California State Board of Pharmacy
1625 N. Market Blvd., N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFAIRS
GOVERNOR EDMUND G. BROWN JR.

August 21, 2012

LETTER OF PUBLIC REPROVAL

Norman Jacobs
P.O. Box 260044
Encino, CA 91426-0044

Re: LETTER OF PUBLIC REPROVAL
In the Matter of the Accusation Against: Norman Jacobs
Pharmacist License No. RPH 22604

Dear Mr. Jacobs:

On October 31, 2011, the Board of Pharmacy, Department of Consumer Affairs, State of California, filed a Second Amended Accusation against your Pharmacist License.

The Second Amended Accusation alleged that you engaged in unprofessional conduct while you were a pharmacist-in-charge of Advanced Compounding Pharmacy (ACP). Specifically, during a June 2011 inspection, Pharmacy Board Inspectors learned that ACP routinely compounded sterile injectable and non-sterile preparations with only one pharmacist on duty at the pharmacy, in violation of pharmacist to pharmacy technician ratio requirements set forth in Business and Professions Code section 4115 (f)(1). Further – in at least 25 instances approximately between April and June of 2011, ACP compounded sterile injectable batch products prepared from a non-sterile source and dispensed the products prior to quarantining the products and receiving acceptable end product pyrogen and sterility results for the products, a violation of Business and Professions Code sections 4301 (o) in conjunction with Title 16, California Code of Regulations section 1751.7 (c).

These are serious violations and accordingly, in resolution of this matter under authority provided under Business and Professions Code section 495, the Board of Pharmacy, Department of Consumer Affairs issues this letter of public reproval.

Sincerely,

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs

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

In the Matter of the Second Amended Accusation Against: **ADVANCED COMPOUNDING PHARMACY; ADVANCED PHYSICIAN SOLUTIONS, INC.** 7225 Fulton Ave. North Hollywood, CA 91605 Pharmacy Permit No. PHY 48591 Pharmacy Permit to Compound Injectable Sterile Drug Products No. LSC 99426 And **NORMAN JACOBS** **Pharmacist-in-Charge** P.O. Box 260044 Encino, CA 91426-0044 Respondent.	Case No. 3251 OAH No. L-2010031804

DECISION AND ORDER AS AGAINST NORMAN JACOBS ONLY

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on September 20, 2012.

It is so ORDERED on August 21, 2012.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
STANLEY C. WEISSER
Board President

KAMALA D. HARRIS
Attorney General of California
GREGORY SALUTE
Supervising Deputy Attorney General
HEATHER HUA
Deputy Attorney General
State Bar No. 223418
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 897-2574
Facsimile: (213) 897-2804
Attorneys for Complainant

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

In the Matter of the Second Amended Accusation Against: **ADVANCED COMPOUNDING PHARMACY; ADVANCED PHYSICIAN SOLUTIONS, INC.** 7225 Fulton Ave. North Hollywood, CA 91605 Pharmacy Permit No. PHY 48591 Pharmacy Permit to Compound Injectable Sterile Drug Products No. LSC 99426 and **NORMAN JACOBS** **Pharmacist-in-Charge** P.O. Box 260044 Encino, CA 91426-0044 Pharmacist License No. RPH 22604 Respondents.	Case No. 3251 OAH No. L-2010031804 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL [NORMAN JACOBS ONLY]** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. VIRGINIA HEROLD (Complainant) is the Executive Officer of the Board of Pharmacy. She 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 Heather Hua, Deputy Attorney General.

2. Respondent Norman Jacobs (Respondent) is represented in this proceeding by attorney Jason B. Friedman, Esq., Law Offices of Ford, Walker, Haggerty & Behar, whose address of record is One World Trade Center, 27th Floor, Long Beach, CA 90831-2700

3. On or about July 30, 1962, the Board of Pharmacy issued Pharmacist License No. RPH 22604 to Norman Jacobs (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought in Second Amended Accusation No. 3251 and will expire on June 30, 2013, unless renewed.

JURISDICTION

4. Second Amended Accusation No. 3251 was filed before the Board of Pharmacy (Board) , Department of Consumer Affairs, and is currently pending against Respondent. The Second Amended Accusation and all other statutorily required documents were properly served on Respondent on February 24, 2012. Respondent timely filed his Notice of Defense contesting the Second Amended Accusation. A copy of Second Amended Accusation No. 3251 is attached as **Exhibit A** and incorporated by this reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Second Amended Accusation No. 3251. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Second Amended Accusation; the right to be represented by counsel at his own expense; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

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CULPABILITY

8. Respondent admits the truth of each and every charge and allegation in Second Amended Accusation No. 3251.

9. Respondent agrees that his Pharmacist License is subject to discipline and he agrees to be bound by the Board of Pharmacy (Board)'s conditional terms as set forth in the Disciplinary Order below.

