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

11 In the Matter of the Accusation Against:

Case No. 3943

12 **KOVAC'S PHARMACY**  
14423 Gilmore Street  
13 Van Nuys, CA 91401  
Original Permit No. PHY 49968,

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

14 **and**

15 **IRINA PUSTILNIKOVA**  
16 14844 Dickens St., #101  
Los Angeles, CA 91403  
17 Registered Pharmacist No. RPH 57750

18 Respondents.

19  
20 Complainant alleges:

21 PARTIES

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

24 2. On or about August 19, 2009, the Board issued Original Permit Number PHY 49968  
25 to Kovac's Pharmacy (Respondent-Pharmacy). The Original Permit was in full force and effect  
26 at all times relevant to the charges brought herein and will expire on August 1, 2011, unless  
27 renewed.  
28





1           11. Section 4169, subdivision (a) of the Code states, in pertinent part:

2           “A person or entity may not do any of the following:

3           . . . .

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

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

8           “The board shall take action against any holder of a license who is guilty of unprofessional  
9 conduct. Unprofessional conduct shall include, but is not limited to, any of the following:

10          . . . .

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

13          . . . .

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

18          13. Section 4342, subdivision (a) of the Code states, “The board may institute any action  
19 or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale  
20 of pharmaceutical preparations and drugs that do not conform to the standard and tests as to  
21 quality and strength, provided in the latest edition of the United States Pharmacopoeia or the  
22 National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law  
23 (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).”

24          14. Section 110290 of the Health and Safety Code states, in pertinent part: “In  
25 determining whether the labeling or advertisement of a . . . drug . . . is misleading, all  
26 representations made or suggested by statement, word, design, device, sound, or any combination  
27 of these, shall be taken into account. The extent that the labeling or advertising fails to reveal  
28

1 facts concerning the . . . drug . . . or consequences of customary use of the . . . drug . . . shall also  
2 be considered.”

3 15. Section 111335 of the Health and Safety Code states, in pertinent part: “Any drug . . .  
4 is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4  
5 (commencing with Section 110290).”

6 16. California Code of Regulations, title 16, section 1715, states, in pertinent part:

7 “(a) The pharmacist-in-charge of each pharmacy as defined under . . . section 4037 . . . shall  
8 complete a self-assessment of the pharmacy’s compliance with federal and state pharmacy law.  
9 The assessment shall be performed before July 1 of every odd-numbered year. The primary  
10 purpose of the self-assessment is to promote compliance through self-examination and education.

11 “(b) In addition to the self-assessment required in subdivision (a) of this section, the  
12 pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

13 “(1) A new pharmacy permit has been issued . . . .”

14 17. California Code of Regulations, title 16, section 1717, states, in pertinent part:

15 . . . .

16 “(b) [T]he following information shall be maintained for each prescription on file and shall  
17 be readily retrievable:

18 . . . .

19 “(3) If a prescription for a drug or device is refilled, a record of each refill, quantity  
20 dispensed, if different, and the initials or name of the dispensing pharmacist.”

21 18. Code of Federal Regulations, title 21, section 1306.22, subdivision (f) authorizes use  
22 of a computer application “for the storage and retrieval of refill information for original paper  
23 prescription orders for controlled substances in Schedule III and IV” subject to enumerated  
24 conditions including:

25 “(3) Documentation of the fact that the refill information entered into the computer each  
26 time a pharmacist refills an original paper, fax, or oral prescription order for a Schedule III or IV  
27 controlled substance is correct must be provided by the individual pharmacist who makes use of  
28 such an application. If such an application provides a hard-copy printout of each day’s controlled

1 substance prescription order refill data, that printout shall be verified, dated, and signed by the  
2 individual pharmacist who refilled such a prescription order. The individual pharmacist must  
3 verify that the data indicated are correct and then sign this document in the same manner as he  
4 would sign a check or legal document (e.g., J.H. Smith, or John H. Smith). . . . This printout of  
5 the day's controlled substance prescription order refill data must be provided to each pharmacy  
6 using such a computerized application within 72 hours of the date on which the refill was  
7 dispensed. It must be verified and signed by each pharmacist who is involved with such  
8 dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate  
9 file, in which each individual pharmacist involved in such dispensing shall sign a statement (in  
10 the manner previously described) each day, attesting to the fact that the refill information entered  
11 into the computer that day has been reviewed by him and is correct as shown. . . ."<sup>2</sup>

#### 12 REASONABLE COSTS

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

#### 17 FIRST CAUSE FOR DISCIPLINE

18 (Failure to Complete Self-Assessment Prior to Inspection Date)

19 20. Respondents are subject to disciplinary action under Code sections 4300 and 4301  
20 and under subdivisions (a) and (b)(1) of section 1715 of title 16 of the California Code of  
21 Regulations in that Respondents failed to complete a timely self-assessment of Respondent-  
22 Pharmacy's compliance with federal and state pharmacy laws. The circumstances are as  
23 follows:

24 a. On or about May 19, 2010, a Board inspection was conducted at  
25 Respondent-Pharmacy. The Board inspector requested Respondent-Pharmacist to give the  
26 inspector a completed self-assessment form, which Respondent-Pharmacist had been required to

27 <sup>2</sup> Section 11056 of the Health and Safety Code lists Schedule III controlled substances,  
28 and section 11057 of the Health and Safety Code lists Schedule IV controlled substances.

1 fill out when she had received her new permit for Respondent-Pharmacy. Respondent-Pharmacist  
2 did not complete the form, and, instead, during the inspection, Respondent-Pharmacy's office  
3 manager began to fill out the form which Respondent-Pharmacist was required to complete.

4 SECOND CAUSE FOR DISCIPLINE

5 (Misbranded Bubble-Packed Dangerous Drugs)

6 21. Respondents are subject to disciplinary action under Code sections 4300 and 4301 in  
7 that Respondents had misbranded bubble-packed dangerous drugs, in violation of Health and  
8 Safety Code sections 111335 and 110290. The circumstances are as follows:

9 a. On or about May 19, 2010, Respondents allowed their staff to repackage drugs from  
10 labeled stock containers into unlabeled bubble packs that failed to have the complete facts  
11 concerning the drugs as they relate to the drug name, strength, lot number, expiration date or  
12 manufacturer.

13 THIRD CAUSE FOR DISCIPLINE

14 (Allowing Staff to Dispense Repackage Drugs from Misbranded Bubble Packs)

15 22. Respondents are subject to disciplinary action under Code sections 4300, 4301, 4169,  
16 subdivision (a)(3), and 4342, subdivision (a) in that Respondents allowed their staff to dispense  
17 repackaged drugs from unlabeled bubble packs that did not have the complete facts concerning  
18 the drugs as they relate to the drug name, strength, lot number, expiration date or manufacturer.  
19 The circumstances are alleged in paragraphs 21 through subparagraph (a), above, inclusive, and  
20 are incorporated by reference as though fully set forth therein.

21 FOURTH CAUSE FOR DISCIPLINE

22 (Lack of Written Policy for Theft or Impairment)

23 23. Respondents are subject to disciplinary action under Code sections 4104, subdivision  
24 (b), 4300 and 4301 in that, on or about May 19, 2010, Respondents did not have a written policy  
25 and procedures for theft or impairment by a licensed employee.

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1 FIFTH CAUSE FOR DISCIPLINE

2 (Failure to Issue Daily Reports and Timely Controlled Substance Printouts)

3 24. Respondents are subject to disciplinary action under Code sections 4300 and 4301  
4 and subdivision (b)(3) of section 1717 of title 16 of the California Code of Regulations in that  
5 Respondents did not properly document refilled prescriptions, in violation of subdivision (f)(3) of  
6 section 1306.22 of the Code of Federal Regulations. The circumstances are as follows:

7 a. On or about May 19, 2010, Respondent-Pharmacist did not print out daily reports or  
8 controlled substance printouts within 72 hours for prescription refills dispensed at Respondent-  
9 Pharmacy.

10 SIXTH CAUSE FOR DISCIPLINE

11 (Misabeled Prescription Containers)

12 25. Respondents are subject to disciplinary action under Code sections 4076, subdivision  
13 (a)(11)(A), 4300 and 4301 in that Respondents had mislabeled prescription containers. The  
14 circumstances are as follows:

15 a. On or about May 19, 2010, Respondent-Pharmacist dispensed the following sixteen  
16 (16) prescriptions of dangerous drugs with the wrong identification codes:

- 17 i. RX 6087435, five (5) milligrams Metolazone, brand name Zaroxolyn, labeled  
18 Blue Round 644/5 but dispensed as M & 173 Orange Round;
- 19 ii. RX 6076795, twenty (20) milligrams Paroxetine, brand name Paxil, labeled  
20 Oval APO/083 but dispensed as White Round ZC/16;
- 21 iii. RX 4008798, one (1) milligram of controlled substance Clonazepam, brand  
22 name Klonopin, labeled Blue Round 274 & 1 but dispensed as Blue Round A  
23 & 2531;
- 24 iv. RX 6088335, five (5) milligrams Oxybutynin, brand name Ditropan, labeled  
25 Blue Round 4853 V but dispensed as Light Blue PLIA 456;
- 26 v. RX 6088606, twelve and a half (12.5) milligrams Carvedilol, brand name  
27 Coreg, labeled R & 254 but dispensed as G & 164;

- 1 vi. RX 6084299, twenty-five (25) milligrams Bethanechol, brand name  
2 Urecholine, labeled Yellow Round Pliva 325 but dispensed as Yellow Oval  
3 W967;
- 4 vii. RX 6080656, three hundred (300) milligrams Gabapentin, brand name  
5 Neurontin, labeled Yellow/Brown Oblong logo/2666 but dispensed as Yellow  
6 Capsule 138/138;
- 7 viii. RX 6076213, three hundred and fifty (350) milligrams Carisoprodol, brand  
8 name Soma, labeled White Round MP/58 but dispensed as White Round  
9 2410/V;
- 10 ix. RX 6071087, five (5) milligrams Warfarin, brand name Coumadin, labeled  
11 Peach Oval 833/5 & barr but dispensed as Peach 5 & TARO;
- 12 x. RX 6084081, ten (10) milligrams Haloperidol, brand name Haldol, labeled  
13 Green Round GG/126 but dispensed as Light Green ZC/08;
- 14 xi. RX 6076213, three hundred and fifty (350) milligrams Carisoprodol labeled  
15 White Round MP/58 but dispensed as White Round V/2410;
- 16 xii. RX 6071578, three hundred (300) milligrams Ranitidine, brand name Zantac,  
17 labeled Peach Oval par/545 but dispensed as White Oval APO & RAN/300;
- 18 xiii. RX 6059485, three hundred (300) milligrams Lithium Carbonate, brand name  
19 Eskalith, labeled Flesh Oblong APO 300 but dispensed as Yellow & Grey  
20 Westward 3189;
- 21 xiv. RX 6086654, twenty-five (25) milligrams Amitriptyline, brand name Elavil,  
22 labeled Green Round GG/44 but dispensed as Yellow V;
- 23 xv. RX 6075710, seventy (70) milligrams Alendronate, brand name Fosamax, with  
24 different NDC numbers, 00591-3173-04 and 41616-638-68, on the labeled  
25 package;
- 26 xvi. Mometasone Furoate Cream with different NDC numbers on the labeled box.

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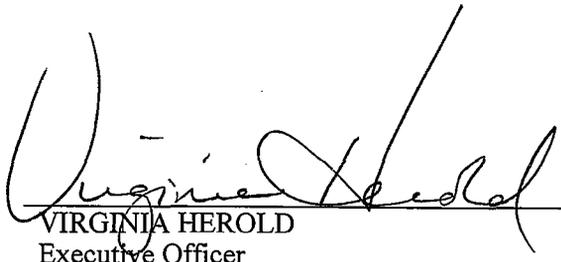
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PRAYER

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 Original Permit Number PHY 49968, issued to Respondent-Pharmacy Kovac's Pharmacy;
2. Revoking or suspending Registered Original Pharmacist License Number RPH 57750, issued to Respondent-Pharmacist Irina Pustilnikova;
3. Ordering Respondents to pay the Board the reasonable costs of the investigation and enforcement of this case, pursuant to section 125.3; and
4. Taking such other and further action as deemed necessary and proper.

DATED: 4/21/11



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

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