

1 XAVIER BECERRA
Attorney General of California
2 DAVID BRICE
Supervising Deputy Attorney General
3 ELENA L. ALMANZO
Deputy Attorney General
4 State Bar No. 131058
1300 I Street, Suite 125
5 P.O. Box 944255
Sacramento, CA 94244-2550
6 Telephone: (916) 210-7902
Facsimile: (916) 327-8643
7 *Attorneys for Complainant*

8 **BEFORE THE**
9 **BOARD OF PHARMACY**
10 **DEPARTMENT OF CONSUMER AFFAIRS**
11 **STATE OF CALIFORNIA**

12 In the Matter of the Accusation Against:

Case No. 5916

13 **RIVER CITY PHARMACY INC.**
14 **5491 Carlson Dr.**
15 **Sacramento, CA 95819**

SECOND AMENDED
ACCUSATION

16 **Pharmacy Permit PHY 51249**
Sterile Compounding Permit No. LSC
100527

17 **MICHELLE DAWN HAVERLOCK,**
18 **1724 Van Damme Dr.**
Davis, CA 95616

19 **Pharmacist License No. RPH 50759**

20 Respondents.

21
22 Complainant alleges:

23 **PARTIES**

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

27 2. On or about January 22, 2013, the Board of Pharmacy issued Pharmacy Permit (PHY)
28 Number 51249 to Option Care Enterprises Inc., Walgreens Infusion Services Inc., Walgreen Co.

1 to do Business as River City Pharmacy Inc.; (Respondent River City Pharmacy). Michelle Dawn
2 Haverlock was the Pharmacist-in Charge from January 22, 2013 to January 26, 2015. The
3 Pharmacy Permit (PHY) was cancelled on January 6, 2015.

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

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

12 JURISDICTION

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

16 6. Section 4300 of the Code states in pertinent part:

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

18 "(b) The board shall discipline the holder of any license issued by the board, whose
19 default has been entered or whose case has been heard by the board and found guilty,
by any of the following methods:

20 "(1) Suspending judgment.

21 "(2) Placing him or her upon probation.

22 "(3) Suspending his or her right to practice for a period not exceeding one year.

23 "(4) Revoking his or her license.

24 "(5) Taking any other action in relation to disciplining him or her as the board in its
25 discretion may deem proper.

26 7. Section 4300.1 of the Code provides:

27 The expiration, cancellation, forfeiture, or suspension of a board-issued license by
28 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

1 investigation of, or action or disciplinary proceeding against, the licensee or to render
2 a decision suspending or revoking the license.

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

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

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

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

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

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

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

25 10. Health and Safety Code Section 111295 provides:

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

28 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,
or whereby it may have been rendered injurious to health.

REGULATIONS

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

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

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

13. California Code of Regulations Section 1751 provides in pertinent part:

1
2 “(a) Any pharmacy engaged in compounding sterile drug preparations shall conform
3 to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.),
4 applicable to all compounding, and shall also conform to the parameters and
5 requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to
6 sterile injectable compounding.

7
8 (b) Any pharmacy compounding sterile injectable drug products shall have a
9 designated area for the preparation of sterile injectable products which shall meet the
10 following standards:

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

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

15 (3) Be ventilated in a manner in accordance with section 505.12 of Title 24, Chapter
16 5 of the California Code of Regulations.

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

21 (5) The Pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part
22 2, Chapter 12, of the California Code of Regulations. Items related to the
23 compounding of sterile injectable products within the compounding area shall be
24 stored in such a way as to maintain the integrity of an aseptic environment....

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

26 (a) No sterile injectable product shall be compounded if it is known, or reasonably
27 should be known, that the compounding environment fails to meet criteria specified
28 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

25 15. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
26 administrative law judge to direct a licentiate found to have committed a violation or violations of
27 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
28

1 enforcement of the case, with failure of the licentiate to comply subjecting the license to not
2 being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs
3 may be included in a stipulated settlement.

4 **BACKGROUND**

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

10 **FIRST CAUSE FOR DISCIPLINE**

11 **(Failure to Provide a Compounding Area Which was Easily Cleanable)**

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

17 **SECOND CAUSE FOR DISCIPLINE**

18 **(Maintenance of Pharmacy Fixtures and Equipment)**

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

24 **THIRD CAUSE FOR DISCIPLINE**

25 **(Compounding in an Area that Failed to Comply with Policies)**

26 19. Respondents River City Pharmacy and Haverlock are subject to disciplinary action
27 under Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16,
28 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

1 products. During the inspection Respondent Haverlock provided the inspectors a copy of River
2 City Policies in place for safe compounding. The inspection revealed that the Pharmacy did not
3 comply with their own policies as follows:

- 4 a. On December 8, 2014, the anteroom used for garbing was dirty.
- 5 b. The Storage room for dangerous injectable drugs contained a yellow sticky substance
6 in which insects were enmeshed. The light fixtures in said room had insects and the base boards
7 had been ripped out leaving exposed wood.
- 8 c. The Compounding area had a dirty fan that was pointed at the hood used for sterile
9 compounding which increased the risk of interruption of airflow and increased the risk of
10 contamination of the final product.

