

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

In the Matter of the Accusation Against:

Case No. 3990

**SANTA CLARA DRUG
"THE COMPOUNDING SHOP"**
2453 Forest Avenue
San Jose, CA 95128

Pharmacy License No. PHY 39079
Sterile Compounding License No. LSC 99114

and

LIONEL FRANCIS JARA
19745 Lamar Drive
Cupertino, CA 95014

Pharmacist License No. RPH 21273

Respondents.

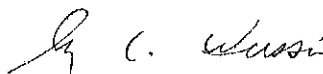
DECISION AND ORDER

The attached Stipulated Surrender of Pharmacy Permit and Pharmacy License and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on April 8, 2013.

It is so ORDERED on March 7, 2013.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

STANLEY C. WEISSER
Board President

1 KAMALA D. HARRIS
Attorney General of California
2 FRANK H. PACOE
Supervising Deputy Attorney General
3 JOSHUA A. ROOM
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Attorneys for Complainant

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

11 In the Matter of the Accusation Against:

Case No. 3990

12 **SANTA CLARA DRUG**
13 **"THE COMPOUNDING SHOP"**
14 **2453 Forest Avenue**
15 **San Jose, CA 95128**

STIPULATED SURRENDER OF
LICENSES AND ORDER

Also Pertaining To

16 **Pharmacy License No. PHY 39079**
17 **Sterile Compounding License No. LSC 99114**

Citation No. CI 2011 49815, and

Citation No. CI 2011 51364

18 **and**

19 **LIONEL FRANCIS JARA**
20 **19745 Lamar Drive**
21 **Cupertino, CA 95014**

22 **Pharmacist License No. RPH 21273**

23 Respondents.

24 In the interest of a prompt and speedy settlement of this matter, consistent with the public
25 interest and the responsibility of the Board of Pharmacy, Department of Consumer Affairs, the
26 parties hereby agree to the following Stipulated Surrender of Licenses and Order to submit to the
27 Board for approval and adoption as the final disposition of the Accusation in this case, and of
28 Citation No. CI 2011 49815 and Citation No. CI 2011 51364, also issued to Respondents.

PARTIES

1. Virginia Herold (Complainant), Executive Officer of the Board of Pharmacy, brought
this action solely in her official capacity and is represented in this matter by Kamala D. Harris,
Attorney General of the State of California, by Joshua A. Room, Deputy Attorney General.

1 2. Both Respondents, Santa Clara Drug Pharmacy, Inc. dba Santa Clara Drug “The
2 Compounding Shop” (Respondent Santa Clara), and Lionel Francis Jara (Respondent Jara), are
3 represented in this proceeding by attorney Ann Nguyen, of Robinson & Wood, Inc., 227 N. 1st
4 Street, San Jose, CA 95113 (telephone (408) 792-5917).

5 3. On or about September 2, 1993, the Board issued Pharmacy License No. PHY 39079
6 to Respondent Santa Clara. On or about July 24, 2003, the Board issued Sterile Compounding
7 License No. LSC 99114 to Respondent Santa Clara. Both licenses were in full force and effect at
8 all times relevant to Accusation No. 3990 and will expire on September 1, 2013, unless renewed.

9 4. On or about July 25, 1959, the Board issued Pharmacist License No. RPH 21273 to
10 Respondent Jara. The Pharmacist License was in full force and effect at all times relevant to the
11 charges herein and will expire on March 31, 2014, unless renewed.

12 ACCUSATION AND CITATIONS

13 5. Accusation No. 3990 was filed before the Board of Pharmacy (Board), Department of
14 Consumer Affairs, and is currently pending against Respondents. The Accusation and all other
15 statutorily required documents were properly served on Respondents on March 27, 2012.
16 Respondents timely filed their Notice(s) of Defense contesting the Accusation. A copy of
17 Accusation No. 3990 is attached as exhibit A and incorporated herein by reference.

18 6. On February 23, 2012, Citation No. CI 2011 49815, with a fine of \$11,750.00, was
19 issued to Respondent Santa Clara. Respondent Santa Clara timely appealed the Citation. A copy
20 of Citation No. CI 2011 49815 is attached as exhibit B and incorporated herein by reference.

21 7. On February 23, 2012, Citation No. CI 2011 51364, with a fine of \$5,000.00, was
22 issued to Respondent Jara. Respondent Jara timely appealed the Citation. A copy of Citation No.
23 CI 2011 51364 is attached as exhibit C and incorporated herein by reference.