10. Taking into consideration that Respondent has been licensed by the California State Board of Pharmacy since July of 1962 with no previous discipline, that the violations referenced in the Second Amended Accusation were promptly corrected, and that there are other mitigating circumstances in this case that support the determination that you are safe to practice as pharmacist, the Board has decided that the charges warrant a public reproval.

11. The public reproval of Respondent's Pharmacist license and the acceptance of the public reproval by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board.

RESERVATION

12. The admissions made by Respondent herein are only for the purposes of this proceeding, or any other proceedings in which the Board of Pharmacy or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation

as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

14. The parties understand and agree that facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including facsimile signatures thereto, shall have the same force and effect as the originals.

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

16. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 22604 issued to Respondent NORMAN JACOBS (Respondent) shall, by way of letter from the Board's Executive Officer, be publicly reproved. The letter shall be in the same form as the letter attached as **Exhibit B** to this stipulation.

IT IS FURTHER ORDERED that Respondent shall pay Five Thousand Dollars ($5,000.00) to the Board for its costs associated with the investigation and enforcement of this matter, no later than May 31, 2013. Respondent shall pay One Thousand Dollars ($1,000.00) within 30 days of the effective date of the Decision. Thereafter, Respondent shall pay quarterly payments for the remaining Four Thousand Dollars ($4,000.00) prior to renewal of his Pharmacist License. If

Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew his Pharmacist License until Respondent completes payment of costs in full.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Jason B. Friedman, Esq. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 4/4/12

NORMAN JACOBS
Respondent

I have read and fully discussed with Respondent Norman Jacobs the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 4/5/12

JASON B. FRIEDMAN, Esq.
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

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Dated: April 9, 2012

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
GREGORY SALUTE
Supervising Deputy Attorney General

HEATHER HUA
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Second Amended Accusation Case No. 3251

KAMALA D. HARRIS
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
SUSAN MELTON WILSON
Deputy Attorney General
HEATHER HUA
Deputy Attorney General
State Bar No. 223418
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 897-2574
Facsimile: (213) 897-2804
E-mail: Heather.Hua@doj.ca.gov
Attorneys for Complainant

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

In the Matter of the Second Amended Accusation Against: **ADVANCED PHYSICIAN SOLUTIONS, INC. dba ADVANCED COMPOUNDING PHARMACY** 7225 Fulton Ave. North Hollywood, CA 91605 Pharmacy Permit No. PHY 48591 Permit to Compound Injectable Sterile Drug Products No. LSC 99426 and **TOORAJ BERELIANI** 7225 Fulton Ave. North Hollywood, CA 91605 Pharmacist License No. RPH 51817 and **NORMAN JACOBS** **Pharmacist-in-Charge** P.O. Box 260044 Encino, CA 91426-0044 Pharmacist License No. RPH 22604 Respondents.	Case No. 3251 **SECOND AMENDED ACCUSATION**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about April 26, 2007, the Board of Pharmacy issued Pharmacy Permit Number PHY 48591 to Advanced Physician Solutions, Inc. dba Advanced Compounding Pharmacy (Respondent Advanced Compounding). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2012, unless renewed.

3. On or about July 3, 2007, the Board of Pharmacy issued a Permit to Compound Injectable Sterile Drug Products Number LSC 99426 to Respondent Advanced Compounding. The Permit to Compound Injectable Sterile Drug Products was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2012, unless renewed.

4. On or about August 30, 2000, the Board of Pharmacy issued Pharmacist License Number RPH 51817 to Tooraj Bereliani (Respondent Bereliani). Respondent Bereliani was pharmacist-in-charge of Advanced Compounding Pharmacy from April 26, 2007 through November 15, 2010. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2012, unless renewed. [1]

5. On or about July 30, 1962, the Board of Pharmacy issued Pharmacist License Number RPH 22604 to Norman Jacobs (Respondent Jacobs). Respondent Jacobs is pharmacist-in-charge of Advanced Compounding Pharmacy from December 14, 2010 through the present. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2013, unless renewed.

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[1] Board approval of a proposed settlement of the First Amended Accusation against Respondent Tooraj Bereliani only is currently pending.

JURISDICTION

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

7. Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

8. Section 4026 of the Code states as follows:

"Furnish" means to supply by any means, by sale or otherwise.

9. Section 4076 of the Code states, in part, as follows:

"(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

. . .

(7) The strength of the drug or drugs dispensed.

. . .

(9) The expiration date of the effectiveness of the drug dispensed. . . ."

10. Section 4077 of the Code states, in pertinent part, that except as provided in subdivisions (b) and (c) of this section, no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

11. Section 4081 of the Code states, in part:

"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit,

registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler . . . shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section. . . ."

12. Section 4113, subdivision (b) 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."

13. Code section 4126.5, subdivision (a), provides:

"(a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a 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.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control."

14. Section 4115 of the Code states:

"(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist.