11 **FOURTH CAUSE FOR DISCIPLINE**
12 **(Failure to Clean Compounding Area)**

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

19 **PRAYER**

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

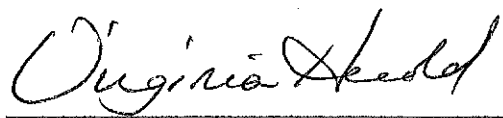
- 22 1. Revoking or suspending Pharmacy Permit PHY 51249, issued to River City
23 Pharmacy Inc.;
- 24 2. Revoking or Original Sterile Compounding Permit Number LSC 100527 issued to
25 River City Pharmacy Inc.;
- 26 3. Revoking or suspending Pharmacist License No. Number RPH 50759, issued to
27 Michelle Dawn Haverlock;

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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

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11 In the Matter of the Accusation Against:

Case No. 5916

12 **RIVER CITY PHARMACY INC.**
13 **5491 Carlson Dr.**
14 **Sacramento, CA 95819**

FIRST AMENDED

15 **Pharmacy Permit PHY 51249**
16 **Sterile Compounding Permit No. LSC**
17 **100527**

ACCUSATION

17 **MICHELLE DAWN HAVERLOCK,**
18 **1724 Van Damme Dr.**
19 **Davis, CA 95616**

20 **Pharmacist License No. RPH 50759**

21 Respondents.

22 Complainant alleges:

23 **PARTIES**

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

27 2. On or about January 22, 2013, the Board of Pharmacy issued Pharmacy Permit (PHY)
28 Number 51249 to River City Pharmacy Inc.; (Respondent River City Pharmacy). Michelle Dawn

1 Haverlock was the Pharmacist-in Charge from January 22, 2013 to January 26, 2015. The
2 Pharmacy Permit (PHY) expired on January 6, 2015, and has not been renewed.

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

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

10 JURISDICTION

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

14 6. Section 4300 of the Code states in pertinent part:

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

16 "(b) The board shall discipline the holder of any license issued by the board, whose
17 default has been entered or whose case has been heard by the board and found guilty,
by any of the following methods:

18 "(1) Suspending judgment.

19 "(2) Placing him or her upon probation.

20 "(3) Suspending his or her right to practice for a period not exceeding one year.

21 "(4) Revoking his or her license.

22 "(5) Taking any other action in relation to disciplining him or her as the board in its
23 discretion may deem proper.

24 7. Section 4300.1 of the Code provides:

25 The expiration, cancellation, forfeiture, or suspension of a board-issued license by
26 operation of law or by order or decision of the board or a court of law, the placement
27 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
28 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:

1 "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
2 conduct shall include, but is not limited to, any of the following:

3 ...“(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
4 licensee or otherwise, and whether the act is a felony or misdemeanor or not.

5 ...“(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.

6 ...“(o) Violating or attempting to violate, directly or indirectly, or assisting in or
7 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,
8 including regulations established by the board or by any other state or federal
regulatory agency.

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

10 (a) The board may institute any action or actions as may be provided by law and that,
11 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,
12 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
13 Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and
Safety Code).

14 10. Health and Safety Code Section 111295 provides:

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

17 11. Health and Safety Code Section 111255 provides:

18 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,
19 or whereby it may have been rendered injurious to health.

20 REGULATIONS

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

22 (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
23 and distributed. The pharmacy shall be of sufficient size and unobstructed area to
accommodate the safe practice of pharmacy.

24 (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
25 insects, and properly lighted. The pharmacy shall be equipped with a sink with hot
and cold running water for pharmaceutical purposes....

26 13. California Code of Regulations Section 1751 provides in pertinent part:

27 “(a) Any pharmacy engaged in compounding sterile drug preparations shall conform
28 to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.),

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

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

7 (1) Clean Room and Work Station Requirements shall be in accordance with Section
8 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.

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

11 (3) Be ventilated in a manner in accordance with section 505.12 of Title 24, Chapter
12 5 of the California Code of Regulations.

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

17 (5) The Pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part
18 2, Chapter 12, of the California Code of Regulations. Items related to the
19 compounding of sterile injectable products within the compounding area shall be
20 stored in such a way as to maintain the integrity of an aseptic environment....

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

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

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

28 (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

1 renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be
2 included in a stipulated settlement.

