1	Kamala D. Harris	·			
2	Attorney General of California THOMAS L. RINALDI				
3	Supervising Deputy Attorney General CRISTINA FELIX				
	Deputy Attorney General				
4	State Bar No. 195663 300 So. Spring Street, Suite 1702				
5	Los Angeles, CA 90013				
6	Telephone: (213) 897-2455 Facsimile: (213) 897-2804				
7	Attorneys for Complainant				
	BEFORE THE				
8	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS				
9	STATE OF C.	ALIFORNIA			
10	Y A MALL CALL CALL	G Nr. 5010			
11	In the Matter of the Statement of Issues Against:	Case No. 5212			
12	ARTESIA PHARMACY, INC. DBA	OAH Case No. 2016090347			
13	TRIAD COMPOUNDING PHARMACY				
	RONALD STEPHEN MILLER, CEO and	WITHDRAWAL OF			
14	Owner	STATEMENT OF ISSUES			
15	Licensed Sterile Compounding License				
10	Applicant				
16.					
16. 17	Applicant				
	Applicant  Respondents.				
17	Applicant  Respondents.  TO ALL INTERESTED PARTIES:				
17 18 19	Applicant  Respondents.  TO ALL INTERESTED PARTIES:	a Herold, solely in her official capacity as the			
17 18 19 20	Applicant  Respondents.  TO ALL INTERESTED PARTIES:				
17 18 19 20 21	Applicant  Respondents.  TO ALL INTERESTED PARTIES:  1. On or about March 16, 2016, Virginia				
17 18 19 20	Applicant  Respondents.  TO ALL INTERESTED PARTIES:  1. On or about March 16, 2016, Virginian Executive Officer of the Board of Pharmacy, Depute Issues No. 5212.	partment of Consumer Affairs, filed Statement of			
17 18 19 20 21	Applicant  Respondents.  TO ALL INTERESTED PARTIES:  1. On or about March 16, 2016, Virginia Executive Officer of the Board of Pharmacy, Deplication of Science 19, 2012.  2. On or about March 7, 2013, the Board of Pharmacy 19, 2013, the Board 19,	partment of Consumer Affairs, filed Statement of d of Pharmacy, Department of Consumer Affairs			
17 18 19 20 21 22	Respondents.  TO ALL INTERESTED PARTIES:  1. On or about March 16, 2016, Virginia Executive Officer of the Board of Pharmacy, Dept Issues No. 5212.  2. On or about March 7, 2013, the Board received an application for a Licensed Sterile Contraction.	partment of Consumer Affairs, filed Statement of d of Pharmacy, Department of Consumer Affairs mpounding License from Respondent. On or			
17 18 19 20 21 22 23 24	Applicant  Respondents.  TO ALL INTERESTED PARTIES:  1. On or about March 16, 2016, Virginian Executive Officer of the Board of Pharmacy, Deplication Services No. 5212.  2. On or about March 7, 2013, the Board received an application for a Licensed Sterile Contabout March 6, 2013, Triad Compounding Pharmacy	partment of Consumer Affairs, filed Statement of d of Pharmacy, Department of Consumer Affairs impounding License from Respondent. On or hacy certified under penalty of perjury to the			
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1	KAMALA D. HARRIS		
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7	Attorneys for Complainant		
8	BEFORE THE BOARD OF PHARMACY		
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
10		·	
11	In the Matter of the Statement of Issues Against:	Case No. 5212	
12	ARTESIA PHARMACY, INC. DBA TRIAD COMPOUNDING PHARMACY	STATEMENT OF ISSUES	
13	RONALD STEPHEN MILLER, CEO and	STATEMENT OF ISSUES	
14	Owner		
15	Licensed Sterile Compounding License Applicant		
16	Respondents.		
17		·	
18	·		
19			
20	Complainant alleges:		
21	PARTIES		
22	1. Virginia Herold (Complainant) brings this Statement of Issues solely in her official		
23	capacity as the Executive Officer of the Board of		
24	• • • • • • • • • • • • • • • • • • • •	issued Pharmacy Permit Number PHY 41551 to	
25	Artesia Pharmacy, Inc., doing business as Triad		
26	Ronald Stephen Miller designated as the Pharma		
27	Permit was in full force and effect at all times rel	evant to the charges brought herein and will	
28	expire on April 1, 2015, unless renewed.		
1			