. . .

(f) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians

performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, and for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117."

15. Section 4169 of the Code states:

"(a) A person or entity may not do any of the following:

...

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code."

16. Section 4300 of the Code states, in pertinent part, that every license issued by the Board is subject to discipline, including suspension or revocation.

17. Section 4301 of the Code states, in part, as follows:

"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 is not limited to, any of the following:

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

. . .

(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.

. . .

(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 by any other state or federal regulatory agency. . . ."

18. Section 4306.5 of the Code states, in part, as follows:

"Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board."

19. Section 4328 of the Code states:

"Except as otherwise provided in this chapter, any person who permits the compounding or dispensing of prescriptions, or the furnishing of dangerous drugs in his or her pharmacy, except by a pharmacist, is guilty of a misdemeanor."

20. Section 4342 of the Code states:

"(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4336 and 4321."

21. California Code of Regulations, Title 16, section 1751.02, subdivision (c), provides, in part, as follows:

"(c) Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:

. . .

(3) Policies and procedures must address at least the following:

. . .

(i) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation. . . ."

22. California Code of Regulations, Title 16, section 1751.3, subdivision (b), provides, in part:

"(b) In addition to the records required by subdivisions (a), for sterile products compounded from one or more non-sterile ingredients the following records must be maintained for at least three years:

. . .

(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results. . . ."

23. California Code of Regulations, Title 16, section 1716.2, provides, in pertinent part, as follows:

"(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:

. . .

(3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is

supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(4) The signature or initials of the pharmacist performing the compounding.

(5) A formula for the compounded product. The formula must be maintained in a readily retrievable form. . . ."

24. California Code of Regulations, Title 16, section 1793.7, provides, in part:

"(a) Except as otherwise provided in section 1793.8, any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.

(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

. . .

(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients. . . ."

25. California Code of Regulations, Title 16, section 1751.2, subdivision (b), provides:

"In addition to existing labeling requirements, a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

. . .

(b) Name and concentrations of ingredients contained in the sterile injectable product. . . ."

26. California Code of Regulations, Title 16, section 1751.7, subdivision (c), provides:

. . .

(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 confirms sterility and acceptable levels of pyrogens.

COST RECOVERY

27. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

28. The classification for the dangerous drugs is listed below:

BRAND NAME	GENERIC NAME	DANGEROUS DRUG PER B & PC 4022	CONTROLLED SUBSTANCE PER H & SC	INDICATIONS FOR USE
Depo Provera	Medroxyprogesterone Acetate 150mg Susp	Yes	No	Contraceptive
Depo Testosterone	Testosterone Cyprionate Inj.	Yes	HSC 11056(f)(30)	Anabolic steroid /male sex hormone
Celestone	Betamethasone Sod. Phosphate Inj.	Yes	No	Anti-inflammatory corticosteroid
Celestone Soluspan	Betamethasone Soluspan	Yes	No	Anti-inflammatory corticosteroid
Depo Estradiol	Estradiol Cyprionate	Yes	No	HRT
Depo Medrol	Methylprednisolone Inj.	Yes	No	Anti-inflammatory corticosteroid
Deca Durabolin	Nandrolone Decanoate Inj.	Yes	HSC 11056(f)(19)	Anabolic Steroid /male sex hormone
Unknown	Sodium Hydroxide Inj.	Yes	No	Unknown
Alprostadil	Prostaglandin PGE-1 Inj.	Yes	No	Used in Trimix for erectile dysfunction
Regitine	Phentolamine Inj.	Yes	No	Used in Trimix for erectile dysfunction
*Not FDA approved	*Polidocanol Inj.	*"Unapproved New Drug" Misbranded-Not Approved by FDA	No	Sclerotherapy
Prednisolone	Prednisolone Inj	Yes	No	Anti-

