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

10 In the Matter of the Accusation Against:
11 **SANTA CLARA DRUG**
12 **"THE COMPOUNDING SHOP"**
13 **2453 Forest Avenue**
14 **San Jose, CA 95128**
15 **Pharmacy License No. PHY 39079**
16 **Sterile Compounding License No. LSC 99114**
17 **and**
18 **LIONEL FRANCIS JARA**
19 **19745 Lamar Drive**
20 **Cupertino, CA 95014**
21 **Pharmacist License No. RPH 21273**
22 Respondents.

Case No. 3990

A C C U S A T I O N

20 Complainant alleges:

21 PARTIES

- 22 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
23 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).
- 24 2. On or about September 2, 1993, the Board issued Pharmacy License No. PHY 39079
25 to Santa Clara Drug Pharmacy Inc. dba Santa Clara Drug "The Compounding Shop" (Respondent
26 Santa Clara). On or about July 24, 2003, the Board issued Sterile Compounding License No.
27 LSC 99114 to Respondent Santa Clara. Both licenses were in full force and effect at all times
28 relevant to the charges herein and will expire on September 1, 2012, unless renewed.

1 (j) The violation of any of the statutes of this state, of any other state, or of the United
2 States regulating controlled substances and dangerous drugs.

3 (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the
4 violation of or conspiring to violate any provision or term of this chapter or of the applicable
5 federal and state laws and regulations governing pharmacy, including regulations established by
6 the board or by any other state or federal regulatory agency.

7 9. Section 4113, subdivision (b) of the Code states:

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

10 10. Section 4342 of the Code provides, in pertinent part, that the Board may institute any
11 action or actions provided by law and deemed necessary to prevent the sale of pharmaceutical
12 preparations and drugs that do not conform to expected quality or strength.

13 11. California Code of Regulations, title 16, section 1716, states in pertinent part:

14 "Pharmacists shall not deviate from the requirements of a prescription except upon the prior
15 consent of the prescriber or to select the drug product in accordance with Section 4073. . . ."

16 12. California Code of Regulations, title 16, section 1735.3, sets forth the record-keeping
17 requirements for all forms of pharmacy compounding, and mandates the minimum records with
18 regard to each drug product compounded in the pharmacy that must be maintained and retained in
19 the pharmacy in a readily retrievable form for a period of at least three years. These records must
20 include, pursuant to section 1735.3, subdivision (a)(6), the name of the manufacturer and the lot
21 number of each component used in the compounded drug product.

22 13. California Code of Regulations, title 16, section 1751.1, subdivision (a), requires that
23 pharmacies compounding sterile injectable drug products for future use keep, in addition to those
24 records required by section 1735.3, records indicating the name, lot number, amount, and date on
25 which products were provided to a prescriber. Subdivision (c) requires that these records be kept
26 and maintained in the pharmacy in a readily retrievable form for at least three years.

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1 14. California Code of Regulations, title 16, section 1751.7, subdivision (c), requires that
2 batch-produced sterile injectable drug products compounded from one or more non-sterile
3 ingredients shall be subject to documented end product testing for sterility and pyrogens and shall
4 be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

5 15. Health and Safety Code section 11165 provides, in pertinent part, for establishment
6 and maintenance of a Controlled Substance Utilization Review and Evaluation System (CURES)
7 for the electronic monitoring of prescribing and dispensing of Schedule II, III, and IV controlled
8 substances, and requires, in pertinent part, that for each prescription for a Schedule II, III, or IV
9 controlled substance, the dispensing pharmacy or clinic transmit a report with certain information
10 on the patient, prescriber, controlled substance, and prescription, to the California Department of
11 Justice, on a weekly basis in a format prescribed by the California Department of Justice.¹

12 16. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
13 administrative law judge to direct a licentiate found to have committed a violation of the licensing
14 act to pay a sum not to exceed its reasonable costs of investigation and enforcement.

15 CONTROLLED SUBSTANCES / DANGEROUS DRUGS

16 17. Section 4021 of the Code provides that a “controlled substance” means any substance
17 listed in Schedules I through V contained in Health and Safety Code section 11053 et seq.

18 18. Section 4022 of the Code states, in pertinent part:

19 “‘Dangerous drug’ or ‘dangerous device’ means any drug or device unsafe for self use,
20 except veterinary drugs that are labeled as such, and includes the following:

21 “(a) Any drug that bears the legend: ‘Caution: federal law prohibits dispensing without
22 prescription,’ ‘Rx only,’ or words of similar import. . . .

23 “(c) Any other drug or device that by federal or state law can be lawfully dispensed only on
24 prescription or furnished pursuant to Section 4006.”

25
26
27 ¹ Health and Safety Code section 11165 was first amended to impose CURES reporting
28 requirements effective January 1, 2005. As of that date prescriptions for Schedule II and III drugs
had to be reported. Effective January 1, 2007, Schedule IV prescriptions also had to be reported.

1 THIRD CAUSE FOR DISCIPLINE

2 (Failure to Maintain Accurate Lot Numbers for Records of Compounded Drug Products)

3 24. Respondents are each and severally subject to discipline under section(s) 4301,
4 4301(j), 4301(o), and/or 4113(b) of the Code, and/or California Code of Regulations, title 16,
5 section 1735.3, subdivision (a)(6) in that on or about August 5, 2010 and/or August 24, 2010,
6 Respondents failed to record accurate lot numbers for two ingredients, **Phentolamine** Mesylate
7 Powder and **Papaverine** HCL 30mg/ml injectable, that were used in the compounding of two lots
8 of **Alprostadil 10mcg/Papaverin 30mg/Phentolamine 1mg/ml**.

9 FOURTH CAUSE FOR DISCIPLINE

10 (Failure to Maintain Records of Compounding for Future Furnishing)

11 25. Respondents are each and severally subject to discipline under under section(s) 4301,
12 4301(j), 4301(o), and/or 4113(b) of the Code, and/or California Code of Regulations, title 16,
13 section(s) 1735.2, 1735.3, and/or 1751.1, in that on or about August 11, 2010 and/or September 8,
14 2010, Respondents were unable to produce or retrieve adequate compounding records for an
15 **Alprostadil 500 mcg/ml** compound and/or solution that was found in the freezer on or about
16 August 11, 2010, or for another **Alprostadil 500mcg/ml** solution that was sent for end product
17 and potency testing on or about August 17, 2010.

18 FIFTH CAUSE FOR DISCIPLINE

19 (Failure to Quarantine Batch-Produced Products for End Product Testing)

20 26. Respondents are each and severally subject to discipline under under section(s) 4301,
21 4301(j), 4301(o), and/or 4113(b) of the Code, and/or California Code of Regulations, title 16,
22 section 1751.7, subdivision (c), in that between on or about July 22, 2010 and on or about
23 September 7, 2010, Respondents dispensed, furnished, caused to be dispensed or furnished,
24 attempted to dispense or furnish, assisted or abetted the dispensing or furnishing of, and/or
25 conspired to dispense or furnish sterile injectable products compounded from one or more non-
26 sterile ingredients, including **Alprostadil 10mcg/ml**, Lot 07282010#3956-01, compounded on or
27 about July 28, 2010, **Alprostadil 20mcg/ml**, Lot 07222010#0913-01, compounded on or about
28 July 22, 201, **Trimix 10mcg/30mg/1mg/ml**, Lot 08052010#2283-01, compounded on or about

1 August 5, 2010, and/or **Trimix** 10mcg/30mg/1mg/ml, Lot 082402010#2283-01, compounded on
2 or about August 24, 2010, without quarantining the products to conduct end-product testing.

3 SIXTH CAUSE FOR DISCIPLINE

4 (Failure to Report Controlled Substance Prescriptions to CURES)

5 27. Respondents are each and severally subject to discipline under section(s) 4301,
6 4301(j), 4301(o), and/or 4113(b) of the Code, and/or Health and Safety Code section 11165, in
7 that between in or about July 2007 and on or about May 11, 2010, Respondents failed to transmit
8 any dispensing data to CURES for Schedule II through IV controlled substances dispensed.

9 DISCIPLINE CONSIDERATIONS

10 28. To determine the level of discipline, if any, to be imposed on Respondent Santa Clara
11 and/or Respondent Jara (collectively, "Respondents"), Complainant further alleges that:

12 a. On or about November 17, 1990, in a prior disciplinary action titled *In the Matter of*
13 *the Accusation Against Lionel F. Jara and Barron Park Pharmacy*, Case No. 1494 filed April 30,
14 1990 before the Board of Pharmacy, Respondent Jara's Pharmacist License No. RPH 21273 was
15 subjected to prior discipline. By way of a Decision and Order of the Board adopting a Proposed
16 Stipulation and Decision effective November 17, 1990, Respondent Jara admitted to misconduct
17 including: failure(s) to maintain a current inventory of drugs and shortages and overages of
18 Demerol, Dilaudid, M.D. Contin, Percocet, and Tylox; filling prescriptions for the drug Darvon
19 without authorization of the prescriber; and refilling prescriptions for Darvon more than five
20 times and more than six months after issuance. Respondent admitted there were grounds for
21 disciplinary action. Respondent's Pharmacist License No. RPH 21273 was revoked, with
22 revocation stayed in favor of a period of probation of three (3) years, with specified terms and
23 conditions. Pursuant to the agreement, the Accusation against Barron Park Pharmacy was
24 dismissed. That decision is now final and is incorporated by reference as if fully set forth herein.

25 b. On or about March 27, 2008, Citation No. CI 2007 34727 with a fine of \$5,000.00
26 was issued to Respondent Santa Clara for violations including failure to maintain a quality
27 assurance program for sterile compounded drugs, maintenance of outdated drugs and chemicals in
28 the pharmacy's inventory, and failure to keep adequate preparation records for compounded

1 products (including the master worksheet, the preparation worksheet, and end-product evaluation
2 results). That citation is now final and is incorporated by reference as if fully set forth herein.

3 c. On or about March 27, 2008, Citation No. CI 2007 35712 with a fine of \$5,000.00
4 was issued to Respondent Jara for violations including failure to maintain a quality assurance
5 program for sterile compounded drugs, maintenance of outdated drugs and chemicals in the
6 pharmacy's inventory, and failure to keep adequate preparation records for compounded products
7 (including the master worksheet, the preparation worksheet, and end-product evaluation results).
8 That citation is now final and is incorporated by reference as if fully set forth herein.

9 PRAYER

10 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
11 and that following the hearing, the Board of Pharmacy issue a decision:

12 1. Revoking or suspending Pharmacy License No. PHY 39079, issued to Santa Clara
13 Drug Pharmacy Inc. dba Santa Clara Drug "The Compounding Shop" (Respondent Santa Clara);

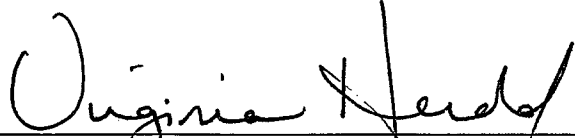
14 2. Revoking or suspending Sterile Compounding License No. LSC 99114, issued to
15 Respondent Santa Clara.

16 3. Revoking or suspending Pharmacist License No. RPH 21273, issued to Lionel
17 Francis Jara (Respondent Jara)

18 4. Ordering Respondent Santa Clara and Respondent Jara to jointly and severally be
19 responsible to pay the Board of Pharmacy the reasonable costs of the investigation and
20 enforcement of this case, pursuant to Business and Professions Code section 125.3;

21 5. Taking such other and further action as is deemed necessary and proper.

22
23
24 DATED: 3/19/12


25 VIRGINIA HEROLD
26 Executive Officer
27 Board of Pharmacy
28 Department of Consumer Affairs
State of California
Complainant

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