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

In the Matter of the Accusation Against:

WELLS PHARMACY NETWORK LLC, dba
WELLS PHARMACY NETWORK LLC,
NEMOMON LLC, SHAREHOLDER,
THE COLLEEN STACY SHAPIRO 2010 TRUST, SHAREHOLDER,
OB JOYFUL DYNASTY TRUST, SHAREHOLDER,
THE SHAPIRO FAMILY D III TRUST, SHAREHOLDER,
RACHEL ELLYN MCKIM, SHAREHOLDER,
KATHEE KRAMM, SHAREHOLDER and MEMBER,
EDWARD KRAMM, SHAREHOLDER and MEMBER,
CLINT EDWARD MYERS, PHARMACIST-IN-CHARGE,

Nonresident Pharmacy Permit No. NRP 1325,
Nonresident Sterile Compounding Pharmacy Permit No. NSC 99824;

WELLS PHARMACY NETWORK LLC, dba
WELLS PHARMACY NETWORK LLC,
OB JOYFUL DYNASTY TRUST, SHAREHOLDER,
THE COLLEEN STACY SHAPIRO 2010 TRUST, SHAREHOLDER,
THE SHAPIRO FAMILY D III TRUST, SHAREHOLDER,
NEMOMON LLC, SHAREHOLDER,
RACHEL ELLYN MCKIM, SHAREHOLDER and MEMBER,
JARRETT TODD BOSTWICK, SECRETARY, SHAREHOLDER, and MEMBER,

WILLIAM EDWARD MCMILLEN, DIRECTOR,
SHIRLEY ANN EIS, SHAREHOLDER,
CLINT EDWARD MYERS, PHARMACIST-IN-CHARGE,

Nonresident Outsourcing Facility Permit No. NSF 129,

Respondents.

Agency Case No. 7101 & 7156

OAH No. 2023030119

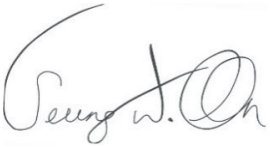
DECISION AND ORDER

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 September 13, 2023.

It is so ORDERED on August 14, 2023.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
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Attorneys for Complainant

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

In the Matter of the Accusation Against: **WELLS PHARMACY NETWORK LLC dba WELLS PHARMACY NETWORK LLC** **NEMOMON LLC, Shareholder;** **THE COLLEEN STACY SHAPIRO 2010 TRUST, Shareholder;** **OB JOYFUL DYNASTY TRUST, Shareholder;** **THE SHAPIRO FAMILY D III TRUST, Shareholder;** **RACHEL ELLYN MCKIM, Shareholder;** **KATHEE KRAMM, Shareholder and Member;** **EDWARD KRAMM, Shareholder and Member;** **CLINT EDWARD MYERS, Pharmacist-in-Charge.** **450 U.S. Hwy 51, Byp. N** **Dyersberg, TN 38024** **Nonresident Pharmacy Permit number NRP 1325** **Nonresident Sterile Compounding Pharmacy Permit number NSC 99824** **WELLS PHARMACY NETWORK LLC dba WELLS PHARMACY NETWORK LLC** **OB JOYFUL DYNASTY TRUST, Shareholder;**	Case No. 7101 & 7156 OAH No. 2023030119 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER** **(As to the Accusation and Statement of Issues)**

THE COLLEEN STACY SHAPIRO 2010 TRUST, Shareholder;
THE SHAPIRO FAMILY D III TRUST, Shareholder;
NEMOMON LLC, Shareholder;
RACHEL ELLYN MCKIM, Shareholder and Member;
JARRETT TODD BOSTWICK, Secretary, Shareholder, and Member;
WILLIAM EDWARD MCMILLEN, Director;
SHIRLEY ANN EIS, Shareholder;
CLINT EDWARD MYERS, pharmacist-in-charge.
450 U.S. Hwy 51, Byp. N
Dyersberg, TN 38024

Nonresident Outsourcing Facility Permit number NSF 129

Respondent.

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

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Kristina T. Jarvis, Deputy Attorney General.

2. Respondent Wells Pharmacy Network, LLC (Respondent) is represented in this proceeding by attorney Jason Balogh.

3. On or about May 28, 2013, the Board of Pharmacy issued Original Nonresident Pharmacy Permit number NRP 1325 to Wells Pharmacy Network, LLC, doing business as (dba) Wells Pharmacy Network, LLC, with Nemomon LLC 24% shareholder, The Colleen Stacy Shapiro 2010 Trust, 13% shareholder, OB Joyful Dynasty Trust, 8% shareholder, The Shapiro Family D III Trust, 8% shareholder, Rachel Ellyn McKim, 8% shareholder, Kathee Kramm, 7% shareholder and member, Edward Kramm, 7% shareholder and member, and Clint Edward Myers, Pharmacist in Charge (PIC) (Respondent NRP/NSC). The Nonresident Pharmacy Permit

was in full force and effect from May 28, 2013, through May 1, 2017. On or about May 1, 2017, the Nonresident Pharmacy Permit expired pursuant to a discontinuance of business.

