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

In the Matter of the Accusation Against: **STROHECKER'S PHARMACY, INC.,** **dba STROHECKERS' PHARMACY** **RONALD DULWICK, PRESIDENT** **2855 A SW Patton Road** **Portland, OR 97201** **Non-Resident Pharmacy Permit No. NRP 705** **Non-Resident Sterile Compounding Permit No. NSC 99432** Respondent. **STROHECKER'S PHARMACY, INC.,** **dba STROHECKERS' PHARMACY** **RONALD DULWICK, PRESIDENT/SECRETARY** **1286 SE Holgate, Suite C-1** **Portland, OR 97202** **Non-Resident Pharmacy Permit No. NRP 1806** Affiliated Party.	Case No. 5784 OAH No. 2017030413

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on August 10, 2017.

It is so ORDERED on July 11, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

XAVIER BECERRA
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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
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STATE OF CALIFORNIA

In the Matter of the Accusation Against: **STROHECKER'S PHARMACY, INC.,** **dba STROHECKER'S PHARMACY** **RONALD DULWICK, PRESIDENT** **2855A SW Patton Road** **Portland, OR 97201** **Non-Resident Pharmacy Permit No. NRP 705** **Non-Resident Sterile Compounding Permit No. NSC 99432** **Respondent.**	Case No. 5784 OAH No. 2017030413 **STIPULATED SURRENDER OF LICENSES AND ORDER**
STROHECKER'S PHARMACY, INC., **dba STROHECKER'S PHARMACY** **RONALD DULWICK, PRESIDENT/SECRETARY** **1286 SE Holgate, Suite C-1** **Portland, OR 97202** **Non-Resident Pharmacy Permit No. NRP 1806** **Affiliated Party.**	

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

PARTIES

1. Virginia Herold (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 Xavier Becerra, Attorney General of the State of California, by David E. Brice, Deputy Attorney General.

2. Strohecker's Pharmacy, Inc. dba Strohecker's Pharmacy (Respondent) is represented in this proceeding by attorney Lee Rosebush, whose address is: Baker Hostetler, 1050 Connecticut Ave, N.W., Suite 1100, Washington, DC 20036-5304.

3. On or about May 25, 2007, the Board issued Non-Resident Pharmacy Permit Number NRP 705 to Strohecker's Pharmacy, Inc., dba Strohecker's Pharmacy, with Ronald Dulwick as president. The non-resident pharmacy permit expired on May 1, 2016, and was canceled on June 6, 2016.

4. On or about May 29, 2007, the Board issued Non-Resident Sterile Compounding Permit Number NSC 99432 to Respondent. The non-resident sterile compounding permit expired on May 1, 2014, but was renewed on or about October 17, 2014. The non-resident sterile compounding permit expired on May 1, 2016, and has not been renewed.

5. On or about June 15, 2016, the Board issued Non-Resident Pharmacy Permit Number NRP 1806 to Respondent with Ronald Dulwick as president and secretary. The non-resident pharmacy permit will expire on June 1, 2017, unless renewed.

JURISDICTION

6. First Amended Accusation No. 5784 was filed before the Board and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on December 14, 2016. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of First Amended Accusation No. 5784 is attached as Exhibit A and incorporated by reference.

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ADVISEMENT AND WAIVERS

7. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 5784. Respondent also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of Licenses and Order.

8. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; 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.

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

CULPABILITY

10. Respondent understands that the charges and allegations in First Amended Accusation No. 5784, if proven at a hearing, constitute cause for imposing discipline upon both of its Non-Resident Pharmacy Permits as well as for its Non-Resident Sterile Compounding Permit.

11. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the eighth, ninth, tenth, eleventh, and twelfth causes for discipline in the First Amended Accusation and that those charges constitute cause for discipline. Respondent hereby gives up its right to contest that cause for discipline exists based on those charges.

12. Respondent understands that by signing this stipulation it enables the Board to issue an order accepting the surrender of both of its Non-Resident Pharmacy Permits and its Non-Resident Sterile Compounding Permit without further process.

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CONTINGENCY

13. This stipulation shall be subject to approval by the Board. Respondent understands and agrees that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and surrender, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Surrender of Licenses and 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.