24 ADVISEMENT AND WAIVERS

25 8. Respondents have carefully read, fully discussed with counsel, and understand the
26 allegations in Accusation No. 3990, and in each of the above-listed Citations (No. CI 2011 49815
27 and CI 2011 51364). Respondents have also carefully read, fully discussed with counsel, and
28 understand the effects of this Stipulated Surrender of Licenses and Order.

1 9. Respondents are fully aware of their legal rights in this matter, including the right to a
2 hearing on the charges and allegations in the Accusation and any pending citation(s); the right to
3 be represented by counsel at their own expense; the right to confront and cross-examine the
4 witnesses against them; the right to present evidence and to testify on their own behalf; the right
5 to the issuance of subpoenas to compel the attendance of witnesses and the production of
6 documents; the right to reconsideration and court review of an adverse decision; and all other
7 rights accorded by the California Administrative Procedure Act and other applicable laws.

8 10. Respondents voluntarily, knowingly, and intelligently waive and give up each and
9 every right set forth above. Respondents withdraw their notice(s) of appeal or other requests for
10 hearing on the above-listed citations, and agree that those citations are final as modified below.

11 CULPABILITY

12 11. Respondents understand that the charges and allegations in Accusation No. 3990, if
13 proven, constitute cause for discipline. For the purpose of resolving the Accusation without the
14 expense and uncertainty of further proceedings, Respondents agree that, at hearing, Complainant
15 could establish a factual basis for the charges in the Accusation and that those charges constitute
16 cause for discipline. Respondents hereby give up their right(s) to contest that cause for discipline
17 exists based on those charges, and agree to accept license discipline.

18 12. Respondent Santa Clara hereby surrenders its Pharmacy License No. PHY 39079 and
19 its Sterile Compounding License No. LSC 99114, and Respondent Jara hereby surrenders his
20 Pharmacist License No. RPH 21273, for the Board's formal acceptance. Respondents understand
21 that by signing this stipulation they enable the Board to issue an order accepting the surrender of
22 their licenses without further process or opportunity to be heard.

23 RESERVATION

24 13. Admissions made by Respondents herein are only for the purposes of this proceeding,
25 or any other proceedings in which the Board of Pharmacy or other professional licensing agency
26 is involved, and shall not be admissible in any other criminal or civil proceeding.

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CONTINGENCY

1
2 14. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents
3 understand and agree that counsel for Complainant and the staff of the Board may communicate
4 directly with the Board regarding this stipulation and settlement, without notice to or participation
5 by Respondents or their counsel. By signing the stipulation, Respondents understand and agree
6 that they may not withdraw their agreement or seek to rescind the stipulation prior to the time the
7 Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and
8 Order, the Stipulated Surrender of Licenses and Order Order shall be of no force or effect, except
9 for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board
10 shall not be disqualified from further action by having considered this matter.

11 15. The parties understand and agree that facsimile copies of this stipulation, including
12 facsimile signatures thereto, shall have the same force and effect as the originals.

13 16. This Stipulated Surrender of Licenses and Order is intended by the parties to be an
14 integrated writing representing the complete, final, and exclusive embodiment of their agreement.
15 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,
16 negotiations, and commitments (written or oral). This Stipulated Surrender of Licenses and Order
17 may not be altered, amended, modified, supplemented, or otherwise changed except by a writing
18 executed by an authorized representative of each of the parties.

19 17. In consideration of the foregoing, the parties agree that the Board may, without
20 further notice or formal proceeding, issue and enter the following Order Modifying Citations and
21 (two) Disciplinary Orders as to each of the two Respondents:

ORDER MODIFYING CITATIONS

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23
24 IT IS HEREBY ORDERED that:

25 18. As to Citation No. CI 2011 49815, issued to Respondent Santa Clara, the \$11,750.00
26 fine assessed by the citation is reduced to zero or eliminated. The Citation in all other respects
27 remains unchanged, and is now final.
28

1 19. As to Citation No. CI 2011 51364, issued to Respondent Jara, the the \$5,000.00 fine
2 assessed by the citation is reduced to zero or eliminated. The Citation in all other respects
3 remains unchanged, and is now final.

4 20. With regard to each of the Citations, this shall constitute a satisfactory resolution of
5 this matter, and shall be represented as such in any public disclosure(s). This stipulation shall
6 become part of the record with regard to each of the respective Citations.
7
8

9 **DISCIPLINARY ORDER AS TO RESPONDENT SANTA CLARA**

10 IT IS HEREBY ORDERED that Pharmacy License No. PHY 39079, and Sterile
11 Compounding License No. LSC 99114, issued to Respondent Santa Clara, are both and each
12 surrendered and accepted by the Board of Pharmacy.