4. On or about May 28, 2013, the Board of Pharmacy issued Nonresident Sterile Compounding Pharmacy Permit number NSC 99824 to Respondent NRP/NSC. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect from May 28, 2013, through May 1, 2017. On or about May 1, 2017, the Nonresident Sterile Compounding Pharmacy Permit expired pursuant to a discontinuance of business.

5. On or about June 28, 2019, the Board of Pharmacy issued Nonresident Outsourcing Facility Permit number NSF 129 to Wells Pharmacy Network, LLC, doing business as (dba) Wells Pharmacy Network, LLC, with OB Joyful Dynasty Trust, 28% shareholder, The Colleen Stacy Shapiro 2010 Trust, 16% shareholder, The Shapiro Family D III Trust, 10% shareholder, Nemomon LLC 8% shareholder, Rachel Ellyn McKim, 10% shareholder and member. (Respondent NSF) The Nonresident Outsourcing Facility Permit was in full force and effect at all times relevant to the charges brought herein and expired on June 1, 2021, the circumstances of which are set forth in paragraph 5, below.

6. Prior to June 1, 2021, Respondent NSF applied for Nonresident Outsourcing Facility Permit number NSF 129 to be renewed. On or about May 14, 2021, the application for renewal was denied after a renewal inspection found that Respondent NSF was not in compliance with current good manufacturing practices (cGMP) and regulations adopted by the Board. On or about May 21, 2021,[1] Respondent NSF timely appealed the denial of the Nonresident Outsourcing Facility Permit renewal.

JURISDICTION

7. Accusation and Statement of Issues No. 7101 & 7156 was filed before the Board, and is currently pending against Respondent. The Accusation and Statement of Issues and all other statutorily required documents were properly served on Respondent on October 15, 2021.

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[1] Although the letter is dated May 21, 2010, it was received by the Board on May 25, 2021, and it is believed the year is a mere typographical error.

Respondent timely filed its Notice of Defense contesting the Accusation, and requested a hearing to contest the Statement of Issues.

8. A copy of Accusation No. 7101 & 7156 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

9. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation and Statement of Issues No. 7101 & 7156. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

10. 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 and Statement of Issues; the right to confront and cross-examine the witnesses against them; 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.

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

CULPABILITY

12. Respondent admits the truth of each and every charge and allegation in Accusation and Statement of Issues No. 7101 & 7156.

13. Respondent agrees that its Nonresident Outsourcing Facility permit is subject to discipline and it agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

14. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to

or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they 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 Settlement 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.

15. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

16. This Stipulated Settlement and Disciplinary 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 Settlement and Disciplinary 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.

17. 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 Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that the Board will rescind the denial of the renewal of Nonresident Outsourcing Facility Permit No. NSF 129 issued to Respondent Wells Pharmacy Network, LLC subject to the inspection requirement set forth in paragraph seventeen (17) below, and once renewed, the permit shall be immediately revoked, with the revocation immediately stayed and Respondent placed on probation for three (3) years on the following terms and conditions:

IT IS FURTHER ORDERED that Nonresident Pharmacy Permit No. NRP 1325, and Nonresident Sterile Compounding Pharmacy Permit No. NSC 99824 remain cancelled pursuant to a discontinuance of business.

1. **Definition: Respondent**

For the purposes of these terms and conditions, "respondent" shall refer to Wells Pharmacy Network, LLC, doing business as (dba) Wells Pharmacy Network, LLC, with Nemomon LLC 24% shareholder, The Colleen Stacy Shapiro 2010 Trust, 13% shareholder, OB Joyful Dynasty Trust, 8% shareholder, The Shapiro Family D III Trust, 8% shareholder, Rachel Ellyn McKim, 8% shareholder, Kathee Kramm, 7% shareholder and member, Edward Kramm, 7% shareholder and member, and Clint Edward Myers, Pharmacist in Charge (PIC). All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by respondent to or before the board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

2. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment;
- a conviction of any crime; or
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's nonresident outsourcing facility permit or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any dangerous drug, and/or dangerous device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

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3. **Report to the Board**

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person, via telephone or virtual meeting, or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

4. **Interview with the Board**

Upon receipt of reasonable prior notice, respondent shall appear in person, via telephone, or via a virtual meeting platform for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

5. **Cooperate with Board Staff**

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of the probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

6. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $25,095.75. Respondent shall make reimbursement payments as approved by the board or its designee in writing. There shall

be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

7. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. These costs will include travel costs for board inspectors to inspect Respondent's physical facility on a quarterly basis. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

8. **Status of License**

Respondent shall, at all times while on probation, maintain an active nonresident outsourcing facility permit with the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

9. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should respondent wish to discontinue business, respondent may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Respondent may not apply for any new license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent further stipulates that it shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

10. **Sale or Discontinuance of Business**

During the period of probation, should respondent sell, trade or transfer all or part of the ownership of the licensed entity, discontinue doing business under the license issued to respondent, or should practice at that location be assumed by another full or partial owner, person, firm, business, or entity, under the same or a different premises license number, the board or its designee shall have the sole discretion to determine whether to exercise continuing jurisdiction over the licensed location, under the current or new premises license number, and/or carry the remaining period of probation forward to be applicable to the current or new premises license number of the new owner.

