUND

16. On or about December 8, 2014, the Board conducted an inspection of the River City Pharmacy. The inspection revealed four rooms used for compounding which did not meet the minimum requirements for compounding. The rooms were unsanitary. During the inspection, cleaning logs were requested. The employees of River City Pharmacy informed investigators that the cleaning logs were initialed even when the area had not been cleaned.

FIRST CAUSE FOR DISCIPLINE
(Failure to Provide a Compounding Area Which was Easily Cleanable)

17. Respondents River City Pharmacy and Haverlock are subject to disciplinary action under Business and Professions Code section 4301(j) and (o) in conjunction with Title 16, California Code of Regulations section 1751 in that they failed to provide a designated area for sterile compounding which was compliant with the requirements of non-porous and easily cleanable surfaces.

SECOND CAUSE FOR DISCIPLINE
(Maintenance of Pharmacy Fixtures and Equipment)

18. Respondents River City Pharmacy and Haverlock are subject to disciplinary action under Business and Professions Code section 4301(j) and (o) in conjunction with Title 16, California Code of Regulations section 1714 in that they failed to provide clean and orderly equipment as follows: a. the equipment was not free from insects; and, b. the storage area contained an unknown, yellow sticky substance.

THIRD CAUSE FOR DISCIPLINE
(Compounding in an Area that Failed to Comply with Policies)

19. Respondents River City Pharmacy and Haverlock are subject to disciplinary action under Business and Professions Code section 4301(j) and (o) in conjunction with Title 16, California Code of Regulations section 1751.4(a) in that the environment used for compounding did not meet the requirements of their own policies for safe compounding of sterile injectable
products. During the inspection Respondent Haverlock provided the inspectors a copy of River City Policies in place for safe compounding. The inspection revealed that the Pharmacy did not comply with their own policies as follows:

a. On December 8, 2014, the anteroom used for garbing was dirty.

b. The Storage room for dangerous injectable drugs contained a yellow sticky substance in which insects were enmeshed. The light fixtures in said room had insects and the base boards had been ripped out leaving exposed wood.

c. The Compounding area had a dirty fan that was pointed at the hood used for sterile compounding which increased the risk of interruption of airflow and increased the risk of contamination of the final product.

FOURTH CAUSE FOR DISCIPLINE

( Failure to Clean Compounding Area)

20. Respondents River City Pharmacy and Haverlock are subject to disciplinary action under section 4301 (f), (j), and (o) in conjunction with title 16, California Code of Regulations section 1751.1 subd. (b) (4) and 1751.4 subd. (d) in that between September 1, 2014, and December 8, 2014, cleaning logs were kept in which it was reported that the compounding area was cleaned, but employees, as well as a visual inspection by the Board’s inspectors confirmed that the area for compounding was not cleaned as reported.

PRAYER

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

1. Revoking or suspending Pharmacy Permit PHY 51249, issued to River City Pharmacy Inc.;

2. Revoking or Original Sterile Compounding Permit Number LSC 100527 issued to River City Pharmacy Inc.;

3. Revoking or suspending Pharmacist License No. Number RPH 50759, issued to Michelle Dawn Haverlock;
4. Ordering River City Pharmacy and Michelle Dawn Haverlock to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 9/28/18

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant
In the Matter of the Accusation Against:  

RIVER CITY PHARMACY INC.  
5491 Carlson Dr.  
Sacramento, CA 95819  
Pharmacy Permit PHY 51249  
Sterile Compounding Permit No. LSC 100527  

MICHELLE DAWN HAVERLOCK,  
1724 Van Damme Dr.  
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Pharmacist License No. RPH 50759  

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3. On or about January 22, 2013, the Board of Pharmacy issued Original Sterile Compounding Permit Number (LSC) Number 100527 issued to River City Pharmacy Inc.; (Respondent River City Pharmacy. The Original Sterile Compounding Permit Pharmacy Permit was cancelled on January 6, 2015.

4. On or about March 30, 1999, the Board of Pharmacy issued Pharmacist License No. RPH 50759 to Michelle Haverlock (Respondent Haverlock). The Pharmacist license will expire September 30, 2018, unless renewed.

JURISDICTION

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...“(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.

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(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

10. Health and Safety Code Section 111295 provides:

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

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REGULATIONS

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(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes....

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applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.

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(2) Walls ceilings and floors shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.

(3) Be ventilated in a manner in accordance with section 505.12 of Title 24, Chapter 5 of the California Code of Regulations.

(4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar flow hoods and clean room requirements in accordance with standards adopted by the United States General Services Administration, Certification records must be retained for at least 3 years.

(5) The Pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment....

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(b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.

(c) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.

(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.....

COST RECOVERY

15. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licentiate to comply subjecting the license to not being
renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

BACKGROUND

16. On or about December 8, 2014, the Board conducted an inspection of the River City Pharmacy. The inspection revealed four rooms used for compounding which did not meet the minimum requirements for compounding. The rooms were unsanitary. During the inspection, cleaning logs were requested. The employees of River City Pharmacy informed investigators that the cleaning logs were initialed even when the area had not been cleaned.

FIRST CAUSE FOR DISCIPLINE
(Failure to Provide a Compounding Area Which was Easily Cleanable)

17. Respondents River City Pharmacy and Haverlock are subject to disciplinary action under Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulations section 1751 in that they failed to provide a designated area for sterile compounding which was compliant with the requirements of non-porous and easily cleanable surfaces.

SECOND CAUSE FOR DISCIPLINE
(Maintenance of Pharmacy Fixtures and Equipment)

18. Respondents River City Pharmacy and Haverlock are subject to disciplinary action under Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulations section 1714 in that they failed to provide clean and orderly equipment as follows: a. the equipment was not free from insects; and, b. the storage area contained an unknown, yellow sticky substance.

