

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

In the Matter of the Accusation Against:

**WELLNESS PHARMACY, INC. DBA
WELLNESS PHARMACY
3401 Independence Dr., #231
Birmingham, AL 35209**

**Non-Resident Sterile Compounding Permit No.
NSC 99103**

Respondents.

Case No. 5845

OAH No. 2016121059

**STIPULATED SETTLEMENT
AND DISCIPLINARY ORDER
FOR PUBLIC REPROVAL**

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary 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 June 30, 2017.

It is so ORDERED on May 31, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President

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Attorney General of California
2 KENT D. HARRIS
Supervising Deputy Attorney General
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Attorneys for Complainant

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9 **BEFORE THE**
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10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11 In the Matter of the Accusation Against:

12 **WELLNESS PHARMACY, INC. DBA**
13 **WELLNESS PHARMACY**
14 **3401 Independence Dr., #231**
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15 **Non-Resident Pharmacy Permit**
16 **No. NRP 549**

17 **Non-Resident Sterile Compounding Permit**
18 **No. NSC 99103**

19 Respondent.

Case No. 5845

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**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER FOR PUBLIC
REPROVAL**

[Bus. & Prof. Code § 495]

20
21 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
22 entitled proceedings that the following matters are true:

23 **PARTIES**

24 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy
25 (Board). She brought this action solely in her official capacity and is represented in this matter by
26 Xavier Becerra, Attorney General of the State of California, by Stanton W. Lee, Deputy Attorney
27 General.

28 ///

1 court review of an adverse decision; and all other rights accorded by the California
2 Administrative Procedure Act and other applicable laws.

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

5 **CULPABILITY**

6 9. Respondent Neither denies or admits the charges and allegations in Accusation No.
7 5845.

8 10. For the purpose of resolving the Accusation without the expense and uncertainty of
9 further proceedings, Respondent hereby gives up its right to contest any of the charges in the
10 Accusation.

11 11. Respondent agrees that its Non-Resident Sterile Compounding Permit is subject to
12 discipline and they agree to be bound by the Disciplinary Order below.

13 **CONTINGENCY**

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


24 13. The parties understand and agree that Portable Document Format (PDF) and facsimile
25 copies of this Stipulated Settlement and Disciplinary Order for Public Repeval, including
26 Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and
27 effect as the originals.

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Repeval and have fully discussed it with my attorney, Tony J. Park. I understand the stipulation and the effect it will have on my Non-Resident Pharmacy Permit, and Non-Resident Sterile Compounding Permit. I enter into this Stipulated Settlement and Disciplinary Order for Public Repeval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy. I further represent that I am fully authorized to enter into this stipulation on behalf of Respondent and my signature binds Respondent to this agreement.

DATED: 5/3/17 
WELLNESS PHARMACY, INC. DBA WELLNESS
PHARMACY
Respondent

I have read and fully discussed with Respondent Wellness Phartnacy, Inc. dba Wellness Pharmacy the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Repeval. I approve its form and content.

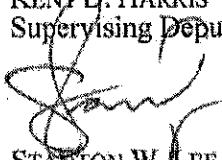
DATED: 05/03/2017 
TONY J. PARK
Attorney for Respondent

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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reapproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 5/4/17

Respectfully submitted,
XAVIER BECERRA
Attorney General of California
KEN D. HARRIS
Supervising Deputy Attorney General

STANTON W. LEE
Deputy Attorney General
Attorneys for Complainant

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12663243.doc

Exhibit A

Accusation No. 5845

1 KAMALA D. HARRIS
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2 KENT D. HARRIS
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3 STANTON W. LEE
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11 In the Matter of the Accusation Against:

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A C C U S A T I O N

15 **Non-Resident Pharmacy Permit**
16 **No. NRP 549**

17 **Non-Resident Sterile Compounding Permit**
18 **No. NSC 99103**

19 Respondent.

20
21 Complainant alleges:

22 **PARTIES**

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

25 2. On or about September 2, 2003, the Board issued Non-Resident Pharmacy Permit
26 Number NRP 549 to Wellness Pharmacy, Inc. dba Wellness Pharmacy (Pharmacy). The permit
27 will expire on September 1, 2016, unless renewed.

