

**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**

**Pharmacy Permit No. PHY 50397**

**CREATIVE COMPOUNDS INC.,  
DBA HARBOR COMPOUNDING PHARMACY**

**Licensed Sterile Compounding Permit No.  
99688**

**MAYANK PARIMAL SHAH  
P.O. Box 65  
Downey, CA 90241**

**Pharmacist License No. RPH 57834**

**MICHAEL CAN HUA**

**Pharmacist License No. RPH 61291**

Case No. 5041

OAH No. 2014070068

**STIPULATED SURRENDER OF  
LICENSE AND ORDER AS TO  
RESPONDENT MAYANK PARIMAL  
SHAH ONLY**

**DECISION AND ORDER**

The attached Stipulated Surrender of License and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective on October 16, 2015.

It is so ORDERED on September 16, 2015.

BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA



By

\_\_\_\_\_  
Amy Gutierrez, Pharm.D.  
Board President

1 KAMALA D. HARRIS  
Attorney General of California  
2 GREGORY J. SALUTE  
Supervising Deputy Attorney General  
3 DESIREE I. KELLOGG  
Deputy Attorney General  
4 State Bar No. 126461  
600 West Broadway, Suite 1800  
5 San Diego, CA 92101  
P.O. Box 85266  
6 San Diego, CA 92186-5266  
Telephone: (619) 645-2996  
7 Facsimile: (619) 645-2061  
*Attorneys for Complainant*

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

11 In the Matter of the Accusation Against:  
12  
13 **CREATIVE COMPOUNDS INC.,**  
**DBA HARBOR COMPOUNDING AND**  
14 **HOME HEALTH CARE PHARMACY**  
2000 Harbor Blvd., Ste. C-100  
15 Costa Mesa, CA 92627  
  
16 **Pharmacy Permit No. PHY 50397**  
  
17 **CREATIVE COMPOUNDS INC.,**  
**DBA HARBOR COMPOUNDING**  
18 **PHARMACY 2000 Harbor Blvd., Ste. C-100**  
Costa Mesa, CA 92627  
  
19 **Licensed Sterile Compounding Permit No.**  
20 **99688**  
  
21 **MAYANK PARIMAL SHAH**  
P.O. Box 65  
22 Downey, CA 90241  
  
23 **Pharmacist License No. RPH 57834**  
  
24 **MICHAEL CAN HUA**  
37255 Tomasek Terrace  
25 Fremont, CA 94536  
  
26 **Pharmacist License No. RPH 61291**  
  
27 Respondents.

Case No. 5041

OAH No. 2014070068

**STIPULATED SURRENDER OF  
LICENSE AND ORDER (MAYANK  
PARIMAL SHAH)**

1 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-  
2 entitled proceedings that the following matters are true:

3 PARTIES

4 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy.  
5 She brought this action solely in her official capacity and is represented in this matter by Kamala  
6 D. Harris, Attorney General of the State of California, by Desiree I. Kellogg, Deputy Attorney  
7 General.

8 2. Mayank Parimal Shah (Respondent) is represented in this proceeding by attorney  
9 Herbert L. Weinberg of Fenton Law Group, LLP whose address is 1990 S. Bundy Drive, Suite  
10 777, Los Angeles, CA 90025.

11 3. On or about November 10, 2005, the Board of Pharmacy issued Pharmacist License  
12 No. RPH 57834 to Mayank Parimal Shah (Respondent). The Pharmacist License was in full  
13 force and effect at all times relevant to the charges brought in First Amended Accusation No.  
14 5041 and will expire on August 31, 2015, unless renewed.

15 JURISDICTION

16 4. First Amended Accusation No. 5041 was filed before the Board of Pharmacy (Board),  
17 Department of Consumer Affairs, and is currently pending against Respondent. The First  
18 Amended Accusation and all other statutorily required documents were properly served on  
19 Respondent on April 28, 2015. Respondent timely filed his Notice of Defense contesting the First  
20 Amended Accusation. A copy of First Amended Accusation No. 5041 is attached as Exhibit A  
21 and incorporated by reference.

