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

11 In the Matter of the Accusation Against:

Case No. 5774

12 **CTMP, INC. DBA CTMP, INC.**
13 **12791 Western Avenue, Suite #D**
14 **Garden Grove, CA 92841**

ACCUSATION

15 **Wholesale Permit No. WLS 5553**

16 **and**

17 **GINA KIM LOANNE TRAN**
18 **8887 Grandville Cir.**
Westminster, CA 92685

19 **Designated Representative License No. EXC**
20508

20 Respondents.

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23 Complainant alleges:

24 **PARTIES**

- 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.
- 27 2. On or about March 17, 2010, the Board of Pharmacy issued Wholesale Permit
28 Number WLS 5553 to CTMP, Inc., doing business as CTMP, Inc. (CTMP, Inc. or Respondents).

1 The Wholesale Permit was in full force and effect at all times relevant to the majority of charges
2 brought herein. The permit expired on December 10, 2015 and was canceled on or about
3 February 3, 2016.

4 3. On or about December 1, 2009, The Board of Pharmacy issued Designated
5 Representative License No. EXC 20508 to Gina Kim Loanne Tran (Gina Tran or Respondents).
6 The Designated Representative License was canceled on December 10, 2015.

7 JURISDICTION

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

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

14 6. Section 4300(a) of the Code provides that every license issued by the Board may be
15 suspended or revoked.

16 7. Section 4300.1 of the Code states:

17 The expiration, cancellation, forfeiture, or suspension of a board-issued license
18 by operation of law or by order or decision of the board or a court of law, the
19 placement of a license on a retired status, or the voluntary surrender of a license by a
20 licensee shall not deprive the board of jurisdiction to commence or proceed with any
investigation of, or action or disciplinary proceeding against, the licensee or to render
a decision suspending or revoking the license.

21 STATUTORY PROVISIONS

22 8. Section 4022 of the Code states:

23 "Dangerous drug" or "dangerous device" means any drug or device unsafe for
self-use in humans or animals, and includes the following:

24 (a) Any drug that bears the legend: "Caution: federal law prohibits
25 dispensing without prescription," "Rx only," or words of similar import.

26 (b) Any device that bears the statement: "Caution: federal law restricts this
27 device to sale by or on the order of a _____," "Rx only," or words of similar import,
28 the blank to be filled in with the designation of the practitioner licensed to use or
order use of the device.

1 (c) Any other drug or device that by federal or state law can be lawfully
2 dispensed only on prescription or furnished pursuant to Section 4006.

3 9. Section 4043 of the Code, in pertinent part, defines "wholesaler" to mean and include
4 "a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor,
5 agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes
6 possession of, any drug or device included in Section 4022."

7 10. Section 4053(a) of the Code states:

8 Notwithstanding Section 4051, the board may issue a license as a designated
9 representative to provide sufficient and qualified supervision in a wholesaler or
10 veterinary food-animal drug retailer. The designated representative shall protect the
11 public health and safety in the handling, storage, and shipment of dangerous drugs
12 and dangerous devices in the wholesaler or veterinary food-animal drug retailer.

13 11. Section 4080 of the Code states:

14 All stock of any dangerous drug or dangerous device or of shipments through a
15 customs broker or carrier shall be, at all times during business hours, open to
16 inspection by authorized officers of the law.

17 12. Section 4081 of the Code states in pertinent part:

18 (a) All records of manufacture and of sale, acquisition, or disposition of dangerous
19 drugs or dangerous devices shall be at all times during business hours open to
20 inspection by authorized officers of the law, and shall be preserved for at least
21 three years from the date of making. A current inventory shall be kept by every
22 manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer,
23 physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution,
24 or establishment holding a currently valid and unrevoked certificate, license,
25 permit, registration, or exemption under Division 2 (commencing with Section
26 1200) of the Health and Safety Code or under Part 4 (commencing with Section
27 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock
28 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.

13. Section 4160 of the Code provides, in pertinent part, that a wholesaler license shall be
required for a person or entity to act as a wholesaler, that every wholesaler shall be supervised or
managed by a Designated Representative in Charge, and that the Designated Representative in
Charge shall be responsible for the wholesaler's compliance with state and federal laws.