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

15. This Stipulated Surrender of Licenses and Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Surrender of Licenses and Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

16. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Order:

ORDER

IT IS HEREBY ORDERED that Non-Resident Pharmacy Permit No. NRP 705, Non-Resident Pharmacy Permit Number NRP 1806, and Non-Resident Sterile Compounding Permit No. NSC 99432 issued to Respondent Strohecker's Pharmacy, Inc. dba Strohecker's Pharmacy, are surrendered and accepted by the Board of Pharmacy.

1. The surrender of Respondent's Non-Resident Pharmacy Permits and Non-Resident Sterile Compounding Permit and the acceptance of the surrendered licenses by the Board shall

constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board of Pharmacy.

2. Respondent shall lose all rights and privileges as a Non-Resident Pharmacy in California as of the effective date of the Board's Decision and Order.

3. Respondent shall cause to be delivered to the Board its pocket licenses and, if one was issued, its wall certificates on or before the effective date of the Decision and Order.

4. If Respondent ever applies for licensure or petitions for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in First Amended Accusation No. 5784 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition.

5. Respondent may not reapply for any license from the board for three (3) years from the effective date of the Board's Decision and Order.

6. Respondent shall pay the agency its costs of investigation and enforcement in the amount of $13,127.50 within thirty (30) days of the effective date of the Board's Decision and Order.

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ACCEPTANCE

I have carefully read the above Stipulated Surrender of Licenses and Order and have fully discussed it with my attorney, Lee Rosebush. I understand the stipulation and the effect it will have on the Non-Resident Pharmacy Permits and Non-Resident Sterile Compounding Permit issued to Strohecker's Pharmacy, Inc., dba Strohecker's Pharmacy.. I enter into this Stipulated Surrender of Licenses and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 6/9/2017

RONALD DULWICK, PRESIDENT
STROHECKER'S PHARMACY, INC. DBA
STROHECKER'S PHARMACY
Respondent

I have read and fully discussed with Ronald Dulwick, president of Respondent Strohecker's Pharmacy, Inc. dba Strohecker's Pharmacy, the terms and conditions and other matters contained in this Stipulated Surrender of Licenses and Order. I approve its form and content.

DATED: 6/14/17

LEE ROSEBUSH
Attorney for Respondent

ENDORSEMENT

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

Dated: 6/14/2017

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General

DAVID E. BRICE
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

First Amended Accusation No. 5784

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

In the Matter of the Accusation Against: **STROHECKER'S PHARMACY, INC.,** **dba STROHECKER'S PHARMACY** **RONALD DULWICK, PRESIDENT** **2855A SW Patton Road** **Portland, OR 97201** **Non-Resident Pharmacy Permit No. NRP 705** **Non-Resident Sterile Compounding Permit No. NSC 99432** **Respondent.**	Case No. 5784 **FIRST AMENDED ACCUSATION**
STROHECKER'S PHARMACY, INC., **dba STROHECKER'S PHARMACY** **RONALD DULWICK, PRESIDENT/SECRETARY** **1286 SE Holgate, Suite C-1** **Portland, OR 97202** **Non-Resident Pharmacy Permit No. NRP 1806** **Affiliated Party.**	

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Complainant alleges:

PARTIES

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

2. On or about May 25, 2007, the Board issued Non-Resident Pharmacy Permit Number NRP 705 to Strohecker's Pharmacy, Inc., doing business as Strohecker's Pharmacy ("Respondent Strohecker's"), with Ronald Dulwick as president. On or about April 4, 2011, T.T. became the pharmacist-in-charge ("PIC"). On or about February 4, 2016, B.S. replaced T.T. as the PIC. The non-resident pharmacy permit expired on May 1, 2016, and was canceled on June 6, 2016.

3. On or about May 29, 2007, the Board issued Non-Resident Sterile Compounding Permit Number NSC 99432 to Respondent Strohecker's. The non-resident sterile compounding permit expired on May 01, 2014, but was renewed on or about October 17, 2014. The non-resident sterile compounding permit expired on May 1, 2016, and has not been renewed.

4. On or about June 15, 2016, the Board issued Non-Resident Pharmacy Permit Number NRP 1806 to Respondent Strohecker's with Ronald Dulwick as president and secretary and T.T. as the PIC. The non-resident pharmacy permit will expire on June 1, 2017, unless renewed.

JURISDICTION

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

6. Code section 4300 states, in pertinent part:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

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

7. Code section 4300.1 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

8. Code section 4301 states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct . . . Unprofessional conduct shall include, but is not limited to, any of the following:

. . . .

(b) Incompetence.

. . . .

(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.