22 ADVISEMENT AND WAIVERS

23 5. Respondent has carefully read, fully discussed with counsel, and understands the  
24 charges and allegations in First Amended Accusation No. 5041. Respondent also has carefully  
25 read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of  
26 License and Order.

27 6. Respondent is fully aware of his legal rights in this matter, including the right to a  
28 hearing on the charges and allegations in the First Amended Accusation; the right to confront and

1 cross-examine the witnesses against him; the right to present evidence and to testify on his own  
2 behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the  
3 production of documents; the right to reconsideration and court review of an adverse decision;  
4 and all other rights accorded by the California Administrative Procedure Act and other applicable  
5 laws.

6 7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and  
7 every right set forth above.

#### 8 CULPABILITY

9 8. Respondent understands that the charges and allegations in First Amended  
10 Accusation No. 5041, if proven at a hearing, constitute cause for imposing discipline upon his  
11 Pharmacist License.

12 9. For the purpose of resolving the First Amended Accusation without the expense and  
13 uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could  
14 establish a factual basis for the charges in the First Amended Accusation and that those charges  
15 constitute cause for discipline. Respondent hereby gives up his right to contest that cause for  
16 discipline exists based on those charges.

17 10. Respondent understands that by signing this stipulation he enables the Board to issue  
18 an order accepting the surrender of her Pharmacist License without further process.

#### 19 CONTINGENCY

20 11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent  
21 understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may  
22 communicate directly with the Board regarding this stipulation and surrender, without notice to or  
23 participation by Respondent or his counsel. By signing the stipulation, Respondent understands  
24 and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the  
25 time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its  
26 Decision and Order, the Stipulated Surrender and Disciplinary Order shall be of no force or  
27 effect, except for this paragraph, it shall be inadmissible in any legal action between the parties,  
28 and the Board shall not be disqualified from further action by having considered this matter.

1           12. The parties understand and agree that Portable Document Format (PDF) and facsimile  
2 copies of this Stipulated Surrender of License and Order, including Portable Document Format  
3 (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

4           13. This Stipulated Surrender of License and Order is intended by the parties to be an  
5 integrated writing representing the complete, final, and exclusive embodiment of their agreement.  
6 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,  
7 negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order  
8 may not be altered, amended, modified, supplemented, or otherwise changed except by a writing  
9 executed by an authorized representative of each of the parties.

10           14. In consideration of the foregoing admissions and stipulations, the parties agree that  
11 the Board may, without further notice or formal proceeding, issue and enter the following Order:

12    **ORDER**

13           IT IS HEREBY ORDERED that Pharmacist License No. RPH 57834, issued to Respondent  
14 Mayank Parimal Shah, is surrendered and accepted by the Board of Pharmacy.

15           1. The surrender of Respondent's Pharmacist License and the acceptance of the  
16 surrendered license by the Board shall constitute the imposition of discipline against Respondent.  
17 This stipulation constitutes a record of the discipline and shall become a part of Respondent's  
18 license history with the Board of Pharmacy.

19           2. Respondent shall lose all rights and privileges as a pharmacist in California as of the  
20 effective date of the Board's Decision and Order.

21           3. Respondent shall cause to be delivered to the Board his pocket license and, if one was  
22 issued, his wall certificate on or before the effective date of the Decision and Order.

23           4. If he ever applies for licensure or petitions for reinstatement in the State of California,  
24 the Board shall treat it as a new application for licensure. Respondent must comply with all the  
25 laws, regulations and procedures for licensure in effect at the time the application or petition is  
26 filed, and all of the charges and allegations contained in First Amended Accusation No. 5041  
27 shall be deemed to be true, correct and admitted by Respondent when the Board determines  
28 whether to grant or deny the application or petition.