11. **Notice to Employees**

Respondent shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to timely provide such notification to employees, or to timely submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

12. **Owners and Officers: Knowledge of the Law**

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%)

or more of the interest in respondent or respondent's stock, and all of its officers, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

13. **Premises Open for Business**

Respondent shall remain open and engaged in its ordinary business as a nonresident outsourcing facility for a minimum of 120 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during with this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is informed otherwise in writing by the board or its designee. If respondent is not open and engaged in its ordinary business as a nonresident outsourcing facility for a minimum of 120 hours in any calendar month, for any reason (including vacation), respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at minimum all of the following: the date(s) and hours respondent was open; the reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on which respondent will resume business as required. Respondent shall further notify the board in writing with ten (10) days following the next calendar month during which respondent is open and engaged in its ordinary business as a nonresident outsourcing facility for a minimum of 120 hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

14. **Posted Notice of Probation**

Respondent shall prominently post a probation notice provided by the board or its designee in a place conspicuous to and readable by the public within two (2) days of receipt thereof from the board or its designee. Respondent shall also provide a copy of the notice of probation in all drug or device shipments to California. Failure to timely post such notice, or to maintain the posting during the entire period of probation, shall be considered a violation of probation.

Respondent shall not, directly or indirectly, engage in any conduct or make any statement

which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

15. **Violation of Probation**

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall be automatically extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

16. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

17. **Inspection Prior to Licensure Restoration**

In the absence of any unforeseen delays, during the week of October 23, 2023, Board inspectors will attempt to inspect Respondent's premises. Respondent must demonstrate that it is in compliance with cGMP and has resolved the issues identified in the Accusation and Statement of Issues prior to the board's denial of renewal of licensure being rescinded and the permit then being issued, revoked, and having the revocation stayed.

If Respondent fails to demonstrate compliance with cGMP and resolution of the identified issues, this stipulation shall be null and void except for this paragraph, and the Accusation and Statement of Issues will continue the administrative process including but not limited to further discussions of settlement, scheduling and proceeding to an administrative hearing, and any other process to which Respondent is entitled. Respondent understands and agrees that should

Respondent fail the inspection as outlined in this paragraph, the inspection report may be considered by the board, may be incorporated into an Amended Accusation and Statement of Issues, and may be considered by the Administrative Law Judge assigned to hear this matter should the Accusation and Statement of Issues proceed to an administrative hearing.

18. **Consultant**

Within 90 days of the effective date of this Decision and Order, Respondent shall submit to the board the name of an expert in cGMP specific to outsourcing facilities to act as an expert consultant subject to the prior approval of the board or its designee. The consultant shall be responsible for conducting quarterly inspections of the facility for compliance with the provisions of federal law and the terms and conditions of probation. The consultant shall provide the board with an inspection agenda for approval prior to conducting the inspection. Any inspection conducted without prior approval of the inspection agenda shall not be accepted. The consultant shall also provide the board with quarterly reports documenting the inspection. The consultant's quarterly reports shall provide the written reports directly to the board, and receive confirmation of receipt from the board, prior to providing the report to the respondent. Should the board or its designee determine that the consultant is not appropriately assessing the operations of respondent, or providing the appropriate written reports, the board or its designee shall require respondent to obtain a different consultant through the same process outlined above, by submitting a new expert for approval within 60 days of Respondent being notified of the need for a new consultant.

19. **On-Site Quality Assurance Personnel – Management Level or Equivalent**

Within 60 days of the effective date of this Decision and Order, Respondent shall submit to the Board a management level or equivalent quality assurance employee, officer, or director, who will be assigned to work on-site at Respondent's nonresident outsourcing facility on a full-time basis, subject to the approval of the board or its designee. This identified individual must have authority over the facility and its personnel such as to be able to ensure compliance with state and federal pharmacy laws and regulations. Should the identified individual leave their employment with Respondent for any reason, Respondent must notify the board within three (3) business days of discovering that this individual will be leaving employment and provide the board with the

effective date. Respondent will have 60 days from the effective date of the identified individual leaving such employment to identify another individual with the same qualifications as set forth above, and provide that individual's name and qualifications to the board for its approval.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Jason Balogh. I understand the stipulation and the effect it will have on my Nonresident Sterile Compounding Pharmacy License, Nonresident Pharmacy Permit, and Nonresident Outsourcing Facility Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

