

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

In the Matter of the Accusation Against:

Case No. 4773

**RX3 PHARMACY
7855 Redpine Road
Richmond, VA 23237**

Non Resident Pharmacy Permit No. NRP 925

Respondent.

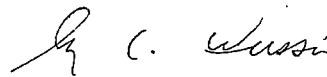
DECISION AND ORDER

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

This decision shall become effective on December 3, 2014.

It is so ORDERED on November 26, 2014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

STAN C. WEISSER
Board President

1 KAMALA D. HARRIS
Attorney General of California
2 FRANK H. PACOE
Supervising Deputy Attorney General
3 NICHOLAS TSUKAMAKI
Deputy Attorney General
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7 *Attorneys for Complainant*

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

11 In the Matter of the Accusation Against:
12 **RX3 PHARMACY**
13 **7855 Redpine Road**
14 **Richmond, VA 23237**
15 **Non Resident Pharmacy Permit No. NRP**
16 **925**
Respondent.

Case No. 4773

**STIPULATED SURRENDER OF
LICENSE AND ORDER**

17
18 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
19 entitled proceedings that the following matters are true:

20 PARTIES

21 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy
22 (Board). She brought this action solely in her official capacity and is represented in this matter by
23 Kamala D. Harris, Attorney General of the State of California, by Nicholas Tsukamaki, Deputy
24 Attorney General.

25 2. RX3 Pharmacy (Respondent) is represented in this proceeding by attorney Tony J.
26 Park, whose address is: 2855 Michelle Drive, Suite 180, Irvine, CA 92606.

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ORDER

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IT IS HEREBY ORDERED that Non Resident Pharmacy Permit No. NRP 925, issued to Respondent RX3 Pharmacy, is surrendered and accepted by the Board of Pharmacy.

1. Respondent shall relinquish the premises wall license and renewal license to the Board within ten (10) days of the effective date of the Board's Decision and Order.

2. The surrender of Respondent's Non Resident Pharmacy Permit and the acceptance of the surrendered license by the Board shall constitute the imposition of discipline against Respondent. This Stipulated Surrender of License and Order constitutes a record of the discipline and shall become a part of Respondent's license history with the Board.

3. Respondent understands and agrees that if it ever files an application for a licensed premises or a petition for reinstatement in the State of California, the Board shall treat it as a new application for licensure.

4. Respondent may not reapply for any license from the Board for three (3) years from the effective date of the Board's Decision and Order. Respondent stipulates that should it apply for any license from the Board on or after the effective date of the Board's Decision and Order, all allegations set forth in Accusation No. 4773 shall be deemed to be true, correct, and admitted by Respondent when the Board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the Board. Respondent is required to report this surrender as disciplinary action.

5. Respondent stipulates that should it apply for any license from the Board on or after the effective date of the Board's Decision and Order, the investigation and prosecution costs in the amount of \$5,416.00 shall be paid to the Board prior to the issuance of the new license.

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ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: *November 3, 2014*

Respectfully submitted,
KAMALA D. HARRIS
Attorney General of California
FRANK H. PACOE
Supervising Deputy Attorney General



NICHOLAS TSUKAMAKI
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 4773

1 KAMALA D. HARRIS
Attorney General of California
2 FRANK H. PACOE
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11 **STATE OF CALIFORNIA**

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Case No. 4773

13 **RX3 PHARMACY**
7855 Redpine Road
Richmond, VA 23237

A C C U S A T I O N

14 **Non Resident Pharmacy Permit No. NRP**
15 **925**

16 Respondent.

17
18 Complainant alleges:

19 **PARTIES**

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

22 2. On or about July 15, 2009, the Board issued Non Resident Pharmacy Permit Number
23 NRP 925 to RX3 Pharmacy (Respondent). The Non Resident Pharmacy Permit expired on July
24 1, 2013, and has not been renewed.

25 **JURISDICTION**

26 3. This Accusation is brought before the Board under the authority of the following
27 laws. All section references are to the Business and Professions Code (Code) unless otherwise
28 indicated.

1 4. Section 4300.1 of the Code states:

2 “The expiration, cancellation, forfeiture, or suspension of a board-issued license by
3 operation of law or by order or decision of the board or a court of law, the placement of a license
4 on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board
5 of jurisdiction to commence or proceed with any investigation of, or action or disciplinary
6 proceeding against, the licensee or to render a decision suspending or revoking the license.”

7 **STATUTORY AND REGULATORY PROVISIONS**

8 5. Section 4300 of the Code states in pertinent part:

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

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

13 “(1) Suspending judgment.

14 “(2) Placing him or her upon probation.

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

16 “(4) Revoking his or her license.

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

19 . . .

20 “(e) The proceedings under this article shall be conducted in accordance with Chapter 5
21 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board
22 shall have all the powers granted therein. The action shall be final, except that the propriety of
23 the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of
24 Civil Procedure.”

