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

In the Matter of the Accusation Against: **CREATIVE COMPOUNDS INC.,** **DBA HARBOR COMPOUNDING AND HOME HEALTH CARE PHARMACY** **2000 Harbor Blvd., Ste. C-100** **Costa Mesa, CA 92627** **Pharmacy Permit No. PHY 50397** **CREATIVE COMPOUNDS INC.,** **DBA HARBOR COMPOUNDING PHARMACY** **2000 Harbor Blvd., Ste. C-100** **Costa Mesa, CA 92627** **Licensed Sterile Compounding Permit No. 99688** **MICHAEL CAN HUA** **37255 Tomasek Terrace** **Fremont, CA 94536** **Pharmacist License No. RPH 61291** Respondents.	Case No. 5041 **ACCUSATION**

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 25, 2010, the Board of Pharmacy issued Pharmacy Permit Number PHY 50397 to Creative Compounds Inc., dba Harbor Compounding and Home Health Care Pharmacy (Respondent Harbor Compounding and Home Health Care Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2014, unless renewed.

3. On or about July 15, 2011, the Board of Pharmacy issued Licensed Sterile Compounding Permit Number 99688 to Creative Compounds Inc., doing business as Harbor Compounding Pharmacy (Respondent Harbor Compounding Pharmacy). The Licensed Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2014, unless renewed.

4. On or about August 6, 2008, the Board of Pharmacy issued Pharmacist License Number RPH 61291 to Michael Can Hua (Respondent Michael Hua). 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

5. 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.

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

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

8. 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

9. Section 4022 of the Code states:

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

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

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

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

10. Section 4113, subdivision (c) of the Code states:

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

11. Section 4127.7 of the Code states:

On or after July 1, 2005, a pharmacy shall compound sterile injectable products from one or more nonsterile ingredients in one of the following environments:

(a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.

(b) An ISO class 5 cleanroom.

(c) A barrier isolator that provides an ISO class 5 environment for compounding.

12. 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.

. . . .

REGULATORY PROVISIONS

13. Title 16, California Code of Regulations, section 1735(a) states in pertinent part:

"Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(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

. . .

14. Title 16, California Code of Regulations, section 1735.2(h) states:

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 sued if it is deemed appropriate in the professional judgment of the responsible pharmacist.

15. Title 16, California Code of Regulations, section 1735.5(c) states:

(c) The policy and procedure manual shall include the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedures manual

(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product;

(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on those procedures as part of the staff training and competency evaluation process.

(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

16. Title 16, California Code of Regulations, section 1735.7(a) states:

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

17. Title 16, California Code of Regulations, section 1751.7(c) states:

Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

18. Title 16, California Code of Regulations, section 1793.7(b) states:

Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

COST RECOVERY

19. 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.

DRUGS

20. Testosterone Pellets are Schedule III controlled substances pursuant to Health and Safety Code section 11056(f)(30) and dangerous drugs pursuant to Business and Professions Code section 4022.

21. Estradiol Pellets are dangerous drugs pursuant to Business and Professions Code section 4022.

FACTUAL ALLEGATIONS

22. Since August 25, 2010, Respondent Michael Hua has been the Pharmacist-in-Charge of Respondent Harbor Compounding and Home Health Care Pharmacy. Since July 15, 2011,

Respondent Michael Hua has been the Pharmacist-in-Charge of Respondent Harbor Compounding Pharmacy.

23. In 2012 and 2013, Respondents compounded and sold testosterone pellets and estradiol pellets, among other sterile and non-sterile injectable drug products.

24. In August 2012, Respondents tested compounded sample numbers W-1-136, W-1-150 and W-1-151 of testosterone pellets for potency, but not for sterility and endotoxins. In November 2012, Respondents tested compounded sample W-1-193 of estradiol pellets for potency and sterility but not for endotoxins.

25. In or about June 2013, Respondents' pharmacists dispensed prescriptions in the retail section of the premises while Respondents' multiple pharmacy technicians and one intern pharmacist compound sterile injectable drug products in the rear of the premises without any pharmacists being present and supervising the compounding being done, including the weighing, mixing, pouring, compounding, and labeling of finished drug products. Respondents also did not provide training to the newly hired pharmacy technician and pharmacist intern or ascertain if they possessed the skills necessary to compound.