- 1           5. If Respondent should ever apply or reapply for a new license or certification, or
- 2 petition for reinstatement of a license, by any other health care licensing agency in the State of
- 3 California, all of the charges and allegations contained in First Amended Accusation No. 5041
- 4 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement
- 5 of Issues or any other proceeding seeking to deny or restrict licensure.
- 6           6. Respondent shall be prohibited from owning, having any legal or beneficial interest
- 7 in, or serving as a manager, administrator, member, officer, director, trustee, associate, or partner
- 8 of any business, firm, partnership, or corporation currently or hereinafter licensed by the board
- 9 until his license is reinstated or his application for a new license is approved.
- 10          7. Respondent may not apply, reapply, or petition for any licensure or registration of the
- 11 Board for three (3) years from the effective date of the Decision and Order.

ACCEPTANCE

12           I have carefully read the above Stipulated Surrender of License and Order and have fully

13 discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it

14 will have on my Pharmacist License. I enter into this Stipulated Surrender of License and Order

15 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the

16 Board of Pharmacy.

17

18

19 DATED: 7/15/2015 

20 MAYANK PARIMAL SHAH  
Respondent

21           I have read and fully discussed with Respondent Mayank Parimal Shah the terms and

22 conditions and other matters contained in this Stipulated Surrender of License and Order. I

23 approve its form and content.

24 DATED: 7/15/2015 

25 HERBERT L. WEINBERG  
Attorney for Respondent Mayank Parimal Shah



ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 2/16/15

Respectfully submitted,

KAMALA D. HARRIS  
Attorney General of California  
GREGORY J. SALUTE  
Supervising Deputy Attorney General

DESIREE I. KELLOGG  
Deputy Attorney General  
*Attorneys for Complainant*

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**Exhibit A**

**First Amended Accusation No. 5041**

1 KAMALA D. HARRIS  
Attorney General of California  
2 GREGORY J. SALUTE  
Supervising Deputy Attorney General  
3 DESIREE I. KELLOGG  
Deputy Attorney General  
4 State Bar No. 126461  
110 West "A" Street, Suite 1100  
5 San Diego, CA 92101  
P.O. Box 85266  
6 San Diego, CA 92186-5266  
Telephone: (619) 645-2996  
7 Facsimile: (619) 645-2061  
*Attorneys for Complainant*

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**BOARD OF PHARMACY**  
10 **DEPARTMENT OF CONSUMER AFFAIRS**  
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11 In the Matter of the Accusation Against:

Case No. 5041

12 **CREATIVE COMPOUNDS INC.,**  
13 **DBA HARBOR COMPOUNDING AND HOME**  
**HEALTH CARE PHARMACY**  
14 **2000 Harbor Blvd., Ste. C-100**  
**Costa Mesa, CA 92627**

**FIRST AMENDED ACCUSATION**

15 **Pharmacy Permit No. PHY 50397**

16 **CREATIVE COMPOUNDS INC.,**  
17 **DBA HARBOR COMPOUNDING PHARMACY**  
**2000 Harbor Blvd., Ste. C-100**  
18 **Costa Mesa, CA 92627**

19 **Licensed Sterile Compounding Permit No. 99688**

20 **MAYANK PARIMAL SHAH**  
**P.O. Box 65**  
21 **Downey, CA 90241**

22 **Pharmacist License No. RPH 57834**

23 **MICHAEL CAN HUA**  
**37255 Tomasek Terrace**  
24 **Fremont, CA 94536**

25 **Pharmacist License No. RPH 61291**

26 Respondents.

1 Complainant alleges:

2 **PARTIES**

3 1. Virginia Herold (Complainant) brings this First Amended Accusation solely in her  
4 official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer  
5 Affairs.

6 2. On or about August 25, 2010, the Board of Pharmacy issued Pharmacy Permit  
7 Number PHY 50397 to a corporate entity, Creative Compounds Inc., dba Harbor Compounding  
8 and Home Health Care Pharmacy (Respondent Harbor Compounding and Home Health Care  
9 Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges  
10 brought herein and will expire on August 1, 2015, unless renewed.

11 3. On or about July 15, 2011, the Board of Pharmacy issued Licensed Sterile  
12 Compounding Permit Number 99688 to a corporate entity, Creative Compounds Inc., doing  
13 business as Harbor Compounding Pharmacy (Respondent Harbor Compounding Pharmacy). The  
14 Licensed Sterile Compounding Permit was in full force and effect at all times relevant to the  
15 charges brought herein and will expire on August 1, 2015, unless renewed.

