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

In the Matter of the Accusation Against:

SPECIALTY COMPOUNDING LLC, DBA SPECIALTY COMPOUNDING LLC 211 S. Bell Boulevard Cedar Park, TX 78613

Nonresident Pharmacy License No. NRP 1021

Nonresident Compounding License No. NSC 99603

Respondent.

Case No. 4917

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 on December 4, 2015.

It is so ORDERED on November 4, 2015.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D. Board President

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1	KAMALA D. HARRIS		
2	Attorney General of California GREGORY J. SALUTE		
3	Supervising Deputy Attorney General DESTREE I. KELLOGG		
4	Deputy Attorney General State Bar No. 126461		
5	600 West Broadway, Suite 1600 San Diego, CA 92101		
6	P.O. Box 85266 San Diego, CA 92186-5266		
7	Telephone: (619) 645-2996 Facsimile: (619) 645-2061		
8	Attorneys for Complainant		
9	BEFORE THE BOARD OF PHARMACY		
10	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
11			
12	In the Matter of the Accusation Against:	Case No. 4917	
13	SPECIALTY COMPOUNDING LLC DBA SPECIALTY COMPOUNDING LLC	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER	
14	211 S. Bell Boulevard Cedar Park, TX 78613		
15		·	
16	Nonresident Pharmacy License No. NRP 1021		
17	Nonresident Compounding License No. NSC 99603		
18	Respondent.		
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21	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-		
22	entitled proceedings that the following matters are true:		
23	PARTIES PARTIES		
24	1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy.		
- 25	She brought this action solely in her official capacity and is represented in this matter by Kamala		
26	D. Harris, Attorney General of the State of California, by Desiree I. Kellogg, Deputy Attorney		
27	General.		
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- 2. Respondent Specialty Compounding LLC, dba Specialty Compounding LLC (Respondent) is represented in this proceeding by attorney Deborah A. Pearce of Deborah A. Pearce, LLC, whose address is: 141 Robert E. Lee Boulevard, Suite 242, New Orleans, Louisiana 90124.
- 3. On or about October 20, 2010, the Board of Pharmacy issued Nonresident Pharmacy License No. NRP 1021 to Specialty Compounding LLC, dba Specialty Compounding LLC (Respondent). The Nonresident Pharmacy License expired on October 1, 2013, was renewed and will expire on October 1, 2016, unless renewed.
- 4. On or about January 21, 2011, the Board of Pharmacy issued Nonresident Compounding License Number NSC 99603 to Specialty Compounding LLC, doing business as Specialty Compounding LLC. The Nonresident Compounding License was cancelled on November 2, 2012 because Respondent was accredited by the Pharmacy Compounding Accreditation Board. On August 10, 2013, the Pharmacy Compounding Accreditation Board suspended Respondent Specialty Compounding LLC, doing business as Specialty Compounding LLC's accreditation.

JURISDICTION

- 5. First Amended Accusation No. 4917 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondent. The First Amended Accusation and all other statutorily required documents were properly served on Respondent on August 24, 2015. Respondent timely filed its Notice of Defense contesting the First Amended Accusation.
- 6. A copy of First Amended Accusation No. 4917 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

7. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 4917. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary 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 and agrees that the charges and allegations in First Amended Accusation No. 4917, if proven at a hearing, constitute cause for imposing discipline upon its Nonresident Compounding License No. NSC 99603 and Nonresident Pharmacy License No. NRP 1021. Respondent hereby gives up its right to contest these charges.
- 11. Respondent agrees that cause exists for discipline and hereby surrenders its Nonresident Compounding License No. NSC 99603 for the Board's formal acceptance.
- 12. Respondent understands that by signing this stipulation, Respondent enables the Board to issue an order accepting the surrender of its Nonresident Compounding License No. NSC 99603 without further process.
- 13. Respondent agrees that its Nonresident Pharmacy License No. NRP 1021 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

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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 Nonresident Compounding License No. NSC 99603 issued to Specialty Compounding LLC, doing business as Specialty Compounding LLC (Respondent) is surrendered and accepted by the Board of Pharmacy.

- 1. The surrender of Respondent's Nonresident Compounding License No. NSC 99603 and the acceptance of the surrendered license 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.
- 2. Respondent shall lose all rights and privileges afforded by the Nonresident Compounding License as of the effective date of the Board's Decision and Order.

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billing, or charging for any drug, device or controlled substance.

which involves respondent's nonresident pharmacy license or which is related to the

practice of pharmacy or the manufacturing, obtaining, handling or distributing,

2. 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 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.

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

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person 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.

4. Cooperate with Board Staff

Respondent shall 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 their probation. Failure to cooperate shall be considered a violation of probation.

5. 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 \$5,000.00. Respondent shall make said payments as follows: \$500.00 on the first of each month until paid, commencing with the effective date of the Decision adopting the Stipulation. 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.

The filing of bankruptcy by respondent shall not relieve respondent of their responsibility to

reimburse the board its costs of investigation and prosecution.