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

9. Code section 4307 states, in pertinent part:

(a) Any person . . . whose license has been revoked or is under suspension . . . or who has been a manager, administrator, owner, member, officer, director, associate, or partner of any partnership, corporation, 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, or partner had knowledge of or knowingly participated in any conduct for which the license was . . . revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

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(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.

(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, or partner," as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in that capacity in or for a licensee . . .

10. Code section 4127.2 states, in pertinent part:

(a) A nonresident pharmacy shall not compound injectable sterile drug products for shipment into the State of California without a license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

. . . .

(e) A pharmacy licensed pursuant to this section shall do all of the following:

. . . .

(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.

11. Code section 4127.9 states:

(a) A pharmacy licensed pursuant to Section 4127.1 or 4127.2, including a pharmacy that is exempt from licensure pursuant to subdivision (d) of Section 4127.1 and subdivision (c) of Section 4127.2, that issues a recall notice regarding a sterile compounded drug shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

(b) A recall notice issued pursuant to subdivision (a) shall be made as follows:

(1) If the recalled drug was dispensed directly to the patient, the notice shall be made to the patient.

(2) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber, who shall ensure the patient is notified.

(3) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy, who shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.

REGULATIONS

12. Title 16, California Code of Regulations ("CCR"), section 1716, states, in pertinent part: "Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code."

13. Title 16, CCR, section 1735.1, subdivision (d), states that "'[q]uality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label."

14. Title 16, CCR, section 1735.2 states, in pertinent part:

. . . .

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration dating requirements.

(4) Inactive ingredients to be used.

(5) Process and/or procedure used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

. . . .

(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

. . . .

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded

drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product . . .

15. Title 16, CCR, section 1735.5 states, in pertinent part:

. . . .

(c) The policy and procedure manual shall include the following

. . . .

(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

16. Title 16, CCR, section 1735.7 states, in pertinent part:

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

. . . .

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

17. Title 16, CCR, section 1751.3 states, in pertinent part:

. . . .

(d) Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:

. . . .

(3) Policies and procedures must address at least the following:

. . . .

(J) Sterilization . . .

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18. Title 16, CCR, section 1751.6 states, in pertinent part:

. . . .

(e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

. . . .

(I) Sterilization techniques . . .

19. Title 16, CCR, section 1751.7 states, in pertinent part:

(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

. . . .

(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

. . . .

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

COST RECOVERY

20. Code section 125.3 provides, in pertinent part, that a Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

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DRUG CLASSIFICATIONS

21. Testosterone is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision (f)(30), and a dangerous drug per Code section 4022. Testosterone is indicated for use as a hormone replacement drug.

22. Estradiol is a dangerous drug pursuant to Code section 4022, and is indicated for use as a hormone replacement drug.

23. Progesterone is a dangerous drug pursuant to Code section 4022, and is indicated for use as a hormone replacement drug.

FACTUAL ALLEGATIONS

24. On or about October 17, 2014, Board Inspector P. was informed by the Board that Respondent Strohecker's' non-resident sterile compounding permit had expired on May 1, 2014, and that the pharmacy may be engaging in unlicensed activity.

25. On or about October 20, 2014, Inspector P. conducted an inspection of the pharmacy and was assisted by Ronald Dulwick ("Dulwick") and pharmacist R. H. PIC T.T. was not present during the inspection.

26. Inspector P. asked for a tour of the compounding area and was taken to the buffer area where pharmacy staff compounded high risk compounded products from non-sterile to sterile ingredients. Inspector P. was then taken to the ante room, which contained an incubator, autoclave, and depyrogenator. Inspector P. observed clean glassware on the shelves. R. H. stated that they cleaned the glassware in their oven by depyrogenation. Inspector P. observed gallon-size bottles of deionized water on the shelves and asked R. H. what they used to rinse the glassware. R. H. showed Inspector P. the deionized water. Inspector P. told R. H. that according to the pharmacy's policies and procedures, they were supposed to use purified water during the cleaning process.

27. Inspector P. told Dulwick that the pharmacy's non-resident sterile compounding permit had expired on May 1, 2014, and asked him if they were still shipping compounded drug products into California. Dulwick said yes.