				inflammatory corticosteroid
Progesterone	Progesterone in Oil Inj.	Yes	No	Progesterone replacement therapy
Sotradecol	Sodium Tetradecyl Sulfate Inj.	Yes	No	Vericose Vein therapy
Vitamin B-1	Thiamine Inj.	Yes	No	Vitamin B-1 deficiency
Kenolog Inj.	Triamincolone Acetonide Inj.	Yes	No	Anti-inflammatory corticosteroid
Tri-Mix	PGE-1+ Papavarine + Phentolamine	Yes	No	Erectile Dysfunction
Depo Winstrol Inj	Depo Stanozolol	Yes	HSC 11056(f)(28)	Anabolic Steroid/ male sex hormone
Delestrogen	Estradiol Valerate Inj.	Yes	No	HRT
Healon or Hyaluronan	Hyaluronic Acid Inj.	Yes	No	Joint & skin repair, eye surgery
Wyadase	Hyaluronidase Inj.	Yes	No.	Enzyme to help absorb medications
17-P	Hydroxyprogesterone Caproate Inj.	Yes	No	Preventing Pre-term Births
Xylocaine	Lidocaine PF Inj.	Yes	No	Numbing Agent
Vitamin B12	Methylcobalamine	Yes	No	Vitamin B 12 deficiency
Celestone Soluspan	Betamethasone Soluspan	Yes	No	Injectable anti-inflammatory
Astamorph	Morphine	Yes	CII HSC 11055(b)(1)(M)	Severe pain
Demerol	Meperidine	Yes	CII HSC 11055(c)(17)	Severe pain
Dilaudid	Hydromorphone	Yes	CII HSC 11055(b)(1)(K)	Severe pain
Duragesic	Fentanyl	Yes	CII HSC 1111055(c)(8)	Severe pain
Ketalar	Ketamine	Yes	CIII HSC 11056(g)	General Anesthetics
Valium	Diazepam	Yes	CIV HSC 11057(d)(9)	Anxiety
Versed	Midazolam	Yes	CIV HSC 11057(d)(21)	Pre-operative sedation
Percocet	Oxycodone w/APAP	Yes	CII HSC 11055(b)	Severe pain
Cocaine Top. Soln.	Cocaine Topical Solution	Yes	CII HSC 11055(b)(6)	Topical Anesthetic
Vicodin	Hydrocodone w/APAP 5/500	Yes	CIII HSC 11056(e)	Moderate to severe pain

FIRST CAUSE FOR DISCIPLINE

(Manufacturing Drugs Sold Through Wholesaler)

[Respondents Advanced Compounding and Bereliani]

29. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under Business and Professions Code Section 4033(a) in that Respondents were a manufacturer when they compounded drugs that were not sold to the ultimate consumer.

On June 19, 2008, during an investigation of Advanced Compounding Pharmacy, Board investigators found that Respondents' records showed they were manufacturing sterile injectable compounded drugs for customers that were brokered through wholesaler Superior Medical Supply, Inc. For instance, the drug Medroxyprogesterone Acetate Suspension 150 mg/ml [2] prefilled syringes were drop shipped from Respondents directly to clinics and doctors' offices. Respondents were paid by the wholesaler Superior Medical Supply, Inc. for the drop shipped drugs rather than by the clinics or doctors' offices as the ultimate consumers.

SECOND CAUSE FOR DISCIPLINE

(Furnishing of Controlled Substance through Unlicensed Wholesaler)

[Respondents Advanced Compounding and Bereliani]

30. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with Code section 4126.5, in that Respondents furnished controlled substances and compounded drugs, as defined in Title 21, Code of Federal Regulations, sections 1301.11 and 1301.13(a), to a wholesaler from whom the controlled substance was not acquired. The circumstances are as follows:

a) Between February 27, 2008 and August 4, 2008, Respondents had a verbal agreement to furnish orders from Superior Medical Supply (located in the State of Colorado) to Superior Medical Supply's customers for controlled substances and then to bill Superior Medical Supply for the purchase of the controlled substances.

[2] Medroxyprogesterone Acetate Suspension 150mg/ml prefilled syringes are the generic name for the commercially available drug Depo Provera 150mg/ml prefilled syringes. The drug is a long acting birth control drug injected every 12 weeks.

Superior Medical Supply was not authorized by the Drug Enforcement Administration to engage in the distribution of controlled substances.

b) The furnishing of the controlled substances occurred as follows: Schedule II, III, IV, and V controlled substances were ordered through Superior Medical Supply for their customers; the controlled substances were drop shipped by Respondents to Superior Medical Supply customers; Respondents billed Superior Medical Supply for the controlled substances; Superior Medical Supply paid the billed invoices from Respondents; Superior Medical Supply then invoiced their customers directly for the drop shipped controlled substances.

c) The controlled substances Respondents shipped to Superior Medical Supply's customers were controlled substances not originally acquired from Superior Medical Supply.

THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Written Policies and Procedures)

[Respondents Advanced Compounding and Bereliani]

31. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with Code section 4081, subdivisions (a) and (b) and California Code of Regulations, Title 16, section 1751.02(c)(3)(I), in that Respondents failed to maintain required written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products. The circumstances are as follows:

a) On June 19, 2008, Board investigators determined that Respondent Bereliani did not have written policies and procedures established for the use of a master formula, worksheets and documentation when compounding sterile batch injectable drugs from non-sterile ingredients.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Preparation Records and/or Master Formulas)

[Respondents Advanced Compounding and Bereliani]

32. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with Code section 4081, subdivisions (a) and (b) and California Code of Regulations, Title 16, section 1751.3(b)(6), in that Respondents failed to maintain, for three years, the preparation records, including Master Formula worksheets, when compounding sterile products from one or more non-sterile ingredients. The circumstances are as follows:

a) On June 19, 2008, Board investigators found that Respondent Bereliani maintained only a few of the required Master Formula worksheets for the pharmacy's compounding of sterile injectable drugs from non-sterile ingredients.

b) On June 19, 2008, Board investigators found that preparation records for the compounding of sterile injectable drugs from non-sterile ingredients showed different expiration dates. For instance, Respondents placed a 180-day expiration date for sterile injectable drugs shipped in California, while Respondents placed a one-year expiration date for the same sterile injectable drugs shipped outside of California. Investigators reviewing preparation records determined that no master formula was present to substantiate the differing expiration dates for the same sterile injectable drugs.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Complete Compounding Records)

[Respondents Advanced Compounding and Bereliani]

33. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with Code section 4081, subdivisions (a) and (b) and California Code of Regulations, Title 16, section 1716.2, in that Respondents failed to maintain complete records required for compounding for future furnishing of drugs. The circumstances are as follows:

a) On June 19, 2008, Board investigators determined that Respondents, as a routine practice, labeled sterile injectable products with a 180-day expiration date for drugs shipped in California and a one-year expiration date for the same drugs shipped outside of California without a written justification for either expiration dates chosen in violation of Regulation section 1716.2(a)(3).

b) On June 19, 2008, Board investigators found that Respondent Bereliani, as a routine practice, failed to sign or initial the Logged Formula Worksheet records in violation of Regulation section 1716.2(a)(4).

c) On June 19, 2008, Board investigators found that no Master Formulas were available to substantiate a one year or 180-day expiration for the same product in violation of Regulation section 1716.2(a)(5).

SIXTH CAUSE FOR DISCIPLINE

(Failure to Document Supervision of Pharmacy Technician)

[Respondents Advanced Compounding and Bereliani]

34. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with Code section 4081, subdivisions (a) and (b) and California Code of Regulations, Title 16, section 1793.7(a), in that Respondents failed to document supervision and verification of duties performed by the pharmacy technician. The circumstances are as follows:

a) On June 19, 2008, Board investigators determined that Respondent Bereliani, as a routine practice, failed to initial or document many of the Logged Formula Worksheet records verifying the supervision and duties performed by compounding pharmacy technician Zherair Aghakhan.

SEVENTH CAUSE FOR DISCIPLINE

(Misbranding of Drugs with False or Misleading Information)

[Respondents Advanced Compounding and Bereliani]

35. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with Code section 4076, subdivisions

(a)(7) and (a)(9) and California Code of Regulations, Title 16, section 1751.2(b), in that Respondents misbranded and labeled drugs with false and misleading information. The circumstances are as follows:

a) On June 19, 2008 and June 24, 2008, Board investigators found that Respondents allowed the compounded drug Medroxyprogesterone Acetate 150mg/ml to be misbranded by falsely labeling the drug with the misleading label as either "Medroxy Progst PF (75/0.5mg) ml" or "Medroxy Proge (75/.5) 75/0.5mg."

b) On June 19, 2008 and June 24, 2008, Board investigators found that Respondents misbranded the prescription labels with false and misleading expiration dates as 180 days for drugs shipped in California and one year expiration date for drugs shipped outside of California for the same drugs.

EIGHTH CAUSE FOR DISCIPLINE

(Sale, Purchase, Trade, or Transfer of Misbranded Drugs)

[Respondents Advanced Compounding and Bereliani]

36. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with Code section 4169, subdivision (a)(3) and Health and Safety Code section 111335, in that Respondents purchased, traded, sold or transferred dangerous drugs that they knew, or reasonably should have known were misbranded. The circumstances are as follows:

a) From on or about February 28, 2008 through on or about June 4, 2008, Respondents drop shipped to doctors and clinics Medroxyprogesterone 150mg/ml pre-filled syringes that were misbranded with false or misleading labels that read "Medroxy Progst PF (75/0.5mg) ml" or "Medroxy Proge (75/.5) 75/0.5mg" that were manufactured by Respondent Advanced Compounding. The drugs were further misbranded in that Respondents placed a 180-day expiration date for drugs shipped in California, while Respondents placed a one-year expiration date for the same drugs shipped outside of California.

NINTH CAUSE FOR DISCIPLINE

(Sale, Purchase, Trade, or Transfer of Misbranded Drugs)

[Respondents Advanced Compounding and Bereliani]

37. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4169, subdivisions (a) and (3), in conjunction with Code section 4342, and Health and Safety Code section 111330, in that Respondents purchased, traded, sold or transferred dangerous drugs that they knew, or reasonably should have known were misbranded. The circumstances are as follows:

a) Approximately on or after June 19, 2008, Respondents Advanced Compounding and Bereliani initiated a drug recall of all compounded injectable drugs whose labeled expiration dates on the finish products exceeded the expiration dates on the Master Formulas.

b) Respondent Bereliani identified on the pharmacy's Drug Recall Report a total of 1732 orders: 1,425 misbranded drug orders drop shipped to clinics and doctors' outside of California and 307 misbranded drug orders shipped to California clinics and doctors.