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1 3. On or about December 9, 2003, the Board issued Non-Resident Sterile Compounding
2 Permit Number NSC 99103 to the Pharmacy. The permit will expire on September 1, 2016,
3 unless renewed.

4 4. Both the Non-Resident Pharmacy Permit and the Non-Resident Sterile Compounding
5 Permit were in full force and effect at all times relevant to the charges brought herein.

6 **JURISDICTION**

7 **(California Business and Professions Code)**

8 5. This Accusation is brought before the Board under the authority of the following
9 laws. All code references are to the Business and Professions Code unless otherwise noted.

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

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

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

14 (1) Suspending judgment.

15 (2) Placing him or her upon probation.

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

17 (4) Revoking his or her license.

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

20

21 7. Section 4300.1 of the Code states:

22 The expiration, cancellation, forfeiture, or suspension of a board-issued
23 license by operation of law or by order or decision of the board or a court of law, the
24 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.

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

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

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(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances or 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 Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law.

....

(California Code of Regulations)

10. California Code of Regulations, title 16, section 1714, states 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.

....

11. California Code of Regulations, title 16, section 1735.2, states in pertinent part:

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(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

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(2) Equipment to be used.

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12. California Code of Regulations, title 16, section 1735.6, states in pertinent part:

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(b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturer's specifications.

.....
13. California Code of Regulations, title 16, section 1751.4, states in pertinent part:

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

.....
14. California Code of Regulations, title 16, section 1751.7, states in pertinent part:

.....
(b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process . . . The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials must be involved. Completed medium samples must be incubated . . .

.....
COST RECOVERY

15. Business and Professions 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.

BACKGROUND

16. On August 20, 2014, the Board conducted an inspection at Respondent's facility located in Birmingham, Alabama. Respondent is an out-of-state pharmacy licensed with both a non-resident pharmacy permit and a non-resident sterile compounding permit.

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1 17. The inspection was conducted by Board inspector P.P.

2 18. After arriving at Respondent's facility, Pharmacist-In-Charge M.D., assisted
3 Inspector P.P. with the investigation by escorting Inspector P.P. through the facility. Upon
4 reaching the compounding area of the pharmacy, Inspector P.P. entered the compounding area for
5 the purpose of inspection.

6 19. Upon entering the compounding area, where Respondent conducted high risk sterile
7 drug compounding, Inspector P.P. observed three laminar flow hoods.¹ Inspector P.P. observed
8 Hood #1 to be in good operating condition. Inspector P.P. observed Hood #2 to have cracked
9 glass and rust or some other substance or debris inside the metal track holding the glass.
10 Respondent did not conduct surface testing to determine whether the rust or other substance or
11 debris was causing any problems with unwanted bacterial or fungal growth. Inspector P.P.
12 observed Hood #3 to have a broken light, an abundance of rust throughout the hood, and a dark
13 and slimy appearing substance inside the grates of the hood.

14 20. While inside the compounding area, Inspector P.P. observed a chair in front of Hood
15 #1 with a damaged seatback. The condition of the chair was such that the inner cushioning of the
16 seatback protruded from the chair.

17 21. When asked, it was determined that Respondent maintained no records of the
18 materials compounded under each hood. Thus, if a problem with contamination occurred, it
19 would be difficult, if not impossible, to narrow down the source of the contamination. When the
20 master formula for compounded materials was reviewed, it was determined that Respondent's
21 master formulas failed to identify the equipment used during and for the compounding.

22 22. Process validation is when an individual demonstrates that he or she is familiar with
23 the techniques to compound or mix medication, aseptically. Process validation is required
24 annually unless the pharmacist completes compounding of medications that are classified as
25 "high risk," in which case process validation is required every six months according to United

26 _____
27 ¹ A laminar flow hood is an enclosed work bench where air is drawn through a filter and
28 blown over the work area in a manner designed to prevent contamination of the materials being prepared within the hood.

1 States Pharmacopeia <797>. Respondent represented that Alabama, the state in which
2 Respondent operates, complies with United States Pharmacopeia <797> and therefore,
3 Respondent was required to complete process validation every six months. Respondent's records
4 indicated that Respondent regularly compounded medication in batches of up to 900ml at a time.
5 Thereafter, the compounded medication would be manipulated or divided into smaller dispensing
6 sizes for distribution. The validation process records indicated that Respondent's compounding
7 staff regularly used a smaller quantity than what was actually compounded for production. The
8 records of process validation showed that Respondent's compounding staff conducted process
9 validation with only approximately 85ml when the intended production batch of medication
10 would be 700ml.

11
12 **FIRST CAUSE FOR DISCIPLINE**
(Failure to Record Equipment Used in Compounding)

13 23. Respondent's Non-Resident Pharmacy Permit and Non-Resident Sterile
14 Compounding Permit are subject to disciplinary action under California Code of Regulations, title
15 16, section 1735.2, subdivision (d)(2) in that Respondent did not specify equipment used in
16 compounding as detailed above in Paragraph 21.

17
18 **SECOND CAUSE FOR DISCIPLINE**
(Failure to Maintain Equipment in Good Working Condition)

19 24. Respondent's Non-Resident Pharmacy Permit and Non-Resident Sterile
20 Compounding Permit are subject to disciplinary action under California Code of Regulations, title
21 16, sections 1714 and 1735.6, subdivision (d)(2) in that Respondent conducted compounding of
22 high risk sterile drug compounds in damaged and dirty laminar flow hoods as detailed above in
23 Paragraph 19.

24
25 **THIRD CAUSE FOR DISCIPLINE**
**(Failure to Use Easily Cleaned and Disinfected
Equipment in Designated Cleanroom)**

26 25. Respondent's Non-Resident Pharmacy Permit and Non-Resident Sterile
27 Compounding Permit are subject to disciplinary action under California Code of Regulations, title
28 16, section 1751.4, subdivision (c) in that Respondent utilized a chair in the sterile compounding

1 room that was in such a condition that it could not be easily cleaned and disinfected as detailed
2 above in Paragraph 20.

3 **FOURTH CAUSE FOR DISCIPLINE**
4 **(Failure to Process Validation Manipulations in Volumes**
5 **Consistent with Amounts Anticipated to be Prepared)**

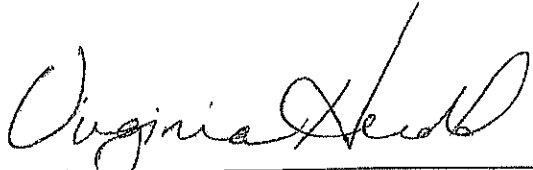
6 26. Respondent's Non-Resident Pharmacy Permit and Non-Resident Sterile
7 Compounding Permit are subject to disciplinary action under California Code of Regulations, title
8 16, section 1751.7 in that Respondent conducted process validation in amounts that were not
9 indicative of the high volume batches prepared by the pharmacy as detailed above in Paragraph
10 22.

11 **PRAYER**

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

- 14 1. Revoking or suspending Non-Resident Pharmacy Permit Number NRP 549, issued to
15 Wellness Pharmacy, Inc. dba Wellness Pharmacy
- 16 2. Revoking or suspending Non-Resident Sterile Compounding Permit Number NSC
17 99103, issued to Wellness Pharmacy, Inc. dba Wellness Pharmacy;
- 18 3. Ordering Wellness Pharmacy, Inc. dba Wellness Pharmacy to pay the Board of
19 Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to
20 Business and Professions Code section 125.3;
- 21 4. Taking such other and further action as deemed necessary and proper.

22
23 DATED: 8/19/16


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

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