13 1. The surrender of Respondent's licenses and the acceptance of the surrendered
14 licenses by the Board shall constitute the imposition of discipline against Respondent. This
15 stipulation constitutes a record of the discipline and shall become a part of Respondent's license
16 history with the Board of Pharmacy.

17 2. Respondent shall lose all rights and privileges as a Pharmacy and as a Sterile
18 Compounding Pharmacy in California as of the effective date of the Board's Decision and Order.

19 3. Respondent shall cause to be delivered to the Board its pocket license(s) and, if they
20 were issued, its wall certificate(s), on or before the effective date of the Decision and Order.

21 4. Respondent may not apply, reapply, or petition for any licensure or registration of the
22 Board for three (3) years from the effective date of the Decision and Order.

23 5. If Respondent ever applies for licensure or petitions for reinstatement in the State of
24 California, the Board shall treat it as a new application for licensure. Respondent must comply
25 with all laws, regulations and procedures for licensure in effect at the time the application or
26 petition is filed, and all of the charges in Accusation No. 3990 shall be deemed to be true, correct
27 and admitted by Respondent when the Board determines whether to grant or deny the application
28 or petition.

1 6. If Respondent ever applies for licensure or petitions for reinstatement in the State of
2 California, Respondent shall pay the Board, on the basis of joint and several liability, any part of
3 the \$7,000.00 in costs of investigation and enforcement of this case, and any part of the civil
4 penalty of \$8,000.00, made payable by Respondent Jara by the Disciplinary Order below, that
5 has/have not yet been paid to the Board or otherwise discharged by Respondent Jara pursuant to
6 the Disciplinary Order below, prior to issuance to Respondent of a new or reinstated license.

7 7. If Respondent ever applies for a license or certification, or petitions for reinstatement
8 of a license, by any other health care licensing agency in the State of California, all of the charges
9 in Accusation No. 3990 shall be deemed to be true, correct, and admitted by Respondent for the
10 purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

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13 **DISCIPLINARY ORDER AS TO RESPONDENT JARA**

14 IT IS HEREBY ORDERED that Pharmacist License No. RPH 21273, issued to Respondent
15 Jara, is surrendered and accepted by the Board of Pharmacy.

16 1. The surrender of Respondent's license and the acceptance of the surrendered license
17 by the Board shall constitute the imposition of discipline against Respondent. This stipulation
18 constitutes a record of the discipline and shall become a part of Respondent's license history with
19 the Board of Pharmacy.

20 2. Within ninety (90) days of the effective date of the Decision and Order, Respondent
21 shall pay to the Board a total of \$15,000.00, based on the following sums: \$7,000.00 payable to
22 the Board for its costs of investigation and prosecution of this case; and \$8,000.00 payable to the
23 Board as a civil penalty. Respondent understands and agrees that this entire amount constitutes
24 an administrative fine pursuant to 11 U.S.C. § 523(a)(7), and is non-dischargeable in bankruptcy.
25 Respondent further understands and agrees that the filing of bankruptcy by Respondent shall not
26 relieve Respondent of the obligation to pay the balance of this amount to the Board.

27 3. Respondent shall lose all rights and privileges as a Pharmacist in California as of the
28 effective date of the Decision and Order.

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4. Respondent shall cause to be delivered to the Board his pocket license(s) and, if one were issued, his wall certificate(s), on or before the effective date of the Decision and Order.

5. Respondent may not apply, reapply, or petition for any licensure or registration of the Board for three (3) years from the effective date of the Board's Decision and Order.

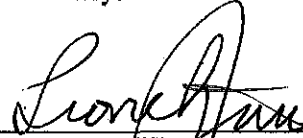
6. If Respondent ever applies for licensure or petitions for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent must comply with all laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges in Accusation No. 3990 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition.

7. If Respondent ever applies for a license or certification, or petitions for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges in Accusation No. 3990 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

ACCEPTANCE

I have carefully read the above Stipulated Surrender of Licenses and Order and have fully discussed it with my attorney, Ann Nguyen. I understand the stipulation and the effect it will have on my Pharmacy License, and Sterile Compounding License. I enter into this Stipulated Surrender of Licenses and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

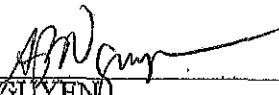
DATED: 1-22-13


Lionel F. Jara, Vice President, for SANTA CLARA DRUG PHARMACY, INC. DBA SANTA CLARA DRUG "THE COMPOUNDING SHOP"
Respondent Santa Clara

1 I have carefully read the above Stipulated Surrender of Licenses and Order and have fully
 2 discussed it with my attorney, Ann Nguyen. I understand the stipulation and the effect it will
 3 have on my Pharmacist License. I enter into this Stipulated Surrender of Licenses and Order
 4 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the
 5 Board of Pharmacy.