c) The Drug Recall Report identified the drug, the total quantity of drug ordered, and the number of orders shipped that contained the misbranded labeled expiration dates that were false and misleading.

d) Based on Respondents' Drug Recall Report the misbranded drugs shipped out of California to clinics and doctors' offices between the period of July 1, 2007 through June 30, 2008 included:

1. Medroxy Proges. Acetate 150mg/ml with total quantity of 50mls from 3 orders
2. Medroxy Progest. Acetate 150mg/ml with total quantity of 11,501mls from 283 orders
3. Medroxy Progst AcetatePF. 150mg/ml with total quantity of 2,033mls from 113 orders
4. Polidocanol 0.5% with total quantity of 780 from 9 orders
5. Polidocanol 0.75% with total quantity of 40mls from 2 orders
6. Polidocanol 1% with total quantity of 3,400mls from 15 orders
7. Polidocanol 2% with total quantity of 280mls from 7 orders
8. Polidocanol 3% with total quantity of 4,230mls from 42 orders
9. Polidocanol 5% with total quantity of 360mls from 4 orders
10. Sodium Tetrad 1% with total quantity of 1120 from 12 orders

11. Sodium Tetrad 2% with total quantity of 230mls from 2 orders
12. Sodium Tetrad 3% with total quantity of 1,110mls from 9 orders
13. Sodium Tetradecyl with total quantity of 1,070mls from 3 orders
14. Triamcinolone Inj. 40mg/ml with total quantity of 15,680mls from 131 orders
15. Methyl Prednisolone with total quantity of 15,365mls from 169 orders
16. Nandrolone Decanoate (all strengths) with total quantity of 1,030mls from 17 orders
17. Sodium Hyaluronate (all strengths) with total quantity of 2,498mls from 43 orders
18. Sodium Hyaluronic Inj with total quantity of 80mls from 2 orders
19. Betam Soluspan Inj 6mg/ml with total quantity of 11,382mls from 105 orders
20. Betamethesone 6mg/ml Inj Sol with total quantity of 340mls from 3 orders
21. Hydroxy Progesterone with total quantity of 30mls from 2 orders
21. HydroxyP4 Caproate 250mg/ml with total quantity of 450mls from 28 orders
22. Winstrol Cmpd with total quantity of 30mls from 1 order
23. Estradiol Cypionate with total quantity of 375mls from 9 orders
24. Estradiol Valerate (all strengths) with total quantity of 455mls from 15 orders
25. Hyaluronidase 150u/m with total quantity of 20mls from 2 orders
26. DMSO 50% Sol with total quantity of 8,050mls from 15 orders
27. Thiamin Inj with total quantity of 10mls from 1 order
28. Methyl Cobalamine (all strengths) with total quantity of 340mls from 6 orders
29. HydroxyP4 Caproate 250mg/ml with total quantity of 20mls from 1 order
30. Testosterone Cyp 200mg/ml Inj with total quantity of 32,005mls from 371 orders

e) The misbranded drugs drop shipped to California clinics and prescribers between January 1, 2008 to June 30, 2008 were:

1. Medroxy Progest. Acetate 150mg/ml with total quantity of 3,585mls from 60 orders
2. Medroxy Progst AcetatePF. 150mg/ml with total quantity of 401mls from 27 orders
3. PGE 1*** with total quantity of 20mls from 4 orders
4. Polidocanol 0.5% with total quantity of 330 from 5 orders
5. Polidocanol 0.75% with total quantity of 50mls from 1 order
6. Polidocanol 1% with total quantity of 610mls from 6 orders
7. Polidocanol 2% with total quantity of 260mls from 3 orders
8. Polidocanol 3% with total quantity of 520mls from 4 orders
9. Polidocanol 5% with total quantity of 120mls from 3 orders
10. Sodium Tetrad 0.125% with total quantity of 70mls from 3 orders
11. Sodium Tetrad 0.25% with total quantity of 60mls from 3orders
12. Sodium Tetrad 0.5% with total quantity of 30mls from 1 orders
13. Sodium Tetrad 1% with total quantity of 170 from 4 orders
14. Sodium Tetrad 2% with total quantity of 120mls from 4 orders
15. Sodium Tetrad 3% with total quantity of 170mls from 4.orders
16. Methyl Prednisolone with total quantity of 1,120mls from 21 orders
17. Triamcinolone Inj. 40mg/ml with total quantity of 3470mls from 43 orders
18. Nandrolone Decanoate (all strengths) with total quantity of 140mls from 7 orders
19. Sodium Hyaluronate (all strengths) with total quantity of 20mls from 1 order
20. Sodium Hyaluronic Inj with total quantity of 40mls from 4 orders
21. Betam Soluspan Inj 6mg/ml with total quantity of 195mls from 4 orders
22. Betamethesone 6mg/ml Inj Sol with total quantity of 5mls from 1 order