25 6. 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 unprofessional
27 conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.
28 Unprofessional conduct shall include, but is not limited to, any of the following:

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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.

...”

7. Section 4303 of the Code states in pertinent part:

“(b) The board may deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon which such action might be taken against a resident pharmacy, provided that the grounds for the action are also grounds for action in the state in which the nonresident pharmacy is permanently located.”

8. California Code of Regulations, title 16, section 1735.3 provides in relevant part:

“(a) For each compounded drug product, the pharmacy records shall include:

“(1) The master formula record.

“(2) The date the drug product was compounded.

“(3) The identity of the pharmacy personnel who compounded the drug product.

“(4) The identity of the pharmacist reviewing the final drug product.

“(5) The quantity of each component used in compounding the drug product.

“(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for ‘Redispensed CSPS’ found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

“(7) A pharmacy assigned reference or lot number for the compounded drug product.

1 “(8) The expiration date of the final compounded drug product.

2 “(9) The quantity or amount of drug product compounded.

3 “(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of
4 chemicals, bulk drug substances, drug products, and components used in compounding.

5 . . .

6 “(d) Pharmacies shall maintain and retain all records required by this article in the
7 pharmacy in a readily retrievable form for at least three years from the date the record was
8 created.”

9 9. California Code of Regulations, title 16, section 1751.7 provides in relevant part:

10 “(c) Batch-produced sterile injectable drug products compounded from one or more non-
11 sterile ingredients shall be subject to documented end product testing for sterility and pyrogens
12 and shall be quarantined until the end product testing confirms sterility and acceptable levels of
13 pyrogens.

14 “(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through
15 process validation for sterility as determined by the pharmacist-in-charge and described in the
16 written policies and procedures.”

17 **COSTS**

18 10. Section 125.3 of the Code states, 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.

22 **FACTUAL BACKGROUND**

23 11. Respondent holds a permit to conduct a pharmacy in the Commonwealth of Virginia
24 (permit no. 0201-003685). Respondent’s pharmacist-in-charge, Christopher K. Currin (Currin), is
25 licensed as a pharmacist by the Virginia Board of Pharmacy (license no. 0202-011727).

26 12. In or around November 2012, an inspector with the Virginia Board of Pharmacy
27 performed an inspection of Respondent’s facility located in Chester, Virginia. Upon inspection,
28 the inspector discovered that in January, February, April, June, August, and October 2012, a total

1 of 114 high-risk compounded sterile products (CSPs) were compounded at Respondent's facility.
2 Of these 114 CSPs, Respondent did not have any records for 110 of the CSPs indicating whether
3 sterility testing had been performed on them or whether the CSPs were batch compounded or
4 compounded for a specific patient. The inspector also determined that the CSPs were labeled
5 with beyond use dates (BUDs) longer than allowed by the United States Pharmacopeia (USP)
6 797.

7 13. The Virginia Board of Pharmacy inspector further discovered that between January 1
8 and October 31, 2012, Respondent compounded and dispensed 9,889 30ml vials of Medi-Bolic
9 Booster and 14,386 30ml vials of pyridoxine/thiamine. When asked to produce compounding
10 records for these products, Currin was only able to produce two records for the Medi-Bolic
11 Booster and three compounding records for the pyridoxine/thiamine, which accounted for only
12 400 total doses. Furthermore, Respondent only had documentation for eight in-house sterility
13 tests. Finally, all of the compounded materials were labeled with BUDs longer than allowed by
14 USP 797.

15 **FIRST CAUSE FOR DISCIPLINE**

16 **(Unprofessional Conduct – Failure to Maintain Pharmacy Records)**

17 14. Respondent is subject to disciplinary action under sections 4300, 4301, subdivision
18 (o), and 4303, subdivision (b) of the Code and California Code of Regulations, title 16, section
19 1735.3, subdivisions (a)(1)-(9), (b), and/or (d), in that Respondent failed to maintain certain
20 pharmacy records for CSPs and other drug products. The circumstances of Respondent's conduct
21 are set forth above in paragraphs 12 and 13.

22 **SECOND CAUSE FOR DISCIPLINE**

23 **(Unprofessional Conduct – Failure to Perform Sterility Testing)**

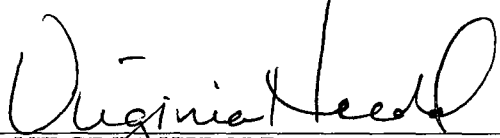
24 15. Respondent is subject to disciplinary action under sections 4300, 4301, subdivision
25 (o), and 4303, subdivision (b) of the Code and California Code of Regulations, title 16, section
26 1751.7, subdivisions (c) and/or (d) in that in 2012, Respondent failed to perform sterility testing
27 on various CSPs and other drug products. The circumstances of Respondent's conduct are set
28 forth above in paragraphs 12 and 13.

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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 925 issued to RX3 Pharmacy;
2. Ordering RX3 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;
3. Taking such other and further action as deemed necessary and proper.

DATED: 5/8/14 

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

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