1	KAMALA D. HARRIS			
2	Attorney General of California LINDA K. SCHNEIDER			
3	Supervising Deputy Attorney General DESIREE I. KELLOGG			
4	Deputy Attorney General 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 Telephone: (619) 645-2996			
7	Facsimile: (619) 645-2061 Attorneys for Complainant			
8				
9	BEFORE THE BOARD OF PHARMACY			
10	DEPARTMENT OF CONSUM STATE OF CALIFOR			
11		1		
· .	In the Matter of the Accusation Against:	Case No. 4917		
12	SPECIALTY COMPOUNDING LLC, DBA			
13	SPECIALTY COMPOUNDING LLC 211 S. Bell Boulevard	ACCUSATION		
14	Cedar Park, TX 78613			
15	Nonresident Pharmacy License No. NRP 1021			
16	Nonresident Compounding License No. NSC 99603			
17	Respondent.			
18				
19				
20	Complainant alleges:			
	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				
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, and has not			
27	been renewed.			
28				
	1			
		Accusation		

.

	·	
1	3. On or about January 21, 2011, the Board of Pharmacy issued Nonresident	
2	Compounding License Number NSC 99603 to Specialty Compounding LLC, doing business as	
3	Specialty Compounding LLC. The Nonresident Compounding License was cancelled on	
4	November 2, 2012 because Respondent was accredited by the Pharmacy Compounding	
5	Accreditation Board. On August 10, 2013, the Pharmacy Compounding Accreditation Board	
6	suspended Respondent Specialty Compounding LLC, doing business as Specialty Compounding	
7	LLC's accreditation.	
8	JURISDICTION	
9	4. This Accusation is brought before the Board of Pharmacy (Board), Department of	
10	Consumer Affairs, under the authority of the following laws. All section references are to the	
11	Business and Professions Code unless otherwise indicated.	
12	5. Section 4011 of the Code provides that the Board shall administer and enforce both	
13	the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances	
14	Act [Health & Safety Code, § 11000 et seq.].	
15	6. Section 4300(a) of the Code provides that every license issued by the Board may be	
16	suspended or revoked.	
17	7. Section 4300.1 of the Code states:	
18	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	
19 20	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	
21	a decision suspending or revoking the license.	
22	8. Section 4303(b) of the Code states:	
23	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	
24	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	
25	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	
26	located.	
27	· · ·	
28		
	2	
	Accusation	

1	STATUTORY AND REGULATORY PROVISIONS		
2	9. Section 4301 of the Code states in pertinent part:		
3			
	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		
5	is not limited to, any of the following:		
5	(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.		
7 8			
9	(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.		
1	(o) Violating or attempting to violate, directly or indirectly, or assisting in or		
2	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.		
4			
5	10. Section 111250 of Health & Safety Code section states:		
5	Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.		
8	11. Section 111255 of Health & Safety Code section states:		
9	Any drug or device is adulterated if it has been produced, prepared, packed, or		
b	held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.		
1	12. Section 111295 of Health & Safety Code section states:		
2	It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.		
3 4	13. Section 111300 of Health & Safety Code section states:		
- 11	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		
5	"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:		
8	(1) Altering the dosage form or delivery system of a drug		
	3		

		l
1	(2) Altering the strength of a drug	
1	(3) Combining components or active ingredients	
2	(4) Preparing a drug product from chemicals or bulk drug substances	
3		
4	COST RECOVERY	
5	15. Section 125.3 of the Code provides, in pertinent part, that the Board may request the	
6	administrative law judge to direct a licentiate found to have committed a violation or violations of	
7	the licensing act to pay a sum not to exceed the reasonable costs of the investigation and	
8		
9	enforcement of the case.	
10	DRUG	ŀ
11	16. <u>Calcium gluconate</u> is used as a calcium replacement and is a dangerous drug pursuant	
12	to Business and Professions Code section 4022.	ļ
13	FACTUAL ALLEGATIONS	ĺ
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	İ
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

4

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.

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

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-incharge 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.

5

26

1

2

3

4

5

6

7

8

27 28

1	FIRST CAUSE FOR DISCIPLINE
2	(Manufacture, Sell, Deliver, Hold or Offer for Sale Adulterated Sterile Injectable Drugs)
3	24. Respondent is subject to disciplinary action for unprofessional conduct under Code
4	section 4301(j), for violating Health and Safety Code section 111295, in that it manufactured,
5	sold, delivered, held or offered for sale, sterile injectable drugs that were adulterated within the
6	meaning of Health and Safety Code sections 111250 and 111255, as set forth in paragraphs 17
7	through 23, which are incorporated herein by reference.
8	SECOND CAUSE FOR DISCIPLINE
9	(Adulterate Sterile Injectable Drugs)
10	25. Respondent is subject to disciplinary action for unprofessional conduct under Code
11	section 4301(j), for violating Health and Safety Code section 111300, in that it adulterated sterile
12	injectable drugs within the meaning of Health and Safety Code sections 111250 and 111255, as
13	set forth in paragraphs 17 through 23, which are incorporated herein by reference.
14	THIRD CAUSE FOR DISCIPLINE
15	(Out of State Discipline)
16	26. Respondent is subject to disciplinary action for unprofessional conduct under Code
17	section 4301(n), in that it was disciplined by the Texas State Board of Pharmacy as described in
18	paragraphs 17 through 23 above, which are incorporated herein by reference.
19	FOURTH CAUSE FOR DISCIPLINE
20	(Unprofessional Conduct)
21	27. Respondent is subject to disciplinary action for unprofessional conduct under Code
22	section 4301, in that it engaged in the activities described in paragraphs 17 through 23 above,
23	which are incorporated herein by reference.
24	PRAYER
25	WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
26	and that following the hearing, the Board of Pharmacy issue a decision:
27	1. Revoking or suspending Nonresident Pharmacy License Number NRP 1021, issued to
28	Specialty Compounding LLC, doing business as Specialty Compounding LLC;
	6
	Accusation

Revoking or suspending Nonresident Compounding License Number NSC 99603, 2. 1 issued to Specialty Compounding LLC, dba Specialty Compounding LLC; 2 Ordering Specialty Compounding LLC, doing business as Specialty Compounding 3. 3 LLC to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of 4 this case, pursuant to Business and Professions Code section 125.3; 5 Taking such other and further action as deemed necessary and proper. 4. 6 7 8 5/10/14 DATED: 9 ÍRGINIA Executive Officer 10 Board of Pharmacy Department of Consumer Affairs 11 State of California Complainant 12 13 SD2013706332 70818697:doc 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 7 Accusation