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

12 In the Matter of the Accusation Against:

Case No. 3108

13 **BIG A. DRUGSTORES, INC., d.b.a.**  
14 **DRUG EMPORIUM NO. 807**  
9922 Katella Avenue  
15 Garden Grove, CA 92804

**A C C U S A T I O N**

16 Pharmacy Permit No. PHY 45373

17 **EDWARD DALLAL, R.P.H.**  
15569 Aqua Verde Drive  
18 Los Angeles, CA 90077

19 Pharmacist License No. RPH 25391

20 Respondents.

21  
22 Complainant alleges:

23 **PARTIES**

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

27 2. On or about August 8, 2001, the Board of Pharmacy issued Pharmacy  
28 Permit Number PHY 45373 to BIG A. DRUGSTORES, INC., doing business as DRUG

1 EMPORIUM NO. 807, a.k.a. Store number 807, a.k.a. Store #807, a.k.a. Drug Emporium #807  
2 ("Respondent Drug Emporium No. 807"). Edward Dallal is the sole owner and president of  
3 Respondent Drug Emporium No. 807, and has been the sole owner and president of Respondent  
4 Drug Emporium No. 807 since August 8, 2001. The Pharmacy Permit will expire on August 1,  
5 2008, unless renewed.

6 3. On or about February 28, 1968, the Board of Pharmacy issued Pharmacy  
7 License No. RPH 25391 to Edward Dallal ("Respondent Dallal"). At all times material herein,  
8 Respondent Dallal was and currently is licensed by the Board as a registered pharmacist. The  
9 license expires on October 31, 2009, unless renewed.

10 4. DIT Healthcare Distributors, located at 4884 Duff Drive, Cincinnati, Ohio  
11 45246 is not licensed by the Board and was not licensed by the Board at any time relevant herein.

#### 12 JURISDICTION

13 5. Complainant brings this Accusation under the power vested in the Board  
14 under Business and Professions Code section 4300(a) to suspend or revoke licenses issued by the  
15 Board pursuant to the California Pharmacy Act, Chapter 9, Division 2, section 4000 et seq. of the  
16 Business and Professions Code. All section references are to the Business and Professions Code  
17 unless otherwise indicated.

#### 18 STATUTORY PROVISIONS AND REGULATIONS

19 6. Section 4301 provides in relevant part:

20 "The board shall take action against any holder of a license who is guilty of  
21 unprofessional conduct or whose license has been procured by fraud or misrepresentation or  
22 issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following

23 "....

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

26 "....

27 "(j) The violation of any of the statutes of this state, of any other state, or of the  
28 United States regulating controlled substances and dangerous drugs.

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“(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.

“ . . . .

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

7. 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."

8. Section 4081 of the Code states, in relevant 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)

1 of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or  
2 dangerous devices.

3 “(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary  
4 food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or  
5 representative-in-charge, for maintaining the records and inventory described in this section. . . .”

6 9. Section 4332 provides in relevant part:

7 “Any person who fails, neglects, or refuses to maintain the records required by  
8 Section 4081 or who, when called upon by an authorized officer or a member of the board, fails,  
9 neglects, or refuses to produce or provide the records within a reasonable time, or who willfully  
10 produces or furnishes records that are false, is guilty of a misdemeanor.

11 10. California Code of Regulations, title 16, section 1718, states:

12 “‘Current Inventory’ as used in Sections 4081 and 4332 of the Business and  
13 Professions Code shall be considered to include complete accountability for all dangerous drugs  
14 handled by every licensee enumerated in Sections 4081 and 4332.

15 “The controlled substances inventories required by Title 21, CFR, Section 1304  
16 shall be available for inspection upon request for at least 3 years after the date of the inventory.”

17 11. Section 4169 provides in relevant part: .

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

19 “(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at  
20 wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy,  
21 in violation of Section 4163. . . .”

22 12. Section 4163 provides:

23 “(a) A manufacturer or wholesaler may not furnish a dangerous drug or dangerous  
24 device to an unauthorized person.

25 “(b) Dangerous drugs or dangerous devices shall be acquired from a person  
26 authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person  
27 acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the

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1 wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it  
2 has not previously acquired dangerous drugs or dangerous devices.

3 “(c) Except as otherwise provided in Section 4163.5, commencing on January 1,  
4 2009, a wholesaler or pharmacy may not sell, trade, or transfer a dangerous drug at wholesale  
5 without providing a pedigree.

6 “(d) Except as otherwise provided in Section 4163.5, commencing on January 1,  
7 2009, a wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree.

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

## 12 **DRUGS**

13 14. Combivir is the trade name for a combination drug containing lamivudine  
14 (trade name Epivir, a.k.a. 3TC) and zidovudine (trade name Retrovir, a.k.a. AZT and ZDV) used  
15 for the treatment of HIV. It is a dangerous drug pursuant to Business and Professions Code  
16 section 4022.

## 17 **FIRST CAUSE FOR DISCIPLINE**

### 18 **(Failure to Maintain and Provide Pharmacy Records)**

19 15. Respondents are subject to disciplinary action under Section 4301,  
20 subdivisions (j) and (o), and Section 4081, subdivisions (a) and (b) in that Respondents failed to  
21 maintain records of acquisition or disposition of dangerous drugs for at least three (3) years and  
22 failed, neglected or refused to provide records of acquisition or disposition of dangerous drugs  
23 upon request by the Board in violation of Section 4332. The circumstances are as follows:

24 16. On or about September 18, 2006, the Board received information and  
25 documentation from the Oregon State Board of Pharmacy concerning purchase orders, invoices  
26 and pedigrees found at Big A. Distributors in Portland, Oregon. The Oregon State Board of  
27 Pharmacy reported that Respondent Drug Emporium No. 807 was selling legend pharmaceuticals  
28 to Big A. Distributors in Portland, Oregon.

1                   17.     On or about March 13, 2007, an F.D.A. investigator informed the Board  
2 that it had discovered misbranded Combivir. The F.D.A. investigator identified pharmacies that  
3 may have received the misbranded Combivir, including Respondent Drug Emporium No. 807.

4                   18.     On or about March 19, 2007, two Board investigators traveled to  
5 Respondent Drug Emporium No. 807 to track down the suspected log numbers of the  
6 misbranded Combivir. The investigators explained to the pharmacist-in-charge at Respondent  
7 Drug Emporium No. 807 that it was possible that Respondent Drug Emporium No. 807 had  
8 received misbranded Combivir. One of the investigators requested the pharmacist-in-charge at  
9 Respondent Drug Emporium No. 807 to check the computer records to determine if Combivir  
10 had been dispensed or purchased by Respondent Drug Emporium No. 807 during the last three  
11 (3) years. The investigators also performed a physical inspection of the premises. There were no  
12 invoices showing any purchases of Combivir. The pharmacist-in-charge showed the investigator  
13 a "Drug Utilization Report" which showed that Respondent Drug Emporium No. 807 had not  
14 dispensed any prescriptions for Combivir from January 1, 2000 to March 19, 2007.

15                   19.     On or about March 19, 2007, the Board requested from Respondent Drug  
16 Emporium all records of acquisition and disposition for Combivir for the time period of January  
17 1, 2004 through March 19, 2007.

18                   20.     On or about March 21, 2007, the Board's investigator received a reply  
19 from Respondent Dallal, president and sole owner of Respondent Drug Emporium No. 807. In  
20 his reply, Respondent Dallal stated that there were no purchases and no sales of Combivir from  
21 Respondent Drug Emporium from January 1, 2004 through March 19, 2007.

22                   21.     In fact, Respondent Drug Emporium No. 807 had purchased Combivir  
23 from DIT Health Care and had transferred Combivir with DIT Health Care between September  
24 15, 2005 and October 18, 2005, including:

25                   a.     on or about September 15, 2005, 30 bottles of Combivir tablets,  
26 with 60 Combivir tablets in each bottle at a wholesale cost of \$15,353.70 per Invoice  
27 Number 38655;

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- 1           b.       on or about September 19, 2005, 40 bottles of Combivir tablets,  
2 with 60 Combivir tablets in each bottle at a wholesale cost of \$20,712.40 per Invoice  
3 Number 38713;
- 4           c.       on or about September 20, 2005, 12 bottles of Combivir tablets,  
5 with 60 Combivir tablets in each bottle at a wholesale cost of \$6,213.72 per Invoice  
6 Number 38782;
- 7           d.       on or about September 26, 2005, 48 bottles of Combivir tablets,  
8 with 60 Combivir tablets in each bottle at a wholesale cost of \$24,854.88 per Invoice  
9 Number 38984;
- 10          e.       on or about September 29, 2005, 70 bottles of Combivir tablets,  
11 with 60 Combivir tablets in each bottle at a wholesale cost of \$36,246.70 per Invoice  
12 Number 39092;
- 13          f.       on or about September 29, 2005, 30 bottles of Combivir tablets,  
14 with 60 Combivir tablets in each bottle at a wholesale cost of \$15,534.30 per Invoice  
15 Number 39107;
- 16          g.       on or about September 30, 2005, 70 bottles of Combivir tablets,  
17 with 60 Combivir tablets in each bottle at a wholesale cost of \$36,247.40 per Invoice  
18 Number 39241;
- 19          h.       on or about October 18, 2005, 70 bottles of Combivir tablets,  
20 with 60 Combivir tablets in each bottle at a wholesale cost of \$36,247.40 per Credit Memo  
21 Number 39777.

**SECOND CAUSE FOR DISCIPLINE**

**(Making a False Document)**

22                           22.       Respondent Dallal is subject to disciplinary action under Section 4301(g)  
23  
24                           in that he knowingly made or signed a document that falsely represented that there were no  
25 purchases of Combivir by Respondent Drug Emporium and no sales of Combivir from  
26 Respondent Drug Emporium from January 1, 2005 through March 19, 2007 as set forth in  
27 paragraphs 15 through 21, inclusive which are incorporated herein by this reference.  
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1 **THIRD CAUSE FOR DISCIPLINE**

2 **(Engaging in Subversive Conduct)**

3 23. Respondent Dallal is subject to disciplinary action under Section 4301(q)  
4 in that he engaged in conduct that subverted or attempted to subvert an investigation of the Board  
5 as set forth in paragraphs 15 through 21, inclusive which are incorporated herein by this  
6 reference.

7 **FOURTH CAUSE FOR DISCIPLINE**

8 **(Purchasing Dangerous Drugs from or Transferring  
9 Dangerous Drugs with Unlicensed Wholesaler)**

10 24. Respondents are subject to disciplinary action under Section 4301,  
11 subsections (j) and (o), and Section 4169 in that they purchased or transferred dangerous drugs at  
12 wholesale with an entity that is not licensed with the Board as a wholesaler or pharmacy in  
13 violation of Section 4163.

14 **PRAYER**

15 WHEREFORE, Complainant requests that a hearing be held on the matters herein  
16 alleged, and that following the hearing, the Board of Pharmacy issue a decision:

17 A. Revoking or suspending Pharmacy Permit Number PHY 45373, issued to  
18 Respondent Drug Emporium No. 807;

19 B. Revoking or suspending Pharmacist License No. RPH 25391, issued to  
20 Edward Dallal, R.P.H.

21 C Ordering Respondent Drug Emporium No. 807 and Respondent Dallal to  
22 pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case,  
23 pursuant to Business and Professions Code section 125.3;

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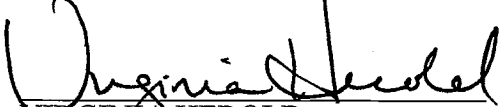
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D. Taking such other and further action as deemed necessary and proper.

DATED: 11/21/07



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

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