_____
Signed

_____
(Print name)
For WELLS PHARMACY NETWORK, LLC
Respondent

I have read and fully discussed with Respondent Wells Pharmacy Network, LLC the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

_____
JASON BALOGH
Attorney for Respondent

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Jason Balogh. I understand the stipulation and the effect it will have on my Nonresident Sterile Compounding Pharmacy License, Nonresident Pharmacy Permit, and Nonresident Outsourcing Facility Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: Jul 14, 2023

Kris Fishman

KRISTOPHER FISHMAN
For WELLS PHARMACY NETWORK, LLC
Respondent

I have read and fully discussed with Respondent Wells Pharmacy Network, LLC the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 7/14/23

JASON BALOGH
Attorney for Respondent

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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: July 19, 2023

Respectfully submitted,

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General

KRISTINA T. JARVIS
Deputy Attorney General
Attorneys for Complainant

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Wells Pharmacy Stip.docx

Exhibit A

Accusation and Statement of Issues No. 7101 & 7156

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Attorneys for Complainant

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In the Matter of the Accusation Against:	Case Nos. 7101 and 7156
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THE COLLEEN STACY SHAPIRO 2010 TRUST, Shareholder;
THE SHAPIRO FAMILY D III TRUST, Shareholder;
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450 U.S. Hwy 51, Byp. N
Dyersberg, TN 38024

Nonresident Outsourcing Facility Permit number NSF 129

Respondent.

PARTIES

1. Anne Sodergren (Complainant) brings this Accusation and Statement of Issues solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about May 28, 2013, the Board of Pharmacy issued Original Nonresident Pharmacy Permit number NRP 1325 to Wells Pharmacy Network, LLC, doing business as (dba) Wells Pharmacy Network, LLC, with Nemomon LLC 24% shareholder, The Colleen Stacy Shapiro 2010 Trust, 13% shareholder, OB Joyful Dynasty Trust, 8% shareholder, The Shapiro Family D III Trust, 8% shareholder, Rachel Ellyn McKim, 8% shareholder, Kathee Kramm, 7% shareholder and member, Edward Kramm, 7% shareholder and member, and Clint Edward Myers, Pharmacist in Charge (PIC) (Respondent NRP/NSC). The Nonresident Pharmacy Permit was in full force and effect from May 28, 2013, through May 1, 2017. On or about May 1, 2017, the Nonresident Pharmacy Permit expired pursuant to a discontinuance of business.

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5. Prior to June 1, 2021, Respondent NSF applied for Nonresident Outsourcing Facility Permit number NSF 129 to be renewed. On or about May 14, 2021, the application for renewal was denied after a renewal inspection found that Respondent NSF was not in compliance with current good manufacturing practices (cGMP) and regulations adopted by the Board. On or about May 21, 2021,[1] Respondent NSF timely appealed the denial of the Nonresident Outsourcing Facility Permit renewal.

JURISDICTION

6. This First Amended Accusation and First Amended Statement of Issues is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

7. Section 4300 of the Code states in pertinent part:

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

. . .

(c) The board may refuse a license to any applicant guilty of unprofessional conduct…

. . .

[1] Although the letter is dated May 21, 2010, it was received by the Board on May 25, 2021, and it is believed the year is a mere typographical error.

(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.

8. 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 PROVISIONS

9. Section 4022 of the Code states

Dangerous drug or dangerous device means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: Caution: federal law prohibits dispensing without prescription, Rx only, or words of similar import.

(b) Any device that bears the statement: Caution: federal law restricts this device to sale by or on the order of a _____, Rx only, or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

10. Section 4129.2, subdivision (b) of the Code states

A nonresident outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities.

11. 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 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, of any other state, or of the United States regulating controlled substances and dangerous drugs.

. . .

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.

(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.

. . .

12. Section 4302 of the Code states:

The board may deny, suspend, or revoke any license where conditions exist in relation to any person holding 10 percent or more of the ownership interest or where conditions exist in relation to any officer, director, or other person with management or control of the license that would constitute grounds for disciplinary action against a licensee.

13. Section 4303, subdivision (b), of the Code states:

The board may cancel, 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.

14. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

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(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

REGULATORY PROVISIONS

15. Title 21, Code of Federal Regulations, (Regulations) Section 210.1 states, in pertinent part:

(a) The regulations set forth in this part and in parts 211, 225, and 226 of this chapter contain the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

(b) The failure to comply with any regulation set forth in this part and in parts 211, 225, and 226 of this chapter in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under section 501(a)(2)(B) of the act and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action. . .

16. Regulations Section 211.22 states, in pertinent part:

(a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

. . .

(c) The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product. . .