STATEMENT OF ISSUES

ł	1				
1	3. On or about March 7, 2013, the Board of Pharmacy, Department of Consumer Affair				
2	received an application for a Licensed Sterile Compounding License from Respondent. On or				
3	about March 6, 2013, Triad Compounding Pharmacy certified under penalty of perjury to the				
4	truthfulness of all statements, answers, and representations in the application. The Board denied				
5	the application on March 19, 2014.				
6	JURISDICTION				
7	4. This Statement of Issues is brought before the Board of Pharmacy (Board),				
8	Department of Consumer Affairs, under the authority of the following laws. All section				
9	references are to the Business and Professions Code unless otherwise indicated.				
0	5. Section 4300 (c), of the Code states:				
1	The board may refuse a license to any applicant guilty of unprofessional				
2	conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure				
3					
4	STATUTORY AND REGULATORY PROVISIONS				
5	6. Section 480 of the Code states, in pertinent part:				
6	(a) A board may deny a license regulated by this code on the grounds that the applicant has one of the following:				
7	•••				
8	(3) Done any act which if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.				
20	7. Section 4040(a)(1)(c) and (c) of the Code states:				
21	(a) "Prescription" means an oral, written, or electronic transmission order that is both				
22	of the following:				
23					
24	(C) The date of issue.				
25					
26	(c) "Electronic transmission prescription" includes both image and data				
27	prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed				
28	prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically				
	11				

	transmitted from a licensed prescriber to a pharmacy.	
1	8. Section 4052(a)(1) of the Code states:	
2	(a) Notwithstanding any other law, a pharmacists:	
3	(1) Furnish a reasonable quantity of compounded drug product to a prescriber for	
4	office use by the prescriber.	
5	9. Section 4126.5 (a) of the Code states:	
6	(a) A pharmacy may furnish dangerous drugs only to the following:	
7	(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.	
9	(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.	
10	(3) A licensed wholesaler acting as a reverse distributor.	
11	(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a	
12	dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.	
13		
14		
15	(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.	
16		
17		
18	10. Section 4163 (a) of the Code states:	
19	A manufacturer, wholesaler, repackager, or pharmacy may not furnish a dangerous drug or dangerous device to an unauthorized person.	
20		
21	11. Section 4169 (a)(1) of the Code states:	
22	A person may not do any of the following: Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not	
23	licensed with the board as a wholesaler.	
24	12. Section 4301 of the Code states in pertinent part:	
25	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	
26	misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:	
27	not mined to, any of the following,	
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(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 any other state or federal regulatory agency.

13. Section 4113 (c) of the Code states:

The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

14. California Code of Regulations, title 16, section 1717 (c) states:

Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing or furnishing. Chart orders as defined in section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

15. California Code of Regulations, title 16, section 1761 (a) states:

No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

#### **FACTUAL ALLEGATIONS**

- 16. At all times referenced herein, Respondent Ronald Miller was the Pharmacist-in-Charge of Respondent Triad Compounding Pharmacy.
- 17. From at least October 28, 2011 through August 8, 2013, Respondents received electronic image and data transmission prescription orders via facsimile or email from an unlicensed entity, SportPharm Pharmaceuticals, Inc. or a wholesaler, Champion Health Services, Inc. instead of a prescriber. Respondents then dispensed, furnished and sold drugs to SportPharm Pharmaceuticals, Inc. which the Board had issued citations and fines for engaging in unlicensed activities and/or to Champion Health Services, Inc..
- 18. Respondents furnished non-patient specific compounded drug products, allegedly for "prescriber office use" to Champion Healthcare Services, Inc. and SportPharm Pharmaceuticals, Inc. who were not prescribers.

- 19. Respondents accepted and filled prescriptions which did not contain the dates of issuance on them. Respondents also accepted and filled prescriptions from sources other than the prescriber, SportsPharm Pharmaceuticals, Inc. and Champion Healthcare Services, Inc. without documenting that they contacted the prescribers to validate the prescriptions. Respondents also did not reduce oral prescriptions to writing nor did pharmacists initial oral prescriptions which were reduced to writing.
- 20. From June 25, 2013 through August 8, 2013, Respondents sold and shipped drugs to states where Respondent Triad Compounding Pharmacy was not licensed to ship drugs but was required to be licensed to ship drugs into those states.

## FIRST CAUSE FOR DENIAL

## (Sold Drugs to Unlicensed Entity)

21. Respondent's application is subject to denial under Code sections 480(a)(3) and 4301(o), for violating Business and Professions Code section 4169(a)(1), in that it sold or transferred dangerous drugs to an unlicensed entity, as set forth in paragraphs 16 through 20 above, which are incorporated herein by reference.