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28. R. H. provided Inspector P. with documentation for compounded products sent to California, including progesterone in ethyl oleate, testosterone cyprionate in oil, and estradiol valerate in oil. Inspector P. requested and obtained a recent compounding worksheet and certificate of analysis for each product. Inspector P. also requested the master formula and reference used to compound each product. R. H. left the room and returned with the references. Inspector P. asked R. H. if these were the specific formulas that were used to make each of the compounded products identified on the worksheets, and he said yes. R. H. stated that the reference was their "recipe" and justification for the BUD (beyond use date or expiration date) used on products that were shipped to California.

29. Inspector P. compared the ingredients listed on the references with the ingredients listed on the compounding worksheets, and found that the testosterone and estradiol were not compounded in compliance with the references. The worksheet for testosterone showed that it was compounded in sesame oil and had a BUD of 180 days; the formula reference for testosterone showed that it was to be compounded in *cottonseed oil and had a BUD of 90 days.* The worksheet for estradiol showed that it was compounded in cottonseed oil and had a BUD of 180 days; the formula reference for estradiol showed that it was to be compounded in *sesame oil and had a BUD of 90 days.*

30. Inspector P. requested that Dulwick send her documentation showing the compounded drug products that were shipped to California from May 1, 2014 through October 20, 2014, as well as testosterone and estradiol products that were shipped to California from October 1, 2014 through October 20, 2014.

31. At the conclusion of the inspection, Inspector P. requested that Dulwick provide her with written justifications of the BUD's that were chosen for the compounded products and master formulas for all routinely compounded products shipped to California.

32. Later that same day (October 20, 2014), Dulwick emailed Inspector P. a list of all sterile compounded drug products the pharmacy had shipped to California from May 1, 2014 to October 20, 2014, a list showing the product name, quantity, and date dispensed, and a list of the patients' names, street addresses, and prescribers' names. Inspector P. found that the pharmacy

had dispensed approximately 1,108 prescriptions to California while its non-resident sterile compounding permit was expired.

33. On or about February 17, 2016, Inspector P. sent T.T. an email requesting the master formulas for the compounded drug products and justification of the BUD's (Dulwick had not provided the BUD justifications or master formulas as previously requested).

34. On or about February 18, 2016, Inspector P. received an email from T.T. with attachments. Each of the attachments contained a report from ARL with a microbiology report and certificate of analysis. Inspector P. found that Strohecker's failed to provide samples which met the minimum standards required by United States Pharmacopeia Chapter 71 (USP <71>) in that they sent ARL sample sizes of two vials for sterility testing instead of the required minimum of ten vials.[1]

35. On or about February 23, 2016, Inspector P. called T.T. to discuss the documentation provided on February 18, 2016. T.T. stated that the ARL reports were used to justify the extended BUD's for testosterone and estradiol. Inspector P. asked T.T. if he had ARL conduct stability testing, and explained that larger samples would have to have been provided to ARL and tested against multiple organisms in order to establish a control for stability of the products. T.T. stated that the pharmacy did not do stability testing and that he relied on the tests shown in the microbiology reports as proof that their products could have a 180 day BUD. Inspector P. told T.T. that the tests in those reports did not comply with USP <71>.

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[1] The failure to provide a USP <71> required sample would not result in a reliable or credible level of sterility assurance for the end product. Sterility assurance level (SAL) is defined as the probability of a non-sterile ingredient making it through the validated sterilization process. A lack of SAL would render the outcome of the sterility test to be invalid due to the inadequate sample size. A pharmacy must provide a USP <71> compliant sample to have assurance that their end product is sterile.

FIRST CAUSE FOR DISCIPLINE

(Unlicensed Activity)

36. Respondent Strohecker's Non-Resident Pharmacy Permit Number 705 and Non-Resident Sterile Compounding Permit Number NSC 99432 are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated Code section 4127.2, as follows: On and between May 1, 2014 and October 20, 2014, Respondent shipped approximately 1,108 high-risk sterile compounded products to California without a valid non-resident sterile compounding permit; the permit had expired on May 1, 2014, as set forth in paragraph 2 above.

SECOND CAUSE FOR DISCIPLINE

(Assignment of Beyond-Use-Dates without Written Justification for the BUD)

37. Respondent Strohecker's Non-Resident Pharmacy Permit Number 705 and Non-Resident Sterile Compounding Permit Number NSC 99432 are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated Title 16, CCR, sections 1735.2, subdivision (h), 1751.7, subdivision (a)(4), and 1735.5, subdivision (c)(5), as follows: On and between May 1, 2014 and October 20, 2014, Respondent assigned a BUD of 180 days to approximately 786 prescriptions for testosterone cyprionate 200 ml/ml in sesame oil and approximately 72 prescriptions for estradiol valerate 40 mg/ml in cottonseed oil without any documentation or written justification for the BUD chosen.

