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

In the Matter of the Accusation Against:	Case No. 5041
CREATIVE COMPOUNDS INC.,	OAH No. 2014070068
DBA HARBOR COMPOUNDING AND	
HOME HEALTH CARE PHARMACY	STIPULATED SETTLEMENT AND
	DISCIPLINARY ORDER AS TO
Pharmacy Permit No. PHY 50397	MICHAEL CAN HUA ONLY
CREATIVE COMPOUNDS INC.,	
DBA HARBOR COMPOUNDING PHARMACY	
Licensed Sterile Compounding Permit No. 99688	
MAYANK PARIMAL SHAH	
Pharmacist License No. RPH 57834	
MICHAEL CAN HUA	

Pharmacist License No. RPH 61291

DECISION AND ORDER

Pursuant to the Board of Pharmacy's action on September 30, 2015, the attached

Stipulated Settlement and Disciplinary Order was adopted by the Board of Pharmacy,

Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective on November 9, 2015.

It is so ORDERED on October 9, 2015.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

Amy Gutierrez, Pharm.D. Board President

By

KAMALA D. HARRIS Attorney General of California	
GREGORY J. SALUTE	
Supervising Deputy Attorney General DESIREE I. KELLOGG	
Deputy Attorney General State Bar No. 126461	
600 West Broadway, Suite 1800	
San Diego, CA 92101 P.O. Box 85266	
San Diego, CA 92186-5266 Telephone: (619) 645-2996	
Facsimile: (619) 645-2061	
ttorneys for Complainant	
	RE THE PHARMACY
DEPARTMENT OF O	CONSUMER AFFAIRS CALIFORNIA
STATE OF	
In the Matter of the Accusation Against:	Case No. 5041
CREATIVE COMPOUNDS INC.,	OAH No. 2014070068
DBA HARBOR COMPOUNDING AND HOME HEALTH CARE PHARMACY	
2000 Harbor Blvd., Ste. C-100 Costa Mesa, CA 92627	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER (MICHAEL CAN HUA)
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	ſ
MAYANK PARIMAL SHAH	
P.O. Box 65 Downey, CA 90241	
Pharmacist License No. RPH 57834	
MICHAEL CAN HUA 37255 Tomasek Terrace	
Fremont, CA 94536	
Pharmacist License No. RPH 61291	
Respondents.	
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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. Respondent Michael Can Hua ("Respondent") is represented in this proceeding by
9	attorney Herbert L. Weinberg of Fenton Law Group, LLP whose address is: 1990 S. Bundy
10	Drive, Suite 777, Los Angeles, CA 90025.
11	3. On or about August 6, 2008, the Board of Pharmacy issued Pharmacist License No.
12	RPH 61291 to Michael Can Hua (Respondent). The Pharmacist License was in full force and
13	effect at all times relevant to the charges brought in First Amended Accusation No. 5041 and will
14	expire on June 30, 2016, 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.
21	5. A copy of First Amended Accusation No. 5041 is attached as exhibit A and
22	incorporated herein by reference.
23	ADVISEMENT AND WAIVERS
24	6. Respondent has carefully read, fully discussed with counsel, and understands the
25	charges and allegations in First Amended Accusation No. 5041. Respondent has also carefully
26	read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and
27	Disciplinary Order.
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7. Respondent is fully aware of his legal rights in this matter, including the right to a
 hearing on the charges and allegations in the First Amended Accusation; the right to confront and
 cross-examine the witnesses against him; the right to present evidence and to testify on his own
 behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the
 production of documents; the right to reconsideration and court review of an adverse decision;
 and all other rights accorded by the California Administrative Procedure Act and other applicable
 laws.

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

CULPABILITY

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

14 10. For the purpose of resolving the First Amended Accusation without the expense and
15 uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could
16 establish a factual basis for the charges in the First Amended Accusation, and that Respondent
17 hereby gives up his right to contest those charges.

18 11. Respondent agrees that his Pharmacist License is subject to discipline and he agrees
19 to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

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CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent
understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may
communicate directly with the Board regarding this stipulation and settlement, without notice to
or participation by Respondent or his counsel. By signing the stipulation, Respondent
understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation
prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation
as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or

effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

13. The parties understand and agree that Portable Document Format (PDF) and facsimile
 copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format
 (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

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

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 61291 issued to Respondent
Michael Can Hua (Respondent) is revoked. However, the revocation is stayed and Respondent is
placed on probation for five (5) years on the following terms and conditions.

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Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within
seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the
 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
 substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any
 criminal complaint, information or indictment
- a conviction of any crime

• discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

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2. **Report to the Board**

Respondent shall report to the board quarterly, on a schedule as directed by the board or its 7 designee. The report shall be made either in person or in writing, as directed. Among other 8 requirements, respondent shall state in each report under penalty of perjury whether there has g been compliance with all the terms and conditions of probation. Failure to submit timely reports 10 in a form as directed shall be considered a violation of probation. Any period(s) of delinquency 11 in submission of reports as directed may be added to the total period of probation. Moreover, if 12 the final probation report is not made as directed, probation shall be automatically extended until 13 such time as the final report is made and accepted by the board. 14

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3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews
with the board or its designee, at such intervals and locations as are determined by the board or its
designee. Failure to appear for any scheduled interview without prior notification to board staff,
or failure to appear for two (2) or more scheduled interviews with the board or its designee during
the period of probation, shall be considered a violation of probation.

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4. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's
monitoring and investigation of respondent's compliance with the terms and conditions of his
probation. Failure to cooperate shall be considered a violation of probation.

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5. Continuing Education

26 Respondent shall provide evidence of efforts to maintain skill and knowledge as a
27 pharmacist as directed by the board or its designee.

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6. Notice to Employers

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During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 5041 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

5 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of 6 respondent undertaking any new employment, respondent shall cause his direct supervisor, 7 pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's 8 tenure of employment) and owner to report to the board in writing acknowledging that the listed 9 individual(s) has/have read the decision in case number 5041, and terms and conditions imposed 10 thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) 11 submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service,
respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity
licensed by the board of the terms and conditions of the decision in case number 5041 in advance
of the respondent commencing work at each licensed entity. A record of this notification must be
provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he has read the decision in case number 5041 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

> "Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any

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position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall be jointly and severally liable with Creative Compounds Inc., dba Harbor Compounding and Home Health Care Pharmacy and Creative Compounds Inc., dba Harbor Compounding Pharmacy and shall pay to the board its costs of investigation and prosecution in the amount of \$12,262.00. Respondent shall make said payments in a payment plan to be approved by the Board.

9 There shall be no deviation from this schedule absent prior written approval by the board or
10 its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of
11 probation.

The filing of bankruptcy by respondent shall not relieve respondent of his responsibility to
 reimburse the board its costs of investigation and prosecution.

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Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

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9. Status of License

Respondent shall, at all times while on probation, maintain an active, current license with
the board, including any period during which suspension or probation is tolled. Failure to
maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time
during the period of probation, including any extensions thereof due to tolling or otherwise, upon
renewal or reapplication respondent's license shall be subject to all terms and conditions of this
probation not previously satisfied.

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10. License Surrender While on Probation/Suspension

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Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

9 Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to
10 the board within ten (10) days of notification by the board that the surrender is accepted.
11 Respondent may not reapply for any license from the board for three (3) years from the effective
12 date of the surrender. Respondent shall meet all requirements applicable to the license sought as
13 of the date the application for that license is submitted to the board, including any outstanding
14 costs.

11. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

12. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met.

During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, 4 respondent must notify the board in writing within ten (10) days of the cessation of practice, and 5 must further notify the board in writing within ten (10) days of the resumption of practice. Any 6 7° failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the 8 provisions of this condition for a total period, counting consecutive and non-consecutive months, 9 exceeding thirty-six (36) months. 10

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

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13. **Violation of Probation**

If a respondent has not complied with any term or condition of probation, the board shall 17 have continuing jurisdiction over respondent, and probation shall automatically be extended, until 18 all terms and conditions have been satisfied or the board has taken other action as deemed 19 appropriate to treat the failure to comply as a violation of probation, to terminate probation, and 20 to impose the penalty that was stayed. 21

If respondent violates probation in any respect, the board, after giving respondent notice 22 and an opportunity to be heard, may revoke probation and carry out the disciplinary order that 23 was stayed. Notice and opportunity to be heard are not required for those provisions stating that a 24 violation thereof may lead to automatic termination of the stay and/or revocation of the license. If 25 a petition to revoke probation or an accusation is filed against respondent during probation, the 26 board shall have continuing jurisdiction and the period of probation shall be automatically 27 extended until the petition to revoke probation or accusation is heard and decided. 28

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14. Completion of Probation

2 Upon written notice by the board or its designee indicating successful completion of 3 probation, respondent's license will be fully restored.

15. **Restricted Practice**

Respondent shall not prepare, oversee or participate in the preparation of compounded drug preparations until he submits proof satisfactory to the board that he has completed ten (10) hours of remedial education in the subject matter area of compounded drug preparations in a course approved by the board. Respondent shall submit proof satisfactory to the board of compliance with this term of probation. Failure to abide by this restriction or to timely submit proof to the board of compliance therewith shall be considered a violation of probation.

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16. **Remedial Education**

Respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education in the subject matter area of the preparation of compounded drug preparations. The program of remedial education shall consist of at least ten (10) hours at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a
violation of probation. The period of probation will be automatically extended until such
remedial education is successfully completed and written proof, in a form acceptable to the board,
is provided to the board or its designee.

Respondent shall be restricted from the practice of preparing compounded drug
preparations until the remedial education program has been successfully completed.

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17. No Ownership of Licensed Premises

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a
manager, administrator, member, officer, director, trustee, associate, or partner of any additional
business, firm, partnership, or corporation licensed by the board. If respondent currently owns or
has any legal or beneficial interest in, or serves as a manager, administrator, member, officer,
director, trustee, associate, or partner of any business, firm, partnership, or corporation currently

or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

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18. Consultant for Owner or Pharmacist-In-Charge

During the period of probation, respondent shall not supervise any intern pharmacist or 5 serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-6 charge of respondents Creative Compounds Inc., doing business as Harbor Compounding and 7 Home Health Care Pharmacy and Harbor Compounding Pharmacy. If during the period of 8 probation respondent serves as the pharmacist-in-charge of Creative Compounds Inc., doing 9 business as Harbor Compounding and Home Health Care Pharmacy and Harbor Compounding 10 Pharmacy, respondent shall submit to the board or its designee within thirty (30) days of the 11 effective date of this decision, for prior approval, the name of an expert in the preparation of 12 compounded drug preparations that shall then be retained by respondents Creative Compounds 13 Inc., doing business as Harbor Compounding and Home Health Care Pharmacy and Harbor 14 Compounding Pharmacy or respondent at their own expense as an independent consultant 15 responsible for reviewing pharmacy operations on a monthly basis during the period of probation 16 for compliance by respondents Creative Compounds Inc., doing business as Harbor 17 Compounding and Home Health Care Pharmacy and Harbor Compounding Pharmacy with state 18 and federal laws and regulations governing the practice of pharmacy and for compliance by 19 respondent with the obligations of a pharmacist-in-charge. The consultant shall not on probation 20 with the board. Respondent shall be responsible for ensuring that the consultant submits timely 21 reports. After twelve monthly reports have been submitted timely, respondent may request that 22 the board or its designee approve transition to quarterly review and reporting by the consultant. 23 Approval or denial of such transition shall be within the discretion of the board or its designee. 24 If an approved consultant is no longer able or willing to serve as a consultant for 25

respondent, respondent shall seek approval of a new consultant within thirty (30) days, and to
ensure timely reporting by the newly-approved consultant. Failure to timely seek approval of,
retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

1	19. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant
2	During the period of probation, respondent shall not supervise any intern pharmacist, be the
3	pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board
4	nor serve as a consultant unless otherwise specified in this order. Assumption of any such
5	unauthorized supervision responsibilities shall be considered a violation of probation.
6	20. Ethics Course
7	Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll
8	in a course in ethics, at respondent's expense, approved in advance by the board or its designee.
9	Failure to initiate the course during the first year of probation, and complete it within the second
10	year of probation, is a violation of probation.
11	Respondent shall submit a certificate of completion to the board or its designee within five
12	days after completing the course.
13	ACCEPTANCE
14	I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
15	discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it
16	will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary
17	Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order
18	of the Board of Pharmacy.
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20	DATED: 71515 111
21	MICHAEL CAN HUA Respondent
22	I have read and fully discussed with Respondent Michael Can Hua the terms and conditions
23	and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve
24	its form and content.
25	DATED: 1/15/2015
26	HERBERT L. WEINBERG Attorney for Respondent Michael Can Hua
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ļ	STIPULATED SETTLEMENT (5041)

1	END	ORSEMENT
2	The foregoing Stipulated Settlement an	d Disciplinary Order is hereby respectfully
3	submitted for consideration by the Board of F	Pharmacy.
4	7/11/10	
5	DATED:	Respectfully submitted,
6		KAMALA D. HARRIS Attorney General of California GREGORY J. SALUTE
7		GREGORY J. SALUTE Supervising Deputy Attorney General
8		
9		DestREE I. KELLOGG
10		Deputy Attorney General Attorneys for Complainant
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	,	STIPULATED SETTLEMENT (504)

Exhibit A

First Amended Accusation No. 5041

ļ		
1 2	KAMALA D. HARRIS Attorney General of California GREGORY J. SALUTE	-
3	Supervising Deputy Attorney General DESIREE 1. KELLOGG	
4	Deputy Attorney General State Bar No. 126461	
5	110 West "A" Street, Suite 1100 San Diego, CA 92101	
6	P.O. Box 85266	
7	San Diego, CA 92186-5266 Telephone: (619) 645-2996 Facsimile: (619) 645-2061	
8	Attorneys for Complainant	
° 9	BEFORE TH BOARD OF PHAR	
	DEPARTMENT OF CONSU	MER AFFAIRS
10	STATE OF CALIFO	
11	In the Matter of the Accusation Against:	Case No. 5041
12	CREATIVE COMPOUNDS INC.,	
13	DBA HARBOR COMPOUNDING AND HOME HEALTH CARE PHARMACY	FIRST AMENDED ACCUSATION
14 15	2000 Harbor Blvd., Ste. C-100 Costa Mesa, CA 92627	
16	Pharmacy Permit No. PHY 50397	
17	CREATIVE COMPOUNDS INC.,	
18	DBA HARBOR COMPOUNDING PHARMACY 2000 Harbor Blvd., Ste. C-100 Costa Mesa, CA 92627	
19		
20	Licensed Sterile Compounding Permit No. 99688 MAYANK PARIMAL SHAH	
20	P.O. Box 65	
21	Downey, CA 90241	
23	Pharmacist License No. RPH 57834	
23	MICHAEL CAN HUA 37255 Tomasek Terrace	
	Fremont, CA 94536	
25	Pharmacist License No. RPH 61291	
26	Respondents.	
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Complainant alleges:

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PARTIES

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

On or about August 25, 2010, the Board of Pharmacy issued Pharmacy Permit
Number PHY 50397 to a corporate entity, 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, 2015, unless renewed.

On or about July 15, 2011, the Board of Pharmacy issued Licensed Sterile
 Compounding Permit Number 99688 to a corporate entity, 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, 2015, unless renewed.

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

5. 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, 2016, unless renewed.

JURISDICTION

6. This First Amended 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.

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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 8	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
9	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.
10	STATUTORY PROVISIONS
11	10. Section 4022 of the Code states:
12 13	Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:
14 15	(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
16 17 18	(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.
19	(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.
20	11. Section 4110(a) of the Code states:
21	No person shall conduct a pharmacy in the State of California unless he or
22	she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be
23	required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation,
24	determine the circumstances under which a license may be transferred.
25	12. Section 4113, subdivision (c) of the Code states:
26	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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	Accusation

Accusation |

1	13. Section 4127.7 of the Code states:
2	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:
3 4	(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.
5	(b) An ISO class 5 cleanroom.
6	(c) A barrier isolator that provides an ISO class 5 environment for
7	compounding.
8	14. Sections 4201(a) and (b)(2) of the Code states:
9	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,
10	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
11	as to each person beneficially interested therein.
12	As used in this section, and subject to subdivision (c), the term "beneficially interested" means and includes:
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14 15	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
16	nonprofit corporation.
17	15. Section 4301 of the Code states in pertinent part:
18 19	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:
20	
21	(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
22	licensee or otherwise, and whether the act is a felony or misdemeanor or not.
23	••••
24	(o) Violating or attempting to violate, directly or indirectly, or assisting in or
25	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
26 27	pharmacy, including regulations established by the board or by any other state or federal regulatory agency.
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1	16. Section 4302 of the Code states:
2	The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate
3	stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action
4	against a licensee.
5	17. Section 4307(a) of the Code states that:
6	Any person who has been denied a license or whose license has been revoked
7	or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner member, officer, director, associate, or partner of any partnership, corporation, firm, or association
8	whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manger, administrator, owner,
9	member, officer, director, associate, or partner had knowledge or knowingly
10	participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manger, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:
11	
12	(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five
13	years.
14	(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.
- 1	DECULATORY PROVISIONS
15	REGULATORY PROVISIONS
15 16	18. Title 16, California Code of Regulations, section 1735(a) states in pertinent part:
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16 17	 18. 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
16 17 18	 18. 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:
16 17 18 19	 18. 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
16 17 18 19 20	 18. 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
16 17 18 19 20 21	 18. 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
16 17 18 19 20 21 22	 18. 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
 16 17 18 19 20 21 22 23 24 	 18. 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 19. Title 16, California Code of Regulations, section 1735.2(h) states: Every compounded drug product shall be given an expiration date representing
 16 17 18 19 20 21 22 23 24 25 	 18. 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 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
 16 17 18 19 20 21 22 22 23 	 18. 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 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
 16 17 18 19 20 21 22 23 24 25 26 	 18. 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 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

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1	subsection may be sued if it is deemed appropriate in the professional judgment of the responsible pharmacist.
2	20. Title 16, California Code of Regulations, section 1735.5(c) states:
3	(c) The policy and procedure manual shall include the following:
4	(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedures manual
5	(2) Documentation of a plan for recall of a dispensed compounded drug product
6 7	where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product;
, 8 , 9	(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.
10	(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
11	(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.
12	21. Title 16, California Code of Regulations, section 1735.7(a) states:
13	Any pharmacy engaged in compounding shall maintain written documentation
14 15	sufficient to demonstrate that the pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.
16	22. Title 16, California Code of Regulations, section 1751.7(c) states:
17	Batch-produced sterile injectable drug products compounded from one or more
18	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.
19	
20	23. Title 16, California Code of Regulations, section 1793.7(b) states:
21 22	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 patienties involved in the supervising and divergence of surdiageties including the
22	activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.
24	COST RECOVERY
25	24. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
26	administrative law judge to direct a licentiate found to have committed a violation or violations of
27	the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
28	enforcement of the case.
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	Accusation

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

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

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FACTUAL ALLEGATIONS

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

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

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

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

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

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

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

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33. 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.

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

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

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

FIRST CAUSE FOR DISCIPLINE

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

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

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SECOND CAUSE FOR DISCIPLINE

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

38. Respondents are subject to disciplinary action under Code section 4301(o), for 22 23 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 24 possess the records necessary to demonstrate that this untrained staff had the skills and training 25 necessary to compound drug products, as set forth in paragraphs 26 through 36, which are 26 incorporated herein by reference. 27

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(0), for
6	violating title 16, California Code of Regulations, section 1735.5(c), 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(0), 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(0), for
24	violating Business and Professions Code section 4127.7, in that on or about June 2013, they
2.5	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.
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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(0), 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 Disbonesty, 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(0),
.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.
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]	Accusation

TENTH CAUSE FOR DISCIPLINE

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(0) 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,		
	12		

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

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

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.

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

DISCIPLINARY CONSIDERATIONS

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

On July 5, 2013, the Board issued Citation number CI 2012 54273 against a. 1 Respondent Harbor Compounding and Home Health Care for violating title 16, California Code 2 of Regulations, sections 1735.4(d), 1751.7(c) and 1735.3(a) for improper compounding. The 3 Board issued a fine which Respondent has paid. 4 b. On July 5, 2013, the Board issued Citation number CI 2012 57447 against 5 Respondent Michael Hua for violating title 16, California Code of Regulations, sections 6 1735.4(d), 1751.7(c) and 1735.3(a) for improper compounding. The Board issued a fine which 7 Respondent has paid. 8 PRAYER 9 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, 10 and that following the hearing, the Board of Pharmacy issue a decision: 11 1. Revoking or suspending Pharmacy Permit Number PHY 50397, issued to Creative 12 Compounds Inc., dba Harbor Compounding and Home Health Care Pharmacy; 13 2. Revoking or suspending Licensed Sterile Compounding Permit Number 99688, 14 issued to Creative Compounds Inc., doing business as Harbor Compounding Pharmacy; 15 3. Revoking or suspending Pharmacist License Number RPH 57834, issued to Mayank 16 Parimal Shah: 17 4. Revoking or suspending Pharmacist License Number RPH 61291, issued to Michael 18 Can Hua; 19 5. Prohibiting Creative Compounds Inc., dba as Harbor Compounding and Home 20 Health Care Pharmacy and Harbor Compounding Pharmacy from serving as a manager, 21 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 are placed on probation or until Pharmacy Permit Number PHY 50397 and Sterile Compounding 24 License Number LSC 99688 are reinstated if Pharmacy Permit Number PHY 50397 and Sterile 25 Compounding License Number LSC 99688 issued to Creative Compounds Inc., dba as Harbor 26 Compounding and Home Health Care Pharmacy and Harbor Compounding Pharmacy are 27 28 revoked:

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

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

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

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

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

 section 125.3; 11. Taking such other and further ac DATED: April 28, 2015 DATED: April 28, 2015 SD2013706404/71067143.docx SD2013706404/71067143.docx SD2013706404/71067143.docx 	etion as deemed necessary and proper. Winginia Heroldo Executive Officer Board of Pharmacy Department of Consumer Affairs State of California Complainant
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