17. Regulations Section 211.28, subdivision (a), states:

Personnel engaged in the manufacture, processing, packing, or holding of a drug product shall wear clean clothing appropriate for the duties they perform. Protective apparel, such as head, face, hand, and arm coverings, shall be worn as necessary to protect drug products from contamination

18. Regulations Section 211.42 states, in pertinent part:

(a) Any building or buildings used in the manufacture, processing, packing, or holding of a drug product shall be of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations.

. . .

(c) Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination or mixups during the course of the following procedures:

(1) Receipt, identification, storage, and withholding from use of components, drug product containers, closures, and labeling, pending the appropriate sampling, testing, or examination by the quality control unit before release for manufacturing or packaging;. . .

19. Regulations Section 211.58 states:

Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a good state of repair.

20. Regulations Section 211.80, subdivision (c) states:

Bagged or boxed components of drug product containers, or closures shall be stored off the floor and suitably spaced to permit cleaning and inspection.

21. Regulations Section 211.84 states, in pertinent part:

(a) Each lot of components, drug product containers, and closures shall be withheld from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit.

. . .

(d) Samples shall be examined and tested as follows:

. . .

(2) Each component shall be tested for conformity with all appropriate written specifications for purity, strength, and quality. In lieu of such testing by the manufacturer, a report of analysis may be accepted from the supplier of a component, provided that at least one specific identity test is conducted on such component by the manufacturer, and provided that the manufacturer establishes the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals. . .

22. Regulations Section 211.94, subdivision (c), states:

Drug product containers and closures shall be clean and, where indicated by the nature of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use. Such depyrogenation processes shall be validated.

23. Regulations Section 211.100, subdivision (b), states:

Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified.

24. Regulations Section 211.125 states, in pertinent part:

(a) Strict control shall be exercised over labeling issued for use in drug product labeling operations. . .

25. Regulations Section 211.180, subdivision (d), states:

Records required under this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records. Where reduction techniques, such as microfilming, are used, suitable reader and photocopying equipment shall be readily available.

COST RECOVERY

26. 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

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the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DEFINITIONS

27. Quad Mix and Tri Mix are Respondent NSF's brand name for the generic drugs alprostadil, atropine, papaverine, and phentolamine. Alprostadil and papaverine are vasodilators, meaning that they open (dilate) blood vessels. Atropine inhibits involuntary nervous system actions, such as decreasing saliva production or dilating the pupils of the eyes. Phentolamine causes muscle relaxation and widening of blood vessels resulting in a lowering of blood pressure. All four of these drugs are dangerous drugs pursuant to Code section 4022. When combined by Respondent NSF into Quad Mix or Tri Mix, the resulting drug is a dangerous drug pursuant to Code section 4022. Quad Mix and Tri Mix are used to treat erectile dysfunction.

28. Testosterone is a hormone found in both genders of humans and is the primary sex hormone and anabolic steroid in males. It is a dangerous drug pursuant to Code section 4022. Respondent NSF compounds testosterone pellets that are implanted under the skin of a patient where they dissolve over time.

29. Estradiol is a form of estrogen, a female sex hormone that regulates many processes in the body. It is a dangerous drug pursuant to Code section 4022. Respondent NSF compounds estradiol into pellets that are implanted under the skin of a patient where they dissolve over time.

BACKGROUND INFORMATION

30. Respondent NSF is the corporate successor of Respondent NRP/NSC. Both Respondents have the same ownership corporation, Wells Pharmacy Network, LLC.

31. From approximately March 23, 2020, through April 23, 2020 (2020 Inspection), Board inspectors conducted an annual re-licensure inspection of Respondent NSF's facility. Due to the COVID-19 pandemic, the inspection was held remotely. Board inspectors found violations of Pharmacy Law as set forth in the first and second causes for discipline, below.

32. Although the violations were referred to the Attorney General's Office for the filing of an Accusation, the license was renewed in June 2020.

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33. In and about January and February 2021 (2021 Inspection), Board inspectors conducted an annual re-licensure inspection of Respondent NSF's facility. Due to the COVID-19 pandemic, the inspection was held remotely. Board inspectors again found violations of Pharmacy Law, some of which were repeated violations from the 2020 Inspection.

34. Many of the violations found in the 2021 Inspection are both cause for discipline of Respondent NSF's permit and are also cause for denial of Respondent NSF's application to renew its permit.

35. In 2016 and 2017, the Alabama State Board of Pharmacy filed disciplinary action against Respondent NRP/NSC resulting in Respondent NRP/NSC voluntarily surrendering its nonresident pharmacy license in the State of Alabama.

FIRST CAUSE FOR DISCIPLINE

(Failed to Complete or Maintain Dissolution Studies for Compounded Pellets to Ensure Quality of Product)

36. Respondent NSF is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (j), in conjunction with Code section 4129.2, subdivision (b), in that Respondent NSF failed to follow federal current good manufacturing practices (cGMP) in violation of Regulation section 211.22, subdivision (c). The circumstances are as follows:

37. During the 2020 Inspection, Board investigators discovered that Respondent NSF had failed to complete or maintain dissolution studies available for compounded pellets of testosterone and estradiol to ensure the quality of the product. This deprived the quality control unit of the ability to exercise its responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product.

