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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **INDIO MEDICAL PHARMACY;** **WANG KAN, PRES/PIC** **81-893 Dr. Carreon Blvd., Ste. 7** **Indio, CA 92201** **Pharmacy Permit No. PHY 21267,** **and** **WANG YUEN KAN** **41-550 Yucca Lane** **Bermuda Dunes, CA 92201** **Pharmacist License No. RPH 30545** Respondents.	Case No. 4569 **A C C U S A T I O N**

Complainant alleges:

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.

2. On or about August 1, 1984, the Board of Pharmacy issued Pharmacy Permit Number PHY 21267 to Indio Medical Pharmacy; with Wang Kan, as the President and Pharmacist in

Charge (PIC) (Respondent). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2013, unless renewed.

3. On or about August 16, 1976, the Board of Pharmacy issued Pharmacist License Number RPH 30545 to Wang Yuen Kan (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2014, 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 118, subdivision (b), of the Code provides that the suspension, expiration, surrender, cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

6. Section 4300 of the Code states in pertinent part:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
>
> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.
>
> . . . .

7. Section 4300.1 of the 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 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.

STATUTORY PROVISIONS

8. Section 4076 of the Code states in pertinent part:

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

. . . .

(11)(A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. . . .

9. 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.

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

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

. . . .

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

. . . .

11. 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.

. . . .

12. Section 4306.5 of the Code states:

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

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

. . . .

FEDERAL PROVISIONS

13. United States Code, title 21, chapter 9, subchapter V, section 353(d) states in part:

(1) Except as provided in paragraphs (2) and (3), no person may distribute any drug sample. For purposes of this subsection, the term "distribute" does not include the providing of a drug sample to a patient by a—

(A) practitioner licensed to prescribe such drug,

(B) health care professional acting at the direction and under the supervision of such a practitioner, or

(C) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample pursuant to paragraph (2) or (3).

(2)(A) The manufacturer or authorized distributor of record of a drug subject to subsection (b) of this section may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. Such a distribution of drug samples may only be made—

(i) in response to a written request for drug samples made on a form which meets the requirements of subparagraph (B), and

(ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or authorized distributor of record.

(B) A written request for a drug sample required by subparagraph (A)(i) shall contain—

. . . .

(C) Each drug manufacturer or authorized distributor of record which makes distributions by mail or common carrier under this paragraph shall maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and shall maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to Federal and State officials engaged in the regulation of drugs and in the enforcement of laws applicable to drugs.

(3) The manufacturer or authorized distributor of record of a drug subject to subsection (b) of this section may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or authorized distributor of record makes the distributions in accordance with subparagraph (A) and carries out the activities described in subparagraphs (B) through (F) as follows:

(A) Drug samples may only be distributed—

(i) to practitioners licensed to prescribe such drugs if they make a written request for the drug samples, or

(ii) at the written request of such a licensed practitioner, to pharmacies of hospitals or other health care entities.

STATE REGULATORY PROVISIONS

14. California Code of Regulations, title 16, section 1714 states in pertinent part:

. . . .

(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

. . . .

15. California Code of Regulations, title 16, section 1735.2 states in pertinent part:

. . . .

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration dating requirements.

(4) Inactive ingredients to be used.

(5) Process and/or procedure used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.

(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

(g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the

pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

16. California Code of Regulations, title 16, section 1735.3 states in pertinent part:

(a) For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

(7) A pharmacy assigned reference or lot number for the compounded drug product.

(8) The expiration date of the final compounded drug product.

(9) The quantity or amount of drug product compounded.

. . . .

17. California Code of Regulations, title 16, section 1735.5 states in pertinent part:

(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

. . . .

18. California Code of Regulations, title 16, section 1735.6 states in pertinent part:

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.

. . . .

19. California Code of Regulations, title 16, section 1735.7 states in pertinent part:

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

. . . .

20. California Code of Regulations, title 16, section 1735.8 states in pertinent part:

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

. . . .

COST RECOVERY

21. 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, with failure of the licentiate to comply subjecting the license to not being

renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

DRUGS

22. Ambien is a brand name for zolpidem, and is a Schedule IV controlled substance as designated by Health and Safety Code section 11057(d)(32) and is a dangerous drug pursuant to Business and Professions Code section 4022.

23. HydroDiuril is a brand name for hydrochlorothiazide, and is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

24. Lopressor and Toprol XL are brand names for metoprolol, and are classified as a dangerous drug pursuant to Business and Professions Code section 4022.

25. Norvasc is a brand name for amlodipine, and is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

26. Prinivil and Zestril are brand names for lisinopril, and are classified as a dangerous drug pursuant to Business and Professions Code section 4022.

27. Tambocor is a brand name for flecainide, and is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

28. Ultram is a brand name for tramadol and is a dangerous drug pursuant to Business and Professions Code section 4022.

29. Xanax and Niravam are brand names for alprazolam and are Schedule IV controlled substances as designated by Health and Safety Code section 11057(d)(1), and dangerous drugs pursuant to Business and Professions Code section 4022. Alprazolam tablets are indicated for the management of anxiety disorder or the short-term relief of symptoms of anxiety.

30. Zocor is a brand name for simvastatin, and is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

FACTUAL ALLEGATIONS

31. On April 10, 2012, a Board inspector performed a routine inspection of Indio Medical Pharmacy located at 81-893 Dr. Carreon Boulevard, Ste. 7, in Indio, California. President and Pharmacist-in-Charge (PIC) Wang Kan was present during the inspection.

32. During the inspection, the Board inspector discovered that the pharmacy was very dirty, with a thick layer of dust on most surfaces. The Board inspector also discovered that the pharmacy was unorganized, and that there were boxes, totes and shelves that contained expired medications in the pharmacy. The Board inspector discovered that there were expired medications throughout the dispensing area and co-mingled with unexpired medications on the pharmacy's shelves. The shelves had not been checked or cleaned routinely and expired medications were not quarantined.

33. The Board inspector also discovered an aisle of the pharmacy was blocked by totes (filled with expired medications) making the shelves inaccessible. When the inspector asked about the area, the PIC informed her that the pharmacy had been broken into during the last week of March 2012, and that the totes were placed in front of the window in an attempt to prevent a second break-in (by blocking this area off.)

34. When the Board inspector reviewed the "will call" area, she discovered that several prescription containers prepared for customers that did not contain the required physical description for the dispensed medication. Specifically, the following nine prescription containers lacked the required physical description:

	Rx Number	Date Filled	Medication
1	7058266	3/12/12	Metoprolol
2	7058269	3/12/12	Amlodipine
3	7058268	3/12/12	Hydrochlorothiazide
4	7058267	3/12/12	Lisinopril
5	7048177	2/12/12	Flecainide
6	4883901	4/9/12	Alprazolam
7	7042507	3/12/12	Simvastatin
8	7042511	3/12/12	Tramadol
9	4884183	4/7/12	Zolpidem

35. During the inspection, the Board inspector also discovered that the pharmacy was compounding[1] non-sterile products on the premises. There was an area in the pharmacy where the compounding medication was stored, and that area was covered in dust, contained expired medication (one expired in June 1992) and there were mis-labeled compounded products. When asked, the PIC was unable to produce any of the required policies, procedures, or documentation for this compounding. The vast majority of the compounded products on the shelves lacked the required expiration dates and pharmacy assigned lot number.

36. The Board inspector discovered a compounded testosterone 2% gel in the pharmacy, which lacked an expiration date and assigned lot number. When asked, the PIC could not produce the master formula and compounding log for the compounded product, but did state that it was compounded on December 15, 2011 by one of his pharmacy technicians. The PIC had also not filled out the required compounding self assessment form. The PIC stated that the pharmacy compounded drugs about once or twice a year and that they would stop all compounding.

