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

In the Matter of the Accusation Against: **TSDR PHARMACY INC., DBA BRANDMD; SAMUEL D. RAOOF, OWNER** 20660 Nordoff St., Unit C Chatsworth, CA 91311 GEORGE DERN, Pharmacist-in-Charge Pharmacy Permit No. PHY 50543 and **GEORGE DERN** 9701 Donna Ave. Northridge, CA 91324 Pharmacist License No. RPH 21251 Respondents.	Case No. 6127 **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 (Board), Department of Consumer Affairs.

2. On or about February 25, 2011, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 50543 to TSDR Pharmacy Inc., dba BrandMD, with George Dern as the Pharmacist-in-Charge, and Samuel D. Raoof as the Chief Executive Officer, 100% shareholder, and Secretary and Treasurer/Chief Financial Officer (Respondent Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2018, unless renewed.

3. On or about July 25, 1959, the Board issued Pharmacist License Number RPH 21251 to George Dern (Respondent Dern). The Pharmacist License was in full force and effect at all times relevant to the charges herein and will expire on April 30, 2018, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

STATUTORY PROVISIONS

5. Code section 4300 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."

6. Code section 4300.1 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. Code section 4301 provides, 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 issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

". . . .

"(j) The violation of any of the statutes of this state, of 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."

8. Section 4307 states, in pertinent part:

"(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

"(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

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"(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated."

9. Code section 4033 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. Code section 4036.5 states:

"Pharmacist-in-charge" means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

11. Health and Safety Code section 111250 states:

"Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance."

12. Health and Safety Code section 111295 states:

"It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated."

13. Health and Safety Code section 111615 states:

"No person shall manufacture any drug or device in this state unless he or she has a valid license from the department. The license is valid for two calendar years from the date of issue, unless it is revoked. The license is not transferable.

"The department may require any manufacturer, wholesaler, or importer of any prescription ophthalmic device in this state to obtain a license."

14. Health and Safety Code section 111650 states:

"Drug manufacturers who have obtained a license or who are applying for a license pursuant to this article shall submit to the California State Board of Pharmacy information as the Board of Pharmacy deems reasonably necessary to carry out its drug distribution responsibilities including, but not limited to, information on drug inventories or restricted dangerous drugs. Failure of any manufacturer to report the information to the Board of Pharmacy in a timely

fashion shall be grounds for the department to deny, suspend, or revoke the manufacturer's license.

"The California State Board of Pharmacy may adopt regulations that are reasonably necessary to implement this section."

REGULATORY PROVISIONS

15. California Code of Regulations, title 16, section 1735 states:

"(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

"(1) Altering the dosage form or delivery system of a drug

"(2) Altering the strength of a drug

"(3) Combining components or active ingredients

"(4) Preparing a compounded drug preparation from chemicals or bulk drug substances

"(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.

"(c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.

"(d) The parameters and requirements stated by Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile compounding are stated by Article 7 (Section 1751 et seq.)."

16. California Code of Regulations, title 16, section 1735.2 states, in pertinent part:

. . .

"(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

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"(1) Active ingredients to be used.

"(2) Inactive ingredients to be used.

"(3) Process and/or procedure used to prepare the drug."

17. California Code of Regulations, title 16, section 1735.3 states, in pertinent part:

"(a) For each compounded drug preparation, pharmacy records shall include:

"(1) The master formula record.

"(2) The date the drug product was compounded.

"(3) The identity of the pharmacy personnel who compounded the drug product.

"(4) The identity of the pharmacist reviewing the final drug product.

"(5) The quantity of each component used in compounding the drug product.

"(6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

"(7) The equipment used in compounding the drug product.

"(8) A pharmacy assigned reference or lot number for the compounded drug product.

"(9) The expiration date of the final compounded drug product.

"(10) The quantity or amount of drug product compounded."

18. California Code of Regulations, title 16, section 1735.5 states, in pertinent part:

"(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

"(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

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"(c) The policy and procedure manual shall include the following:

"(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

"(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

"(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

"(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

"(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products."

19. California Code of Regulations, title 16, section 1735.7 states:

"(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

"(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

"(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding any drug product."

COST RECOVERY

20. Section 125.3 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.

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DRUG DEFINITIONS

21. Tretinoin, retinoic acid, under the brand name Retin-A, is medication used for the treatment of acne and acute promyelocytic leukemia. It is available only by prescription, and therefore a dangerous drug pursuant to Business and Professions Code Section 4022(c).

22. Hydroquinone, under the brand name Lustra, is a topical agent used for reducing skin pigmentation. Any strength of this drug in excess of 2 percent is available only by prescription, and therefore a dangerous drug pursuant to Business and Professions Code Section 4022(c).

FACTUAL BACKGROUND

23. On January 22, 2015, May 12, 2016 and July 15, 2016, the Board received complaints alleging that Respondent Pharmacy was compounding non-patient specific dermatological preparations and selling them to physicians. The Board's subsequent investigation substantiated that Respondent Pharmacy was acting as a manufacturer by compounding and selling non-patient specific dermatological preparations to physicians, who then sold the preparations to their patients in their respective offices. These complaints alleged that Respondent Pharmacy was compounding and selling non-patient specific dermatological preparations such as tretinoin 0.1%, 0.05%, 0.025%, hydroquinone 12%, and other prescription strength products in large quantity to physicians for them to sell directly to their patients.

24. On July 26, 2016, a Board Inspector conducted an inspection and complaint investigation at Respondent Pharmacy. Respondent Dern, who is the Pharmacist-in-Charge (PIC) at Respondent Pharmacy, and Samuel Raoof, CEO and owner of Respondent Pharmacy, were present and assisted with the inspection. Thereafter, upon conducting a further investigation of Respondent Pharmacy, which included interviews of relevant persons and the obtainment and analysis of various relevant documents and records, the Board Inspector arrived at the following factual conclusions in regard to Respondent Pharmacy and Respondent Dern:

- Drugs were compounded in Respondent Pharmacy by Respondent Dern without the pharmacy having first prepared a written master formula with all the required elements.

- Respondent Pharmacy and Respondent Dern were not compliant with the law governing correct compounding policies and procedures, in that the policy and procedure manual of Respondent Pharmacy was not reviewed on an annual basis by Respondent Dern, the PIC.
- Respondent Pharmacy and Respondent Dern were not compliant with the law governing correct compounding policies and procedures, in that the policy and procedure manual of Respondent Pharmacy did not include procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual. In addition, the policy and procedure manual of Respondent Pharmacy did not include documentation of a plan for recall of a dispensed compounded drug product. Respondent Pharmacy's policy and procedure manual also did not include the procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of Respondent Pharmacy's staff training and competency evaluation process. In addition, Respondent Pharmacy's policy and procedure manual did not include documentation of the methodology used to test the integrity, potency, quality, and labeled strength of compounded drug products. Moreover, Respondent Pharmacy's policy and procedure manual did not include documentation of the methodology used to determine appropriate expiration dates for compounded drug products.
- Respondent Pharmacy and Respondent Dern were not compliant with the law governing the appropriate training of Respondent Pharmacy's compounding staff. In this regard, the Board inspector found that Respondent Dern (the PIC) was engaged in compounding without having the skills and training required to properly and accurately perform his assigned responsibilities related to compounding. In addition, Respondent Pharmacy and Respondent Dern did not maintain documentation of any and all training related to compounding undertaken by Respondent Pharmacy's personnel. And further, Respondent Dern was assigned to compounding duties without demonstrating knowledge about the processes and procedures used in compounding prior to compounding any drug product.

- Respondent Pharmacy and Respondent Dern were not compliant with the law governing recordkeeping of compounded drug products, as the expiration dates of final drug products were not listed in Respondent Pharmacy's compounding records.
- Various compounded drug lots found during the July 26, 2016 inspection at Respondent Pharmacy were compounded using expired ingredients, as follows: HQRA + Base (No Fragrance) – Batch Number 3305-1270, prepared on 7/23/2016, expired on 7/23/2016; HQRA + Base (No Fragrance) – Batch Number 3305-1238, prepared on 7/18/2016, expired on 7/18/2016; HQRA + Base (No Fragrance) – Batch Number 3305-1207, prepared on 6/27/2016, expired on 6/27/2016; and HQRA FF - Batch Number 3305-1224, prepared on 7/11/2016, expired on 7/11/2016.
- Respondent Pharmacy was acting as a drug manufacturer, despite the fact that it was not licensed as a drug manufacturer. In this regard, Respondent Pharmacy and Respondent Dern compounded non-patient specific topical dermatological preparations and sold these preparations to prescribers, and not directly to patients. These compounded preparations were then sold by the prescribers to their patients in the prescribers' respective offices.
- Respondent Dern committed an act of inappropriate exercise of his education, training and experience as a pharmacist by allowing unlicensed personnel to assist him in compounding.

FIRST CAUSE FOR DISCIPLINE

(Failure to Prepare Master Formula)

25. Respondent Pharmacy and Respondent Dern are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.2, subdivision (d) in that a Board inspection conducted on or about July 26, 2016, and further investigation by the Board Inspector revealed that drugs were compounded in and by Respondent Pharmacy by Respondent Dern without the pharmacy having first prepared a written master formula with all the required elements. Complainant hereby incorporates by reference paragraphs 23 and 24 above, as though fully set forth herein.

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SECOND CAUSE FOR DISCIPLINE

(Failure to Review Pharmacy Policy and Procedure Manual)

26. Respondent Pharmacy and Respondent Dern are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.5, subdivision (b), in that a Board inspection conducted on or about July 26, 2016, and further investigation by the Board Inspector revealed that Respondent Pharmacy's policy and procedure manual was not reviewed on an annual basis by the Pharmacist-in-Charge. Complainant hereby incorporates by reference paragraphs 23 and 24 above, as though fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

(Non-Compliant with Compounding Law)

27. Respondent Pharmacy and Respondent Dern are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.5, subdivision (c)(1-5), in that a Board inspection conducted on or about July 26, 2016, and further investigation by the Board Inspector revealed that Respondent Pharmacy and Respondent Dern were not compliant with the law governing correct compounding policies and procedures, in that the policy and procedure manual of Respondent Pharmacy did not include procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual. In addition, the policy and procedure manual of Respondent Pharmacy did not include documentation of a plan for recall of a dispensed compounded drug product. Respondent Pharmacy's policy and procedure manual also did not include the procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of Respondent Pharmacy's staff training and competency evaluation process. In addition, Respondent Pharmacy's policy and procedure manual did not include documentation of the methodology used to test the integrity, potency, quality, and labeled strength of compounded drug products. Moreover, Respondent Pharmacy's policy and procedure manual did not include documentation of the methodology used

to determine appropriate expiration dates for compounded drug products. Complainant hereby incorporates by reference paragraphs 23 and 24 above, as though fully set forth herein.

FOURTH CAUSE FOR DISCIPLINE

(Non-Compliant with Training Law)

28. Respondent Pharmacy and Respondent Dern are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.7, subdivisions (a-c), in that a Board inspection conducted on or about July 26, 2016, and further investigation by the Board Inspector revealed that Respondent Pharmacy and Respondent Dern were not compliant with the law governing the appropriate training of Respondent Pharmacy's compounding staff. In this regard, the Board inspector found that Respondent Dern (the PIC) was engaged in compounding without having the skills and training required to properly and accurately perform his assigned responsibilities related to compounding. In addition, Respondent Pharmacy and Respondent Dern did not maintain documentation of any and all training related to compounding undertaken by Respondent Pharmacy's personnel. And further, Respondent Dern was assigned to compounding duties without demonstrating knowledge about the processes and procedures used in compounding prior to compounding any drug product. Complainant hereby incorporates by reference paragraphs 23 and 24 above, as though fully set forth herein.

FIFTH CAUSE FOR DISCIPLINE

(Non-Compliant with Recordkeeping Law)

29. Respondent Pharmacy and Respondent Dern are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.3, subdivision (a)(8), in that a Board inspection conducted on or about July 26, 2016, and further investigation by the Board Inspector revealed that Respondent Pharmacy and Respondent Dern were not compliant with the law governing recordkeeping of compounded drug products, as the expiration dates of final drug products were not listed in Respondent Pharmacy's compounding records. Complainant hereby incorporates by reference paragraphs 23 and 24 above, as though fully set forth herein.

SIXTH CAUSE FOR DISCIPLINE

(Drugs Compounded with Expired Ingredients)

30. Respondent Pharmacy and Respondent Dern are subject to disciplinary action under Code section 4301, subdivision (o), for violating Health and Safety Code section 111250, in conjunction with Health and Safety Code section 111295, in that a Board inspection conducted on or about July 26, 2016, and further investigation by the Board Inspector revealed that various compounded drug lots found during that inspection at Respondent Pharmacy were compounded using expired ingredients. Complainant hereby incorporates by reference paragraphs 23 and 24 above, as though fully set forth herein.

SEVENTH CAUSE FOR DISCIPLINE

(Not Licensed as Drug Manufacturer)

31. Respondent Pharmacy and Respondent Dern are subject to disciplinary action under Code section 4301, subdivision (o), for violating Health and Safety Code section 111615, in conjunction Health and Safety Code section 111650, and Code section 4033, subdivision (a)(1), in that a Board inspection conducted on or about July 26, 2016, and further investigation by the Board Inspector revealed that Respondent Pharmacy was acting as a drug manufacturer, despite the fact that it was not licensed as a drug manufacturer. In this regard, Respondent Pharmacy and Respondent Dern compounded non-patient specific topical dermatological preparations and sold these preparations to prescribers, and not directly to patients. These compounded preparations were then sold by the prescribers to their patients in the prescribers' respective offices. Complainant hereby incorporates by reference paragraphs 23 and 24 above, as though fully set forth herein.

EIGHTH CAUSE FOR DISCIPLINE

(Aided and Abetted Unlicensed Personnel)

32. Respondent Dern is subject to disciplinary action under Code sections 4301, subdivision (o), for violating 4306.5, subdivision (a), in that a Board inspection conducted on or about July 26, 2016, and further investigation by the Board Inspector revealed that Respondent Dern committed an act of inappropriate exercise of his education, training and experience as a

pharmacist by allowing unlicensed personnel to assist him in compounding. Complainant hereby incorporates by reference paragraphs 23 and 24 above, as though fully set forth herein.

DISCIPLINE CONSIDERATION

33. To determine the degree of discipline, if any, to be imposed on Respondent Dern, Complainant alleges that in a disciplinary action entitled "*In the Matter of the Accusation Against Kovacs Pharmacy, Gary J. Hughes, and George Dern*," Case No. 904, the Board of Pharmacy issued a Decision and Order effective September 7, 1978, in which Respondent Dern's Pharmacist License was revoked. However, the revocation was stayed and Respondent Dern's Pharmacist License was placed on probation for one (1) year with terms and conditions, including a ten (10) day suspension. A copy of that Decision and Order is attached as Exhibit A and is incorporated herein by reference.

OTHER MATTERS

34. Pursuant to section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50543 issued to TSDR Pharmacy Inc., doing business as BrandMD, TSDR Pharmacy Inc. shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50543 is placed on probation or until Pharmacy Permit Number PHY 50543 is reinstated if the license is revoked.

35. Pursuant to section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50543 issued to TSDR Pharmacy Inc., doing business as BrandMD, while Samuel D. Raoof has been an officer or owner, and had knowledge of, or knowingly participated in, any conduct for which TSDR Pharmacy Inc. was disciplined, Samuel D. Raoof shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50543 is placed on probation or until Pharmacy Permit Number PHY 50543 is reinstated if the license is revoked.

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:

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1. Revoking or suspending Pharmacy Permit Number PHY 50543 issued to TSDR Pharmacy Inc., dba BrandMD;

2. Prohibiting TSDR Pharmacy Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50543 is placed on probation or until Pharmacy Permit Number PHY 50543 is reinstated if Pharmacy Permit Number PHY 50543 issued to TSDR Pharmacy Inc., doing business as BrandMD, is revoked;

2. Prohibiting Samuel D. Raoof from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50543 is placed on probation or until Pharmacy Permit Number PHY 50543 is reinstated if Pharmacy Permit Number PHY 50543 issued to TSDR Pharmacy Inc., doing business as BrandMD, is revoked;

4. Revoking or suspending Pharmacist License Number RPH 21251 issued to George Dern;

5. Ordering TSDR Pharmacy Inc., dba BrandMD, and George Dern 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; and

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

DATED: 2/28/18

Virginia Herold

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