38. During the 2021 Inspection, Board investigators discovered that Respondent NSF had failed to complete or maintain dissolution studies available for compounded pellets of testosterone and estradiol to ensure the quality of the product. This deprived the quality control unit of the ability to exercise its responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product. This is

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a repeated violation from the 2020 Inspection, indicating that Respondent NSF refused to correct their procedures in the intervening year.

39. During the 2020 Inspection, Board investigators discovered that Respondent NSF failed to complete or maintain stability testing or studies for the frozen sterile injectable products Quad Mix and Tri Mix once the product was thawed for injection into the patient. This deprived the quality control unit of the ability to exercise the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product.

SECOND CAUSE FOR DISCIPLINE

(Failed to Maintain Quality of Compounded Sterile Preparations)

40. Respondent NSF is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (j), in conjunction with Code section 4129.2, subdivision (b), in that Respondent NSF failed to follow cGMP and is in violation of Regulation section 211.22, subdivision (b). The circumstances are that during the 2020 Inspection, Board investigators discovered that Respondent NSF failed to complete or maintain shipping studies for shipping frozen vials of Quad Mix and Tri Mix to ensure that the vials remained frozen throughout the shipping process. This deprived the quality control unit of the ability to exercise the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products. The quality control unit did not have control over the distribution of their frozen product.

THIRD CAUSE FOR DISCIPLINE

(Failed to Exercise Strict Control over Labeling)

41. Respondent NSF is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (j), in conjunction with Code section 4129.2, subdivision (b), in that Respondent NSF failed to follow cGMP and is in violation of Regulation section 211.125, subdivision (a). The circumstances are that during the 2021 Inspection, Board investigators discovered that Respondent NSF failed to have appropriate labeling. The primary label attached to the container for pellets did not contain the quantity or proportion of inactive ingredients, the

date the drug was compounded, or the address and telephone number of the outsourcing facility as required.

FOURTH CAUSE FOR DISCIPLINE

(Production and Furnishing of Adulterated Products)

42. Respondent NSF is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (j), in conjunction with Code section 4129.2, subdivision (b), in that Respondent NSF failed to follow cGMP and is in violation of Regulation sections 210.1, by failing to comply with multiple regulations set forth below, thereby causing all drug products produced at their facility to be adulterated. Respondent NSF then furnished these adulterated products into the State of California. The circumstances are that Respondent NSF had major deficiencies in each of the nine major systems identified by Regulations Part 211, including lack of training of staff, lack of quality control staff with decision-making authority on site, dirty warehouse, lack of cleaning validation studies, no sanitization of the water system, lack of validations on equipment, inappropriate receiving control and storage control, lack of accuracy of batch record production, labels not in compliance, no shipping studies mimicking real life situations, lack of dissolution studies, lack of control of records of incoming components and container closures. Additionally, during the 2021 Inspection, Board investigators observed that Respondent NSF was in violation of the following regulations:

A. Regulations section 211.180, subdivision (d), in conjunction with Regulations section 211.84, subdivision (a), in that there is no documented review process for garbing materials purporting to be sterile prior to being used in cleanroom operations. Additionally, item numbers assigned to unique materials which are cross referenced and correspond to specifications and reviewed during the receiving process are not evaluated individual through a change control process.

B. Regulations section 211.125, subdivision (a) labeling issuance. Respondent NSF's primary and secondary labeling was not compliant in that the primary label for pellets, a blister pack, did not contain required elements of Section 503(B), subdivisions (a)(10)(A)(i), (ii), (iii)(IV, V, VII, VIII, IX, X). Specifically, the labels failed to provide a list of active and inactive

ingredients, identified by established name, and the quantity or proportion of each ingredient. Additionally, T/A 200/20mg and Progesterone 100mg did not include the quantity or proportion of inactive ingredients, the date the drug was compounded, and the address and phone number of the outsourcing facility. Respondent NSF stated they have used this label since 2017, indicating they have been in violation of these regulations for approximately four years. This violation is also set forth in paragraph 41, above.

C. Regulations section 211.100, subdivision (b), written procedures. Testosterone 200mg pellets, lot number 03252020TN5, was produced on March 25, 2020, but the batch record was not issued until April 13, 2020.

D. Regulations section 211.94, subdivision (c), drug product containers and closures. Respondent performs in-house rinsing to remove pyrogens and particulate matter from non-sterile components. No processing validations have been done by Respondent NSF to demonstrate that this rinsing is adequate.