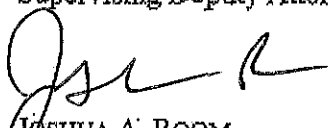
6
 7 DATED: 1-22-13 
 8 LIONEL FRANCIS JARA
 9 Respondent Jara

10 I have read and fully discussed with Respondent Santa Clara and Respondent Jara the terms
 11 and conditions and other matters contained in the above Stipulated Surrender of Licenses and
 12 Order. I approve its form and content.

13
 14 DATED: 1/22/13 
 15 ANN NGUYEN
 16 Robinson & Wood, Inc.
 17 Attorneys for Respondents

18 ENDORSEMENT

19 The foregoing Stipulated Surrender of Licenses and Order is hereby respectfully submitted
 20 for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

21 Dated: 2/4/2013 Respectfully submitted,
 22 KAMALA D. HARRIS
 23 Attorney General of California
 24 FRANK H. PACOE
 25 Supervising Deputy Attorney General
 26 
 27 JOSHUA A. ROOM
 28 Deputy Attorney General
 Attorneys for Complainant

SF2011200941; 40635325.doc

Exhibit A

Accusation No. 3990

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Attorney General of California
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Attorneys for Complainant

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 3. On or about July 25, 1959, the Board issued Pharmacist License Number RPH 21273
2 to Lionel Francis Jara (Respondent Jara). The Pharmacist License was in full force and effect at
3 all times relevant to the charges herein and will expire on March 31, 2012, unless renewed. Since
4 on or about January 1, 1994, Respondent Jara has served and/or been reflected in Board records
5 as the Pharmacist in Charge (PIC) for Respondent Santa Clara.

6 JURISDICTION

7 4. This Accusation is brought before the Board of Pharmacy (Board), Department of
8 Consumer Affairs, under the authority of the following laws. All section references are to the
9 Business and Professions Code (Code) unless otherwise indicated.

10 5. Section 4011 of the Code provides that the Board shall administer and enforce both
11 the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances
12 Act [Health & Safety Code, § 11000 et seq.].

13 6. Section 4300(a) of the Code provides that every license issued by the Board may be
14 suspended or revoked.

15 7. Section 118(b) of the Code provides, in pertinent part, that the suspension, expiration,
16 surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a
17 disciplinary action during the period within which the license may be renewed, restored, reissued
18 or reinstated. Section 4402(a) of the Code provides that any pharmacist license that is not
19 renewed within three years following its expiration may not be renewed, restored, or reinstated
20 and shall be canceled by operation of law at the end of the three-year period. Section 4402(e) of
21 the Code provides that any other license issued by the Board may be canceled by the Board if not
22 renewed within 60 days after its expiration, and any license canceled in this fashion may not be
23 reissued but will instead require a new application to seek reissuance.

24 STATUTORY AND REGULATORY PROVISIONS

25 8. Section 4301 of the Code provides, in pertinent part, that the Board shall take action
26 against any holder of a license who is guilty of "unprofessional conduct," defined to include, but
27 not be limited to, any of the following:

28 ///

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."

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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 19. **Alprostadil** is a dangerous drug as designated by Business and Professions Code
2 section 4022. It is a drug used to treat sexual dysfunction.

3 20. **Phentolamine** is a dangerous drug as designated by Business and Professions Code
4 section 4022. It is a drug used to treat sexual dysfunction.

5 21. **Papaverine** is a dangerous drug as designated by Business and Professions Code
6 section 4022. It is a drug used to treat sexual dysfunction.