16 4. On or about November 10, 2005, the Board of Pharmacy issued Pharmacist License  
17 Number RPH 57834 to Mayank Parimal Shah (Respondent Mike Shah). The Pharmacist License  
18 was in full force and effect at all times relevant to the charges brought herein and will expire on  
19 August 31, 2015, unless renewed.

20 5. On or about August 6, 2008, the Board of Pharmacy issued Pharmacist License  
21 Number RPH 61291 to Michael Can Hua (Respondent Michael Hua). The Pharmacist License  
22 was in full force and effect at all times relevant to the charges brought herein and will expire on  
23 June 30, 2016, unless renewed.

24 **JURISDICTION**

25 6. This First Amended Accusation is brought before the Board of Pharmacy (Board),  
26 Department of Consumer Affairs, under the authority of the following laws. All section  
27 references are to the Business and Professions Code unless otherwise indicated.

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

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

6 9. Section 4300.1 of the Code states:

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

### 10 STATUTORY PROVISIONS

11 10. Section 4022 of the Code states:

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

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

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

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

22 11. Section 4110(a) of the Code states:

23 No person shall conduct a pharmacy in the State of California unless he or  
24 she has obtained a license from the board. A license shall be required for each  
25 pharmacy owned or operated by a specific person. A separate license shall be  
26 required for each of the premises of any person operating a pharmacy in more than  
27 one location. The license shall be renewed annually. The board may, by regulation,  
28 determine the circumstances under which a license may be transferred.

12. 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.

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13. 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.

14. Sections 4201(a) and (b)(2) of the Code states:

Each application to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.

As used in this section, and subject to subdivision (c), the term "beneficially interested" means and includes:

...

If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

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:

....

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

....

(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.

....

1 16. Section 4302 of the Code states:

2 The board may deny, suspend, or revoke any license of a corporation where  
3 conditions exist in relation to any person holding 10 percent or more of the corporate  
4 stock of the corporation, or where conditions exist in relation to any officer or  
5 director of the corporation that would constitute grounds for disciplinary action  
6 against a licensee.

7 17. Section 4307(a) of the Code states that:

8 Any person who has been denied a license or whose license has been revoked  
9 or is under suspension, or who has failed to renew his or her license while it was  
10 under suspension, or who has been a manager, administrator, owner member, officer,  
11 director, associate, or partner of any partnership, corporation, firm, or association  
12 whose application for a license has been denied or revoked, is under suspension or  
13 has been placed on probation, and while acting as the manger, administrator, owner,  
14 member, officer, director, associate, or partner had knowledge or knowingly  
15 participated in any conduct for which the license was denied, revoked, suspended, or  
16 placed on probation, shall be prohibited from serving as a manger, administrator,  
17 owner, member, officer, director, associate, or partner of a licensee as follows:

18 (1) Where a probationary license is issued or where an existing license is placed  
19 on probation, this prohibition shall remain in effect for a period not to exceed five  
20 years.

21 (2) Where the license is denied or revoked, the prohibition shall continue until  
22 the license is issued or reinstated.

23 **REGULATORY PROVISIONS**

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

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

- 28 (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

...

19. 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

1 subsection may be sued if it is deemed appropriate in the professional judgment of the  
2 responsible pharmacist.

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

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

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

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

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

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

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

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

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

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

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

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

28 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

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

1 **DRUGS**

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

5 26. Estradiol Pellets are dangerous drugs pursuant to Business and Professions Code  
6 section 4022.