23. HydroxyP4 Caproate 250mg/ml with total quantity of 20mls from 1 order
24. Winstrol Cmpd. with total quantity of 40mls from 2 orders
25. Estradiol Cypionate with total quantity of 350mls from 8 orders
26. Hyaluronidase 150u/m with total quantity of 280mls from 9 orders
27. DMSO 50% Sol with total quantity of 500mls from 5 orders
28. Thiamine Inj. with total quantity of 120mls from 4 orders
29. Methyl Cobalamin (all strengths) with total quantity of 565mls from 13 orders
30. Testosterone Cyp. 200mg/ml Inj. with total quantity of 2,805mls from 52 orders

TENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Misuse of Knowledge of Pharmacy Law)

[Respondents Advanced Compounding and Bereliani]

38. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4306.5, subdivision (a), in that Respondent committed unprofessional conduct for acting or omitting that involve, in whole or in part, the inappropriate exercise of his education, training or experience as a pharmacist. The circumstances are as follows:

a) On February 14, 2008, Respondents failed to verify the accuracy of the Logged Formula Worksheet for Tri-Mix (Phen/PGE/PAPA) 1mg/20mcg/30mg/ml Injection which showed two ingredients were miscalculated and transposed so that patient R. Thorne received 3 times the dose of Phentolamine and 1/3 the dose of Prostaglandin (PGE) on his Tri-Mix Injection.

b) Additionally, Respondent Bereliani, as a routine practice, failed to document on the worksheet his supervision of the compounding pharmacy technician Zherair Aghakhan.

c) On May 1, 2007, Respondents incorrectly calculated his stock solution of 30cc-Phentolamine 50mg/ml stock solution under lot #05012007@3. The active drug Phentolamine Mesylate powder was incorrectly calculated at 500mg instead of 1500mg. This incorrectly compounded stock solution was then used to mix 6 TriMix preparations on the following dates:

1. December 10, 2007
2. February 6, 2008
3. February 14, 2008
4. February 27, 2008
5. February 27, 2008
6. February 27, 2008

d) Respondent Bereliani, on a routine practice, failed to check the lot numbers on the ingredients used, which showed that the Phentolamine stock solution made on May 1, 2007 had already expired.

ELEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Misrepresentation)

[Respondents Advanced Compounding and Bereliani]

39. Respondents Advanced Compounding and Bereliani are subject to disciplinary action under section 4301, subdivision (g), in that Respondents knowingly made or signed a certificate or other document that falsely represented the existence or nonexistence of a state of facts. The circumstances are as follows:

a) The word "Soluspan" is a registered trademark name of Schering-Plough's Celestone Soluspan 6mg/ml, which describes their brand of rapid and repository injectable. On June 19, 2008, Board investigators discovered that Respondents falsely represented the compounded product of "betamethasone suspension" by labeling it "Betam Soluspan Inj 6mg/ml" without authorization from Schering-Plough.

b) Respondents were not a member of the Pharmaceutical Compounding Centers of America (hereinafter PCCA) and were not authorized to copy their formulas without PCCA's permission. Though they had not been given permission by PCCA to reference their formulas, Respondents did so in at least 7 formulas sent to the Board as follows:

1. The Medroxyprogesterone Acetae (New) 150mg/ml referenced PCCA Formula 7404 but stated "This formula is a trade secret of ADVANCED PHARMACY".
2. The Medroxyprogesterone Acetae Suspension Vehic referenced PCCA Formula 7405 but stated "This formula is a trade secret of ADVANCED PHARMACY".
3. The MethylPrednisolone 40mg/ml Injectable referenced PCCA Formula 5678 but stated "This formula is a trade secret of ADVANCED PHARMACY".
4. The MethylPrednisolone 80mg Injectabl referenced PCCA Formula 5678 but stated "This formula is a trade secret of ADVANCED PHARMACY".
5. The Triamcinolone Acetonide 40mg/ml referenced PCCA Formula 4359 but stated "This formula is a trade secret of ADVANCED PHARMACY".
6. The Tri-Mix 0.5mg/5.88mcg/30mg Injectable referenced PCCA Formula 4338 but stated "This formula is a trade secret of ADVANCED PHARMACY".
7. The Testosterone Cypionate 200mg/ml Injectable referenced PCCA Formula 7719 but stated "This formula is a trade secret of ADVANCED PHARMACY".

