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

12 In the Matter of the Accusation Against:

Case Nos. 7101 and 7156

13 **WELLS PHARMACY NETWORK LLC**
14 **dba WELLS PHARMACY NETWORK**
LLC
15 **NEMOMON LLC, Shareholder;**
16 **THE COLLEEN STACY SHAPIRO 2010**
TRUST, Shareholder;
17 **OB JOYFUL DYNASTY TRUST,**
Shareholder;
18 **THE SHAPIRO FAMILY D III TRUST,**
Shareholder;
19 **RACHEL ELLYN MCKIM, Shareholder;**
20 **KATHEE KRAMM, Shareholder and**
Member;
21 **EDWARD KRAMM, Shareholder and**
Member;
22 **CLINT EDWARD MYERS, Pharmacist-in-**
Charge.
450 U.S. Hwy 51, Byp. N
Dyersberg, TN 38024

FIRST AMENDED ACCUSATION

AND

FIRST AMENDED STATEMENT OF
ISSUES

23 **Nonresident Pharmacy Permit number NRP**
1325
24 **Nonresident Sterile Compounding**
Pharmacy Permit number NSC 99824

25
26 **WELLS PHARMACY NETWORK LLC**
dba WELLS PHARMACY NETWORK
LLC
27 **OB JOYFUL DYNASTY TRUST,**
Shareholder;
28

1 **THE COLLEEN STACY SHAPIRO 2010**
2 **TRUST, Shareholder;**
3 **THE SHAPIRO FAMILY D III TRUST,**
4 **Shareholder;**
5 **NEMOMON LLC, Shareholder;**
6 **RACHEL ELLYN MCKIM, Shareholder**
7 **and Member;**
8 **JARRETT TODD BOSTWICK, Secretary,**
9 **Shareholder, and Member;**
10 **WILLIAM EDWARD MCMILLEN,**
11 **Director;**
12 **SHIRLEY ANN EIS, Shareholder;**
13 **CLINT EDWARD MYERS, pharmacist-in-**
14 **charge.**
15 **450 U.S. Hwy 51, Byp. N**
16 **Dyersberg, TN 38024**

17 **Nonresident Outsourcing Facility Permit**
18 **number NSF 129**

19 Respondent.

20 **PARTIES**

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

24 2. On or about May 28, 2013, the Board of Pharmacy issued Original Nonresident
25 Pharmacy Permit number NRP 1325 to Wells Pharmacy Network, LLC, doing business as (dba)
26 Wells Pharmacy Network, LLC, with Nemomon LLC 24% shareholder, The Colleen Stacy
27 Shapiro 2010 Trust, 13% shareholder, OB Joyful Dynasty Trust, 8% shareholder, The Shapiro
28 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.

3. 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

1 May 1, 2017. On or about May 1, 2017, the Nonresident Sterile Compounding Pharmacy Permit
2 expired pursuant to a discontinuance of business.

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

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

17 **JURISDICTION**

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

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

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

24 ...

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

27 ...

28 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.

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

6 8. Section 4300.1 of the Code states:

7 The expiration, cancellation, forfeiture, or suspension of a board-issued license
8 by operation of law or by order or decision of the board or a court of law, the
9 placement of a license on a retired status, or the voluntary surrender of a license by a
10 licensee shall not deprive the board of jurisdiction to commence or proceed with any
11 investigation of, or action or disciplinary proceeding against, the licensee or to render
12 a decision suspending or revoking the license.

13 STATUTORY PROVISIONS

14 9. Section 4022 of the Code states

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

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

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

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

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

26 A nonresident outsourcing facility shall compound all sterile products and
27 nonsterile products to be distributed or used in this state in compliance with regulations
28 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.

...

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

9 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
10 abetting the violation of or conspiring to violate any provision or term of this chapter
11 or of the applicable federal and state laws and regulations governing pharmacy,
12 including regulations established by the board or by any other state or federal
13 regulatory agency.

14 ...

15 12. Section 4302 of the Code states:

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

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

22 The board may cancel, deny, revoke, or suspend a nonresident pharmacy
23 registration, issue a citation or letter of admonishment to a nonresident pharmacy, or
24 take any other action against a nonresident pharmacy that the board may take against
25 a resident pharmacy license, on any of the same grounds upon which such action
26 might be taken against a resident pharmacy, provided that the grounds for the action
27 are also grounds for action in the state in which the nonresident pharmacy is
28 permanently located.

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

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

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

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

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

16 **REGULATORY PROVISIONS**

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

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

25 (b) The failure to comply with any regulation set forth in this part and in parts 211, 225, and
26 226 of this chapter in the manufacture, processing, packing, or holding of a drug shall render such
27 drug to be adulterated under section 501(a)(2)(B) of the act and such drug, as well as the person
28 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.

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(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.

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

3 DEFINITIONS

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

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

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

19 BACKGROUND INFORMATION

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

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

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

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

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

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

11 **FIRST CAUSE FOR DISCIPLINE**

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

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

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

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

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

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

9 **SECOND CAUSE FOR DISCIPLINE**

10 **(Failed to Maintain Quality of Compounded Sterile Preparations)**

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

21 **THIRD CAUSE FOR DISCIPLINE**

22 **(Failed to Exercise Strict Control over Labeling)**

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

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

3 **FOURTH CAUSE FOR DISCIPLINE**

4 **(Production and Furnishing of Adulterated Products)**

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

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

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

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

7 C. Regulations section 211.100, subdivision (b), written procedures. Testosterone
8 200mg pellets, lot number 03252020TN5, was produced on March 25, 2020, but the batch record
9 was not issued until April 13, 2020.

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

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

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

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

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

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

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

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

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

24 **FIFTH CAUSE FOR DISCIPLINE**

25 **(Out of State Discipline)**

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

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

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

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

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

13 **STATEMENT OF ISSUES**

14 **FIRST CAUSE FOR DENIAL**

15 **(Failure to Comply with cGMP)**

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

20 **SECOND CAUSE FOR DENIAL**

21 **(Unprofessional Conduct)**

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

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1 **THIRD CAUSE FOR DENIAL**

2 **(Pending Disciplinary Action)**

3 47. Respondent NSF’s application for renewal is subject to denial pursuant to Code
4 section 4302 and Code section 4307, due to the pending disciplinary action set forth in paragraphs
5 30 through 44, above. The circumstances are as follows:

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

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

17 **DISCIPLINARY CONSIDERATIONS**

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

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OTHER MATTERS

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

12 50. Pursuant to Code section 4307, if discipline is imposed in the Accusation against
13 Nonresident Pharmacy Permit number NRP 1325, or Nonresident Sterile Compounding Permit
14 number NSC 99824, issued to Wells Pharmacy Network, LLC, Nemomon LLC 24% shareholder,
15 The Colleen Stacy Shapiro 2010 Trust, 13% shareholder, OB Joyful Dynasty Trust, 8%
16 shareholder, The Shapiro Family D III Trust, 8% shareholder, Rachel Ellyn McKim, 8%
17 shareholder, Kathee Kramm, member and 7% shareholder, Edward Kramm, member and 7%
18 shareholder, and Clint Edward Myers, PIC, shall be prohibited from serving as a manager,
19 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
20 Nonresident Pharmacy Permit number NRP 1325, or Nonresident Sterile Compounding Permit
21 number NSC 99824 is placed on probation or until Nonresident Pharmacy Permit number NRP
22 1325, or Nonresident Sterile Compounding Permit number NSC 99824 is reinstated if it is
23 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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