3 **BACKGROUND**

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

9 **FIRST CAUSE FOR DISCIPLINE**

10 **(Failure to Provide a Compounding Area Which was Easily Cleanable)**

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

16 **SECOND CAUSE FOR DISCIPLINE**

17 **(Maintenance of Pharmacy Fixtures and Equipment)**

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

23 **THIRD CAUSE FOR DISCIPLINE**

24 **(Compounding in an Area that Failed to Comply with Policies)**

25 19. Respondents River City Pharmacy and Haverlock are subject to disciplinary action
26 under Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16,
27 California Code of Regulations section 1751.4 (a) in that the environment used for compounding
28 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

1 City Policies in place for safe compounding. The inspection revealed that the Pharmacy did not
2 comply with their own policies as follows:

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

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

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

10 **FOURTH CAUSE FOR DISCIPLINE**
11 **(Failure to Clean Compounding Area)**

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

18 **PRAYER**

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

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

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

25 3. Revoking or suspending Pharmacist License No. Number RPH 507599, issued to
26 Michelle Dawn Haverlock;

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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

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
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State of California
Complainant

SA2016103064/12878349.doc

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14 5491 Carlson Dr.	
15 Sacramento, CA 95819	
16 Pharmacy Permit (PHY) No. 51249	
17 MICHELLE DAWN HAVERLOCK,	
18 1724 Van Damme Dr.	
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24 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
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26 Number 51249 to River City Pharmacy Inc.; Michelle Dawn Haverlock, PIC (Respondent River
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28 renewed.

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10 provided in the latest edition of the United States Pharmacopoeia or the National
11 Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic
12 Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and
13 Safety Code).

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

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

27 (c) The pharmacy and fixtures and equipment shall be maintained in a clean and
28 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....

12. 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.

1 (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.

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

4 (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
5 accordance with standards adopted by the United States General Services
Administration, Certification records must be retained for at least 3 years.

6 (5) The Pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part
7 2, Chapter 12, of the California Code of Regulations. Items related to the
compounding of sterile injectable products within the compounding area shall be
8 stored in such a way as to maintain the integrity of an aseptic environment....

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

10 (a) No sterile injectable product shall be compounded if it is known, or reasonably
11 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.

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

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

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

17 COST RECOVERY

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

24 BACKGROUND

25 15. On or about December 8, 2014, the Board conducted an inspection of the River City
26 Pharmacy. The inspection revealed four rooms used for compounding which did not meet the
27 minimum requirements for compounding. The rooms were unsanitary. During the inspection,
28

1 cleaning logs were requested. The employees of River City Pharmacy informed investigators that
2 the cleaning logs were initialed even when the area had not been cleaned.

3 **FIRST CAUSE FOR DISCIPLINE**

4 **(Failure to Provide a Compounding Area Which was Easily Cleanable)**

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

10 **SECOND CAUSE FOR DISCIPLINE**

11 **(Maintenance of Pharmacy Fixtures and Equipment)**

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

17 **THIRD CAUSE FOR DISCIPLINE**

18 **(Compounding in an Area that Failed to Comply with Policies)**

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

- 26 a. On December 8, 2016, the anteroom used for garbing was dirty.
27 b. The Storage room for dangerous injectable drugs contained a yellow sticky substance
28 in which insects were enmeshed. The light fixtures in said room had insects and the base boards
had been ripped out leaving exposed wood.

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

4 **FOURTH CAUSE FOR DISCIPLINE**
5 **(Failure to Clean Compounding Area)**

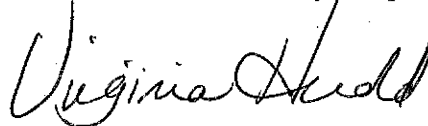
6 19. Respondents River City Pharmacy and Halverlock are subject to disciplinary action
7 under section 4301 (f), (j), and (o) in conjunction with title 16, California Code of Regulations
8 section 1751.1 subd. (b) (4) and 1751.4 subd. (d) in that between September 1, 2014, and
9 December 8, 2014, cleaning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

12 **PRAYER**

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

- 15 1. Revoking or suspending Pharmacy Permit (PHY) Number 51249, issued to River City
16 Pharmacy Inc.; Michelle Dawn Haverlock,, PIC
17 2. Revoking or suspending Pharmacist License No. Number RPH 507599, issued to
18 Michelle Dawn Haverlock.
19 3. Ordering River City Pharmacy and Michelle Dawn Haverlock to pay the Board of
20 Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to
21 Business and Professions Code section 125.3; and,
22 4. Taking such other and further action as deemed necessary and proper.

23
24 DATED: 9/5/17



25 VIRGINIA HEROLD
26 Executive Officer
27 Board of Pharmacy
28 Department of Consumer Affairs
State of California
Complainant

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