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8		RE THE	
9	DEPARTMENT OF C	PHARMACY CONSUMER AFFAIRS	
10	STATE OF C	CALIFORNIA	
11	In the Matter of the Accusation Against:	Case No. 5636	
12	RXCHANGE CO., STEPHEN M. COSTA, President,		
13	MOHAMMAD M. SALEMI, Director, and DRIC SRBUSH TONELYAN	ACCUSATION	
14	2545 N. Ontario Street Burbank, CA 91504		
15	Wholesale Permit No. WLS 5795		
16	and		
17	SRBUSH TONELYAN		
18	219 E. Garfield Avenue., #4 Glendale, CA 91205		
19	Certificate Number EXC 18823		
20	Respondents.		
21	C 1		
22	Complainant alleges:	TIES	
23			
24 25	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity		
26	 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs. 2. On or about August 19, 2011, the Board of Pharmacy issued Wholesale Permit 		
27	Number WLS 5795 to Nuline Pharmaceuticals (now known as RxChange Co.), which was		
28	located at 434 West Broadway, Glendale, CA 91	- · ·	
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President, and Srbush Tonelyan, as Designated Representative-in-Charge (Respondent Wholesaler). On or about August 1, 2012, Respondent Wholesaler (WLS 5795) changed its address of record with the Board from 434 West Broadway, Glendale, CA 91204 to 2545 N. Ontario St, Burbank, CA 91504. On or about March 8, 2013, Nuline Pharmaceuticals changed its trade style name to RxChange Co. with the Board. Srbush Tonelyan is and has been the Designated Representative-in-Charge (DRIC) of Respondent Wholesaler since August 19, 2011. Stephen M. Costa is and has been the President of Respondent Wholesaler since August 19, 2011. Mohammad M. Salemi is and has been a Director of Respondent Wholesaler since July 15, 2013. Wholesale Permit number WLS 5795 was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2016, unless renewed.

3. On or about September 24, 2006, the Board of Pharmacy issued original Certificate Number EXC 18823 to Srbuhi Tonelyan to act as a Designated Representative-in-Charge (Respondent Tonelyan). The license was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2016, unless renewed.

JURISDICTION |

- 4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.
- 5. Section 4300 of the Code (Code) provides, in part, that every license issued by the Board is subject to discipline, including suspension or revocation.
 - 6. Section 4300.1 of the Code (Code) 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

¹ On or about October 16, 2006, the Board issued Wholesale Permit Number WLS 4964 to Nuline Pharmaceuticals, located at 434 West Broadway, Glendale, CA 91204. Respondent Tonelyan was Designated Representative-in-Charge for WLS 4964. On or about August 19, 2011, there was a change of ownership of the business and WLS 4964 was canceled.

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physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

"(b) This section does not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the drug or device, and its quantity. This section does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied."

- Section 4081 of the Code states, in part: 10.
- "(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) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.
- "(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-incharge, for maintaining the records and inventory described in this section."
 - 11. Section 4105 of the Code states, in part:
- "(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

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"(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

"(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records within three business days of the time the request was made..."

- 12. Section 4160 of the Code states, in part:
- "(a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

. . .

- "(c) (1) A separate license shall be required for each place of business owned or operated by a wholesaler or third-party logistics provider. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). Each license shall be renewed annually and shall not be transferable.
- "(d) Every wholesaler shall be supervised or managed by a designated representative-incharge. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers."
 - 13. Section 4163 of the Code states, in part:
- "(a) A manufacturer, wholesaler, repackager, or pharmacy may not furnish a dangerous drug or dangerous device to an unauthorized person.
- "(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices."

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14. Section 4163.1 of the Code² states:

"It is the intent of the Legislature that commencing on January 1, 2007, and continuing through the full implementation of the pedigree requirements specified by Section 4163, manufacturers and wholesalers shall use best efforts to provide in the most readily accessible form possible, information regarding the manufacturer's specific relationships in the distribution of dangerous drugs with wholesalers."

- 15. Section 4169 of the Code states, in part:
 - "(a) A person or entity shall not do any of the following:
- (1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy.
- (5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years."

REGULATIONS

16. California Code of Regulations, title 16, section 1770, states:

"For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare."

² Section 4163.1 was repealed as of January 1, 2015.

