1 2 3 4 5 6 7 8 9	KAMALA D. HARRIS Attorney General of California LINDA K. SCHNEIDER Supervising Deputy Attorney General ANTOINETTE B. CINCOTTA Deputy Attorney General State Bar No. 120482 110 West "A" Street, Suite 1100 San Diego, CA 92101 P.O. Box 85266 San Diego, CA 92186-5266 Telephone: (619) 645-2095 Facsimile: (619) 645-2061 Attorneys for Complainant BEFORE THE BOARD OF PHARM	IACY	
10	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
11	ange		
12	In the Matter of the Accusation Against:	Case No. 4671	
13	SOUTHERN CALIFORNIA COMPOUNDING PHARMACY LLC		
14	11125 Flintkote Ave. #F San Diego, CA 92121	ACCUSATION	
15	Pharmacy Permit No. PHY 49147 Sterile Compounding Permit No. LSC 99510		
16 17	MARK BADRIA 11125 Flintkoke Ave., #F San Diego, CA 92121		
18			
19	Pharmacist License No. RPH 41678		
20	Respondents.		
21	Complainant alleges:		
22	PARTIES		
23	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity		
24	as the Executive Officer of the Board of Pharmacy, Depa	rtment of Consumer Affairs.	
25	2. On or about October 29, 2008, the Board of I	Pharmacy issued Pharmacy Permit No.	
26	PHY 49147 to Southern California Compounding Pharmacy LLC (Respondent Pharmacy). The		
27	Pharmacy Permit was in full force and effect at all times	relevant to the charges brought herein,	
28	and will expire on October 1, 2014, unless renewed.		
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1	3.	On or about December 2, 2008, the Board of Pharmacy issued Sterile Compounding	
2	Permit No.	LSC 99510 to Southern California Compounding Pharmacy LLC (Respondent	
3	Pharmacy).	The Sterile Compounding Permit was in full force and effect at all times relevant to	
4	the charges	brought herein and will expire on October 1, 2014, unless renewed.	
5	4.	On or about April 23, 1988, the Board of Pharmacy issued Pharmacist License No.	
6	RPH 41678	to Mark John Badria (Respondent Badria). The Pharmacist License was in full force	
7	and effect at all times relevant to the charges brought herein, and will expire on September 30,		
8	2015, unless renewed.		
9		JURISDICTION	
10	5.	This Accusation is brought before the Board of Pharmacy (Board), Department of	
11	Consumer A	Affairs, under the authority of the following laws. All section references are to the	
12	Business an	d Professions Code (Code) unless otherwise indicated.	
13	6,	Section 4300 of the Code states:	
14		(a) Every license issued may be suspended or revoked.	
15		(b) The board shall discipline the holder of any license issued by the board, use default has been entered or whose case has been heard by the board and	
16 17	Iour	ad guilty, by any of the following methods:	
17		<ul> <li>(1) Suspending judgment.</li> <li>(2) Planing him on her upon production</li> </ul>	
18		(2) Placing him or her upon probation.	
19 20	year	(3) Suspending his or her right to practice for a period not exceeding one	
20		(4) Revoking his or her license.	
21 22	in it	(5) Taking any other action in relation to disciplining him or her as the board s discretion may deem proper.	
23			
24		(e) The proceedings under this article shall be conducted in accordance with	
25	Gov	pter 5 (commencing with Section 11500) of Part 1 of Division 3 of the remment Code, and the board shall have all the powers granted therein. The	
26		on shall be final, except that the propriety of the action is subject to review by superior court pursuant to Section 1094.5 of the Code of Civil Procedure.	
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1	7. Section 4300.1 of the Code states:
2	The expiration, cancellation, forfeiture, or suspension of a board-issued
3	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
4	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
5	licensee or to render a decision suspending or revoking the license.