### SECOND CAUSE FOR DENIAL

### (Furnished Drugs to Unauthorized Entities)

22. Respondent's application is subject to denial under Code sections 480(a)(3) and 4301(o), for violating Business and Professions Code section 4126.5(a)(1), in that it furnished dangerous drugs to an unlicensed entity and a wholesaler, as set forth in paragraphs 16 through 20 above, which are incorporated herein by reference.

### THIRD CAUSE FOR DENIAL

### (Furnished Drugs to Unauthorized Person)

23. Respondent's application is subject to denial under Code sections 480(a)(3) and 4301(o), for violating Business and Professions Code section 4163(a)(1), in that it furnished dangerous drugs to an unauthorized person, an unlicensed entity, as set forth in paragraphs 16 through 20 above, which are incorporated herein by reference.

### **FOURTH CAUSE FOR DENIAL**

## (Sold or Delivered Drugs Out of State Without Licensure)

24. Respondent's application is subject to denial under Code sections 480(a)(3) and 4301(o), for violating Business and Professions Code section 4059.5(e), in that it sold and shipped dangerous drugs into states where Respondent Triad Compounding Pharmacy was unlicensed to ship drugs but was required to be licensed to do so, as set forth in paragraphs 16 through 20 above, which are incorporated herein by reference.

## FIFTH CAUSE FOR DENIAL

# (Failure to Reduce Oral Prescriptions to Writing or Initial Them)

25. Respondent's application is subject to denial under Code sections 480(a)(3) and 4301(o), for violating California Code of Regulations, title 16, section 1717(c), in that it failed to reduce oral prescriptions to writing and failed to have the pharmacist initial oral prescriptions reduced to writing, as set forth in paragraphs 16 through 20 above, which are incorporated herein by reference.

# SIXTH CAUSE FOR DENIAL

# (Failure to Contact Prescriber to Validate Prescriptions)

26. Respondent's application is subject to denial under Code sections 480(a)(3) and 4301(o), for violating California Code of Regulations, title 16, section 1761(a), in that it did not contact the prescriber to validate prescriptions received from sources other than the prescribers, as set forth in paragraphs 16 through 20 above, which are incorporated herein by reference.

## SEVENTH CAUSE FOR DENIAL

# (Accepted and Filled Prescriptions Without Date of Issue)

27. Respondent's application is subject to denial under Code sections 480(a)(3) and 4301(o), for violating Business and Professions Code sections 4040(a)(1)(C) and 1761(a), in that it accepted and filled prescriptions which did not contain the date issue written on them, as set forth in paragraphs 16 through 20 above, which are incorporated herein by reference.

### EIGHTH CAUSE FOR DENIAL

## (Accepted and Received Prescriptions From Unlicensed Entity and Wholesaler)

28. Respondent's application is subject to denial under Code sections 480(a)(3) and 4301(o), for violating Business and Professions Code section 1761(a) in that it accepted and filled electronic transmission prescriptions from an unlicensed entity and a wholesaler, as set forth in paragraphs 16 through 20 above, which are incorporated herein by reference.

## **NINTH CAUSE FOR DENIAL**

# (Furnished Non-Patient Specific Compounded Drugs to Unlicensed Entity and Wholesaler)

29. Respondent's application is subject to denial under Code sections 480(a)(3) and 4301(o), for violating Business and Professions Code section 4052(a)(1), in that it furnished nonpatient specific compounded drugs for "prescriber office use" to entities who were not prescribers, as set forth in paragraphs 16 through 20 above, which are incorporated herein by reference.

## TENTH CAUSE FOR DENIAL

# (Unprofessional Conduct)

30. Respondent's application is subject to denial under Code sections 480(a)(3) and 4301(o), for unprofessional conduct in that it engaged in the activities described in paragraphs 16 through 20 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:

Denying the application of Artesia Pharmacy, Inc., doing business as Triad 1. Compounding Pharmacy for a Licensed Sterile Compounding License;

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1	2. Taking such other and	further action as deemed necessary and proper.
2	DATED: 3/16/16	Diginie Skeold
3	DATED:	VIRGINIA HEROLD
4		Executive Officer Board of Pharmacy
5		Board of Pharmacy Department of Consumer Affairs State of California
6		Complainant
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