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

In the Matter of the Accusation Against:

REGENTS OF THE UNIVERSITY OF CALIFORNIA DBA RONALD REAGAN UCLA PHARMACY, JOHNESE SPISSO, ADMINISTRATOR Permit No. PHE 48971,

and

HEIDI W. HENEN
Pharmacist License No. RPH 60494,

Respondents.

Agency Case No. 7390

OAH NO. 2023070837

DECISION AND ORDER

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 at 5:00 p.m. on August 1, 2024.

It is so ORDERED on July 2, 2024.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Seung W. Oh, Pharm.D. Board President

1	ROB BONTA		
2	Attorney General of California THOMAS L. RINALDI		
3	Supervising Deputy Attorney General LESLIE A. WALDEN		
4	Deputy Attorney General State Bar No. 196882		
5	300 So. Spring Street, Suite 1702		
6	Los Angeles, CA 90013 Telephone: (213) 269-6293 Facsimile: (916) 731-2126		
7	Attorneys for Complainant		
8	DEFOR		
	BEFORE THE BOARD OF PHARMACY		
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
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11		LC N 7200	
12	In the Matter of the Accusation Against:	Case No. 7390	
13	REGENTS OF THE UNIVERSITY OF CALIFORNIA DBA RONALD REAGAN	OAH No. 2023070837	
14	UCLA PHARMACY Johnese Spisso, Administrator	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC	
15	757 Westwood Plaza, Ste. B140 Los Angeles, CA 90095	REPROVAL AS TO REGENTS OF THE UNIVERSITY OF CALIFORNIA DBA	
16	Permit No. PHE 48971,	RONALD REAGAN UCLA PHARMACY	
17	and	[Bus. & Prof. Code § 495]	
18	HEIDI W. HENEN 5220 Lindley Ave, #1		
19	Encino, CA 91316 Pharmacist License No. RPH 60494		
20	Respondents.		
21	Respondents.		
22			
23	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-		
24	entitled proceedings that the following matters are true:		
25	<u>PARTIES</u>		
26	1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy.		
27	She brought this action solely in her official capacity and is represented in this matter by Rob		
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Bonta, Attorney General of the State of California, by Leslie A. Walden, Deputy Attorney General.

2. Respondent Regents of the University of California dba Ronald Reagan UCLA Pharmacy (Respondent) is represented in this proceeding by attorney Natalia Mazina, whose address is: Mazina Law, 100 Pine Street, Suite 1250, San Francisco, CA 94111-5235.

JURISDICTION

- 3. On or about February 1, 2008, the Board issued Permit No. PHE 48971 to Respondent. The Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 7390 and will expire on November 1, 2024, unless renewed.
- 4. Accusation No. 7390 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on May 17, 2023. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 7390 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7390. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval as to Respondent Regents of the University of California dba Ronald Reagan UCLA Pharmacy.
- 6. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its 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.

CULPABILITY

- 8. Respondent understands and agrees that the charges and allegations in Accusation No. 7390, if proven at a hearing, constitute cause for imposing discipline upon its Pharmacy Permit
- 9. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up its right to contest those charges.
- 10. Respondent agrees that its Pharmacy Permit is subject to discipline and they agree to be bound by the Disciplinary Order below.

CONTINGENCY

- 11. 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 its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its 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 as to Respondent Regents of the University of California dba Ronald Reagan UCLA Pharmacy 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.
- 12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval as to Respondent Regents of the University of California dba Ronald Reagan UCLA Pharmacy, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.
- 13. This Stipulated Settlement and Disciplinary Order for Public Reproval as to Respondent Regents of the University of California dba Ronald Reagan UCLA Pharmacy 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 as to Respondent Regents of the University of California dba Ronald Reagan UCLA Pharmacy may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. 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 Pharmacy Permit No. PHE 48971 issued to Respondent Regents of the University of California dba Ronald Reagan UCLA Pharmacy shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 7390, attached as exhibit A.

Cost Recovery. No later than one (1) year from the effective date of the Decision, Respondent shall pay \$16,512 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew their Permit until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in Accusation No. 7390, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Pharmacy Permit No. PHE 48971.

DATED:		
REGENTS OF THE UNIVERSITY OF CALIFORNIA DBA RONALD REAGAN UCLA PHARMACY		
JOHNESE SPISSO, ADMINISTRATOR Respondent		
I have read and fully discussed with Respondent Regents of the University of California		
dba Ronald Reagan UCLA Pharmacy 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:		
NATALIA MAZINA Attorney for Respondent REGENTS OF THE UNIVERSITY OF		
REGENTS OF THE UNIVERSITY OF CALIFORNIA DBA RONALD REAGAN UCLA PHARMACY		
5		