21. **DRUG CLASSIFICATIONS**

Generic Name	Dangerous Drug Per Bus. & Prof. Code § 4022	Scheduled Drug per Health & Safety Code (HSC)	Indications For Use
Carisoprodol ³ (brand name, Soma)	Yes	Not scheduled in California. Carisoprodol is a Schedule IV under federal law per 21 CFR 1308.14(c)(6).	Muscle relaxant
Hydrocodone/ Acetaminophen (APAP) (brand names include Norco, Vicodin, and Lorcet)	Yes	Schedule II Per HSC § 11055(b)(1)	Pain
Lorazepam (brand name, Ativan)	Yes	Schedule IV Per HSC § 1057(d)(16)	Anxiety
Zolpidem (non-barbiturate, non- benzodiazepine sedative hypnotic) (brand name, Ambien)	Yes	Schedule IV Per HSC § 1057(d)(32)	Insomnia

13.

FACTUAL SUMMARY

22. On or about November 14, 2013, a Board inspector conducted a routine inspection of Respondent Wholesaler's facility, located at 2545 N. Ontario St., Burbank, CA 91504. The inspection revealed that Respondent Wholesaler was purchasing dangerous drugs, including controlled substances, from an unlicensed wholesaler broker, SCT RX Health, 1500 Walnut St. Philadelphia, PA 19102 (SCT RX Health). At times those purchases were being ordered from and delivered to an unlicensed premises in California.

FIRST CAUSE FOR DISCIPLINE

(Failure to Comply with Record-Keeping Requirements)

23. Respondent Wholesaler and Respondent Tonelyan are subject to disciplinary action under Section 4301, subdivisions (j) and (o), for violating sections 4081, subsection (a), and 4105 and Californian Code of Regulations, title 16, section 1718, in that, while Respondent Tonelyan was serving as the DRIC, Respondent Wholesaler failed to have all records of acquisition of all

³ Drug abusers are known to combine Soma with hydrocodone to produce similar effects to those of Heroin.

dangerous drugs open for inspection and preserved for at least three years from the making and failed to maintain complete accountability for all dangerous drugs.

- a. Specifically, on or about November 14, 2013, during the Board's inspection, it was discovered that Respondent Wholesaler was storing over 3000 pills of carisprodol 350mg, a dangerous drug, in its quarantine area. DRIC Tonelyan told the Board's inspector that Respondent Wholesaler received 3,000 extra carisoprodol from their supplier and was informed by the supplier to keep the product at no charge. An invoice documenting the purchase was not available or supplied at any time during the Board's investigation.
- b. In addition, during the inspection, Respondents provided the inspector with partial copies of purchase orders of dangerous drugs, as follows:
- i. Respondent Wholesaler's Purchase Order #700002335, dated July 19, 2012, refers to invoice # 54325-05 from SCT RX Health, dated July 16, 2012, but the purchase order does not match the related invoice. Invoice #54325-05 documents an order of 25 x 1000 famotidine 20mg and 50 x 500 hydrocodone/apap 5/500mg, but the purchase order does not list famotidine or hydrocodone. Also, the bottom of the purchase order document says "continued" and there is no dollar total on the document. Respondent Wholesaler either did not retain or have the complete record available for review by the Board's inspector.

SECOND CAUSE FOR DISCIPLINE

(Purchasing from Unlicensed Wholesaler)

- 24. Respondent Wholesaler and Respondent Tonelyan are subject to disciplinary action under Section 4301, subdivision (j), for violating Section 4169, subdivision (a)(1), in that, while Respondent Tonelyan was serving as the DRIC, Respondent Wholesaler purchased controlled substances and/or dangerous drugs from SCT RX Health, an entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy. The purchases are documented by the following invoices:
- a. Invoice #54325-01, dated June 18, 2012, documented Respondent Wholesaler's purchase of 48 x 5000 fluoxetine 20mg from SCT RX Health.

	b. Invoice #54325-02,	dated June 21,	2012,	documented Responden	t Wholesaler's	purchase
f 50	x 1000 carisprodol 35	Omg from SCT	RX H	ealth.		

