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

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	W D. H		
1	KAMALA D. HARRIS Attorney General of California		
2	FRANK H. PACOE Supervising Deputy Attorney General		
3	NICHOLAS TSUKAMAKI Deputy Attorney General	·	
4	State Bar No. 253959 455 Golden Gate Avenue, Suite 11000		
5	San Francisco, CA 94102-7004 Telephone: (415) 703-1188		
6	Facsimile: (415) 703-5480 E-mail: Nicholas.Tsukamaki@doj.ca.gov		
7	Attorneys for Complainant		
8	BEFORE THE		
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS		
10	STATE OF C	CALIFORNIA	
11	In the Matter of the Accusation Against:	Case No. 4773	
12	RX3 PHARMACY		
13	7855 Redpine Road Richmond, VA 23237	STIPULATED SURRENDER OF	
14	Non Resident Pharmacy Permit No. NRP	LICENSE AND ORDER	
15	925	·	
16	Respondent.		
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18	IT IS HERERY STIPLU ATED AND ACI	REED by and between the parties to the above-	
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j	entitled proceedings that the following matters are true:		
20	<u>PARTIES</u>		
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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3. On or about July 15, 2009, the Board of Pharmacy issued Non Resident Pharmacy Permit No. NRP 925 to Respondent. The Non Resident Pharmacy Permit expired on July 1, 2013, and has not been renewed.

JURISDICTION

4. Accusation No. 4773 was filed before the Board and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on June 6, 2014. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 4773 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

- 5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 4773. Respondent also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of License and Order.
- 6. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against it; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.
- 7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent agrees there is cause for discipline, and hereby surrenders its Non Resident Pharmacy Permit No. NRP 925 for the Board's formal acceptance.

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9. Respondent understands that by signing this stipulation it enables the Board to issue an order accepting the surrender of Respondent's Non Resident Pharmacy Permit without further process.

CONTINGENCY

- 10. This stipulation shall be subject to approval by the Board. Respondent understands and agrees that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and surrender without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Surrender and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 11. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Surrender of License and Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.
- 12. This Stipulated Surrender of License and Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 13. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Order:

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ORDER

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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ACCEPTANCE

I am authorized to sign the above Stipulated Surrender of License and Order on behalf of Respondent RX3 Pharmacy. I have carefully read the Stipulated Surrender of License and Order and have fully discussed it with my attorney, Tony J. Park. I understand the stipulation and the effect it will have on Respondent's Non Resident Pharmacy Permit. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 10-31-14 Chris K. Currin, RPh, Owner

RX3 PHARMACY Respondent

I have read and fully discussed with Chris K. Currin, RPh the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: 10/31/2014 Inc. Jank

Attorney for Respondent

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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 Necholos Duhamel. NICHOLAS TSUKAMAKI Deputy Attorney General Attorneys for Complainant SF2013405523 41112596.docx

Exhibit A

Accusation No. 4773

KAMALA D. HADDIS			
Attorney General of California			
Supervising Deputy Attorney General			
Deputy Attorney General			
455 Golden Gate Avenue, Suite 11000			
Telephone: (415) 703-1188			
Facsimile: (415) 703-5480 E-mail: Nicholas.Tsukamaki@doj.ca.gov Attorneys for Complainant			
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	ACCUSATION		
Non Resident Pharmacy Permit No. NRP			
925			
Respondent.			
Complainant alleges:			
PARTIES			
1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity			
as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.			
2. On or about July 15, 2009, the Board issued Non Resident Pharmacy Permit Number			
NRP 925 to RX3 Pharmacy (Respondent). The Non Resident Pharmacy Permit expired on July			
1, 2013, and has not been renewed.			
JURIS	SDICTION		
3. This Accusation is brought before the Board under the authority of the following			
laws. All section references are to the Business and Professions Code (Code) unless otherwise			
indicated.			
	1	ACCUSATION	
	FRANK H. PACOE Supervising Deputy Attorney General NICHOLAS TSUKAMAKI Deputy Attorney General State Bar No. 253959 455 Golden Gate Avenue, Suite 11000 San Francisco, CA 94102-7004 Telephone: (415) 703-1188 Facsimile: (415) 703-5480 E-mail: Nicholas. Tsukamaki@doj.ca.gov Attorneys for Complainant BEFG BOARD O DEPARTMENT OF STATE OF In the Matter of the Accusation Against: RX3 PHARMACY 7855 Redpine Road Richmond, VA 23237 Non Resident Pharmacy Permit No. NRP 925 Respondent Complainant alleges: PA 1. Virginia Herold (Complainant) bri as the Executive Officer of the Board of Pharm 2. On or about July 15, 2009, the Boa NRP 925 to RX3 Pharmacy (Respondent). Th 1, 2013, and has not been renewed. JURIS 3. This Accusation is brought before laws. All section references are to the Busines	Attorney General of California FRANK H. PACOE Supervising Deputy Attorney General Nicholas Tsukamaki Deputy Attorney General State Bar No. 253959 455 Golden Gate Avenue, Suite 11000 San Francisco, CA 94102-7004 Telephone: (415) 703-1188 Facsimile: (415) 703-5480 E-mail: Nicholas Tsukamaki@doj.ca.gov Attorneys for Complainant BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA In the Matter of the Accusation Against: RX3 PHARMACY 7855 Redpine Road Richmond, VA 23237 Non Resident Pharmacy Permit No. NRP 925 1. Virginia Herold (Complainant) brings this Accusation solely in her offi as the Executive Officer of the Board of Pharmacy (Board), Department of Consun 2. On or about July 15, 2009, the Board issued Non Resident Pharmacy P NRP 925 to RX3 Pharmacy (Respondent). The Non Resident Pharmacy Permit ex 1, 2013, and has not been renewed. JURISDICTION 3. This Accusation is brought before the Board under the authority of the laws. All section references are to the Business and Professions Code (Code) unles indicated.	

4. 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."

STATUTORY AND REGULATORY PROVISIONS

- 5. 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.

. . .

- "(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."
 - 6. 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:

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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.

- "(8) The expiration date of the final compounded drug product.
- "(9) The quantity or amount of drug product compounded.
- "(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

. . .

- "(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created."
 - 9. California Code of Regulations, title 16, section 1751.7 provides in relevant part:
- "(c) Batch-produced sterile injectable drug products compounded from one or more nonsterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.
- "(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures."

COSTS

10. Section 125.3 of the Code states, 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.

FACTUAL BACKGROUND

- 11. Respondent holds a permit to conduct a pharmacy in the Commonwealth of Virginia (permit no. 0201-003685). Respondent's pharmacist-in-charge, Christopher K. Currin (Currin), is licensed as a pharmacist by the Virginia Board of Pharmacy (license no. 0202-011727).
- 12. In or around November 2012, an inspector with the Virginia Board of Pharmacy performed an inspection of Respondent's facility located in Chester, Virginia. Upon inspection, the inspector discovered that in January, February, April, June, August, and October 2012, a total

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

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

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Failure to Maintain Pharmacy Records)

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

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Failure to Perform Sterility Testing)

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

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:

- Revoking or suspending Non Resident Pharmacy Permit Number NRP 925 issued to RX3 Pharmacy;
- Ordering RX3 Pharmacy to pay the Board of Pharmacy the reasonable costs of the 2. 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.

VIRGINIA Executive Officer

Board of Pharmacy Department of Consumer Affairs

State of California Complainant

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ACCUSATION

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