E. Regulations section 211.84, subdivision (d)(2), testing and approval or rejection of components. Respondent NSF failed to complete testing to confirm the Certificates of Analysis (COAs) of vendors and their incoming materials. Respondent's vendor qualification process is incomplete and does not confirm that the component meets applicable United States Pharmacopeia (USP) or National Formulary (NF) monographs. There is no quarantine or control over container closures, or other materials used in the manufacturing or compounding of drug products.

F. Regulations section 211.58, maintenance. Board Inspectors observed that the building was not in good repair. Specifically, there was a pool of standing water present at the loading dock. Totes of sterile garbing material are received from the loading dock adjacent to the pool of water and then stored on the warehouse floor. The warehouse space is swept once weekly by an outside vendor. This is not adequate to prevent contamination of materials.

G. Regulations section 211.42, subdivision (c)(1), design and construction features. Respondent NSF provided photos of their facility to Board Inspectors. Respondent NSF's facility was not appropriate for compounding based on the materials pass-through having

apparent degradation or filth contamination. Set screws on the door and sidewalls of the pass-through were discolored and with apparent rust.

H. Regulations section 211.42, subdivision (c)(1), design and construction features. In conjunction with Regulations section 211.80, subdivision (c), general requirements, Board inspectors observed during a virtual walkthrough it was observed that there were no clear areas in the warehouse for designated product and subsequent process for what is quarantined. Container closures were being stored directly on the floor.

I. Regulations section 211.28, subdivision (a), personnel responsibilities. During a virtual walkthrough of the facility during the 2021 Inspection, inspectors observed two operators, K.S. and M.L., to be performing compounding while improperly garbed to prevent contamination. For both individuals, garbing material was seen protruding from the head and neck region possibly exposing skin. Both individuals, once this was called to their attention, simply adjusted their garbing and continued compounding without addressing the possibly contaminated garb.

J. Regulations section 211.22, subdivisions (b) responsibilities of quality control unit. Lots PV-01232020TN1, PV-01242020TN1, and PV-12192019TN2 failed their respective container closure integrity tests in January 2020. Respondent failed to begin investigating these failures until March 24, 2020, and sterile products continued to be produced and released using the same product formulations and container closure configurations despite these failures.

K. Regulations section 211.22, subdivision (c), responsibilities of quality control unit. There were no dissolution studies or appropriate laboratory testing for implantable pellets that supports conformance to specifications for the rate of release of each active ingredient as also set forth above in paragraphs 37 and 38.

FIFTH CAUSE FOR DISCIPLINE

(Out of State Discipline)

43. Respondent NRP/NSC is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (n), in that Respondent NRP/NSC has been disciplined by other States in which it holds licensure. The circumstances are as follows:

44. On or about November 4, 2016, the Alabama State Board of Pharmacy issued a Notice of Emergency Suspension of License as to Sterile Compounding. On June 13, 2017, Respondent NRP/NSC voluntarily surrendered its nonresident pharmacy license and paid $10,000 in costs. This disciplinary action was based on the following:

A. A FDA 483 warning letter issued on September 13, 2016, released after a 2016 FDA inspection, noted concerns over a lack of sterility assurance of compounded products.

B. A voluntary agreement to restrict practice of sterile compounding in the state of Florida, this agreement was reached and issued as a result of the September 13, 2016, FDA 483 letter.

C. A voluntary recall of all sterile human and veterinary products prepared between February 22, 2016, and September 14, 2016, this recall was issued as a result of the September 13, 2016, FDA 483 letter.

STATEMENT OF ISSUES

FIRST CAUSE FOR DENIAL

(Failure to Comply with cGMP)

45. Respondent NSF's application for renewal is subject to denial pursuant to Code section 4129.2, subdivision (c), for failing to comply with Code section 4129.2, subdivision (b), in that Respondent NSF has failed to compound in compliance with cGMP and Regulations. The circumstances are as set forth in paragraphs 30 through 44, above.

SECOND CAUSE FOR DENIAL

(Unprofessional Conduct)

46. Respondent NSF's application for renewal is subject to denial for unprofessional conduct pursuant to Code section 4300, subdivision (c), as defined by Code section 4301, subdivision (j), for violating statutes and regulations regulating controlled substances and dangerous drugs as set forth in paragraphs 30 through 44, above.

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THIRD CAUSE FOR DENIAL

(Pending Disciplinary Action)

47. Respondent NSF's application for renewal is subject to denial pursuant to Code section 4302 and Code section 4307, due to the pending disciplinary action set forth in paragraphs 30 through 44, above. The circumstances are as follows:

A. Pursuant to Code section 4302, if the Accusation results in discipline against Respondent NSF, then Wells Pharmacy Network LLC, and shareholders OB Joyful Dynasty Trust, The Colleen Stacy Shapiro 2010 Trust, The Shapiro Family D III Trust, and Rachel Ellyn McKim, as well as officers and managers Kristopher Jay Fishman, Jarrett Todd Bostwick, and William Edward McMillen shall be prohibited from owning or managing any pharmacy.