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6. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. 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.

Status of License 7.

Respondent shall, at all times while on probation, maintain current licensure with the board. If respondent submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by 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.

8. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent 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.

Upon acceptance of the surrender, respondent shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

Respondent shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing

patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent may not apply for any new licensure 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 he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. 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 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.

10. 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 any officer, 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.

11. Posted Notice of Probation

Respondent shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period 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.

Failure to post such notice shall be considered a violation of probation.

12. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent license, 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. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. 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.

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13. Completion of Probation

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

ACCEPTANCE

I, Raymond L. Solano, am the managing member of Respondent. On behalf of Respondent, I have carefully read the Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Deborah A. Pearce. I understand the stipulation and the effect it will have on Respondent's Nonresident Compounding License. On behalf of Respondent, 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 Phannacy.

DATED: 8/24/15

RAYMOND L. SOLANO FOR

SPECIALTY COMPOUNDING LLC, DRA

SPECIALTY COMPOUNDING Respondent

ACCEPTANCE

I, Raymond L. Solano, am the managing member of Respondent. On behalf of Respondent, I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Deborah A. Pearce. I understand the stipulation and the effect it will have on Respondent's Nonresident Pharmacy License. On behalf of Respondent, 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: \$/26/15

RAYMOND L. BOLANO POR SPECIALTY COMPOUNDING LLC, DBA SPECIALTY

COMPOUNDING LLC

Respondent

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1	I have read and fully discussed with Respondent Specialty Compounding LLC, doing		
2	business as Specialty Compounding LLC the terms and conditions and other matters contained in		
3	the above Stipulated Settlement and Disciplinary Order. I approve its form and content.		
4	enterman.		
5	DATED: 08/26/2015 Saley: Have		
6	DEBORAH A. PEARCE Attorney for Respondent		
7	·		
8	ENDORSEMENT		
9	The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully		
10	submitted for consideration by the Board of Pharmacy.		
11	DATED: 826/15 Respectfully submitted,		
12	DATED: SCORECTFULLY submitted, KAMALA D. HARRIS		
.13	Amara : Markis Augrney General of California Gregory J. Salute		
14	Supervising Deputy Attorney General		
15			
16	DESIREE I. KELLOGO		
17	Deputy Attorney General Attorneys for Complainant		
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Exhibit A

First Amended Accusation No. 4917

1	KAMALA D. HARRIS Attorney General of California			
2	LINDA K. SCHNEIDER Supervising Deputy Attorney General			
3	Desiree I. Kellogg Deputy Attorney General			
4	State Bar No. 126461 110 West "A" Street, Suite 1100			
5	San Diego, CA 92101 P.O. Box 85266			
6	San Diego, CA 92186-5266			
7	Telephone: (619) 645-2996 Facsimile: (619) 645-2061			
8	Attorneys for Complainant			
9	BEFORE THE BOARD OF PHARMACY			
10	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA			
11		C N 4017		
12	In the Matter of the Accusation Against:	Case No. 4917		
13	SPECIALTY COMPOUNDING LLC, DBA SPECIALTY COMPOUNDING LLC			
14	211 S. Bell Boulevard Cedar Park, TX 78613	FIRST AMENDED ACCUSATION		
15	Nonresident Pharmacy License No. NRP 1021 Nonresident Compounding License No. NSC 99603			
16	Respondent.			
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19	Complainant alleges:			
20	PARTIES			
21	1. Virginia Herold (Complainant) brings this First Amended Accusation solely in her			
22	official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer			
23	Affairs.			
24	2. On or about October 20, 2010, the Board of Pharmacy issued Nonresident Pharmacy			
25	License Number NRP 1021 to Specialty Compounding LLC, doing business as Specialty			
26	Compounding LLC. The Nonresident Pharmacy License expired on October 1, 2013, was			
27	renewed and will expire on October 1, 2016, unless renewed.			
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3. On or about January 21, 2011, the Board of Pharmacy issued Nonresident Compounding License Number NSC 99603 to Specialty Compounding LLC, doing business as Specialty Compounding LLC. The Nonresident Compounding License was cancelled on November 2, 2012 because Respondent was accredited by the Pharmacy Compounding Accreditation Board. On August 10, 2013, the Pharmacy Compounding Accreditation Board suspended Respondent Specialty Compounding LLC, doing business as Specialty Compounding LLC's accreditation.

JURISDICTION

- 4. This First Amended Accusation 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 unless otherwise indicated.
- 5. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].
- 6. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.
 - 7. 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.

8. Section 4303(b) of the Code states:

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

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The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but

is not limited to, any of the following:

Section 4301 of the Code states in pertinent part:

(j) The violation of any of the statutes of this state, or 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.

(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.

10. Section 111250 of Health & Safety Code section states:

Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

11. Section 111255 of Health & Safety Code section states:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

12. Section 111295 of Health & Safety Code section states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

13. Section 111300 of Health & Safety Code section states:

It is unlawful for any person to adulterate any drug or device.

