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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. 4826

12 **VITSHANTA, INC.**
13 **DBA SIERRA PHARMACY**
4108 N. Sierra Way
14 San Bernardino, CA 92407

A C C U S A T I O N

15 Pharmacy Permit No. PHY 49260

16 **PRADEEP KUMAR AMIN**
4108 N. Sierra Way
17 San Bernardino, CA 92407

18 Pharmacist License No. RPH 40574

19 Respondent.
20

21
22 Complainant alleges:

23 **PARTIES**

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

26 2. On or about December 5, 2008, the Board of Pharmacy issued Pharmacy Permit
27 Number PHY 49260 to Vitshanta, Inc., doing business as Sierra Pharmacy (Respondent Sierra
28

1 Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges
2 brought herein and will expire on December 1, 2014, unless renewed.

3 3. On or about September 24, 1986, the Board of Pharmacy issued Pharmacist License
4 Number RPH 40574 to Pradeep Kumar Amin (Respondent Pradeep Amin). The Pharmacist
5 License was in full force and effect at all times relevant to the charges brought herein and will
6 expire on December 1, 2016, unless renewed.

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 AND REGULATORY PROVISIONS

22 8. Section 4301 of the Code states in pertinent part:

23 The board shall take action against any holder of a license who is guilty of
24 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:

25 ...

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

28 ...

1 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
2 abetting the violation of or conspiring to violate any provision or term of this chapter
3 or of the applicable federal and state laws and regulations governing pharmacy,
4 including regulations established by the board or any other state or federal regulatory
5 agency.

6 ...

7 9. Section 4113 (c) of the Code states:

8 The pharmacist-in-charge shall be responsible for a pharmacy's compliance
9 with all state and federal laws and regulations pertaining to the practice of pharmacy.

10 10. Section 4306.5 of the Code states, in pertinent part:

11 Unprofessional conduct for a pharmacist may include any of the following:

12 Acts or omissions that involve, in whole or in part, the inappropriate exercise of
13 his or her education, training, or experience as a pharmacist, whether or not the act
14 or omission arises in the course of the practice of pharmacy or the ownership,
15 management, administration, or operation of a pharmacy or other entity licensed by
16 the board.

17 Acts or omissions that involve, in whole or in part, the failure to consult
18 appropriate patient, prescription, and other records pertaining to the performance of
19 any pharmacy function.

20 ...

21 11. Code section 4115 (f)(1) states:

22 A pharmacy with only one pharmacist shall have no more than one pharmacy
23 technician performing the tasks specified in subdivision (a). The ratio of pharmacy
24 technicians performing the tasks specified in subdivision (a) to any additional
25 pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel
26 performing clerical functions pursuant to Section 4116 or 4117. This ratio is
27 applicable all practice settings, except for an inpatient of a licensed health facility, a
28 patient of a licensed home health agency, as specified in paragraph (2), an inmate of a
correctional facility of the Department of Corrections and Rehabilitation, and for a
person receiving treatment in a facility operated by the State Department of State
Hospitals, the State Department of Developmental Services, or the Department of
Veterans Affairs.

12. Health and Safety Code section 11153 (a) states:

A prescription for a controlled substance shall only be issued for a legitimate
medical purpose by an individual practitioner acting in the usual course of his or her
professional practice. The responsibility for the proper prescribing and dispensing of
controlled substances is upon the prescribing practitioner, but a corresponding
responsibility rests with the pharmacist who fills the prescription. Except as
authorized by this division, the following are not legal prescriptions: (1) an order
purporting to be a prescription which is issued not in the usual course of
professional treatment or in legitimate and authorized research; or (2) an order for an
addict or habitual user of controlled substances, which is issued not in the course of
professional treatment or as part of an authorized narcotic treatment program, for the
purpose of providing the user with controlled substances, sufficient to keep him or

her comfortable by maintaining customary use.

....

13. Health and Safety Code section 11165 (d) states, in pertinent part:

To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

...

For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedule in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

...

14. Section 1761 of title 16, California Code of Regulations states:

(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

COST RECOVERY

15. Section 125.3 of the Code provides, 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.

1 **DRUGS**

2 16. Hydrocodone/APAP, is the generic name for Vicodin and Norco, a Schedule III
3 controlled substance pursuant to Health and Safety Code section 11056 (e)(5) and a dangerous
4 drug pursuant to Business and Professions Code section 4022.