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14. Section 4169 of the Code states in pertinent part:

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

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

....

15. Section 4301 of the Code states in pertinent part:

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

....

(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.

....

REGULATORY PROVISIONS

16. California Code of Regulations, title 16, sections 1780(a), (c) and (f)(1) states:

The following minimum standards shall apply to all wholesale establishments for which permits have been issued by the board:

(a) A wholesaler shall store dangerous drugs in a secure and locked area.

...

(c) Entry into areas where prescriptions drugs are held shall be limited to authorized personnel.

...

(f) Policies and procedures must be written and made available upon request by the board.

(1) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security,

1 storage, inventory and distribution of prescription drugs, including policies and
2 procedures for identifying, record, and reporting losses or thefts, for correcting all
3 errors and inaccuracies in inventories, and for maintaining records to document
4 proper storage.

5 17. California Code of Regulations, title 16, section 1784(a) states:

6 The designated representative-in-charge of each wholesaler as defined under
7 section 4160 of the Business and Professions Code shall complete a self-assessment
8 of the wholesaler's compliance with federal and state pharmacy law. The assessment
9 shall be performed before July 1 of every odd-numbered year. The primary purpose
10 of the self-assessment is to promote compliance through self-examination and
11 education.

12 18. Code of Federal Regulations, title 21, Part 203.50(a) and (b) provides:

13 (a) *Identifying statement for sales by unauthorized distributors.* Before the
14 completion of any whole distribution by a wholesale distributor of a prescription
15 drug for which the seller is not an authorized distributor of record to another
16 wholesale distributor or retail pharmacy, the seller shall provide to the purchaser a
17 statement identifying each prior sale, purchase, or trade of such drug. This
18 identifying statement shall include:

- 19 (1) The proprietary and established name of the drug;
- 20 (2) Dosage;
- 21 (3) Container size;
- 22 (4) Number of containers;
- 23 (5) The drug's lot or control number (s);
- 24 (6) The business name and address of all parties to each prior transaction
25 involving the drug, starting with the manufacturer; and
- 26 (7) The date of each previous transaction.

27 (b) The drug origin statement is subject to the record retention requirements
28 of 203.60 and must be retained by all wholesale distributors involved in the
distribution of the drug product, whether authorized or unauthorized, for 3 years.

.....

24 COST RECOVERY

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

1 **FACTUAL ALLEGATIONS**

2 20. At all times referenced herein, Gina Tran was the President and Designated
3 Representative-in-Charge (DRIC) of CTMP, Inc.

4 21. Gina Tran did not complete any self-assessments of CTMP, Inc.'s compliance with
5 federal and state pharmacy law. Respondents also failed to possess any written policies and
6 procedures, including policies and procedures for the receipt, security, storage, inventory and
7 distribution of prescription drugs.

8 22. Specialty Wholesale Industries, LLC was located in Albuquerque, New Mexico and
9 did not hold any licenses with the Board and did not have a wholesale license in New Mexico
10 after December 21, 2013.

11 23. On or about November 12, 2012 through November 28, 2014, Respondents purchased
12 20,199 units of dangerous drugs, totaling \$4,287,539.40 from Specialty Wholesale Industries,
13 LLC.

14 24. Respondents did not create and retain drug origin statements for the sales of
15 dangerous drugs Respondents made to CT Pharmacy nor did they receive and retain pedigrees,
16 transaction histories or drug origin statements from the purchases of dangerous drugs from
17 Specialty Wholesale Industries, LLC.

18 25. On or about November 25, 2015, the Board requested that Gina Tran provide a
19 written statement about the purchases of dangerous drugs from Specialty Wholesale Industries,
20 LLC. She failed to provide that statement.

21 26. On or about December 2, 7 and 11, 2015, Board inspectors arrived unannounced at
22 CTMP, Inc. in order to conduct inspections of CTMP, Inc. but discovered that CTMP, Inc. was
23 not open for business. Board inspectors made numerous inquiries to Respondents requesting the
24 hours of operation for CTMP, Inc. They were then forced to make an appointment to inspect
25 CTMP, Inc.