14. California Code of Regulations, title 16, section 1735(a) states in pertinent part:

"Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

of possible adverse effects associated with the calcium gluconate infusions produced by Respondent. On that same day, Respondent issued a Notice voluntarily recalling all of its unexpired compounded sterile injectable products dispensed since May 9, 2013.

- 21. On August 9, 2013, the Board issued a Cease and Desist Order, directing Respondent not to ship, furnish, transfer, or provide, either directly or indirectly compounded sterile injectable drugs into or through California. On or about August 23, 2013, Respondent entered into a Stipulated Extension of that Cease and Desist Order, until a decision of the Board of Pharmacy following the filing of an accusation and a hearing.
- 22. On November 15, 2013, the FDA released laboratory results from samples it obtained of Respondent's sterile injectable products taken at Respondent's sterile drug compounding and manufacturing facility and at various health care facilities. The FDA's analysis of these samples identified the following contaminants in recalled products: (1) Lot Number 05142013M14 of calcium gluconate 10% tested positive for the presence of non-viable mold-like hyphae *Kocuria Varians* and *Kocuria Krinae* and (2) Lot Number 0792013M16 of calcium gluconate 2gm in 100ml sodium chloride, 0.9% injectable tested positive for the presence of *Gardnerella Vaginalis*, *Streptococcus Pluranimalium* and *Streptococcus Thoraltensis*. The FDA opined that "based on our inspectional findings and the sample results, we do not believe [Respondent] should perform any sterile drug production at this time."
- 23. On or about February 11, 2014, the Texas State Board of Pharmacy entered Agreed Board Order # K-13-015 B in a disciplinary action entitled "In the matter of Specialty Compounding, LLC." The Order was based on allegations that Respondent's pharmacist-in-charge failed to properly supervise pharmacy personnel and an employee engaged in the duties of a pharmacy technician trainee without a valid registration. The Order imposed a \$3,000 administrative penalty and required Respondent to develop and implement certain policies and procedures.
- 24. On or about February 23, 2015, the United States of America filed a Complaint for Permanent Injunction against Specialty Compounding LLC, Raymond L. Solano III and William L. Swail in *United States of America v. Specialty Compounding LLC, et al.*, Case Number

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A15CV0148LY, alleging among other things that Respondents compounded drugs that were adulterated and misbranded due to filth, insanitary conditions and current good manufacturing practice violations and that Respondent's actions violated numerous federal laws and regulations. On or about March 10, 2015, the Consent Decree of Permanent Injunction was entered against Respondent, precluding among other things, the compounding of sterile drug products.

Board Order # K-13-029 in a disciplinary action entitled "In the matter of Specialty Compounding, LLC." The Order was based on the entry of the Consent Decree of Permanent Injunction in United States v. Specialty Compounding LLC, et al. Case Number A15CV0148LY, United States District Court for the Western District of Texas. The Order placed Respondent on probation for a period of two years, ordered them not to violate any pharmacy or drug statute or rule of Texas, another state, or the United States with respect to pharmacy, controlled substances, and dangerous drugs, ordered them to pay a probation fee and comply with other terms of probation, including developing and implementing policies and procedures for a Continuous Quality Improvement Program and retaining a sterile compounding consultant.

FIRST CAUSE FOR DISCIPLINE

(Manufacture, Sell, Deliver, Hold or Offer for Sale Adulterated Sterile Injectable Drugs)

26. Respondent is subject to disciplinary action for unprofessional conduct under Code section 4301(j), for violating Health and Safety Code section 111295, in that it manufactured, sold, delivered, held or offered for sale, sterile injectable drugs that were adulterated within the meaning of Health and Safety Code sections 111250 and 111255, as set forth in paragraphs 17 through 25, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Adulterated Sterile Injectable Drugs)

27. Respondent is subject to disciplinary action for unprofessional conduct under Code section 4301(j), for violating Health and Safety Code section 111300, in that it adulterated sterile injectable drugs within the meaning of Health and Safety Code sections 111250 and 111255, as set forth in paragraphs 17 through 25, which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Out of State Discipline)

28. Respondent is subject to disciplinary action for unprofessional conduct under Code section 4301(n), in that it was disciplined by the Texas State Board of Pharmacy as described in paragraphs 17 through 25 above, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

29. Respondent is subject to disciplinary action for unprofessional conduct under Code section 4301, in that it engaged in the activities described in paragraphs 17 through 25 above, which are incorporated herein by reference.

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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 License Number NRP 1021, issued to Specialty Compounding LLC, doing business as Specialty Compounding LLC;
- 2. Revoking or suspending Nonresident Compounding License Number NSC 99603, issued to Specialty Compounding LLC, dba Specialty Compounding LLC;
- 3. Ordering Specialty Compounding LLC, doing business as Specialty Compounding 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;
 - 4. Taking such other and further action as deemed necessary and proper.

DATED: August 24, 2015

VIRGINIA HEROLD

Executive Officer

Board of Pharmacy

Department of Consumer Affairs

State of California

Complainant

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