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Comply with Pharmacy Technician Ratio Requirements)

[Respondents Advanced Compounding and Jacobs]

40. Respondents Advanced Compounding and Jacobs are subject to disciplinary action under section 4115, subdivision (f)(1), in that on or about June 30, 2011, an inspection of Respondent Advanced Compounding revealed that on that date, three pharmacy technicians employed by Respondent Advanced Compounding routinely compounded sterile injectable and non-sterile preparations with only one pharmacist on duty at the pharmacy during the morning shift (approximately 9 a.m. to 1 p.m.), in violation of pharmacist to pharmacy technician ratio requirements.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Provide Quality Assurance in Sterile Compounding)

[Respondents Advanced Compounding and Jacobs]

41. Respondents Advanced Compounding and Jacobs are subject to disciplinary action under Business and Professions Code section 4301, subdivision (o) in conjunction with Title 16, California Code of Regulations section 1751.7, subdivision (c), in that on or about June 30, 2011, an inspection of Respondent Advanced Compounding revealed that approximately between April 27, 2011 and June 28, 2011, the pharmacy compounded sterile injectable batch products prepared from a non-sterile source and dispensed the products prior to quarantining the products and receiving acceptable end product pyrogen and sterility results for the products in at least 25 instances, as follows:

Drug	Lot #	Date Prepared	Date Testing Results Received	Date Drug Dispensed	RX#
Testosterone Propionate 150mg/ml	06162011 @2	6/16/11	6/24/11	6/16/11	66767
Nandrolone Decanoate 200mg/ml	06132011 @17	6/13/11	6/27/11	6/20/11	68927
Nandrolone Decanoate 200mg/ml	06132011 @17	6/13/11	6/27/11	6/17/11	68870
Nandrolone Decanoate 200mg/ml	06132011 @17	6/13/11	6/27/11	6/20/11	69078
Hyaluronidase 150u/ml	04272011 @14	4/27/11	5/11/11	4/27/11	67655
Hyaluronidase 150u/ml	04272011 @14	4/27/11	5/11/11	5/10/11	66821
Hyaluronidase 150u/ml	04272011 @14	4/27/11	5/11/11	5/3/11	67769
Hydroxyprogesterone Caproate 250mg/ml	06222011 @15	6/22/11	6/29/11	6/23/11	69133
Hydroxyprogesterone Caproate 250mg/ml	06222011 @15	6/22/11	6/29/11	6/28/11	69135

Hydroxyprogesterone Caproate 250mg/ml	06222011 @15	6/22/11	6/29/11	6/27/11	60345
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/12/11	65649
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/12/11	66339
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/12/11	65037
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/13/11	64952
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/13/11	65016
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/16/11	66069
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/16/11	66158
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/16/11	65814
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/17/11	64985
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/17/11	66215
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/17/11	66368
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/18/11	65238
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/19/11	68225
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/18/11	65385
Medroxyprogesterone 150mg/ml	05112011 @2	5/11/11	5/23/11	5/19/11	68257

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:

1. Revoking or suspending Pharmacy Permit Number PHY 48591, issued to Respondent Advanced Physician Solutions, Inc. dba Advanced Compounding Pharmacy.

2. Revoking or suspending Permit Number LSC 99426, issued to Respondent Advanced Physician Solutions, Inc. dba Advanced Compounding Pharmacy.

3. Revoking or suspending Pharmacist License Number RPH 51817, issued to Respondent Tooraj Bereliani.

4. Revoking or suspending Pharmacist License Number RPH 22604, issued to Respondent Norman Jacobs.

5. Ordering Respondents Advanced Physician Solutions, Inc. dba Advanced Compounding Pharmacy, Tooraj Bereliani, and Norman Jacobs to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3.

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6. Taking such other and further action as deemed necessary and proper.

DATED: 10/31/11

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

Exhibit B

Letter of Public Reproval in Case No. 3251

Date: _____

Norman Jacobs
Post Office Box 260044
Encino, CA 91426-0044

Re: **LETTER OF PUBLIC REPROVAL**
In the Matter of the Second Amended Accusation Against:
Norman Jacobs, Pharmacist License No. RPH 22604

Dear Mr. Jacobs:

On October 31, 2011, the Board of Pharmacy, Department of Consumer Affairs, State of California, filed a Second Amended Accusation against your Pharmacist License.

The Second Amended Accusation alleged that you engaged in unprofessional conduct while you were a pharmacist-in-charge of Advanced Compounding Pharmacy (ACP). Specifically, during a June 2011 inspection, Pharmacy Board Inspectors learned that ACP routinely compounded sterile injectable and non-sterile preparations with only one pharmacist on duty at the pharmacy, in violation of pharmacist to pharmacy technician ratio requirements set forth in Business And Professions Code section 4115(f)(1). Further - in at least 25 instances approximately between April and June of 2011, ACP compounded sterile injectable batch products prepared from a non-sterile source and dispensed the products prior to quarantining the products and receiving acceptable end product pyrogen and sterility results for the products, a violation of Business and Professions Code sections 4301(o) in conjunction with Title 16, California Code of Regulations section 1751.7 (c).

These are serious violations and accordingly, in resolution of this matter under the authority provided under Business and Professions Code section 495, the Board of Pharmacy, Department of Consumer Affairs issues this letter of public reproval.

Sincerely,

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs