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

In the Matter of the Accusation Against:

UNIVERSITY RX SPECIALIST, DBA UNIVERSITY COMPOUNDING PHARMACY 1875 3RD Avenue San Diego, CA 92101

Pharmacy Permit No. PHY 45621 Sterile Compounding License No. LSC 99018

JOSEPH GRASELA 4767 Ocean Blvd., #1001 San Diego, CA 92109

Pharmacist License No. RPH 40868

Case No. 4347

OAH No. 2015020529

STIPULATED SETTLEMENT AND DISCIPLINARY ORDER

Respondents.

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is here by adopted by the Board of

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

This Decision shall become effective at 5:00 p.m. on April 1, 2016.

It is so ORDERED on March 2, 2016.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D. Board President

	,		
1	Kamala D. Harris		
2	Attorney General of California GREGORY J. SALUTE		
3	Supervising Deputy Attorney General DESIREE I. KELLOGG		
4	Deputy Attorney General State Bar No. 126461		
5	600 West Broadway, Suite 1800 San Diego, CA 92101		
6	P.O. Box 85266 San Diego, CA 92186-5266		
7	Telephone: (619) 645-2996 Facsimile: (619) 645-2061		
8	Attorneys for Complainant		
9	BEFORE THE		
10	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS		
11	STATE OF CALIFORNIA		
12	In the Matter of the Accusation Against: Case No. 4347		
13	UNIVERSITY RX SPECIALIST, OAH No. 2015020529		
14	DBA UNIVERSITY COMPOUNDING PHARMACY 1875 3rd Avenue		
15	San Diego, CA 92101 Pharmany Pormit No. DHV 45(21) STIPULATED SETTLEMENT AND DISCIPLINARY ORDER		
16	Pharmacy Permit No. PHY 45621 Sterile Compounding License No. LSC 99018		
17	and		
18	JOSEPH GRASELA		
19	4767 Ocean Blvd., #1001 San Diego, CA 92109		
20			
21	Pharmacist License No. RPH 40868		
22	Respondents.		
23			
24	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-		
25	entitled proceedings that the following matters are true:		
26	<u>PARTIES</u> 1. Virginia Herold ("Complainant") is the Executive Officer of the Decul. (D)		
27	Bring a constant (complement) is the Executive Officer of the Board of Pharmacy.		
28	She brought this action solely in her official capacity and is represented in this matter by Kamala		

STIPULATED SETTLEMENT (4347)

D. Harris, Attorney General of the State of California, by Desiree I. Kellogg, Deputy Attorney General.

Respondents University RX Specialist, dba University Compounding Pharmacy and
 Joseph Grasela ("Respondents") are represented in this proceeding by attorney Tony J. Park,
 Pharm.D., J.D., whose address is: 2855 Michelle Drive, Suite 180, Irvine, CA, 92606-1027.

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3. On or about March 31, 1987, the Board of Pharmacy issued Pharmacist License No. RPH 40868 to Joseph Grasela (Respondent Joseph Grasela). The Pharmacist License was in full force and effect at all times relevant to the charges brought in Accusation No. 4347 and will expire on November 30, 2016, unless renewed.

4. On or about August 23, 2002, the Board of Pharmacy issued Pharmacy Permit
 Number PHY 45621 to University RX Specialist, doing business as University Compounding
 Pharmacy (Respondent UCP) with Joseph Grasela as the President and Pharmacist-in-Charge.
 The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in
 Accusation No. 4347 and will expire on August 1, 2016, unless renewed.

5. On or about July 1, 2003, the Board of Pharmacy issued Sterile Compounding
 License Number LSC 99018 to University RX Specialist, doing business as University
 Compounding Pharmacy (Respondent UCP). The Sterile Compounding License was in full force
 and effect at all times relevant to the charges brought in Accusation No. 4347 and will expire on
 August 1, 2016, unless renewed.

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JURISDICTION

Accusation No. 4347 was filed before the Board of Pharmacy (Board), Department of
 Consumer Affairs, and is currently pending against Respondents. The Accusation and all other
 statutorily required documents were properly served on Respondents on January 15, 2015.
 Respondents timely filed its Notice of Defense contesting the Accusation. The Board filed First
 Amended Accusation on November 20, 2015.

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7. A copy of First Amended Accusation No. 4347 is attached as exhibit A and
27 incorporated herein by reference.

ADVISEMENT AND WAIVERS

8. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in First Amended Accusation No. 4347. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order.

9. Respondents are fully aware of their 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 them; the right to present evidence and to testify on their own 9 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: 10 and all other rights accorded by the California Administrative Procedure Act and other applicable 11 laws. 12

Respondents voluntarily, knowingly, and intelligently waive and give up each and 10. every right set forth above.

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CULPABILITY

11. Respondents understand and agree that the charges and allegations in First Amended 16 Accusation No. 4347, if proven at a hearing, constitute cause for imposing discipline upon their 17 18 Pharmacist License, Pharmacy Permit, and Sterile Compounding License.

12. For the purpose of resolving the First Amended Accusation without the expense and 19 20 uncertainty of further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual basis for the charges in the First Amended Accusation, and that Respondents 21 22 hereby give up their right to contest those charges.

Respondents agree that Pharmacist License No. RPH 40868, Pharmacy Permit No. 13. 23 PHY 45621, and Sterile Compounding License Number LSC 99018 are subject to discipline and 24 they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order 25 below. 26

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CONTINGENCY

This stipulation shall be subject to approval by the Board of Pharmacy. Respondents 14. understand and agree 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 Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw their agreement or seek to rescind the 6 stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this 7 stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of 8 no force or effect, except for this paragraph, it shall be inadmissible in any legal action between 9 the parties, and the Board shall not be disqualified from further action by having considered this 10 matter. 11

15. The parties understand and agree that Portable Document Format (PDF) and facsimile 12 copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile 13 signatures thereto, shall have the same force and effect as the originals. 14

15 16. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. 16 17 It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary 18 Order may not be altered, amended, modified, supplemented, or otherwise changed except by a 19 writing executed by an authorized representative of each of the parties. 20

17: In consideration of the foregoing admissions and stipulations, the parties agree that 21 22 the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order: 23

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DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 40868 to Joseph Grasela 25 26 (Respondent Joseph Grasela), Pharmacy Permit No. PHY 45621 issued to Respondent University 27 RX Specialist, dba University Compounding Pharmacy (Respondent UCP), and Sterile Compounding License Number LSC 99018 issued to University RX Specialist, doing business as 28

University Compounding Pharmacy (Respondent UCP) are revoked. However, the revocation is stayed and Respondents are placed on probation for four (4) years on the following terms and conditions.

1. Suspension

As part of probation, Respondent UCP's Sterile Compounding License Number LSC 99018 is suspended from compounding any nonsterile to sterile drug products beginning the effective date of this decision until the Board or it's representative has confirmed that all nonsterile to sterile compounding performed at Respondent UCP is done in compliance with the laws and regulations.

During the period of suspension, Respondent UCP shall not compound nonsterile to sterile products or dispense to patients, nonsterile to sterile drug products compounded by UCP. Failure to comply with this suspension shall be considered a violation of probation.

On or before the effective date of this decision, the Board or its representative will make best efforts to conduct an inspection(s) of Respondent's compliance with the laws and regulations.

2. Obey All Laws

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Respondents shall obey all state and federal laws and regulations.

18 Respondents shall report any of the following occurrences to the Board, in writing, within

19 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

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a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment

 \Box a conviction of any crime

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

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

3. Report to the Board

Respondents shall report to the Board quarterly, on a schedule as directed by the Board or 2 its designee. The report shall be made either in person or in writing, as directed. Among other 3 requirements, Respondents shall state in each report under penalty of perjury whether there has 4 been compliance with all the terms and conditions of probation. Failure to submit timely reports 5 in a form as directed shall be considered a violation of probation. Any period(s) of delinquency 6 in submission of reports as directed may be added to the total period of probation. Moreover, if 7 8 the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board. 9

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4. Interview with the Board

Upon receipt of reasonable prior notice, Respondents 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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5. Cooperate with Board Staff

17 Respondents shall cooperate with the Board's inspection program and with the Board's
18 monitoring and investigation of respondent's compliance with the terms and conditions of their
19 probation. Failure to cooperate shall be considered a violation of probation.

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6. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Respondents shall pay to the Board its costs of investigation and prosecution in the amount of \$20,000.00. Respondents shall be jointly and severally liable for payment of these costs. Commencing on the effective date of this Decision, Respondents shall make payments of \$1,000.00 per month until paid in full.

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

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The filing of bankruptcy by Respondents shall not relieve Respondents of their responsibility to reimburse the Board its costs of investigation and prosecution.

7. Probation Monitoring Costs

Respondents 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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8. Status of License

Respondents shall, at all times while on probation, maintain current licensure with the Board. Failure to maintain active, current licenses shall be considered a violation of probation.

If Respondent UCP submits an application to the Board, and the application is approved,
for a change of location, change of permit or change of ownership, the Board shall retain
continuing jurisdiction over the license, and Respondent UCP shall remain on probation as
determined by the Board.

If Respondents' licenses expire or are 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 Respondents' licenses shall be subject to all terms and conditions
of this probation not previously satisfied.

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9. Pharmacy Permit Surrender While on Probation/Suspension

Following the effective date of this decision, should Respondent UCP discontinue business, Respondents may tender the premises 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 UCP will no longer be subject to the terms and conditions of probation.

- Upon acceptance of the surrender, Respondent owner shall relinquish the premises wall and renewal license to the Board within ten (10) days of notification by the Board that the surrender is accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to Board guidelines and shall notify the Board of the records inventory transfer.
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Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the Board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days. 10

Respondent owner may not apply for any new licensure from the Board for three (3) years 11 from the effective date of the surrender. Respondent owner shall meet all requirements applicable 12 to the license sought as of the date the application for that license is submitted to the Board. 13

Respondent owner further stipulates that he or she shall reimburse the Board for its costs of 14 investigation and prosecution prior to the acceptance of the surrender. 15

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10. Pharmacist License Surrender While on Probation/Suspension

Following the effective date of this decision, should Respondent Joseph Grasela 17 cease practice due to retirement or health, or be otherwise unable to satisfy the terms and 18 conditions of probation, Respondent Joseph Grasela may tender his Pharmacist License to the 19 Board for surrender. The Board or its designee shall have the discretion whether to grant the 20 21 request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent Joseph Grasela will no longer be subject to 22 the terms and conditions of probation. This surrender constitutes a record of discipline and shall 23 become a part of the Respondent Joseph Grasela's license history with the Board. 24

25 Upon acceptance of the surrender, Respondent Joseph Grasela shall relinquish his pocket and wall license to the Board within ten (10) days of notification by the Board that the surrender 26 is accepted. Respondent Joseph Grasela may not reapply for any license from the Board for three 27 (3) years from the effective date of the surrender. Respondent Joseph Grasela shall meet all 28

requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

11. Notice to Employees

Respondent UCP shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. 6 If the notice required by this provision is posted, it shall be posted in a prominent place and shall 7 remain posted throughout the probation period. Respondent owner shall ensure that any 8 employees hired or used after the effective date of this decision are made aware of the terms and 9 conditions of probation by posting a notice, circulating a notice, or both. Additionally, 10 respondent owner shall submit written notification to the Board, within fifteen (15) days of the 11 effective date of this decision, that this term has been satisfied. Failure to submit such 12 notification to the Board shall be considered a violation of probation. 13

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

12. **Owners and Officers: Knowledge of the Law**

18 Respondent UCP shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten 19 20 percent (10%) or more of the interest in Respondent or Respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and 21 22 federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation. 23

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Posted Notice of Probation 13.

Respondent UCP shall prominently post a probation notice provided by the Board in a place 25 conspicuous and readable to the public. The probation notice shall remain posted during the 26 27 entire period of probation.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

14. Violation of Probation

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

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

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15. Completion of Probation

20 Upon written notice by the Board or its designee indicating successful completion of 21 probation, Respondents' licenses will be fully restored.

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16. Continuing Education

Respondent Joseph Grasela shall provide evidence of efforts to maintain skill and
knowledge as a pharmacist as directed by the Board or its designee.

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17. Notice to Employers

During the period of probation, Respondent Joseph Grasela shall notify all present and prospective employers of the decision in case number 4347 and the terms, conditions and restrictions imposed on Respondent Joseph Grasela by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent Joseph Grasela's undertaking any new employment, he shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 4347, and terms and conditions imposed thereby. It shall be Respondent Joseph Grasela's responsibility to ensure that 6 his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board. 7

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If Respondent Joseph Grasela works for or is employed by or through a pharmacy 8 employment service, he must notify his direct supervisor, pharmacist-in-charge, and owner at 9 every entity licensed by the Board of the terms and conditions of the decision in case number 10 4347 in advance of the Respondent Joseph Grasela commencing work at each licensed entity. A 11 record of this notification must be provided to the board upon request. 12

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen 13 (15) days of Respondent Joseph Grasela undertaking any new employment by or through a 14 pharmacy employment service, he shall cause his direct supervisor with the pharmacy 15 employment service to report to the Board in writing acknowledging that he has read the decision 16 in case number 4347 and the terms and conditions imposed thereby. It shall be Respondent 17 Joseph Grasela's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely 18 acknowledgment(s) to the Board. 19

20 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 21 22 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 position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

18. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant

During the period of probation, Respondent Joseph Grasela shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the Board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

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

Respondent Joseph Grasela 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 Joseph Grasela 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.

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20. Tolling of Probation

Except during periods of suspension, Respondent Joseph Grasela shall, at all times while on probation, be employed as a pharmacist in California for a minimum of thirty (30) 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 Joseph Grasela must nonetheless comply with all terms and conditions of probation.

Should Respondent Joseph Grasela, regardless of residency, for any reason (including
vacation) cease practicing as a pharmacist for a minimum of thirty (30) hours per calendar month
in California, he must notify the board in writing within ten (10) days of the cessation of practice,
and must further notify the board in writing within ten (10) days of the resumption of practice.
Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent Joseph Grasela's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and nonconsecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least thirty (30) 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 thirty (30) hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

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21. Remedial Education

Within sixty (60) days of the effective date of this decision, Respondent Joseph Grasela shall submit to the Board or its designee, for prior approval, an appropriate program of remedial education related to compounding and legal requirements. The program of remedial education shall consist of at least six (6) hours, which shall be completed within six (6) months at Respondent Joseph Grasela'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.

Following the completion of each course, the Board or its designee may require Respondent Joseph Grasela, at his own expense, to take an approved examination to test the respondent's knowledge of the course. If the Respondent Joseph Grasela does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

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22. No New Ownership of Licensed Premises

Respondent Joseph Grasela 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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23. Consultant for Owner or Pharmacist-In-Charge

During the period of probation, Respondent Joseph Grasela shall not supervise any intern 12 pharmacist or serve as a consultant to any entity licensed by the Board. Respondent Joseph 13 Grasela may be a pharmacist-in-charge at Respondent UCP only. However, if during the period 14 of probation Respondent Joseph Grasela serves as a pharmacist-in-charge at Respondent UCP, he 15 shall retain an independent consultant at his own expense who shall be responsible for reviewing 16 pharmacy operations on a monthly basis for compliance by Respondents with state and federal 17 laws and regulations governing the practice of pharmacy and for compliance by Respondent 18 Joseph Grasela with the obligations of a pharmacist-in-charge. The consultant shall be a 19 pharmacist licensed by and not on probation with the Board who has expertise in compounding 20 21 and whose name shall be submitted to the Board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. Respondent Joseph Grasela shall not be a 22 23 pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he is not the sole owner. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant 24 25 shall be considered a violation of probation.