7 **FACTUAL ALLEGATIONS**

8 27. On or about July 19, 2010, on behalf of Respondent Harbor Compounding and Home  
9 Health Care Pharmacy, Rebecca Rodriguez-Torres, Respondent Mike Shah and Respondent  
10 Michael Hua submitted an application for a pharmacy permit. The application stated that “any  
11 material misrepresentation in the answer of any question is grounds for refusal or subsequent  
12 revocation of a license, and is a violation of the Penal Code of California.” Respondent Michael  
13 Hua and Rebecca Rodriguez-Torres certified under penalty of perjury under the laws of the State  
14 of California that each and all statements made in the application and supplemental statements  
15 were true and that no person other than the applicants had any direct or indirect interest in the  
16 applicants’ business. In the application, Respondent Mike Shah, Respondent Michael Hua and  
17 Rebecca Rodriguez-Torres identified Rebecca Rodriguez-Torres as a seventy-nine percent owner  
18 and Respondent Michael Hua as a twenty-one percent owner of Respondent Harbor  
19 Compounding and Health Care Pharmacy. Respondent Mike Shah was not identified as an owner  
20 when in fact, Mike Shah was an owner of Harbor Compounding and Home Health Care  
21 Pharmacy and has been operating that pharmacy in his capacity as an owner.

22 28. On or about April 11, 2011, Rebecca Rodriguez-Torres, Respondent Mike Shah and  
23 Respondent Michael Hua submitted an application for a sterile compounding license in  
24 connection with their pharmacy permit. The application stated that “any material  
25 misrepresentation in the answer of any question is grounds for refusal or subsequent revocation of  
26 a license, and is a violation of the Penal Code of California.” Respondent Michael Hua certified  
27 under penalty of perjury under the laws of the State of California that each and all statements  
28 made in the application and supplemental statements were true and that no person other than the



1 applicant has any direct or indirect interest in the applicant's business. He also acknowledged  
2 that any falsification of any information in this application may constitute grounds for denial or  
3 subsequent revocation of license. Respondent Mike Shah was not identified as an owner of  
4 Respondent Harbor Compounding Pharmacy.

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

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

11 31. In August 2012, Respondents tested compounded sample numbers W-1-136, W-1-  
12 150 and W-1-151 of testosterone pellets for potency, but not for sterility and endotoxins. In  
13 November 2012, Respondents tested compounded sample W-1-193 of estradiol pellets for  
14 potency and sterility but not for endotoxins.

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

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

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

1 35. Respondents compounded drug products with expired chemical ingredients in June  
2 2013 and assigned beyond use dates which exceeded the shortest expiration date of components  
3 used to compound drugs.

4 36. Respondents compounded sterile injectable products, namely testosterone and  
5 estradiol pellets, but failed to perform the compounding in either: (a) an ISO class 5 laminar  
6 airflow hood within an ISO class 7 cleanroom with a positive air pressure differential relative to  
7 the adjacent areas; (b) an ISO class 5 cleanroom or (c) a barrier isolator that provides an ISO class  
8 5 environment for compounding.

9 **FIRST CAUSE FOR DISCIPLINE**

10 **(Allowing Pharmacy Technicians to Compound Without Direct Supervision of Pharmacist**  
11 **against Respondents Harbor Compounding and Home Health Care Compounding**  
12 **Pharmacy, Harbor Compounding Pharmacy and Michael Hua)**

13 37. Respondents are subject to disciplinary action under Code section 4301(o), for  
14 violating title 16, California Code of Regulations, section 1793.7(b), in that they allowed  
15 pharmacy technicians to compound drug products when they were not under the direct  
16 supervision of a pharmacist, as set forth in paragraphs 26 through 36, which are incorporated  
17 herein by reference.

18 **SECOND CAUSE FOR DISCIPLINE**

19 **(Allowing Untrained Staff to Perform Compounding against Respondents Harbor**  
20 **Compounding and Home Health Care Compounding Pharmacy, Harbor Compounding**  
21 **Pharmacy and Michael Hua )**

22 38. Respondents are subject to disciplinary action under Code section 4301(o), for  
23 violating title 16, California Code of Regulations, section 1735.7(a), in that they allowed an  
24 untrained pharmacy technician and an intern pharmacist to compound drug products and did not  
25 possess the records necessary to demonstrate that this untrained staff had the skills and training  
26 necessary to compound drug products, as set forth in paragraphs 26 through 36, which are  
27 incorporated herein by reference.