37. During the inspection, the Board inspector also found large amounts of professional samples in drawers in the dispensing area, and in totes and boxes in the blocked off aisle. Most of the samples were expired and some had been expired since 1994. There were no records of acquisition for the professional samples. When the PIC was specifically asked about the unexpired samples in the dispensing area, he stated that "these samples were provided by [his] personal physician for self-use." The PIC stated that he collected samples "for some doctors going to Mexico" and that he never got around to disposing of them once expired.

FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Clean and Orderly Conditions in Pharmacy)

38. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1714 (c) in that Respondents failed

[1] Compounding is the pharmacy practice of mixing, combining, or altering ingredients to create a drug product. Pursuant to California Code of Regulations, title 16, section 1735, compounding is defined as: (1) altering the dosage form or delivery system of a drug; (2) altering the strength of a drug; (3) combining components or active ingredients; (4) preparing a drug product from chemicals or bulk drug substances.

to maintain the pharmacy in a clean and orderly condition, as set forth in paragraphs 31 through 37, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Failure to Prevent Sales of Drugs Lacking Quality of Strength)

39. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of section 4169, subdivision (a)(4) in that Respondents had expired medications for transfer throughout the dispensing area and co-mingled with unexpired medications of the pharmacy shelves, as set forth in paragraphs 31 through 37, which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Incorrect Prescription Container Labeling)

40. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of section 4076 (a)(11)(A) in that during the inspection of the pharmacy, nine prescription containers in the will call area were found to have lacked auxiliary labels with the required physical description for the dispensed medication, as set forth in paragraph 34, which is incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Written Documentation of Staff Training Related to Compounding)

41. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1735.7(a) in that Respondents failed to maintain training records for pharmacy personnel that demonstrate that personnel have the skills and training required to properly and accurately perform their assigned responsibilities related to compounding, as set forth in paragraphs 35 through 36, which are incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Maintain a Compounding Quality Assurance Plan)

42. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1735.8(a) in that Respondents failed

to maintain or produce as required, its written quality assurance plan designed to monitor and ensure the integrity, potency, quality and labeled strength of compounded drug products, as set forth in paragraphs 35 through 36, which are incorporated herein by reference.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Compounding Policy and Procedures)

43. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1735.5(a) in that Respondents failed to maintain as required, a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding, as set forth in paragraphs 35 through 36, which are incorporated herein by reference.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Documentation Re Facilities & Equipment Necessary for Safe & Accurate Compounded Products)

44. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1735.6(a) in that Respondents failed to maintain as required, written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products, as set forth in paragraphs 35 through 36, which are incorporated herein by reference.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Compounded Drug Products)

45. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1735.3(a) in that Respondents failed to maintain as required, pharmacy records of compounded drug products, as set forth in paragraphs 35 through 36, which are incorporated herein by reference.

NINTH CAUSE FOR DISCIPLINE

(Failure to Complete Self-Assessment Prior to Compounding)

46. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1735.2(j) in that Respondents failed to complete as required, the self-assessment form developed by the Board prior to compounding drug products, as set forth in paragraphs 35 through 36, which are incorporated herein by reference.

TENTH CAUSE FOR DISCIPLINE

(Failure to Maintain and/or Produce Adequate Records of Acquisition)

47. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of section 4081, subdivision (a), for failure to maintain records of acquisition for the professional samples that were found in the pharmacy as required by law, as set forth in paragraph 37, which are incorporated herein by reference.

ELEVENTH CAUSE FOR DISCIPLINE

(Unlawful Samples in a Retail Pharmacy)

48. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of section 4306.5(a), in that during the inspection of the pharmacy, the PIC admitted that the large amounts of professional samples that were found in the pharmacy were being collected with the intent of distributing them to doctors, in violation of 21 U.S.C. § 353(d), which are acts that demonstrate an inappropriate exercise of education, training or experience, as set forth in paragraph 37, 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 Pharmacy Permit Number PHY 21267, issued to Indio Medical Pharmacy; with Wang Kan as the President and Pharmacist in Charge;

2. Revoking or suspending Pharmacist License Number RPH 30545, issued to Wang Yuen Kan;

3. Ordering Respondents 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: 4/4/13

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

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