6	STATUTORY AUTHORITY
7	8. Section 4301 of the Code states:
8	The board shall take action against any holder of a license who is guilty of
9	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:
10	
11	(o) Violating or attempting to violate, directly or indirectly, or assisting in or
12	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
13 14	pharmacy, including regulations established by the board or by any other state or federal regulatory agency.
15	••••
16	REGULATIONS
17	9. California Code of Regulations, title 16, section 1751.7, states in relevant part:
18	
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19 20	(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
21	confirms sterility and acceptable levels of pyrogens.
22	
23	COSTS
24	10. Section 125.3 of the Code states, in pertinent part, that the Board may request the
25	administrative law judge to direct a licentiate found to have committed a violation or violations of
26	the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
27	enforcement of the case. If a case settles, recovery of investigation and enforcement costs may be
28	included in a stipulated settlement.
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**CAUSE FOR DISCIPLINE** 1 2 (Unprofessional Conduct - Failure to Perform End Product Testing on Batch-Produced Sterile Injectable Drug Products) 3 11. Respondents are subject to disciplinary action for unprofessional conduct under Code 4 section 4301, subdivision (o), for failing to perform end product testing on batch-produced sterile 5 injectable drug products in violation of California Code of Regulations, title 16, section 1751.7, 6 subdivision (c) as follows: 7 On a routine inspection conducted at Respondent Pharmacy on April 19, 2013, the a. 8 Board's investigators discovered that 51 sterile injectable drug products were made from batch-9 produced sterile injectable drug products compounded from one or more non-sterile ingredients. 10 Respondents dispensed these 51 sterile injectable drug products before completing end product 11 testing for sterility and acceptable levels of pyrogens. 12 **DISCIPLINE CONSIDERATIONS** 13 To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy, 12. 14 Complainant alleges that on or about June 9, 2011, in a prior action, the Board of Pharmacy 15 issued Citation Number CI 2010 46603 charging Respondent Pharmacy with violation of 16 California Code of Regulations, title 16, section 1714, subdivisions (b), (d) and (e), for operating 17 standards and security violations, and California Code of Regulations, title 16, section 1716, and 18 Business and Professions Code section 4076, subdivision (a)(2), for dispensing prescriptions not 19 correctly labeled with directions for use of the drug. Respondent Pharmacy was ordered to pay a 20 fine in the amount of \$1,000.00 by July 9, 2011. That Citation is now final and is incorporated by 21 reference as if fully set forth. 22To determine the degree of discipline, if any, to be imposed on Respondent Badria 13. 23 Complainant alleges that on or about June 9, 2011, in a prior action, the Board of Pharmacy 24 issued Citation Number CI 2010 48429 charging Respondent Badria with violation of California 25 Code of Regulations, title 16, section 1714, subdivisions (b), (d) and (e), for operating standards 26 and security violations, and California Code of Regulations, title 16, section 1716, and Business 27 and Professions Code section 4076, subdivision (a)(2), for dispensing prescriptions not correctly 28

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1	labeled with directions for use of the drug. Respondent Badria was ordered to pay a fine in the		
2	amount of \$1,375.00 by July 9, 2011. That Citation is now final and is incorporated by reference		
3	as if fully set forth.		
4	PRAYER		
5	WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,		
6	and that following the hearing, the Board of Pharmacy issue a decision:		
7	1. Revoking or suspending Pharmacy Permit No. PHY 49147 issued to Southern		
8	California Compounding Pharmacy LLC;		
9	2. Revoking or suspending Sterile Compounding Permit No. LSC 99510, issued to		
10	Southern California Compounding Pharmacy LLC;		
11	3. Revoking or suspending Pharmacist License No. RPH 41678 issued to Mark John		
12	Badria;		
13	4. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the		
14	investigation and enforcement of this case, pursuant to Business and Professions Code section		
15	125.3;		
16	5. Taking such other and further action as deemed necessary and proper		
17	DATED: 827/14 Jusine Luig		
18	Executive Officer Board of Pharmacy		
19 20	Department of Consumer Affairs State of California		
20	Complainant		
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