THIRD CAUSE FOR DISCIPLINE
(Compounding in an Area that Failed to Comply with Policies)

19. Respondents River City Pharmacy and Haverlock are subject to disciplinary action under Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulations section 1751.4 (a) in that the environment used for compounding did not meet the requirements of their own policies for safe compounding of sterile injectable products. During the inspection Respondent Haverlock provided the inspectors a copy of River
City Policies in place for safe compounding. The inspection revealed that the Pharmacy did not comply with their own policies as follows:

a. On December 8, 2016, the anteroom used for garbing was dirty.

b. The Storage room for dangerous injectable drugs contained a yellow sticky substance in which insects were enmeshed. The light fixtures in said room had insects and the base boards had been ripped out leaving exposed wood.

c. The Compounding area had a dirty fan that was pointed at the hood used for sterile compounding which increased the risk of interruption of airflow and increased the risk of contamination of the final product.

FOURTH CAUSE FOR DISCIPLINE
(Failure to Clean Compounding Area)

20. Respondents River City Pharmacy and Haverlock are subject to disciplinary action under section 4301 (f), (j), and (o) in conjunction with title 16, California Code of Regulations section 1751.1 subd. (b) (4) and 1751.4 subd. (d) in that between September 1, 2014, and December 8, 2014, cleaning logs were kept in which it was reported that the compounding area was cleaned, but employees, as well as a visual inspection by the Board’s inspectors confirmed that the area for compounding was not cleaned as reported.

PRAYER

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

1. Revoking or suspending Pharmacy Permit PHY 51249, issued to River City Pharmacy Inc.;

2. Revoking or Original Sterile Compounding Permit Number LSC 100527 issued to River City Pharmacy Inc.;

3. Revoking or suspending Pharmacist License No. Number RPH 507599, issued to Michelle Dawn Haverlock;
4. Ordering River City Pharmacy and Michelle Dawn Haverlock to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 12/12/17

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

SA2016103064/12878349.doc
Complainant alleges:

PARTIES

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

2. On or about January 22, 2013, the Board of Pharmacy issued Pharmacy Permit (PHY) Number 51249 to River City Pharmacy Inc.; Michelle Dawn Haverlock, PIC (Respondent River City Pharmacy). The Pharmacy Permit (PHY) expired on January 6, 2015, and has not been renewed.
3. On or about March 30, 1999, the Board of Pharmacy issued Pharmacist License No. RPH 50759 to Michelle Haverlock (Respondent Haverlock). The Pharmacist license will expire September 30, 2018, unless renewed.

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REGULATIONS

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(3) Be ventilated in a manner in accordance with section 505.12 of Title 24, Chapter 5 of the California Code of Regulations.

(4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar flow hoods and clean room requirements in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.

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COST RECOVERY

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FIRST CAUSE FOR DISCIPLINE  
(FAILURE TO PROVIDE A COMPOUNDING AREA WHICH WAS EASILY CLEANABLE)

16. Respondents River City Pharmacy and Halverlock are subject to disciplinary action under Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulations section 1751 in that they failed to provide a designated area for sterile compounding which was compliant with the requirements of non-porous and easily cleanable surfaces.

SECOND CAUSE FOR DISCIPLINE  
(MAINTENANCE OF PHARMACY FIXTURES AND EQUIPMENT)

17. Respondents River City Pharmacy and Halverlock are subject to disciplinary action under Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulations section 1714 in that they failed to provide clean and orderly equipment as follows: a. the equipment was not free from insects; and, b. the storage area contained an unknown, yellow sticky substance.

THIRD CAUSE FOR DISCIPLINE  
(COMPOUNDING IN AN AREA THAT FAILED TO COMPLY WITH POLICIES)

18. Respondents River City Pharmacy and Halverlock are subject to disciplinary action under Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulations section 1751.4 (a) in that the environment used for compounding did not meet the requirements of their own policies for safe compounding of sterile injectable products. During the inspection Respondent Halverlock provided the inspectors a copy of River City Policies in place for safe compounding. The inspection revealed that the Pharmacy did not comply with their own policies as follows:

a. On December 8, 2016, the anteroom used for garbing was dirty.

b. The Storage room for dangerous injectable drugs contained a yellow sticky substance in which insects were enmeshed. The light fixtures in said room had insects and the base boards had been ripped out leaving exposed wood.
c. The Compounding area had a dirty fan that was pointed at the hood used for sterile compounding which increased the risk of interruption of airflow and increased the risk of contamination of the final product.

FOURTH CAUSE FOR DISCIPLINE
( Failure to Clean Compounding Area)

19. Respondents River City Pharmacy and Haverlock are subject to disciplinary action under section 4301 (f), (j), and (a) in conjunction with title 16, California Code of Regulations section 1751.1 subd. (b) (4) and 1751.4 subd. (d) in that between September 1, 2014, and December 8, 2014, cleaning logs were kept in which it was reported that the compounding area was cleaned, but employees, as well as a visual inspection by the Board's inspectors confirmed that the area for compounding was not cleaned as reported.

PRAYER

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

1. Revoking or suspending Pharmacy Permit (PHY) Number 51249, issued to River City Pharmacy Inc.; Michelle Dawn Haverlock, PIC

2. Revoking or suspending Pharmacist License No. Number RPH 507599, issued to Michelle Dawn Haverlock.

3. Ordering River City Pharmacy and Michelle Dawn Haverlock 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,

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

DATED: 9/5/17

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

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