- c. Invoice #54325-03, dated June 26, 2012, documented Respondent Wholesaler's purchase of 10 x 500 hydrocodone/apap 10/325 and 10 x 500 hydrocodone/apap 10/650, meloxicam and Baclofen from SCT RX Health.
- d. Invoice #54325-04, dated July 10, 2012, documented Respondent Wholesaler's purchase of Baclofen, famotidine, folic acid lmg, Gabapentin, tramadol, 10 x 500 hydrocodone/apap 10/325, 6 x 500 hydrocodone 10/500 and 8 x 500 hydrocodone 7.5/750, from SCT RX Health.
- e. Invoice #54325-05, dated July 16, 2012, documented Respondent Wholesaler's purchase of famotidine 20mg, citalopram 20mg, azithromycin, Fluoxetine 20mg, hydrochlorothiazide, lisinopril 20mg, lorazepam lmg, omeprazole and 50 x 500 hydrocodone/apap 5/500, from SCT RX Health.
- f. Invoice #54325-06, dated July 17, 2012, documented Respondent Wholesaler's purchase of 42 x 1000 carisprodol 350mg, from SCT RX Health.
- g. Invoice #54325-07, dated July 27, 2012, documented Respondent Wholesaler's purchase of baclofen 10mg, 20 x 500 zolpidem 10mg, ranitidine 150mg, ibuprofen 600, folic acid 2mg and 40 x 100 hydrocodone/apap 7.5/325, from SCT RX Health.
- h. Invoice #54325-08, dated August 3, 2012, documented Respondent Wholesaler's purchase of 36 x 500 hydrocodone/apap 10/500, baclofen, famotidine, folic acid, lisinopril, citalopram, ibuprofen and meloxicam, from SCT RX Health.
- i. Invoice #54325-09, dated August 13, 2012, documented Respondent Wholesaler's purchase of folic acid, ibuprofen, lisinopril, metformin, 17 x 100 hydrocodone 7.5/325 and 60 x 500 hydrocodone/apap 7.5/500, from SCT RX Health.
- j. Invoice #54325-10, dated September 13, 2012, documented Respondent Wholesaler's purchase of azithromycin, baclofen, citalopram, Famotidine, folic acid, furosemide, hydrochlorothiazide, ibuprofen, lisinopril, ranitidine, tramadol, 30 x 100 hydrocodone/apap 7.5/325, 30 x 500 hydrocodone/apap 5/500, 24 x 500 hydrocodone 7.5/500 and 20 x 1000 carisprodol 350mg, from SCT RX Health.

k. Invoice #54325-11, dated September 27, 2012, documented Respondent Wholesaler's purchase of ibuprofen, 6 x 500 hydrocodone/apap 10/325 and 6 x 500 hydrocodone/apap 10/500, from SCT RX Health.

THIRD CAUSE FOR DISCIPLINE

(Unlicensed Activity)

- 25. Respondent Wholesaler and Respondent Tonelyan are subject to disciplinary action under Section 4301, subdivision (j), for violating Section 4160, in that, while Respondent Tonelyan was serving as the DRIC, Respondent Wholesaler engaged in unlicensed activity. Section 4160, subdivision (c), provides that a separate license shall be required for each place of business owned or operated by a wholesaler, and that each license shall be renewed annually and shall not be transferable. Specifically, on August 1, 2012, the Board approved a change of location for Respondent Wholesaler from their original address in Glendale, CA to 2545 N. Ontario St., Burbank, CA. Respondent Wholesaler's records show that controlled substances and dangerous drugs were ordered and received by it at the Glendale address after August 1, 2012, as follows:
- a. Invoice #54325-08, dated August 3, 2012, documented Respondent Wholesaler's purchase of 36 x 500 hydrocodone /apap 10/500, baclofen, famotidine, folic acid, lisinopril, citalopram, ibuprofen and meloxicam, from SCT RX Health. The invoice indicated that the order was billed to Respondent Wholesaler at 434 West Broadway, Glendale, CA 91204 and shipped to Respondent Wholesaler at 434 West Broadway, Glendale, CA 91204.
- b. Invoice # 54325-09, dated August 13, 2012, documented Respondent Wholesaler's purchase of folic acid, ibuprofen, lisinopril, metformin, 17 x 100 hydrocodone 7.5/325 and 60 x 500 hydrocodone/apap 7.5/500, from SCT RX Health. The invoice indicated that the order was billed to Respondent Wholesaler at 434 West Broadway, Glendale, CA 91204 and shipped to Respondent Wholesaler at 434 West Broadway, Glendale, CA 91204.
- c. Invoice # 54325-10, dated September 13, 2012, documented Respondent Wholesaler's purchase of azithromycin, baclofen, citalopram, famotidine, folic acid, furosemide, hydrochlorothiazide, ibuprofen, lisinopril, ranitidine, tramadol, 30 x 100 hydrocodone/apap

7.5/325, 30 x 500 hydrocodone/apap 5/500, 24 x 500 hydrocodone 7.5/500 and 20 x 1000 carisprodol 350mg, from SCT RX Health. The invoice indicated that the order was billed to Respondent Wholesaler at 434 West Broadway, Glendale, CA 91204 and shipped to Respondent Wholesaler at 434 West Broadway, Glendale, CA 91204.

d. Invoice # 54325-11, dated September 27, 2012, documented Respondent Wholesaler's purchase of ibuprofen, 6 x 500 hydrocodone/apap 10/325 and 6 x 500 hydrocodone/apap 10/500, from SCT RX Health. The invoice indicated that the order was billed to Respondent Wholesaler at 434 West Broadway, Glendale, CA 91204 and shipped to Respondent Wholesaler at 434 West Broadway, Glendale, CA 91204.