5 17. Phenergan with Codeine is the brand name for promethazine with codeine, a Schedule
6 V controlled substance pursuant to Health and Safety Code section 11058 (c)(1) and is a
7 dangerous drug pursuant to Business and Professions Code section 4022.

8 18. Xanax is the brand name for alprazolam, a Schedule IV controlled substance pursuant
9 to Health and Safety Code section 11057 (d)(1) and a dangerous drug pursuant to Business and
10 Professions Code section 4022.

11 **FACTUAL ALLEGATIONS**

12 19. From December 5, 2008 and at all times mentioned herein, Respondent Pradeep Amin
13 was the Pharmacist-in-Charge of Respondent Sierra Pharmacy.

14 20. From January 4, 2010 to September 26, 2011, Respondents filled 1,220 prescriptions
15 for controlled substances which were written by Dr. A.S. None of the five pharmacies closest in
16 geographical proximity to Respondent Sierra Pharmacy dispensed a single prescription written by
17 Dr. A.S. The amounts of hydrocodone/apap dispensed by Respondents during the same time
18 frame was higher than neighboring pharmacies.

19 21. On July 22, 2005, an accusation was filed against Dr. A.S., a physician with a primary
20 practice area of family and general practice, charging Dr. A.S. with gross negligence, repeated
21 negligent acts, incompetence, dishonesty and prescribing without medical indication or
22 performing a good faith physical examination, among other violations of the Medical Practice
23 Act. On April 30, 2007, a stipulated settlement and disciplinary order was adopted by the
24 Medical Board, placing Dr. A.S. on probation for four years.

25 22. On June 18, 2009, another accusation and a petition to revoke probation was filed
26 against Dr. A.S. charging him with dishonesty and failing to comply with the term and condition
27 of his probation requiring him to maintain a drug log for all controlled substances ordered,
28 prescribed, dispensed, administered or possessed by him. On March 26, 2010, another stipulated

1 settlement and disciplinary order was adopted by the Medical Board, extending his probation for
2 four additional years on the same terms and conditions in addition to prohibiting him from
3 writing prescriptions for Schedule II controlled substances.

4 23. On September 20, 2012, an interim suspension order was issued against Dr. A.S. On
5 November 7, 2012, a third accusation and second petition to revoke probation was filed against
6 Dr. A.S. charging him with gross negligence, repeated negligent acts, incompetence, prescribing
7 to addicts, prescribing without performing physical examination or medical indication or both,
8 failure to maintain adequate and accurate medical records, excessive prescribing and violation of
9 drug statutes, as well as writing prescriptions for Schedule II controlled substances in violation of
10 the terms and conditions of his probation.

11 24. To obtain controlled substances from Respondents, Dr. A.S.'s patients traveled an
12 average of 46 miles from their residences to Respondent Sierra Pharmacy and traveled an average
13 of 56 miles from Dr. A.S.'s offices to Respondent Sierra Pharmacy.

14 25. Groups of patients were furnished controlled substances by Respondents at the same
15 time.

16 26. Respondents dispensed and filled prescriptions for controlled substances which were
17 written in an identical fashion for multiple patients. For example, many prescriptions were
18 written by Dr. A.S., each for different patients, for hydrocodone/apap 10/325, alprazolam 2mg
19 and promethazine with codeine 480ml. Almost ninety-five percent of the prescriptions written by
20 Dr. A.S. and filled by Respondents were for controlled substances.

21 27. Not all of prescriptions written by Dr. A.S. and filled by Respondents identified
22 diagnoses for his patients. For the prescriptions written for alprazolam where a diagnosis was
23 documented, the diagnosis was identical, "anxiety." For the prescriptions written for
24 promethazine with codeine where a diagnosis was documented, the diagnosis was identical,
25 "bronchitis," without a concurrent prescription for an antibiotic or other respiratory medication.
26 For the majority of the prescriptions written for hydrocodone/apap with a diagnosis documented,
27 the diagnosis was identical, "back pain" with no referral to a pain specialist and concurrent
28

1 prescriptions written for other medications routinely prescribed for chronic pain such as
2 amitriptyline and gabapentin.

3 28. Respondents did not verify or otherwise research whether the prescriptions described
4 in paragraph 20 were written for a legitimate medical purpose before filling them, including
5 verifying whether there were any disciplinary proceedings pending against Dr. A.S.'s license to
6 practice medicine.

7 29. From January 2010 through November 2012, Respondents did not provide any
8 information for each prescription dispensed for a Schedule II, Schedule III or Schedule IV
9 controlled substance to the Department of Justice on a weekly basis for inclusion in the
10 Controlled Substance Utilization Review and Evaluation System ("CURES").