28

1 THIRD CAUSE FOR DISCIPLINE

2 (Failure to Clean Compounding Equipment and Maintain Cleaning Records against  
3 Respondents Harbor Compounding and Home Health Care Compounding Pharmacy,  
4 Harbor Compounding Pharmacy and Michael Hua )

5 39. Respondents are subject to disciplinary action under Code section 4301(o), for  
6 violating title 16, California Code of Regulations, section 1735.5(e), in that they did not  
7 document the cleaning, maintenance, storing, calibrating and disinfecting of the compounding  
8 equipment and maintain the records necessary to show that they cleaned such equipment, as set  
9 forth in paragraphs 26 through 36, which are incorporated herein by reference.

10 FOURTH CAUSE FOR DISCIPLINE

11 (Using Expired Chemical Ingredients to Compound Drug Products and Assigning  
12 Improper Beyond Use Dates against Respondents Harbor Compounding and Home Health  
13 Care Compounding Pharmacy, Harbor Compounding Pharmacy and Michael Hua)

14 40. Respondents are subject to disciplinary action under Code section 4301(o), for  
15 violating title 16, California Code of Regulations, section 1735.2(h), in that they used expired  
16 chemical ingredients to compound drug products and assigned beyond use dates which exceeded  
17 the shortest expiration date of components in the compounded drugs, as set forth in paragraphs 26  
18 through 36, which are incorporated herein by reference.

19 FIFTH CAUSE FOR DISCIPLINE

20 (Failure to Compound Sterile Injectable Drugs in Authorized Environment against  
21 Respondents Harbor Compounding and Home Health Care Compounding Pharmacy,  
22 Harbor Compounding Pharmacy and Michael Hua)

23 41. Respondents are subject to disciplinary action under Code section 4301(o), for  
24 violating Business and Professions Code section 4127.7, in that on or about June 2013, they  
25 compounded sterile injectable drugs from non-sterile ingredients, in an environment which was  
26 not authorized by law, as set forth in paragraphs 26 through 36, which are incorporated herein by  
27 reference.  
28

1 SIXTH CAUSE FOR DISCIPLINE

2 (Failure to Properly Test Sterile Injectable Drug Products against Respondents Harbor  
3 Compounding and Home Health Care Compounding Pharmacy, Harbor Compounding  
4 Pharmacy and Michael Hua)

5 42. Respondents are subject to disciplinary action under Code section 4301(o), for  
6 violating title 16, California Code of Regulations, section 1751.7(c), in that they failed to properly  
7 test certain samples of testosterone and estradiol pellets, as set forth in paragraphs 26 through 36,  
8 which are incorporated herein by reference.

9 SEVENTH CAUSE FOR DISCIPLINE

10 (Commission of Act Involving Dishonesty, Fraud, Deceit or Corruption against  
11 Respondents Mike Shah and Michael Hua)

12 43. Respondents Mike Shah and Michael Hua are subject to disciplinary action under  
13 Code section 4301(f), for committing acts involving dishonesty, fraud, deceit or corruption, as set  
14 forth in paragraphs 26 through 36, which are incorporated herein by reference.

15 EIGHTH CAUSE FOR DISCIPLINE

16 (Operating a Pharmacy Without a License Against Respondent Mike Shah)

17 44. Respondent Mike Shah is subject to disciplinary action under Code section 4301(o),  
18 for violating Business and Professions Code section 4110(a), in that he operated a pharmacy  
19 without a permit, as set forth in paragraphs 26 through 36, which are incorporated herein by  
20 reference.

21 NINTH CAUSE FOR DISCIPLINE

22 (Failure to Disclose All Owners on Applications Against Respondents)

23 45. Respondents are subject to disciplinary action under Code section 4301(o), for  
24 violating Business and Professions Code section 4201(b)(2), in that they hid the true ownership of  
25 Respondents Harbor Compounding and Home Health Care Pharmacy and Harbor Compounding  
26 Pharmacy by failing to disclose that Respondent Mike Shah was an owner and by representing  
27 that Rebecca Rodriguez-Torres was the majority owner, as set forth in paragraphs 26 through 36,  
28 which are incorporated herein by reference.

1 TENTH CAUSE FOR DISCIPLINE

2 (Misconduct by Owners and/or Corporate Officers Against Respondents Harbor  
3 Compounding and Home Health Care Pharmacy and Harbor Compounding Pharmacy)

4 46. Respondents Harbor Compounding and Home Health Care Pharmacy and Harbor  
5 Compounding Pharmacy are subject to disciplinary action under Code sections 4301(o) and 4302,  
6 in that a person holding more than ten percent of the stock of those corporations and corporate  
7 officers and directors engaged in conduct that constitutes grounds for disciplinary action, as set  
8 forth in paragraphs 26 through 36, which are incorporated herein by reference.

9 ELEVENTH CAUSE FOR DISCIPLINE

10 (Unprofessional Conduct)

11 47. Respondents are subject to disciplinary action under Code section 4301 for  
12 unprofessional conduct in that they engaged in the activities described in paragraphs 26 through  
13 36 above, which are incorporated herein by reference.

14 OTHER MATTERS

15 48. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number  
16 PHY 50397 and Sterile Compounding License Number LSC 99688 issued to Creative  
17 Compounds Inc., dba Harbor Compounding and Home Health Care Pharmacy and Harbor  
18 Compounding Pharmacy, they shall be prohibited from serving as a manager, administrator,  
19 owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy  
20 Permit Number PHY 50397 and Sterile Compounding License Number LSC 99688 are placed  
21 on probation or until Pharmacy Permit Number PHY 50397 and Sterile Compounding License  
22 Number LSC 99688 are reinstated if they are revoked.

23 49. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit  
24 Number PHY 50397 and Sterile Compounding License Number LSC 99688 issued to Creative  
25 Compounds Inc., dba Harbor Compounding and Home Health Care Pharmacy and Harbor  
26 Compounding Pharmacy, while Mayank Parimal Shah has been an officer and owner and had  
27 knowledge of or knowingly participated in any conduct for which the licensee was disciplined,  
28 Mayank Parimal Shah shall be prohibited from serving as a manager, administrator, owner,

1 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit  
2 Number PHY 50397 and Sterile Compounding License Number LSC 99688 are placed on  
3 probation or until Pharmacy Permit Number PHY 50397 and Sterile Compounding License  
4 Number LSC 99688 are reinstated if they are revoked.

5 50. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit  
6 Number PHY 50397 and Sterile Compounding License Number LSC 99688 issued to Creative  
7 Compounds Inc., dba Harbor Compounding and Home Health Care Pharmacy and Harbor  
8 Compounding Pharmacy, while Michael Can Hua has been an officer and owner and had  
9 knowledge of or knowingly participated in any conduct for which the licensee was disciplined,  
10 Michael Can Hua shall be prohibited from serving as a manager, administrator, owner, member,  
11 officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number  
12 PHY 50397 and Sterile Compounding License Number LSC 99688 are placed on probation or  
13 until Pharmacy Permit Number PHY 50397 and Sterile Compounding License Number LSC  
14 99688 are reinstated if they are revoked.

15 51. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License  
16 No. RPH 57834 issued to Mayank Parimal Shah, Mayank Parimal Shah shall be prohibited from  
17 serving as a manager, administrator, owner, member, officer, director, associate, or partner of a  
18 licensee for five years if Pharmacist License Number RPH 57834 is placed on probation or until  
19 Pharmacist License Number RPH 57834 is reinstated if it is revoked.

20 52. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License  
21 No. RPH 61291 issued to Michael Can Hua, Michael Can Hua shall be prohibited from serving  
22 as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee  
23 for five years if Pharmacist License Number RPH 61291 is placed on probation or until  
24 Pharmacist License Number RPH 61291 is reinstated if it is revoked.

#### 25 **DISCIPLINARY CONSIDERATIONS**

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

28

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

5 b. On July 5, 2013, the Board issued Citation number CI 2012 57447 against  
6 Respondent Michael Hua for violating title 16, California Code of Regulations, sections  
7 1735.4(d), 1751.7(c) and 1735.3(a) for improper compounding. The Board issued a fine which  
8 Respondent has paid.

9 **PRAYER**

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

12 1. Revoking or suspending Pharmacy Permit Number PHY 50397, issued to Creative  
13 Compounds Inc., dba Harbor Compounding and Home Health Care Pharmacy;

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

16 3. Revoking or suspending Pharmacist License Number RPH 57834, issued to Mayank  
17 Parimal Shah;

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

20 5. Prohibiting Creative Compounds Inc., dba as Harbor Compounding and Home  
21 Health Care Pharmacy and Harbor Compounding Pharmacy from serving as a manager,  
22 administrator, owner, member, officer, director, associate, or partner of a licensee for five years  
23 if Pharmacy Permit Number PHY 50397 and Sterile Compounding License Number LSC 99688  
24 are placed on probation or until Pharmacy Permit Number PHY 50397 and Sterile Compounding  
25 License Number LSC 99688 are reinstated if Pharmacy Permit Number PHY 50397 and Sterile  
26 Compounding License Number LSC 99688 issued to Creative Compounds Inc., dba as Harbor  
27 Compounding and Home Health Care Pharmacy and Harbor Compounding Pharmacy are  
28 revoked;

1           6. Prohibiting Mayank Parimal Shah from serving as a manager, administrator, owner,  
2 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit  
3 Number PHY 50397 and Sterile Compounding License Number LSC 99688 are placed on  
4 probation or until Pharmacy Permit Numbers PHY 50397 and Sterile Compounding License  
5 Number LSC 99688 are reinstated if Pharmacy Permit Number PHY 50397 and Sterile  
6 Compounding License Number LSC 99688 issued to Creative Compounds Inc., dba as Harbor  
7 Compounding and Home Health Care Pharmacy and Harbor Compounding Pharmacy are  
8 revoked;

9           7. Prohibiting Michael Can Hua from serving as a manager, administrator, owner,  
10 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit  
11 Number PHY 50397 and Sterile Compounding License Number LSC 99688 are placed on  
12 probation or until Pharmacy Permit Number PHY 50397 and Sterile Compounding License  
13 Number LSC 99688 are reinstated if Pharmacy Permit Number PHY 50397 and Sterile  
14 Compounding License Number LSC 99688 issued to Creative Compounds Inc., dba as Harbor  
15 Compounding and Home Health Care Pharmacy and Harbor Compounding Pharmacy are  
16 revoked;

17           8. Prohibiting Mayank Parimal Shah from serving as a manager, administrator, owner,  
18 member, officer, director, associate, or partner of a licensee for five years if Pharmacist License  
19 Number RPH 57834 is placed on probation or until Pharmacist License Number RPH 44796 is  
20 reinstated if Pharmacist License Number RPH 57834 issued to Mayank Parmil Shah is revoked;

21           9. Prohibiting Michael Can Hua from serving as a manager, administrator, owner,  
22 member, officer, director, associate, or partner of a licensee for five years if Pharmacist License  
23 Number RPH 61291 is placed on probation or until Pharmacist License Number RPH 44796 is  
24 reinstated if Pharmacist License Number RPH 61291 issued to Michael Can Hua Shah is  
25 revoked;

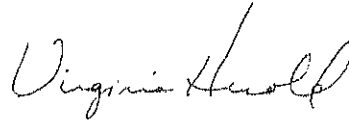
26           10. Ordering Creative Compounds Inc., dba Harbor Compounding and Home Health  
27 Care Pharmacy, Creative Compounds Inc., doing business as Harbor Compounding Pharmacy,  
28 Mayank Parimal Shah and Michael Can Hua to pay the Board of Pharmacy the reasonable costs



1 of the investigation and enforcement of this case, pursuant to Business and Professions Code  
2 section 125.3;

3 11. Taking such other and further action as deemed necessary and proper.

4 DATED: April 28, 2015

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7  
8 VIRGINIA HEROLD  
9 Executive Officer  
10 Board of Pharmacy  
11 Department of Consumer Affairs  
12 State of California  
13 *Complainant*

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