26. Respondents did not maintain written policies and procedures for maintaining, storing, calibrating, cleaning and disinfecting their compounding equipment, including the new capsule machine, the ungunators, the Mills for creams/ointments, the V-blender or the pellet presses. Respondents did not possess the records to show that they had cleaned them.

27. Respondents refilled stock bottle containers of cream from the barrels of over stock cream bases without cleaning the stock bottle containers, thereby increasing the possibility of contamination.

28. Respondents compounded drug creams, tablets, troches, sublinguals and solutions with expired chemical ingredients.

29. Respondents compounded sterile injectable products, namely testosterone and estradiol pellets, but failed to perform the compounding in either: (a) an ISO class 5 laminar airflow hood within an ISO class 7 cleanroom with a positive air pressure differential relative to

the adjacent areas; (b) an ISO class 5 cleanroom or (c) a barrier isolator that provides an ISO class 5 environment for compounding.

FIRST CAUSE FOR DISCIPLINE

(Allowing Pharmacy Technicians to Compound Without Direct Supervision of Pharmacist)

30. Respondents are subject to disciplinary action under Code section 4301(o), for violating title 16, California Code of Regulations, section 1793.7(b), in that they allowed pharmacy technicians to compound drug products when they were not under the direct supervision of a pharmacist, as set forth in paragraphs 22 through 29, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Allowing Untrained Staff to Perform Compounding)

31. Respondents are subject to disciplinary action under Code section 4301(o), for violating title 16, California Code of Regulations, section 1735.7(a), in that they allowed an untrained pharmacy technician and an intern pharmacist to compound drug products and did not possess the records necessary to demonstrate that this untrained staff had the skills and training necessary to compound drug products, as set forth in paragraphs 22 through 29, which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Failure to Clean Compounding Equipment and Maintain Cleaning Records)

32. Respondents are subject to disciplinary action under Code section 4301(o), for violating title 16, California Code of Regulations, section 1735.5(c), in that they did not document the cleaning, maintenance, storing, calibrating and disinfecting of the compounding equipment and maintain the records necessary to show that they cleaned such equipment, as set forth in paragraphs 22 through 29, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Using Expired Chemical Ingredients to Compound Drug Products)

33. Respondents are subject to disciplinary action under Code section 4301(o), for violating title 16, California Code of Regulations, section 1735.2(h), in that they used expired

chemical ingredients to compound drug products, as set forth in paragraphs 22 through 29, which are incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Compound Sterile Injectable Drugs in Authorized Environment)

34. Respondents are subject to disciplinary action under Code section 4301(o), for violating Business and Professions Code section 4127.7, in that on or about June 2013, they compounded sterile injectable drugs from non-sterile ingredients, in an environment which was not authorized by law, as set forth in paragraphs 22 through 29, which are incorporated herein by reference.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Properly Test Sterile Injectable Drug Products)

35. Respondents are subject to disciplinary action under Code section 4301(o), for violating title 16, California Code of Regulations, section 1751.7(c), in that they failed to properly test certain samples of testosterone and estradiol pellets, as set forth in paragraphs 22 through 29, which are incorporated herein by reference.

DISCIPLINARY CONSIDERATIONS

36. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges:

a. On July 5, 2013, the Board issued Citation number CI 2012 54273 against Respondent Harbor Compounding and Home Health Care for violating title 16, California Code of Regulations, sections 1735.4(d), 1751.7(c) and 1735.3(a) for improper compounding. The Board issued a fine which that Respondent paid.

b. On July 5, 2013, the Board issued Citation number CI 2012 57447 against Respondent Michael Hua for violating title 16, California Code of Regulations, sections 1735.4(d), 1751.7(c) and 1735.3(a) for improper compounding. The Board issued a fine which that Respondent paid.

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 50397, issued to Creative Compounds Inc., dba Harbor Compounding and Home Health Care Pharmacy;

2. Revoking or suspending Licensed Sterile Compounding Permit Number 99688, issued to Creative Compounds Inc., doing business as Harbor Compounding Pharmacy;

3. Revoking or suspending Pharmacist License Number RPH 61291, issued to Michael Can Hua;

4. Ordering Creative Compounds Inc., dba Harbor Compounding and Home Health Care Pharmacy, Creative Compounds Inc., doing business as Harbor Compounding Pharmacy and Michael Can Hua 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;

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

DATED: 5/8/14

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

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