26 27. On December 14, 2015, Board inspectors arrived at CTMP, Inc. for a previously
27 scheduled inspection of CTMP, Inc. and conducted that inspection. However, neither Gina Tran
28 nor any other designated representative for CTMP, Inc. were present during the inspection.

1 28. Respondents gave their attorney the key to storage areas which held prescription
2 drugs.

3 **FIRST CAUSE FOR DISCIPLINE**

4 **(Purchasing Drugs from Unlicensed Entity)**

5 29. Respondents are subject to disciplinary action under Code section 4301(o), for
6 violating Code section 4169 (a)(1) in that Respondents purchased drugs from an entity, Specialty
7 Wholesale Industries, LLC, which was not licensed in California as a pharmacy or wholesaler, as
8 set forth in paragraphs 20 through 28, which are incorporated herein by reference.

9 **SECOND CAUSE FOR DISCIPLINE**

10 **(Failure to Retain Pedigree Records)**

11 30. Respondents are subject to disciplinary action under Code section 4301(o), for
12 violating Code of Federal Regulations, title 21, Part 203.5(a) and (b), in that Respondents failed
13 to create and retain pedigrees, transaction histories or drug origin statements for the sales of
14 dangerous drugs Respondents made to CT Pharmacy and failed to receive and retain pedigrees,
15 transaction histories or drug origin statements for the purchases of dangerous drugs from
16 Specialty Wholesale Industries, Inc., as set forth in paragraphs 20 through 28, which are
17 incorporated herein by reference.

18 **THIRD CAUSE FOR DISCIPLINE**

19 **(Subverting Investigation of Board against Respondent Gina Tran)**

20 31. Respondent Gina Tran is subject to disciplinary action under Code section 4301(q),
21 for unprofessional conduct in that she subverted an investigation of the Board by failing to
22 provide a statement as requested on November 25, 2015, failing to respond to numerous inquiries
23 about the hours of operation for CTMP, Inc. and failing to appear at the scheduled inspection on
24 December 14, 2015, as set forth in paragraphs 20 through 28 above, which are incorporated
25 herein by reference.
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FOURTH CAUSE FOR DISCIPLINE

(Failure to Keep Records and Stock Open for Inspection)

32. Respondents are subject to disciplinary action under Code section 4301(o), for violating Business and Professions Code sections 4080 and 4081, in that Respondents failed to keep the stock and records of dangerous drugs open for inspection by authorized officers of the law, as set forth in paragraphs 20 through 28, which are incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Secure Drugs and Allowing Unauthorized Personnel Where Drugs are Held)

33. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, sections 1780(a) and (c), in that Respondents failed to secure dangerous drugs in a secured and locked area and allowed unauthorized personnel entry into areas where prescription drugs were held, as set forth in paragraphs 20 through 28, which are incorporated herein by reference.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Possess Written Policies and Procedures for Receipt, Security, Storage, Inventory and Distribution of Drugs)

34. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1780(f)(1), in that Respondents failed to possess written policies and procedures for the receipt, security, storage, inventory and distribution of prescription drugs, as set forth in paragraphs 20 through 28, which are incorporated herein by reference.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Complete Wholesaler Self-Assessments)

35. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1784(a), in that Respondents failed to complete self-assessments of CTMP, Inc.'s compliance with federal and state pharmacy law, as set forth in paragraphs 20 through 28, which are incorporated herein by reference.

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EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

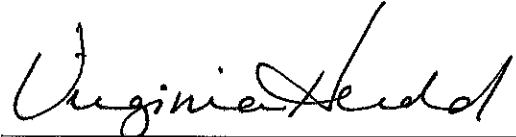
36. Respondents are subject to disciplinary action under Code section 4301 for unprofessional conduct in that they engaged in the activities described in paragraphs 20 through 28 above, which are incorporated herein by reference.

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 5553, issued to CTMP, Inc. doing business as CTMP, Inc.;
2. Revoking or suspending Designated Representative License Number EXC 20508, issued to Gina Kim Loanne Tran;
3. Ordering CTMP, Inc., doing business as CTMP, Inc. and Gina Kim Loanne Tran 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.

DATED: 9/14/16



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

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