B. Pursuant to Code section 4307, if the Accusation results in discipline against Respondent NSF, then Wells Pharmacy Network LLC, and shareholders OB Joyful Dynasty Trust, The Colleen Stacy Shapiro 2010 Trust, The Shapiro Family D III Trust, Nemomon LLC, Rachel Ellyn McKim, and Shirley Ann Eis, as well as officers and managers Kristopher Jay Fishman, Jarrett Todd Bostwick, and William Edward McMillen shall be prohibited from owning or managing any pharmacy.

DISCIPLINARY CONSIDERATIONS

48. On or about July 26, 2017, Respondent NRP/NSC was publicly reproved by the Board, and ordered to pay cost recovery in the amount of $6,155.25. The circumstances are that on October 14, 2016, the Executive Officer of the Board filed an accusation against Respondent NRP/NSC alleging two causes for discipline, compounding sterile from non-sterile drugs in an improper environment, and failing to document quality assurance. Respondent NRP/NSC was engaged in compounding sterile drugs from non-sterile ingredients in a clean room that was not certified as an ISO 5 environment as required. Respondent also shipped approximately 2,890 batch-produced non-sterile to sterile compounded injectable drug products into California without documentation of end product sterility or pyrogen testing.

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OTHER MATTERS

49. Pursuant to Code section 4307, if discipline is imposed in the Accusation against Nonresident Outsourcing Facility Permit number NSF 129, issued to Wells Pharmacy Network, LLC, OB Joyful Dynasty Trust, 28% shareholder, The Colleen Stacy Shapiro 2010 Trust, 16% shareholder, The Shapiro Family D III Trust, 10% shareholder, Rachel Ellyn McKim, member and 10% shareholder, Nemomon LLC, 8% shareholder, Kristopher Jay Fishman, CEO, Jarrett Todd Bostwick, Secretary and Shareholder, William Edward McMillen, Director, and Shirley Ann Eis, Shareholder, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Outsourcing Facility Permit number NSF 129 is placed on probation or until Nonresident Outsourcing Facility Permit number NSF 129 is reinstated if it is revoked.

50. Pursuant to Code section 4307, if discipline is imposed in the Accusation against Nonresident Pharmacy Permit number NRP 1325, or Nonresident Sterile Compounding Permit number NSC 99824, issued to Wells Pharmacy Network, LLC, Nemomon LLC 24% shareholder, The Colleen Stacy Shapiro 2010 Trust, 13% shareholder, OB Joyful Dynasty Trust, 8% shareholder, The Shapiro Family D III Trust, 8% shareholder, Rachel Ellyn McKim, 8% shareholder, Kathee Kramm, member and 7% shareholder, Edward Kramm, member and 7% shareholder, and Clint Edward Myers, PIC, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Pharmacy Permit number NRP 1325, or Nonresident Sterile Compounding Permit number NSC 99824 is placed on probation or until Nonresident Pharmacy Permit number NRP 1325, or Nonresident Sterile Compounding Permit number NSC 99824 is reinstated if it is revoked.

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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 Nonresident Pharmacy Permit number NRP 1325, issued to Wells Pharmacy Network, LLC;

2. Revoking or suspending Nonresident Sterile Compounding Pharmacy Permit number NSC 99824, issued to Wells Pharmacy Network, LLC;

3. Revoking or suspending Nonresident Outsourcing Facility Permit Number NSF 129, issued to Wells Pharmacy Network, LLC;

4. Prohibiting the owners and managers of Respondent NSF, Wells Pharmacy Network, LLC, OB Joyful Dynasty Trust, The Colleen Stacy Shapiro 2010 Trust, The Shapiro Family D III Trust, Rachel Ellyn McKim, Nemomon LLC, Kristopher Jay Fishman, Jarrett Todd Bostwick, William Edward McMillen, and Shirley Ann Eis, from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Outsourcing Facility Permit number NSF 129 is placed on probation or until Nonresident Outsourcing Facility Permit number NSF 129 is reinstated if Nonresident Outsourcing Facility Permit number NSF 129 is revoked;

5. Prohibiting the owners and managers of Respondent NRP/NSC, Wells Pharmacy Network, LLC, Nemomon LLC The Colleen Stacy Shapiro 2010 Trust, OB Joyful Dynasty Trust, The Shapiro Family D III Trust, Rachel Ellyn McKim, Kathee Kramm, Edward Kramm, and Clint Edward Myers, from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Pharmacy Permit number NRP 1325, or Nonresident Sterile Compounding Permit number NSC 99824 is placed on probation or until Nonresident Pharmacy Permit number NRP 1325, or Nonresident Sterile Compounding Permit number NSC 99824 is reinstated if Nonresident Pharmacy Permit number NRP 1325, or Nonresident Sterile Compounding Permit number NSC 99824 is revoked;

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6. Ordering Wells Pharmacy Network LLC 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,

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

DATED: 11/11/2021

Signature on File

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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