11 30. On December 20, 2012, two pharmacy technicians were on duty and performing
12 packaging, manipulative, repetitive, or other nondiscretionary tasks while there was only one
13 pharmacist on duty at Respondent Sierra Pharmacy.

14 **FIRST CAUSE FOR DISCIPLINE**

15 **(Failing to Comply with Corresponding Responsibility**
16 **for Legitimate Controlled Substance Prescriptions)**

17 31. Respondents are subject to disciplinary action under Code section 4301(j), for
18 violating Health and Safety Code section 11153(a), in that they failed to comply with their
19 corresponding responsibility to ensure that controlled substances were dispensed for a legitimate
20 medical purpose when Respondents furnished prescriptions for controlled substances even though
21 "red flags" were present to indicate those prescriptions were not issued for a legitimate medical
22 purpose, as set forth in paragraphs 19 through 30 above, which are incorporated herein by
23 reference.

24 **SECOND CAUSE FOR DISCIPLINE**

25 **(Dispensing Controlled Substance Prescriptions with Significant Errors, Omissions,**
26 **Irregularities, Uncertainties, Ambiguities or Alterations)**

27 32. Respondents are subject to disciplinary action under Code section 4301(o), for
28 violating title 16, California Code of Regulations, sections 1761(a) and (b), in that they dispensed

1 prescriptions for controlled substances, which contained significant errors, omissions,
2 irregularities, uncertainties, ambiguities or alterations, as set forth in paragraphs 19 through 30
3 above, which are incorporated herein by reference.

4 **THIRD CAUSE FOR DISCIPLINE**

5 **(Failure to Exercise or Implement Best Professional Judgment or Corresponding**
6 **Responsibility when Dispensing Controlled Substances**
7 **against Respondent Pradeep Amin)**

8 33. Respondent Pradeep Amin is subject to disciplinary action under Code section
9 4301(o), for violating Business and Professions Code section 4306.5(a) and (b), in that he failed
10 to exercise or implement his best professional judgment or corresponding responsibility when
11 dispensing controlled substances, as set forth in paragraphs 19 through 30 above, which are
12 incorporated herein by reference.

13 **FOURTH CAUSE FOR DISCIPLINE**

14 **(Failure to Report Dispensing of Controlled Prescriptions to CURES against Respondents)**

15 34. Respondents are subject to disciplinary action under Code section 4301(j), for
16 violating Health and Safety Code section 11165(d), in that they failed to provide any information
17 for each prescription dispensed of a Schedule II, Schedule III or Schedule IV controlled substance
18 to the Department of Justice on a weekly basis for inclusion in CURES, as set forth in paragraphs
19 19 through 30 above, which are incorporated herein by reference.

20 **FIFTH CAUSE FOR DISCIPLINE**

21 **(Failure to Adhere to Pharmacy Technician Ratios)**

22 35. Respondents are subject to disciplinary action under Code section 4301(o), for
23 violating Business and Professions Code section 4115(f)(1), in that on December 20, 2012, two
24 pharmacy technicians were on duty and performing their tasks with only one pharmacist present
25 and on duty, as set forth in paragraphs 19 through 30 above, which are incorporated herein by
26 reference.

1 SIXTH CAUSE FOR DISCIPLINE

2 (Unprofessional Conduct)

3 36. Respondents are subject to disciplinary action under Code section 4301 for
4 unprofessional conduct in that they engaged in the activities described in paragraphs 19 through
5 30 above, which are incorporated herein by reference.

6 PRAYER

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

9 1. Revoking or suspending Pharmacy Permit Number PHY 49260, issued to Vitshanta
10 Inc., doing business as Sierra Pharmacy;

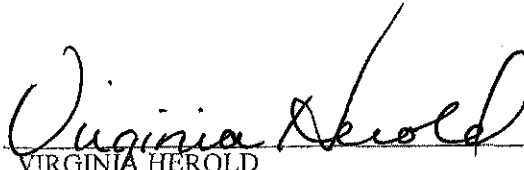
11 2. Revoking or suspending Pharmacist License Number RPH 40574, issued to Pradeep
12 Kumar Amin;

13 3. Ordering Vitshanta Inc., doing business as Sierra Pharmacy and Pradeep Kumar Amin
14 to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this
15 case, pursuant to Business and Professions Code section 125.3;

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

17
18 DATED: _____

9/20/14



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

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