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8	BEFORE THE BOARD OF PHARMACY		
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
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11	In the Matter of the Accusation Against:	Case No. 5463	
12	NU LIFE PHARMACEUTICALS, INC., MARIA LUZ DE JESUS PACIA,		
13	PRESIDENT 13026 Saticoy Street #4	ACCUSATION	
14	North Hollywood, CA 91605		
15	Wholesale Permit No. WLS 5709,		
16	and		
17	LUZ DE JESUS MARQUEZ LIM AKA MARIA LUZ PACIA		
18	aka Maria Luz Pacia 13026 Saticoy St. #4		
19	North Hollywood, CA 91605		
20	Designated Representative No. EXC 20854		
21	Respondents.		
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23	Complainant alleges:	•	
24	PARTIES  1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.		
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- "(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.
- "(b) Notwithstanding any other provision of law, a violation of this section or of subdivision (c) or (d) of Section 4163 may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.
- "(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.
- "(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Public Health."
  - 7. 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, the designated representative shall sign for and receive the delivery.
- "(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.
- "(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.
- "(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist

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acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

- "(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.
- "(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:
- "(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.
- "(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-incharge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.
- "(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.
- "(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility."
  - 8. Section 4081 of the Code states:
- "(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-in-charge, for maintaining the records and inventory described in this section.
- "(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate."
  - 9. Section 4105 of the Code states:
- "(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.
- "(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.
- "(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.
- "(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

- "(e)(1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.
- "(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.
- "(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. The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board."
  - 10. Section 4307 of the Code states:

"Individuals with Denied, Revoked, Suspended, etc. Licenses Prohibited From Pharmacy Ownership or Association with Board Licensed Entities"

- "(a) 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 manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or 99 placed on probation, shall be prohibited from serving as a manager, 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.
- "(b) "Manager, administrator, owner, member, officer, director, associate, or partner," as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in that capacity in or for a licensee.
- "(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law."

## COST RECOVERY

11. 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.

### CONTROLLED SUBSTANCES

12. <u>Promethazine with Codeine</u>. Generic for Phenergan with Codeine and is a dangerous drug pursuant to Business and Professions Code section 4022. It is also a Schedule V controlled substance pursuant to Health and Safety Code section 11058 subdivision (c)(1).

#### FIRST CAUSE FOR DISCIPLINE

(Prohibited Acts).

13. Respondents are subject to disciplinary action under section 4169 subdivision (a)(1) in that they purchased, traded, sold or transferred dangerous drugs or dangerous devices at

The circumstances are as follows:

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for the transaction.

14. From in or about June 2011 through September 2013, invoice evidence demonstrated that Respondent's purchased dangerous drugs and/or controlled substances from Wesley Pharmacal Co., an unlicensed wholesaler in the state of Pennsylvania on at least 73 different occasions. The following table shows the date and corresponding invoice number that was used

wholesale with a person or entity that is not licensed with the Board as a wholesaler or pharmacy.

Invoice Number	
55138	
55147	
55157	
55163	
55162	
55175	<u> </u>
55182	
55199	
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	02/23/2012	56432
1	03/15/2012	56575
	03/19/2012	56444
2	03/21/2012	56607
3	03/29/2012	56651
	04/03/2012	56675
4	04/04/2012	56692
	04/06/2012	56714
5	04/10/2012	56736
	04/13/2012	56787
6	04/27/2012	56873
	05/03/2012	56938
7	05/03/2012	56920
´	05/09/2012	56962
8	05/10/2012	56970
-	05/17/2012	57036
9	05/29/2012	57098
Ī	07/10/2012	57342
10	08/03/2012	57558
	10/04/2012	57960
11	11/06/2012	58102
	11/16/2012	58151
12	01/03/2013	58397
.	01/09/2013	58451
13	01/09/2013	58447
14	01/21/2013	58504
14	02/05/2013	58586
15	02/07/2013 02/22/2013	58613 58692
	04/19/2013	58964
16	05/03/2013	59043
	07/03/2013	59279
17	07/25/2013	59364
	08/06/2013	59424
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# SECOND CAUSE FOR DISCIPLINE

(Sale and Delivery of Dangerous Drugs)

- 15. Respondents are subject to disciplinary action under section 4059.5 subdivision (d), which requires that 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. The circumstances are as follows:
- 16. From in or about June 2011 through September 2013, Respondents allowed promethazine with codeine to be picked up directly from the wholesaler by one individual

representing several doctors in violation of pharmacy law. Respondent incorporates by reference paragraphs 12 and 13 above as though set forth in full.

## THIRD CAUSE FOR DISCIPLINE

(Records of Acquisition and Disposition)

- 17. Respondents are subject to disciplinary action under sections 4081 subdivision (a) and 4105 subdivision (a), which requires a wholesaler to account for all records of acquisition and disposition and the current inventory (as defined by the California Code of Regulations section 1718) of all dangerous drugs and devices. The circumstances are as follows:
- 18. From in or about June 2011 through September 2013, Respondents had no records of, and could not account for, an inventory loss of approximately 51,932 ounces of promethazine with codeine. Respondent incorporates by reference paragraphs 12 through 15 above as though set forth in full.

### **OTHER MATTERS**

19. Pursuant to Code section 4307, if discipline is imposed on Wholesale Permit No. WLS 5709, issued to Nu Life Pharmaceuticals, Inc., and Maria Luz De Jesus Pacia, President (Pacia) while acting as the manager, administrator, owner, member, officer, director, associate, or partner of Nu Life Pharmaceuticals, Inc., had knowledge of or knowingly participated in any conduct for which Wholesale Permit No. WLS 5709, issued to Nu Life Pharmaceuticals, Inc. was revoked, suspended or placed on probation, Pacia shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesale Permit No. WLS 5709, issued to Nu Life Pharmaceuticals, Inc. is placed on probation or until Wholesale Permit No. WLS 5709, issued to Nu Life Pharmaceuticals, Inc. is reinstated if it is revoked.

# **DISCIPLINE CONSIDERATIONS**

- 20. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges as follows:
- a) On or about August 22, 2014, in a prior action, the Board of Pharmacy issued Citation Number CI 2014 62180 to Respondent Nu Life Pharmaceuticals, Inc., for violations of

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1	5. Taking such other and further action as deemed necessary and proper.		
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