7 **CAUSES FOR DISCIPLINE, AS TO BOTH RESPONDENTS**

8 FIRST CAUSE FOR DISCIPLINE

9 (Dispensing of Preparations or Drugs Deviating from Expected Quality or Strength)

10 22. Respondents are each and severally subject to discipline under section(s) 4301,
11 4301(j), 4301(o), 4113(b), and/or 4342 of the Code, in that between on or about July 28, 2010 and
12 September 7, 2010, Respondents dispensed, furnished, caused to be dispensed or furnished,
13 attempted to dispense or furnish, assisted or abetted the dispensing or furnishing of, and/or
14 conspired to dispense or furnish, preparations or drugs that deviated from the expected quality or
15 strength. Namely, Respondents dispensed **Alprostadil** 10mcg/ml, to patients, where the strength
16 of the active ingredient **Alprostadil** was tested to be actually 13.5mcg/ml (135% potency). In
17 addition, a **Trimix** product with labeled strengths of **Alprostadil** 10mcg/ml, **Papaverin** 30mg/ml,
18 **Phentolamine** 1mg/ml was dispensed to patients, where the strengths of the active ingredients
19 were tested to be: **Alprostadil** 14.289mcg/ml (142.9% potency); **Papaverine** 28.92 mg/ml
20 (96.4% potency); and **Phentolamine** 1.71mg/ml (171% potency).

21 SECOND CAUSE FOR DISCIPLINE

22 (Deviation from Prescription)

23 23. Respondents are each and severally subject to discipline under section(s) 4301,
24 4301(j), 4301(o), and/or 4113(b) of the Code, and/or California Code of Regulations, title 16,
25 section 1716, in that as described in paragraph 21 above, Respondents dispensed, furnished,
26 caused to be dispensed or furnished, attempted to dispense or furnish, assisted or abetted the
27 dispensing or furnishing of, and/or conspired to dispense or furnish drug(s) to patient(s) in a
28 strength or strengths that varied from the prescribed and labeled strength(s).

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.

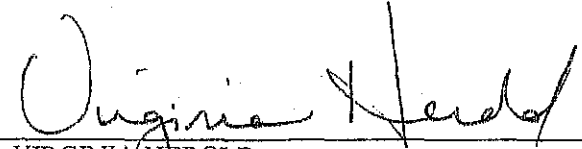
3 c. On or about March 27, 2008, Citation No. CI 2007 35712 with a fine of \$5,000.00
4 was issued to Respondent Jara for violations including failure to maintain a quality assurance
5 program for sterile compounded drugs, maintenance of outdated drugs and chemicals in the
6 pharmacy's inventory, and 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 DATED: 3/19/12



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

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Exhibit B

Citation No. CI 2011 49815

**BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

CITATION AND FINE

Citation Number CI 2011 49815	Name, License No. Santa Clara Drug "The Compounding Shop", PHY 39079
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JURISDICTION: Bus. & Prof. Code § 4005; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)		
VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4126.5 subd. (a)(4)	Furnishing Dangerous Drugs by Pharmacy; pharmacy or wholesale... alleviate temporary shortage	\$11,750.00

CONDUCT:

Non-compliant Sales to a wholesaler. Santa Clara Drug 'The Compounding Shop' was not in compliance with Business and Professions Code section 4126.5, subd. (a)(4) which states a pharmacy may furnish dangerous drugs only to the following: Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care and only in quantities sufficient to alleviate the shortage. Specifically, Santa Clara Drug 'The Compounding Shop' located at 2453 Forest Avenue in San Jose, CA did not have the dangerous drugs in stock, ordered them from Amerisource Bergen and Cardinal Health, a wholesaler, and resold them to Priority Pharmaceutical located at 4040 Sorrento Valley Blvd Ste D, San Diego, CA 92121. Santa Clara Drug 'The Compounding Shop' did not have independent knowledge of the temporary shortage and allowed Priority Pharmaceuticals to specify the drugs in short supply they wanted the pharmacy to purchase for them. The pharmacy was acting as a purchasing agent for Priority, in addition Santa Clara Drugs gave their AmeriSource Bergen account number # and Cardinal Health account number # to Priority and authorization to order drugs without Santa Clara Drugs knowing what was being ordered. Santa Clara Drug 'The Compounding Shop' depended on Priority to identify the shortages, know what quantity of dangerous drugs was needed to alleviate specific shortages, if a temporary shortage actually existed, or if lack of the drug would result in a denial of health care, thus increasing the shortage on the following dates and invoice numbers:

DATE	INVOICE NO	WHOLESALERS	AMOUNT
7/18/2011	1	PRIORITY	\$130.63

7/25/2011	2	PRIORITY	\$1,375.03
8/2/2011	3	PRIORITY	\$499.47
8/4/2011	4	PRIORITY	\$1,213.31
8/8/2011	5	PRIORITY	\$1,144.89
8/10/2011	6	PRIORITY	\$787.41
8/31/2011	7	PRIORITY	\$221.19
9/1/2011	8	PRIORITY	\$272.70
9/22/2011	9	PRIORITY	\$635.40
9/22/2011	10	PRIORITY	\$230.00
9/26/2011	11	PRIORITY	\$783.00
			\$7,293.03

This is a violation of pharmacy law.