ACCEPTANCE 1 2 I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval as to Respondent Regents of the University of California dba Ronald Reagan UCLA 3 4 Pharmacy and have fully discussed it with my attorney, Natalia Mazina. I understand the 5 stipulation and the effect it will have on my Permit. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be 6 7 bound by the Decision and Order of the Board of Pharmacy. 8 DATED: 9 05/03/2024 10 CALIFORNIA DBA RONALD REAGAN UCLA PHARMACY 11 JOHNESE SPISSO, ADMINISTRATOR Respondent 12 13 I have read and fully discussed with Respondent Regents of the University of California 14 dba Ronald Reagan UCLA Pharmacy the terms and conditions and other matters contained in the 15 above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and 16 content. 17 18 DATED: 05/03/2024 19 Attorney for Respondent 20 REGENTS OF THE UNIVERSITY OF CALIFORNIA DBA RONALD REAGAN UCLA 21 PHARMACY 22 //// 23 24 //// 25 26 27 28

ENDORSEMENT The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval as to Respondent Regents of the University of California dba Ronald Reagan UCLA Pharmacy is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs. Respectfully submitted, DATED: _____ **ROB BONTA** Attorney General of California THOMAS L. RINALDI Supervising Deputy Attorney General LESLIE A. WALDEN Deputy Attorney General Attorneys for Complainant LA2022603756 66754032.docx

ENDORSEMENT 1 2 The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval as to Respondent Regents of the University of California dba Ronald Reagan UCLA Pharmacy is 3 hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of 4 Consumer Affairs. 5 6 DATED: 5/3/24 Respectfully submitted, 7 **ROB BONTA** 8 Attorney General of California THOMAS L. RINALDI 9 Supervising Deputy Attorney General Leslie Walden 10 11 LESLIE A. WALDEN Deputy Attorney General 12 Attorneys for Complainant 13 14 15 LA2022603756 16 66754032.docx 17 18 19 20 21 22 23 24 25 26 27 28

Exhibit A

Accusation No. 7390

ROB BONTA	
THOMAS L. RINALDI	
Leslie A. Walden	
State Bar No. 196882	
Los Angeles, CA 90013	
Facsimile: (916) 731-2126	
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BEFORE THE BOARD OF PHARMACY	
DEPARTMENT OF CONSUMER AFFAIRS	
STATE OF C.	ALIFORNIA
In the Matter of the Assessation Assistant	L C N 7200
	Case No. 7390
CALIFORNIA DBA RONALD REAGAN	ACCUSATION
Johnese Spisso, Administrator	ACCUSATION
Los Angeles, CA 90095	
Permit No. PHE 48971,	
and	
HEIDI W. HENEN 5220 Lindley Ave, #1	
Respondents.	
	1 IA DBA RONALD REAGAN UCLA PHARMACY and
	Attorney General of California THOMAS L. RINALDI Supervising Deputy Attorney General LESLIE A. WALDEN Deputy Attorney General State Bar No. 196882 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 269-6293 Facsimile: (916) 731-2126 Attorneys for Complainant BEFOR BOARD OF I DEPARTMENT OF CONSTATE OF CONST

HEIDI W. HENEN) ACCUSATION

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PARTIES

- 1. Anne Sodergren (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 February 1, 2008, the Board of Pharmacy issued Permit Number PHE 48971 to Regents of the University of California dba Ronald Reagan UCLA Pharmacy, Johnese Spisso Administrator (UCLA). The Permit was in full force and effect at all times relevant to the charges brought herein and will expire on November 1, 2023, unless renewed.
- 3. On or about November 28, 2007, the Board of Pharmacy issued Pharmacist License Number RPH 60494 to Heidi W. Henen (Henen). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2023, unless renewed. Henen was the Pharmacist in Charge at UCLA at all times relevant to the charges brought herein

JURISDICTION

- 4. This Accusation is brought before the Board of Pharmacy (Board), under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.
- 5. Code section 4011 provides that the Board shall administer and enforce both the Pharmacy Law (Bus. & Prof. Code, § 4000 et seq.) and the Uniform Controlled Substances Act (Health & Safety Code, § 11000 et seq.).
- 6. Code section 4300, subdivision (a) provides that every license issued by the Board may be suspended or revoked.
 - 7. 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.

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8. Code section 4307, subdivision (a) states:

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 manger, administrator, owner, member, officer, director, associate, or partner had knowledge 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 manger, 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.
- (2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.
 - 9. Code section 4342, subdivision (a) states:

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 & Safety Code).

STATUTORY PROVISIONS

10. Code section 4023.5 states:

For the purposes of this chapter, "direct supervision and control" means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist.

11. 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.
 - 12. Code section 4113, subdivision (c) 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 4115, subdivision (a) states:

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. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

14. Code section 4116, subdivision (a) states:

No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

15. 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 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, 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 any other state or federal regulatory agency....
 - 16. Section 4059.5 of the Code states:
- (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, or in the case of a reverse distributor a designated representative-reverse distributor, that individual shall sign for and receive the delivery.

REGULATORY PROVISIONS

17. California Code of Regulations, title 16, section 1714, subdivision (d) states:

Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

COST RECOVERY

18. 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.

DRUG DEFINITIONS

- 19. Gengraf, a brand name for Cyclsporine, is a dangerous drug pursuant to Business & Professions Code section 4022. Gengraf is used to treat organ rejection.
- 20. Coly-Mycin, a brand name for Cholistimethate, is a dangerous drug pursuant to Business & Professions Code section 4022. Coly-Mycin is an antibiotic.
- 21. Leukine, a brand name for Sargramostim, is a dangerous drug pursuant to Business & Professions Code section 4022. Leukine is used to treat Leukemia.
- 22. Klonopin, a brand name for Clonazepam, is Schedule IV controlled substance as designated by Health and Safety Code section 11057(d)(7), and is a dangerous drug pursuant to Business & Professions Code section 4022. Klonopin is used to treat panic disorders and seizures.
- 23. Opium Tincure is Schedule II controlled substance as designated by Health and Safety Code section 11055(b)(1)(F), and is a dangerous drug pursuant to Business & Professions Code section 4022. Opium Tincure is used to treat diarrhea.
- 24. Duragesic, a brand name for Fentanyl, is Schedule II controlled substance as designated by Health and Safety Code section 11055(c)(8), and is a dangerous drug pursuant to Business & Professions Code section 4022. Duragesic is used to treat pain.
- 25. Vyvanse, a brand name for Lisdexamfetamine Dimesylate, is Schedule II controlled substance as designated by Health and Safety Code section 11055(f)(1), and is a dangerous drug pursuant to Business & Professions Code section 4022. Vyvanse is used to treat Attention Deficit Hyperactivity Disorder.
- 26. Dilaudid, a brand name for Hydromorphone, is Schedule II controlled substance as designated by Health and Safety Code section 11055(b)(1)(J), and is a dangerous drug pursuant to Business & Professions Code section 4022. Dilaudid is used to treat pain.

FACTUAL ALLEGATIONS

27. On or about December 2, 2021 and December 14, 2021, the Board received anonymous complaints from employees at UCLA alleging that Henen, the Pharmacists in charge at UCLA, allowed a non-pharmacist to open the pharmacy and sign for the delivery of controlled substances. The Board commenced an investigation, which revealed that from on or about May 1, 2019 through May 1, 2020, UCLA and Henen allowed non-pharmacists to sign for the delivery of approximately 9005 containers of non-controlled prescription medications, 415 containers of Schedule III-V prescription medications, and 421 containers of Schedule II prescription medications from Amerisourse Wholesaler. The investigation revealed that different pharmacy technicians signed for and received approximately 270 delivery manifests containing dangerous drugs and devices, including but not limited to Gengraf, Coly-Mycin. Leukine, Klonopin, Opium Tincure, Duragesic, Vyvanse and Dilaudid.

FIRST CAUSE FOR DISCIPLINE

(Allowing Non-Pharmacists to Sign For and Receive Dangerous Drugs and Controlled Substances)

28. Respondents UCLA and Henen are subject to disciplinary action under Code sections 4301 subdivisions (j) and (o), and 4059.5 in that they allowed non-pharmacists to sign for and receive controlled substances and dangerous drugs from on or about May 1, 2019 through May 1, 2020 at UCLA. The circumstances surrounding this violation are set forth in paragraph 27 above, and are incorporated herein as though set forth in full.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain the Security of the Prescription Department at UCLA)

29. Respondent Henen is subject to disciplinary action under Business and Professions Code section 4301, subdivision (o) in conjunction with title 16, of the California Code of Regulations, section 1714, subdivision (d) for failing to ensure the security of the prescription department at UCLA. The circumstances surrounding this violation are set forth in paragraph 27 above, and are incorporated herein as though set forth in full.

DISCIPLINE CONSIDERATIONS

30. To determine the degree of discipline, if any, to be imposed on Respondent UCLA, Complainant alleges that on or about April 28, 2020, the Board issued Letter of Admonishment Number to CI 2018 84033 to UCLA under Business and Professions Code sections 4315 and 1707.5 subdivision (a)(1) for failure to print the drug manufacturer on prescription labels.

OTHER MATTERS

- 31. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHE 48971 issued to Regents of the University of California dba Ronald Reagan UCLA Pharmacy, it 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 PHE 48971 is placed on probation or until Pharmacy Permit Number PHE 48971 is reinstated if it is revoked.
- 32. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHE 48971 issued to Regents of the University of California dba Ronald Reagan UCLA Pharmacy, while Johnese Spisso was the Administrator, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Spisso 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 PHE 48971 is placed on probation or until Pharmacy Permit Number PHE 48971 is reinstated if it is revoked.
- 33. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 60494 issue to Heidi W. Henen, Henen shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 60494 is placed on probation or until Pharmacist License Number RPH 60494 is reinstated if it 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: