KAMALA D. HARRIS
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General
ELENA L. ALMANZO
Deputy Attorney General
State Bar No. 131058
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 322-5524
Facsimile: (916) 327-8643
Attorneys for Complainant

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

In the Matter of the Accusation Against: **PHARMEDIUM HEALTHCARE CORP** **DBA PHARMEDIUM SERVICES LLC** **12620 W. Airport Boulevard, Suite 130** **Sugar Land, Texas 77478** **Non-Resident Pharmacy Permit No. NRP 590** **PHARMEDIUM SERVICES LLC** **12620 W. Airport Boulevard, Suite 130** **Sugar Land, Texas 77478** **Non-Resident Sterile Compounding license No. NSC 99221** Respondent.	Case No. 4625 **A C C U S A T I O N**

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 August 4, 2004, the Board of Pharmacy issued Non-Resident Pharmacy Permit Number NRP 590 to Pharmedium Healthcare Corp dba Pharmedium Services LLC

(Respondent). The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2014, unless renewed.

3. On or about August 9, 2004, the Board of Pharmacy issued Non-Resident Sterile Compounding license Number NSC 99221 to Pharmedium Services LLC (Respondent). The Non-Resident Sterile Compounding license was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2015, unless renewed.

JURISDICTION

4. 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.

5. Section 4300 of the Code states in pertinent part:

"(a) Every license issued may be suspended or revoked.

"(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

"(3) Suspending his or her right to practice for a period not exceeding one year.

"(4) Revoking his or her license.

"(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

"(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

6. Section 4300.1 of the Code states:

"The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

7. Section 4301 of the Code states in pertinent part:

"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:

"(a) Gross immorality.

"(b) Incompetence.

"(c) Gross negligence.

"(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

"(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.

"(p) Actions or conduct that would have warranted denial of a license.

"(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

"(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

8. Section 4022 of the Code states

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

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

"(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

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

9. Section 4033 of the Code states in pertinent part:

(a)(1) "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer

10. Section 4033 of the Code states in pertinent part:

(a)(1) "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer.

(2) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription

11. Section 4059 of the Code states in pertinent part:

(a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7..

(b) This section does not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the drug or device, and its quantity. This section does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied.

12. Section 4123 of the Code provides as follows:

Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. That information shall be reported by the pharmacy performing the compounding services within 30 days of commencing that compounding.

13. Section 4169 of the Code states in pertinent part:

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

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew

or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 11250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 11335 of the Health and Safety Code.

14. Section 4342 of the Code provides as follows:

(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 withSection 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.

15. Health and Safety Code section 111395 provides as follows:

Any drug is misbranded in any of the following cases:

(a) It is an imitation of another drug.

(b) It is offered for sale under the name of another drug.

(c) The contents of the original package have been, wholly or partly, removed and replaced with other material in the package.

16. 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.

17. California Code of Regulations Section 1735.2 provides in pertinent part:

(a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

18. California Code of Regulations Section 1735.4 provides:

(a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain

the generic name(s) of the principal active ingredient(s).

(b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.

(c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date.

FIRST CAUSE FOR DISCIPLINE
(Unlicensed Manufacturing.)

19. Respondents are subject to disciplinary action under sections 4301 and 4033 for the unlicensed manufacture of medication in that they prepared injectable medication that was not provided directly to a consumer. The circumstances are as follows:

20. Documents provided on May 10, 2012 and November 27, 2012 indicated Pharmedium Services LLC sold the following injectable products: #48 25mg nicardipine hydrochloride 0.1mg/ml in 5% dextrose 250ml AVIVA bags, #24 3ml 4% sodium citrate syringes, and #1 0.2% ropivacaine HCL 550ml injection to John Muir Medical Center Concord Campus Pharmacy (HSP 42916) between 3/8/12 and 10/17/12. Documents provided on 5/10/12 and 7/19/12 indicated Pharmedium Services LLC sold the following injectable products:#160 nicardipine hydrochloride 0.1mg/ml in 0.9% sodium chloride 10ml syringes, #96 4mg norepinephrine bitartrate (16mcg/ml), #12 150mg amiodarone HCL in 5% dextrose, #72 1.25g vancomycin HCL in 5% dextrose, #24 1.5g vancomycin HCL in 5% dextrose, #120 1g magnesium sulfate in 5% dextrose, #500 10mg/ml rocuronium bromide, #550 20mg/ml succinylcholine chloride, #400 5mg/ml ephedrine sulfate, #400 100mcg/ml phenylephrine HCL, #30 5mg/ml labetalol, #300 5mg labetalol (no overwrap), #72 125mg diltiazem HCL in 5% dextrose, #20 0.1% ropivacaine HCL in 0.9% sodium chloride, #216 2g cefazolin in 5% dextrose, #36 50mg phenylephrine HCL (0.1mg/ml) in 5% dextrose, and #5 0.25% bupivacaine HCL in 0.9% sodium chloride to Community Hospital Monterey (HSP 30134) between 1/12/12 and

7/11/12. All products were sold without a valid license to manufacture FDA approved drugs and without receipt of a valid prescription for an individual patient. The following table shows the injectable medications sold:

Compounded medication furnished to a sample of licensed hospitals in California

Drug	Dates	Invoice #/ Document #	Sold to	Total Quantity
nicardipine 0.1mg/ml 10ml syringe	1/12/12 1/31/12 2/2/12 3/12/12 4/6/12 4/11/12 5/8/12 6/25/12 7/5/12 7/11/12	A571580 A579832 A581416 A598834 A611130 A613149 A624220 A643900 A648371 A651062	CH-M *	160
4mg norepinephrine bitartrate (16mcg/ml)	1/31/12 6/25/12 7/11/12	A579832 A643900 A651062	CH-M	96
150mg amiodarone in 5% dextrose	1/31/12	A579832	CH-M	12
1.25g vancomycin in 5% dextrose	1/31/12 6/25/12 7/5/12	A579832 A643900 A648371	CH-M	72
1.5g vancomycin in 5% dextrose	1/31/12	A579832	CH-M	24
1g magnesium sulfate in 5% dextrose	1/31/12 3/12/12 7/11/12	A579832 A598834 A651062	CH-M	120
10mg/ml rocuronium bromide	1/31/12 2/2/12 3/12/12 4/6/12 5/8/12 7/5/12 7/11/12	A579832 A581416 A598834 A611130 A624220 A648371 A651062	CH-M	500
20mg/ml succinylcholine chloride	1/31/12 2/2/12 3/12/12 4/6/12 5/8/12 7/5/12	A579832 A581416 A598834 A611130 A624220 A648371	CH-M	550

	7/11/12	A651062		
5mg/ml ephedrine sulfate	2/2/12 3/12/12 4/6/12 5/8/12 7/5/12 7/11/12	A581416 A598834 A611130 A624220 A648371 A651062	CH-M	400
100mcg/ml phenylephrine HCL	2/2/12 3/12/12 4/6/12 5/8/12 7/5/12 7/11/12	A581416 A598834 A611130 A624220 A648371 A651062	CH-M	400
5mg/ml labetalol	2/2/12 3/12/12	A581416 A598834	CH-M	30
5mg/ml labetalol (no overwrap)	2/2/12 3/12/12 4/6/12 5/8/12 7/5/12 7/11/12	A581416 A598834 A611130 A624220 A648371 A651062	CH-M	300
125mg diltiazem HCL in 5% dextrose	3/12/12 6/25/12 7/11/12	A598834 A643900 A651062	CH-M	72
0.1% ropivacaine HCL in 0.9% sodium chloride	4/11/12	A613149	CH-M	20
2g cefazolin in 5% dextrose	5/8/12 6/25/12 7/11/12	A624220 A643900 A651062	CH-M	216
50mg phenylephrine HCL in 5% dextrose	6/25/12 7/11/12	A643900 A651062	CH-M	36
0.25% bupivacaine HCL in 0.9% sodium chloride	7/5/12	A648371	CH-M	5
25mg nicardipine (0.1mg/ml) in 5% dextrose 250ml AVIVA bag	3/9/12 6/1/12 8/29/12 10/17/12	558459 594179 629096 649014	JMCC-C**	48
4% sodium citrate 3ml	8/29/12	629096	JMCC-C	24

syringe				
0.2% ropivacaine HCL 550ml injection	8/29/12	629096	JMCC-C	1

*Ch-M= Community Hospital Monterey
**JMMC-C=John Muir Medical Center-Concord

SECOND CAUSE FOR DISCIPLINE

(Selling Misbranded Drugs)

21. Respondents are subject to disciplinary action under section Business and Professions Code section 4169, in that they sold drugs which were misbranded as more specifically set forth above in paragraph 11 and the table set forth above.

THIRD CAUSE FOR DISCIPLINE
(Manufacture and sale of Commercially Available Drugs)

22. Respondents are subject to disciplinary action under section 4342 (a) in that section 111395 of the Health and Safety Code states that a drug is misbranded if it is an imitation of another drug, and on or about March 8, 2012 and October 17, 2012, Pharmedium Services LLC compounded and sold to John Muir Medical Center Concord Campus Pharmacy (HSP 42916) #48 bags of 25mg nicardipine hydrochloride 250ml (0.1mg/ml) in 5% dextrose. The commercially available product, Cardene, is 20mg nicardipine hydrochloride 200ml (0.1mg/ml) in 4.8% dextrose.

FOURTH CAUSE FOR DISCIPLINE
(Manufacture and Sale of Unapproved Drugs)

23. Respondents are subject to disciplinary action under section 4342 (a) in that Respondent sold injectables without FDA approval and without the receipt of a valid prescription. The circumstances are as follows:

24. On or about Specifically, between January 12, 2012 and July 11, 2012, Pharmedium Services LLC sold to Community Hospital Monterey (HSP 30134) #160 10ml

syringes of injectable nicardipine hydrochloride 0.1mg/ml in 0.9% sodium chloride, an unapproved drug.

FIFTH CAUSE FOR DISCIPLINE
(selling adulterated drugs)

25. Respondents are subject to disciplinary action under section 4342 (a) in conjunction with Health and Safety Code section 11128 and California Code of Regulations section 1735.1 in that Respondent sold drugs lacking in quality or strength. The circumstances are as follows:

26. Documents provided on May 10, 2012 and June 20, 2012 indicated Pharmedium Services LLC compounded Batch Number 12117009S on 4/26/2012 with a labeled strength of 50mg nicardipine 0.2mg/ml in 250ml 0.9% sodium chloride, when quantitative analysis indicated the actual product strength was beyond the industry accepted range of +/- 10% with concentrations of nicardipine 0.173, 0.169, and 0.173 mg/ml. Expected concentration should be nicardipine 0.180-0.220 mg/ml. This quantitative analysis report indicated a potency of "P" for pass.

SIXTH CAUSE FOR DISCIPLINE
(Not Compounding pursuant to a Patient Specific Prescription)

27. Respondents are subject to disciplinary action under California Code of Regulations Section 1735.2 in that documents provided on May 10, 2012 and November 27, 2012 indicated Pharmedium Services LLC sold the following injectable products: #48 25mg nicardipine hydrochloride 0.1mg/ml in 5% dextrose 250ml AVIVA bags, #24 3ml 4% sodiumcitrate syringes, and #1 0.2% ropivacaine HCL 550ml injection to John Muir Medical Center Concord Campus Pharmacy (HSP 42916) between 3/8/12 and 10/17/12. Documents provided on5/10/12 and 7/19/12 indicated Pharmedium Services LLC sold the following injectable products:#160 nicardipine hydrochloride 0.1mg/ml in 0.9% sodium chloride 10ml syringes, #96 4 mgnorepinephrine bitartrate (16mcg/ml), #12 150mg amiodarone HCL in 5%

dextrose, #72 1.25 gvancomycin HCL in 5% dextrose, #24 1.5g vancomycin HCL in 5% dextrose, #120 1 gmagnesium sulfate in 5% dextrose, #500 10mg/ml rocuronium bromide, #550 20mg/ml succinylcholine chloride, #400 5mg/ml ephedrine sulfate, #400 100mcg/ml phenylephrine HCL, #30 5mg/ml labetalol, #300 5mg labetalol (no overwrap), #72 125mg diltiazem HCL in 5% dextrose, #20 0.1% ropivacaine HCL in 0.9% sodium chloride, #216 2g cefazolin in 5% dextrose, #36 50mg phenylephrine HCL (0.1mg/ml) in 5% dextrose, and #5 0.25% bupivacaine HCL in 0.9% sodium chloride to Community Hospital Monterey (HSP 30134) between 1/12/12 and 7/11/12. All products were sold without receipt of a valid prescription for an individual patient and without a license to manufacture FDA approved drugs. As set forth more specifically above in paragraph 11, table 1.

SEVENTH CAUSE FOR DISCIPLINE
(Selling a Mislabled Drug Product)

28. Respondents are subject to disciplinary action under section 4169 (a) (3) in that Respondent sold drugs which were misbranded. The circumstances are as follows:

29. On or about July 19 2012, at Community Hospital Monterey (HSP 30134), the labels on nicardipine hydrochloride 0.1mg/1ml 0.9% sodium chloride 10ml syringes provided by Pharmedium Services LLC stated "Use as Directed. Rx Only", "Store at Room Temp.", and indicated a 90-day expiration date. Pharmedium Services LLC stated in writing on 6/5/12 "the labeled statement of use is: See Manufacturer's Package Insert. Use as directed. Rx Only." The "Drug Presentation" screen provided by Pharmedium Services LLC to Community Hospital Monterey on 7/19/12 provided Drug Manufacturer's Package Inserts for Emcure Pharmaceuticals and Sun Pharmaceuticals. Both manufacturer's package inserts stated "vials must be diluted before infusion" and "the diluted solution is stable for 24 hours at room temperature". No patient specific directions were provided.

EIGHTH CAUSE FOR DISCIPLINE
(No Compounding Statement on Products)

30. Respondents are subject to disciplinary action under California Code of Regulations Section 1735.4(b) in that they failed to provide a product statement on compounded medications. The circumstances are as follows:

31. On or about July 19, 2012, during an inspection of Community Hospital Monterey (HSP 30134), nicardipine syringes compounded and sold by Pharmedium Services LLC found in the inventory did not contain a compounded drug product statement.

NINTH CAUSE FOR DISCIPLINE
(Failure to Report Contracts)

32. Respondents are subject to disciplinary action under section 4123 for failure to report its contractual arrangement to compound drugs for other pharmacies. The circumstances are as follows:

33. Documents provided on June 5, 2012 indicated Pharmedium Services LLC contracted with pharmacies in California to "compound injectable sterile drugs for parenteral use pursuant to California's Business and Professions Code Section 4123" and the drugs for parenteral therapy were not compounded pursuant to a prescription but by invoice at wholesale, as set forth more specifically in paragraph 11 and table 1, above.

TENTH CAUSE FOR DISCIPLINE
(Improper Invoicing)

34. Respondents are subject to disciplinary action under section 4059 (b) for improper invoicing in that they failed to properly list the address of their supplier. The circumstances are as follows:

35. Documents provided on July 19, 2012 and November 27, 2012 indicated Pharmedium Services LLC invoiced from 39797 Treasury Center, Chicago, IL 60694 and 43

Distribution Blvd., Edison, NJ 08817 which were not the address of the supplier in each instance. Pharmedium Services LLC was in violation for the eleven invoices with an incorrect supplier address. See Table 2 below.

Date	PO#:	Record #:	Type of Record:	Pharmadium address	Hospital customer
1/12/12	RX8524	A571580	Invoice	39797 Treasury Center, Chicago, IL 60694	CH-M
1/31/12	RX8555	A579832	Invoice	39797 Treasury Center, Chicago, IL 60694	CH-M
2/2/12	RX8564	A581416	Invoice	39797 Treasury Center, Chicago, IL 60694	CH-M
3/12/12	RX8x642	A598834	Invoice	39797 Treasury Center, Chicago, IL 60694	CH-M
4/6/12	RX8709	A611130	Invoice	39797 Treasury Center, Chicago, IL 60694	CH-M
4/11/12	RX8717	A613149	Invoice	39797 Treasury Center, Chicago, IL 60694	CH-M
5/8/12	RX8771	A624220	Invoice	39797 Treasury Center, Chicago, IL 60694	CH-M
6/25/12	RX8861	A648371	Invoice	39797 Treasury	CH-M

				Center, Chicago, IL 60694	
7/5/12	RX8885	A648371	Invoice	39797 Treasury Center, Chicago, IL 60694	CH-M
7/11/12	RX8904	A651062	Invoice	39797 Treasury Center, Chicago, IL 60694	CH-M
10/17/12	101212FJ	WEB0649014-A	Packing Slip	43 Distribution Blvd., Edison, NJ 08817	JMMC-C

DISCIPLINE CONSIDERATIONS

36. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that on or about April 14, 2011, in a prior action, the Board of Pharmacy issued Citation Number CI 2010 47609 for violating Business and Profession Code section 4123 and ordered Respondent, Pharmedium Healthcare Corp dba Pharmedium Services LLC, to pay a fine of $4,460.00. That Citation is now final and is incorporated by reference as if fully set forth.

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 Non-Resident Pharmacy Permit Number NRP 590, issued to Pharmedium Healthcare Corp dba Pharmedium Services LLC;

2. Revoking or suspending Non-Resident Sterile Compounding license Number NSC 99221 to Pharmedium Services LLC;

3. Ordering Pharmedium Healthcare Corp. and Pharmedium Services LLC 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;

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

DATED: 9/13/14

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

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