FOURTH CAUSE FOR DISCIPLINE

(Unregistered Activity)

26. Respondent Wholesaler and Respondent Tonelyan are subject to disciplinary action under Section 4301, subdivision (o), for violating Code of Federal Regulations, title 21, section 1301.11, subdivision (a), in that, while Respondent Tonelyan was serving as the DRIC, Respondent Wholesaler ordered and received controlled substances without a valid DEA registration. In order for a wholesaler's place of business to be registered with the DEA, it must be licensed by the entity's home state. Specifically, on August 1, 2012, Respondent Wholesaler changed its address with the Board from 434 West Broadway, Glendale, CA 91204 to 2545 N. Ontario Street, Burbank, CA 91504 and did not notify the DEA of its change of address. Therefore, Respondent Wholesaler's DEA registration was considered invalid at the Glendale location, because Respondent Wholesaler no longer had a California wholesaler's license for that location, and Respondent Wholesaler was not registered with the DEA at the Burbank location, as it failed to notify the DEA of its change of address. Respondent Wholesaler's orders and deliveries of controlled substances that were made without a valid DEA registration are documented in the following invoices:

⁴ See 21 U.S.C., §823 (DEA registration requirements for distributors of controlled substances).

a. Invoice #54325-08, dated August 3, 2012, documented Respondent Wholesaler's
purchase of 36 x 500 hydrocodone /apap 10/500 from SCT Rx Health. The invoice provided that
the order was billed to Respondent Wholesaler at 434 West Broadway, Glendale, CA 91204 and
shipped to Respondent Wholesaler at 434 West Broadway, Glendale, CA 91204.

- b. Invoice #54325-09, dated August 13, 2012, documented Respondent Wholesaler's purchase of 17 x 100 hydrocodone 7.5/325 and 60 x 500 hydrocodone/apap 7.5/500 from SCT Rx Health. The invoice provided that the order was to be billed and shipped to Nuline Pharmaceuticals, 434 West Broadway, Glendale, CA 91204.
- c. Invoice # 54325-10, dated September 13, 2012, documented Respondent Wholesaler's purchase of 30 x 100 hydrocodone/apap 7.5/325, 30 x 500 hydrocodone/apap 5/500, 24 x 500 hydrocodone 7.5/500 and 20 x 1000 carisprodol 350mg, from SCT Rx Health. The invoice provided that the order was billed and shipped to Respondent Wholesaler at 434 West Broadway, Glendale, CA 91204.
- d. Invoice #54325-11, dated September 27, 2012, documented Respondent Wholesaler's purchase of ibuprofen, 6 x 500 hydrocodone/apap 10/325 and 6 x 500 hydrocodone/apap 10/500, from SCT Rx Health. The invoice provided that the order was billed and shipped to Respondent Wholesaler at 434 West Broadway, Glendale, CA 91204.

FIFTH CAUSE FOR DISCIPLINE

(Non-Compliant Furnishing of Dangerous Drugs)

- 27. Respondent Wholesaler and Respondent Tonelyan are subject to disciplinary action under Section 4301, subdivision (j), for violating Section 4059, subdivision (b), by furnishing a dangerous drug without correctly providing the name of the supplier. Specifically, Respondent Wholesaler, while Respondent Tonelyan served as the DRIC, sold dangerous drugs to pharmacies and other wholesalers using invoices under the name of Nuline Pharmaceuticals, which was no longer a licensee in California, on the following dates and invoices. On or about March 8, 2013, Respondent Wholesaler had changed its name to RxChange Co.
- a. Invoice #1000007114, dated June 27, 2013, documenting a sale of dangerous drugs to Garden Grove Community Pharmacy, located at 12665 Garden Grove Blvd., Garden Grove, CA

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Ensure Compliance)

29. Respondent Tonelyan is subject to disciplinary action under Section 4301, subdivision (j), for violating Section 4160, subdivision (d), in that he failed to ensure Respondent Wholesaler's compliance with state laws governing wholesalers. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 22 through 28, as though set forth fully herein.

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 Wholesale Permit Number WLS 5795 issued to RxChange Co.;
 - 2. Revoking or suspending Certificate Number EXC 18823 issued to Srbuhi Tonelyan;
- 3. Ordering RxChange Co. and Srbuhi Tonelyan 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;
 - 4. Taking such other and further action as deemed necessary and proper.

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DATED: 3/19/16

VIRGINIA HEROLD

Executive Officer

Board of Pharmacy

Department of Consumer Affairs

State of California

Complainant