THIRD CAUSE FOR DISCIPLINE

(Failure to Prepare Master Formulas Prior to Compounding)

38. Respondent Strohecker's Non-Resident Pharmacy Permit Number 705 and Non-Resident Sterile Compounding Permit Number NSC 99432 are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated Title 16, CCR, section 1735.2, subdivision (d), as follows: On and between May 1, 2014 and October 20, 2014, Respondent shipped approximately 786 prescriptions for testosterone cyprionate 200 ml/ml in sesame oil and approximately 72 prescriptions for estradiol valerate 40

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mg/ml in cottonseed oil to California when, in fact, a written master formula had not been prepared prior to compounding each drug product.

FOURTH CAUSE FOR DISCIPLINE

(Incomplete Training of Compounding Staff)

39. Respondent Strohecker's Non-Resident Pharmacy Permit Number 705 and Non-Resident Sterile Compounding Permit Number NSC 99432 are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated Title 16, CCR, sections 1735.7, subdivisions (a) and (e), and 1751.6, subdivision (e)(1), as follows: On or about October 20, 2014, pharmacist R. H., while supervising non-sterile to sterile compounding, failed to demonstrate knowledge of the pharmacy's policies and procedures regarding sterilization techniques. Specifically, R. H. allowed the use of deionized water for the rinsing of glassware to be used in non-sterile to sterile compounding when, in fact, the pharmacy's policy and procedure required the use of purified water during that sterilization technique.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Perform Valid End Product Sterility Testing)

40. Respondent Strohecker's Non-Resident Pharmacy Permit Number 705 and Non-Resident Sterile Compounding Permit Number NSC 99432 are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated Title 16, CCR, section 1751.7, subdivision (c), as follows: Respondent failed to perform valid end product sterility testing on Lot T-2016S13 and Lot T-0725S14 for testosterone cyprionate 200 ml/ml, Lot E-0826S14 for estradiol valerate 40 mg/ml in cottonseed oil, and Lot EO-0716E14 for progesterone 50 mg/ml in ethyl oleate.

SIXTH CAUSE FOR DISCIPLINE

(Improper Method of Sterilization)

41. Respondent Strohecker's Non-Resident Pharmacy Permit Number 705 and Non-Resident Sterile Compounding Permit Number NSC 99432 are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent

violated Title 16, CCR, sections 1735.1, subdivision (d), 1735.2, subdivisions (f) and (i), 1751.3, subdivision (d)(3)(J), and 1751.6, subdivision (e)(1)(I), as follows: Respondent used autoclaving as the method of sterilization on Lot T-0926S14 for testosterone cyprionate 200 ml/ml in sesame oil and Lot E-0810S14 for estradiol valerate 40 mg/ml in cottonseed oil when, in fact, autoclaving is not an acceptable or valid means of sterilization for an oil based product.

SEVENTH CAUSE FOR DISCIPLINE

(Incompetence)

42. Respondent Strohecker's Non-Resident Pharmacy Permit Number 705 and Non-Resident Sterile Compounding Permit Number NSC 99432 are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (b), in that Respondent committed acts or omissions constituting incompetence, as set forth in paragraph 41 above.

EIGHTH CAUSE FOR DISCIPLINE

(Out-of-State Discipline)

43. Respondent Strohecker's Non-Resident Pharmacy Permit Number 705 and Non-Resident Sterile Compounding Permit Number NSC 99432 are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (n), in that Respondent was disciplined by another state as follows: On or about November 6, 2015, Respondent, through its authorized representative, signed a Consent Order in Case No. 2015-0211, *In the Matter of the Drug Outlet Registration of Strohecker's Pharmacy, Inc.*, Before the Board of Pharmacy, State of Oregon, requiring payment of a civil penalty in the amount of $10,000, with $10,000 stayed pending no further similar violation for three years and compliance with the terms of the order. The terms of the Consent Order were to 1) develop and implement a Quality Assurance Plan to address compounding procedures, documentation of compounding, batch lot sizes, ingredient testing of every lot, excursion, and recalls; 2) the pharmacist-in-charge shall directly supervise all compounding practices; 3) provide a list of all patients or representatives that have been contacted regarding the recall, or post a notice to their website; and 4) comply with all laws and rules regarding pharmacy practice. The circumstances are as follows:

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44. On or about December 1, 2014, Respondent compounded testosterone cypionate lot # T-1201S14 and inadvertently added estradiol valerate to the compound. Respondent dispensed this lot of testosterone cypionate to 351 patients in 35 states, including 90 patients in California. Respondent did not follow procedure when compounding lot # T-1201S14 and in documenting the compounding of lot # T-1201S14. Respondent did not following procedure or take appropriate action after receiving the potency test result for lot # T-1201S14 and identifying the product was not in the customary range. Respondent did not take appropriate action after being notified of the error. Respondent was alerted to the error on or about April 6, 2015, and a recall was issued on April 9, 2015. Patients were not contacted in a timely manner and, in the course of the recall, Respondent did not contact every patient, did not contact every practitioner, and did not ask every patient if they had experienced any adverse events.

NINTH CAUSE FOR DISCIPLINE

(Failure to Report Recall to Board)

45. Respondent Strohecker's Non-Resident Pharmacy Permit Number 705 and Non-Resident Sterile Compounding Permit Number NSC 99432 are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated Code section 4127.2, subdivision (e)(3), in that Respondent failed to provide to the board, within 12 hours, with the recall notice for sterile drugs it compounded and shipped into California, referenced in paragraph 44 above.

TENTH CAUSE FOR DISCIPLINE

(Medication Error)

46. Respondent Strohecker's Non-Resident Pharmacy Permit Number 705 and Non-Resident Sterile Compounding Permit Number NSC 99432 are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated Title 16, CCR, section 1716 as follows: Respondent dispensed an incorrectly compounded drug product to patients in California, as set forth in paragraph 44 above.

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ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Notify Patients of Recall)

47. Respondent Strohecker's Non-Resident Pharmacy Permit Number 705 and Non-Resident Sterile Compounding Permit Number NSC 99432 are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated Code section 4127.9, in that Respondent failed to contact patients, as soon as possible within 12 hours of the recall notice, that the use or exposure to the recalled drug shipped into California may cause serious adverse health consequences, as referenced in paragraph 44 above.

TWELFTH CAUSE FOR DISCIPLINE

(Out-of-State Discipline)

48. Respondent Strohecker's Non-Resident Pharmacy Permit Number 705 and Non-Resident Sterile Compounding Permit Number NSC 99432 are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (n), in that Respondent was disciplined by another state as follows: On or about February 24, 2016, in Case No. 15 PHM 193, *In the Matter of Disciplinary Proceedings Against Stroheckers Pharmacy, Respondent*, Before the Pharmacy Examining Board, State of Wisconsin, Respondent was reprimanded and ordered to pay a forfeiture of $500.00 and costs of $100.00. The case was based on the discipline entered by the Board of Pharmacy of the State of Oregon, which is set forth in paragraphs 43 and 44 above.

OTHER MATTERS

49. Ronald Dulwick had knowledge of and/or knowingly participated in the acts or omissions alleged above constituting grounds for discipline against Respondent Strohecker's.

50. Pursuant to Code section 4307, if discipline is imposed on Non-Resident Pharmacy Permit Number NRP 705, issued to Strohecker's Pharmacy, Inc., doing business as Strohecker's Pharmacy, Ronald Dulwick shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner for any licensee, including, but not limited to, Non-Resident Pharmacy Permit Number NRP 1806, issued to Strohecker's Pharmacy, Inc., doing business as Strohecker's Pharmacy, during the time the discipline is imposed.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Non-Resident Pharmacy Permit Number NRP 705, issued to Strohecker's Pharmacy, Inc., doing business as Strohecker's Pharmacy;

2. Revoking or suspending Non-Resident Sterile Compounding Permit Number NSC 99432, issued to Strohecker's Pharmacy, Inc., doing business as Strohecker's Pharmacy;

3. Prohibiting Ronald Dulwick from serving as a manager, administrator, owner, member, officer, director, associate, or partner for any licensee including, but not limited to, Non-Resident Pharmacy Permit Number NRP 1806, issued to Strohecker's Pharmacy, Inc., doing business as Strohecker's Pharmacy, during the time the discipline is imposed on Non-Resident Pharmacy Permit Number NRP 705, issued to Strohecker's Pharmacy, Inc., doing business as Strohecker's Pharmacy;

4. Ordering Strohecker's Pharmacy, Inc., doing business as Strohecker's Pharmacy, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

DATED: 5/26/17

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

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