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7
8 **BEFORE THE**
BOARD OF PHARMACY
9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

10 In the Matter of the Accusation Against:

Case No. 5004

11 **ENCINO CARE PHARMACY, INC., DBA**
12 **ENCINO CARE PHARMACY II**
16001 Ventura Blvd., Suite 135
13 Encino, CA 91436

A C C U S A T I O N

14 **Pharmacy Permit No. PHY 50459**

15 **and**

16 **NIRA HARIRI**
16950 Strawberry Drive
17 Encino, CA 91436

18 **Pharmacist License No. RPH 52003**

19 Respondents.

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21 Complainant alleges:

22 **PARTIES**

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

25 2. On or about November 10, 2010, the Board of Pharmacy issued Pharmacy Permit
26 Number PHY 50459 to Encino Care Pharmacy, Inc., dba Encino Care Pharmacy II; Nira Hariri,
27 President, located at 16001 Ventura Blvd., Suite 135, Encino, CA 91436 (Respondent). The
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1 Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein
2 and will expire on November 1, 2014, unless renewed.

3 3. On or about September 6, 2000, the Board of Pharmacy issued Original Pharmacist
4 License No. RPH 52003 to Nira Hariri. The pharmacist license was in full force and effect at all
5 times relevant to the charges brought herein and will expire on January 31, 2016, unless renewed.

6 **JURISDICTION**

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

10 5. Section 4011 provides that the Board shall administer and enforce both the Pharmacy
11 Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health &
12 Safety Code, § 11000 et seq.].

13 6. Section 4300, subdivision (a) provides that every license issued by the Board may be
14 suspended or revoked.

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

19 8. Section 4402(e) of the Code provides that any pharmacist license issued by the Board
20 may be canceled by the Board if not renewed within three years after its expiration, and any
21 license canceled in this fashion may not be reissued but will instead require a new application.
22 Any other license issued by the Board may be canceled by the Board if not renewed within 60
23 days of its expiration.

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1 **STATUTORY AND REGULATORY PROVISIONS**

2 9. Section 4169 of the Code states in pertinent part:

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

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

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8 10. Section 4301 of the Code provides, in pertinent part, that:

9 The Board shall take action against any holder of a license who is guilty
10 of unprofessional conduct or whose license has been procured by fraud or
11 misrepresentation or issued by mistake. Unprofessional conduct shall include, but is
12 not limited to, any of the following:

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

16

17 (o) Violating or attempting to violate, directly or indirectly, or assisting in
18 or abetting the violation of or conspiring to violate any provision or term of this
19 chapter or of the applicable federal and state laws and regulations governing
20 pharmacy, including regulations established by the board or by any other state or
21 federal regulatory agency.

22 11. Health and Safety Code section 111330 states that any drug or device is misbranded if
23 its labeling is false or misleading in any particular.

24 12. Health and Safety Code section 111335 provides that "Any drug or device is
25 misbranded if its labeling or packaging does not conform to the requirements of Chapter 4
26 (commencing with Section 110290)."

27 13. Health and Safety Code section 111340 states as follows:

28 Any drug or device is misbranded unless it bears a label containing all of
the following information:

(a) The name and place of business of the manufacturer, packer, or
distributor.

(b) An accurate statement of the quantity of the contents in terms of
weight, measure, or numerical count.

1 Reasonable variations from the requirements of subdivision (b) shall be
2 permitted. Requirements for placement and prominence of the information and
3 exemptions as to small packages shall be established in accordance with regulations
4 adopted pursuant to Section 110380.

5
6 14. Health and Safety Code section 111440 states that “[i]t is unlawful for any person to
7 manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.”

8 **DANGEROUS DRUGS**

9 15. “**Benicar**” (olmesartan) is used for controlling blood pressure and is a dangerous
10 drug under Section 4022.

11 16. “**Clozapine**” is an anti-psychotic medication and is a dangerous drug under Section
12 4022.

13 **FACTUAL BACKGROUND**

14 **FIRST BOARD INSPECTION – MAY 7, 2013**

15 17. On or about May 7, 2013, an inspection was done by the Board at Encino Care
16 Pharmacy II, which is a closed door pharmacy that primarily services patients in assisted living
17 and board and care facilities. Medications are processed and prepared and then delivered to each
18 facility. The pharmacy compounds non-sterile preparations.

19 **SECOND BOARD INSPECTION – August 8, 2013**

20 18. On or about June 10, 2013, the Board received an anonymous complaint that stated:
21 “I am not a patient I work in the facility and am being forced to use packaged medicine that has
22 been returned from facilities for new facilities. I also have viewed this store to release controlled
23 and narcotics without hard copy prescriptions.” The informant also indicated the filling area was
24 dirty.

25 19. On or about August 8, 2013, the Board conducted a second inspection at Encino Care
26 Pharmacy II (the pharmacy). The inspection determined that misbranded drugs were held in the
27 pharmacy’s normal drug stock. A random sample of medication stock bottles which were
28 potentially overfilled were counted, and the results were as follows:

Table 1. Stock Bottle Labeled Quantity versus Physical Count

Medication	Labeled Quantity by Manufacturer	Count Inside Bottle
galantamine 8 mg #1	30	78

1	galantamine 8 mg #2	30	60
	Benicar 20/12.5 #1	30	145
2	Benicar 20/12.5 #2	30	146
	carbidopa/levodopa 50/200	100	131.5
3	carbidopa/levodopa/entacapone 37.5/150/200 #1	100	155
4	carbidopa/levodopa/entacapone 37.5/150/200 #2	100	158
5	levothyroxine 88 mcg	100	258
	Azor 5/40	30	83
6	Azor 10/40	30	86
	carbidopa/levodopa ER 25/100	100	176
7	Ramipril 2.5 mg	100	148
	clozapine 25 mg	100	239
8	fluphenazine 10 mg	100	216
	galantamine er 16 mg	30	54
9	Bystolic 2.5 mg	30	79
	flurazepam 30	100	143
10	Norvasc 5 mg	90	257
	Geodon 20 mg	60	141
11	Stalevo 75	100	123
	bupirone 5 mg	500	846
12	Seroquel 50 mg	100	328
	levofloxacin 250 mg	50	91
13	mirtazapine 45 mg	30	71
	clozapine 100 mg #1	100	133.5
14	Detrol LA 4 mg #1	90	130
	Abilify 15 mg	30	80
15	Detrol LA 4 mg #2	90	130
	clozapine 100 mg #2	100	240
16	Metoclopramide 5 mg	100	305
	fenofibrate 145 mg	90	94
17	oxybutynin 5 mg	100	155
	felodipine 5 mg	100	130
18	Menest 0.3 mg	100	137
	doxepin 25 mg	100	114
19	spironolactone 50 mg	100	140
20	nortriptyline 25 mg	100	120
	cefadroxil 500	50	67
21	Lipitor 40 mg	90	120
	methimazole 10 mg	100	122
22	Prandin 2 mg	100	193

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24 20. With respect to the Carbidopa/Levodopa/Entacapone 37.5/150/200 and Detrol LA 4

25 mg., both the lot numbers and the expiration dates were the same. However, with respect to the

26 Benicar 20/12/5 and Clozapine 100 mg, the lot numbers or the expiration dates were different.

27 The medications which Respondent was holding in the pharmacy were misleading and/or

28 inaccurate because the bottles contained more tablets/capsules than the quantity which was

1 indicated on the bottles, and/or some bottles of medications did not include an accurate statement
2 about the quantity of the contents in terms of weight, measure, or numerical count, in violation of
3 Health & Safety Code sections 111330, 111335, 111340, subdivision (b).

4 **FIRST CAUSE FOR DISCIPLINE**

5 **(Misbranded Drugs)**

6 21. Respondents are subject to disciplinary action for unprofessional conduct under
7 Sections 4301, subdivisions (j) and/or (o) and 4169, subdivision (a)(3), in conjunction with
8 Health and Safety Code sections 111330, 111335, 111340, subdivision (b) and 111440, for
9 holding in the pharmacy misbranded drugs, in that the drugs contained inaccurate statements of
10 the numerical count and/or the quantity of drugs was not listed on the label and/or the bottles of
11 medications that had the quantity of drugs on the label held more tablets and/or capsules than the
12 quantity which was stated on the label. Complainant incorporates by reference the allegations of
13 Paragraphs 17 through 20, as though fully set forth.

14 **SECOND CAUSE FOR DISCIPLINE**

15 **(Unprofessional Conduct)**

16 22. Respondents are subject to disciplinary action under Section 4301 for unprofessional
17 conduct. Complainant refers to and by this reference incorporates the allegations set forth in
18 Paragraphs 17 through 21, inclusive, as though set forth fully.

19 **PRAYER**

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

22 1. Revoking or suspending Pharmacy Permit Number PHY 50459, issued to Encino
23 Care Pharmacy, Inc., dba Encino Care Pharmacy II; Nira Hariri ;

24 2. Revoking or suspending Original Pharmacist License No. RPH 52003 issued to Nira
25 Hariri;

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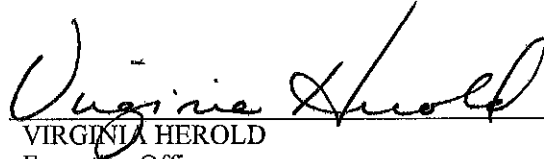
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1 3. Ordering Encino Care Pharmacy, Inc., dba Encino Care Pharmacy II and Nira Hariri,
2 jointly and severally, to pay the Board of Pharmacy the reasonable costs of the investigation and
3 enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

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6 DATED: _____

9/5/14



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

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