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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 Pharmacy Permit** **No. NRP 549** **Non-Resident Sterile Compounding Permit** **No. NSC 99103** Respondent.	Case No. 5845 **FIRST AMENDED ACCUSATION**

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 (Board), Department of Consumer Affairs.

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

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

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

JURISDICTION

(California Business and Professions Code)

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

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 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.

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 procured by fraud or

misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

. . . .

(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:

. . . .

(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:

. . . .

(2) Equipment to be used.

. . . .

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

. . . .

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

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

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

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

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

22. Process validation is when an individual demonstrates that he or she is familiar with the techniques to compound or mix medication, aseptically. Process validation is required annually unless the pharmacist completes compounding of medications that are classified as

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

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

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

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

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

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

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

25. Respondent's Non-Resident Pharmacy Permit and Non-Resident Sterile Compounding Permit are subject to disciplinary action under California Code of Regulations, title

16, section 1751.4, subdivision (c) in that Respondent utilized a chair in the sterile compounding room that was in such a condition that it could not be easily cleaned and disinfected as detailed above in Paragraph 20.

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

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

DISCIPLINARY CONSIDERATIONS

27. To determine the degree of discipline to be assessed against Respondent Wellness Pharmacy, if any, Complainant alleges that between September 22, 2014 and September 30, 2014, the United States Food and Drug Administration (FDA) completed an inspection at Respondent's facility and issued a report. The FDA inspection noted multiple areas of deficiency including, but not limited to, failure to complete endotoxin testing and potency testing on 100% of products, failure to routinely calibrate thermometers, hygrometers, and pressure gauges, failure to produce stability data for purported sterile drug products, and stability data accounting for expiration dates assigned to drug products.

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 Non-Resident Pharmacy Permit Number NRP 549, issued to Wellness Pharmacy, Inc. dba Wellness Pharmacy

2. Revoking or suspending Non-Resident Sterile Compounding Permit Number NSC 99103, issued to Wellness Pharmacy, Inc. dba Wellness Pharmacy;

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3. Ordering Wellness Pharmacy, Inc. dba Wellness Pharmacy 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;

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

DATED: 1/12/17

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

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

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Complainant alleges:

PARTIES

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

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

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> (2) Placing him or her upon probation.
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> (3) Suspending his or her right to practice for a period not exceeding one year.
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> (4) Revoking his or her license.
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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.

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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.

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COST RECOVERY

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

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

PRAYER

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1. Revoking or suspending Non-Resident Pharmacy Permit Number NRP 549, issued to Wellness Pharmacy, Inc. dba Wellness Pharmacy

2. Revoking or suspending Non-Resident Sterile Compounding Permit Number NSC 99103, issued to Wellness Pharmacy, Inc. dba Wellness Pharmacy;

3. Ordering Wellness Pharmacy, Inc. dba Wellness Pharmacy 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;

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

DATED: 8/19/16

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

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