CITATION ISSUED ON: February 23, 2012	TOTAL AMOUNT OF FINE(S): \$11,750.00
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PAYMENT OF FINE(S) DUE BY: March 24, 2012

Exhibit C

Citation No. CI 2011 51364

**BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

**CITATION AND FINE
Order of Abatement**

Citation Number CI 2011 51364	Name, License No. LIONEL FRANCIS JARA, RPH 21273
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JURISDICTION: Bus. & Prof. Code § 4005; CCR, title 16, § 1775; Bus. & Prof. Code § 4113 subd. (c)		
VIOLATION CODE SECTION	OFFENSE	AMOUNT OF FINE
Bus. & Prof. Code § 4126.5 subd. (a)(4)	Furnishing Dangerous Drugs by Pharmacy; pharmacy or wholesale... alleviate temporary shortage	\$5,000.00

CONDUCT:

Non-compliant Sales to a wholesaler. RPH Lionel Jara while he was Pharmacist-in-Charge at Santa Clara Drug 'The Compounding Shop' was not in compliance with Business and Professions Code section 4126.5, subd. (a)(4) which states a pharmacy may furnish dangerous drugs only to the following: Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care and only in quantities sufficient to alleviate the shortage. Specifically, RPH Lionel Jara while he was Pharmacist-Charge of Santa Clara Drug 'The Compounding Shop' located at 2453 Forest Avenue in San Jose, CA did not have the dangerous drugs in stock, ordered them from Amerisource Bergen and Cardinal Health, a wholesaler, and resold them to Priority Pharmaceutical located at 4040 Sorrento Valley Blvd Ste D, San Diego, CA 92121. Santa Clara Drug 'The Compounding Shop' did not have independent knowledge of the temporary shortage and allowed Priority Pharmaceuticals to specify the drugs in short supply they wanted the pharmacy to purchase for them. The pharmacy was acting as a purchasing agent for Priority, in addition Santa Clara Drugs gave their AmeriSource Bergen account number # and Cardinal Health account number # to Priority and authorization to order drugs without Santa Clara Drugs knowing what was being ordered. Santa Clara Drug 'The Compounding Shop' depended on Priority to identify the shortages, know what quantity of dangerous drugs was needed to alleviate specific shortages, if a temporary shortage actually existed, or if lack of the drug would result in a denial of health care, thus increasing the shortage on the following dates and invoice numbers:

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8/4/2011	4	PRIORITY	\$1,213.31
8/8/2011	5	PRIORITY	\$1,144.89
8/10/2011	6	PRIORITY	\$787.41
8/31/2011	7	PRIORITY	\$221.19

9/1/2011	8	PRIORITY	\$272.70
9/22/2011	9	PRIORITY	\$635.40
9/22/2011	10	PRIORITY	\$230.00
9/26/2011	11	PRIORITY	\$783.00
			\$7,293.03

This is a violation of pharmacy law

ORDER OF ABATEMENT

By the abatement date submit to the Board the following:

- Proof of enrollment in an ethics course, approved in advance by the Board or its designee, meeting the requirements of California Code of Regulations, title 16, section 1773.5. RPH Lionel Jara shall thereafter initiate and successfully participate the ethics course within eighteen (18) months of the abatement date, and shall successfully complete the approved ethics course, including the longitudinal follow-up contacts, within two (2) years of the abatement date. Any failure to do so shall be deemed a failure to meet the abatement requirements of this citation.

If RPH Lionel Jara timely seeks pre-approval of the ethics course, timely enrolls in an approved ethics course, and timely submits proof of that enrollment, the fine(s) levied by this citation shall be stayed pending completion of the approved ethics course. If RPH Lionel Jara timely enrolls, initiates, and successfully completes the ethics course, the fine(s) levied by this citation shall be reduced to zero and completion of the ethics course shall be considered satisfactory abatement of the citation. If RPH Lionel Jara fails to timely seek pre-approval, enroll, initiate, or successfully complete the ethics course, the stay shall be lifted and the fine(s) shall be due and owing from RPH Lionel Jara within thirty (30) days of any such failure.

CITATION ISSUED ON: February 23, 2012

TOTAL AMOUNT OF FINE(S): \$5,000.00

PAYMENT OF FINE(S) DUE BY: March 24, 2012