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

11 In the Matter of the Accusation Against:

Case No. 4917

12 **SPECIALTY COMPOUNDING LLC, DBA**
13 **SPECIALTY COMPOUNDING LLC**
14 **211 S. Bell Boulevard**
Cedar Park, TX 78613

ACCUSATION

15 **Nonresident Pharmacy License No. NRP 1021**
16 **Nonresident Compounding License No. NSC 99603**

17 Respondent.

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19 Complainant alleges:

20 **PARTIES**

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

23 2. On or about October 20, 2010, the Board of Pharmacy issued Nonresident Pharmacy
24 License Number NRP 1021 to Specialty Compounding LLC, doing business as Specialty
25 Compounding LLC. The Nonresident Pharmacy License expired on October 1, 2013, and has not
26 been renewed.
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- 1 (2) Altering the strength of a drug
2 (3) Combining components or active ingredients
3 (4) Preparing a drug product from chemicals or bulk drug substances
4 ...

5 **COST RECOVERY**

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

10 **DRUG**

11 16. Calcium gluconate is used as a calcium replacement and is a dangerous drug pursuant
12 to Business and Professions Code section 4022.

13 **FACTUAL ALLEGATIONS**

14 17. On or about November 7, 2007, the Texas State Board of Pharmacy issued Pharmacy
15 License Number 25802 to Respondent which will expire on November 30, 2015, unless renewed.

16 18. From approximately January 21, 2010 through August 9, 2013, Respondent
17 compounded sterile and non-sterile injectable compounded drug products at their compounding
18 facility in Texas and furnished certain of those drug products to patients in California.

19 19. On or about August 7, 2012, the Texas State Board of Pharmacy entered Agreed
20 Board Order #K-10-065-B in a disciplinary action entitled "*In the matter of Specialty*
21 *Compounding, LLC.*" The Order was based on allegations that Respondent unlawfully engaged in
22 the practice of pharmacy, in that Respondent dispensed and sold 224 prescription drugs to patients
23 in 10 states where Respondent did not possess a license from the respective states' board of
24 pharmacy or other state licensing entity necessary to operate in each state as a pharmacy or
25 wholesale facility. The Order imposed a \$5,000.00 administrative penalty and required
26 Respondent to develop and implement certain policies and procedures.

27 20. On August 9, 2013, the FDA issued a Health Alert, notifying health care professionals
28 not to use any sterile products supplied by Respondent because there were reports of possible

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

4 21. On August 9, 2013, the Board issued a Cease and Desist Order, directing Respondent
5 not to ship, furnish, transfer, or provide, either directly or indirectly compounded sterile injectable
6 drugs into or through California. On or about August 23, 2013, Respondent entered into a
7 Stipulated Extension of that Cease and Desist Order, until a decision of the Board of Pharmacy
8 following the filing of an accusation and a hearing.

9 22. On November 15, 2013, the FDA released laboratory results from samples it obtained
10 of Respondent's sterile injectable products taken at Respondent's sterile drug compounding and
11 manufacturing facility and at various health care facilities. The FDA's analysis of these samples
12 identified the following contaminants in recalled products: (1) Lot Number 05142013M14 of
13 calcium gluconate 10% tested positive for the presence of non-viable mold-like hyphae *Kocuria*
14 *Varians* and *Kocuria Krinae* and (2) Lot Number 0792013M16 of calcium gluconate 2gm in
15 100ml sodium chloride, 0.9% injectable tested positive for the presence of *Gardnerella*
16 *Vaginalis*, *Streptococcus Plurimalium* and *Streptococcus Thoraltensis*. The FDA opined that
17 "based on our inspectional findings and the sample results, we do not believe [Respondent]
18 should perform any sterile drug production at this time."

19 23. On or about February 11, 2014, the Texas State Board of Pharmacy entered Agreed
20 Board Order # K-13-015 B in a disciplinary action entitled "*In the matter of Specialty*
21 *Compounding, LLC.*" The Order was based on allegations that Respondent's pharmacist-in-
22 charge failed to properly supervise pharmacy personnel and an employee engaged in the duties of
23 a pharmacy technician trainee without a valid registration. The Order imposed a \$3,000
24 administrative penalty and required Respondent to develop and implement certain policies and
25 procedures.

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FIRST CAUSE FOR DISCIPLINE

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

24. 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 23, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Adulterate Sterile Injectable Drugs)

25. 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 23, which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Out of State Discipline)

26. 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 23 above, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

27. 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 23 above, which are incorporated herein by reference.

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;

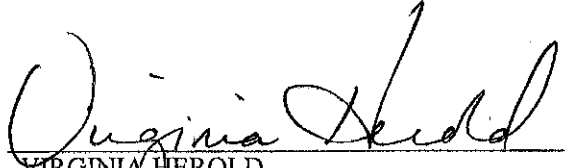
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2. Revoking or suspending Nonresident Compounding License Number NSC 99603,
issued to Specialty Compounding LLC, dba Specialty Compounding LLC;

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: 5/10/14



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

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