During the period of probation, the Board or its designee, retains the discretion to reduce
the frequency of the pharmacist consultant's review of Respondent UCP's operations.

ACCEPTANCE

1 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully 2 discussed it with my attorney, Tony J. Park, Pharm.D., J.D. I understand the stipulation and the 3 effect it will have on my Pharmacist License No. RPH 40868, Pharmacy Permit No. PHY 45621, 4 and Sterile Compounding License Number LSC 99018. I enter into this Stipulated Settlement 5 and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the 6 Decision and Order of the Board of Pharmacy. 7 8 DATED: 9 IOSÉPH GRASELA, as an individual and as 10 authorized agent on behalf of UNIVERSITY RX SPECIALIST, DBA UNIVERSITY COMPOUNDING 11 PHARMACY Respondents 12 I have read and fully discussed with Respondents the terms and conditions and other 13 matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form 14 and content. 15 DATED: 16 Tony J. Park, Pharm.D., J.D. Attorney for Respondents 17 18 ENDORSEMENT 19 The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully 20 submitted for consideration by the Board of Pharmacy. 21 22 3115 Respectfully submitted, Dated: 23 Kamala D. Harris Attorney General of California 24 GREGORY J. SALUTE Supervising Deputy Attorney General 25 26 De - KELLOGG Deputy Attorney General 27 Attorneys for Complainant 28 SD201570029581210331.doc 15 STIPULATED SETTLEMENT (4347)

Exhibit A

Accusation No. 4347

1 2 3 4 5 6 7 8 9	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 Attorneys for Complainant BEFORE THE BOARD OF PHARMA DEPARTMENT OF CONSUME	ERAFFATRS
11	STATE OF CALIFOR	NIA
12	In the Matter of the Accusation Against:	Case No. 4347
13	UNIVERSITY RX SPECIALIST,	
14	DBA UNIVERSITY COMPOUNDING PHARMACY 1875 3rd Avenue San Diego, CA 92101	FIRST AMENDED ACCUSATION
15	Pharmacy Permit No. PHY 45621	
16	Sterile Compounding License No. LSC 99018	
17	and	
18	JOSEPH GRASELA 4767 Ocean Blvd., #1001 San Diego, CA 92109	
19	Pharmacist License No. RPH 40868	
20	Respondents.	
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Accusation

Complainant alleges:

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PARTIES

1. 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 March 31, 1987, the Board of Pharmacy issued Pharmacist License No.
 RPH 40868 to Joseph Grasela (Respondent Joseph Grasela). The Pharmacist License was in full
 force and effect at all times relevant to the charges brought herein and will expire on November
 30, 2016, unless renewed.

On or about August 23, 2002, the Board of Pharmacy issued Pharmacy Permit
 Number PHY 45621 to University RX Specialist, doing business as University Compounding
 Pharmacy (Respondent UCP) with Joseph Grasela as the President and Pharmacist-in-Charge.
 The Pharmacy Permit was in full force and effect at all times relevant to the charges brought.
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4. On or about July 1, 2003, the Board of Pharmacy issued Sterile Compounding
 License Number LSC 99018 to University RX Specialist, doing business as University
 Compounding Pharmacy (Respondent University Compounding Pharmacy). The Sterile
 Compounding License was in full force and effect at all times relevant to the charges brought
 herein and will expire on August 1, 2016, unless renewed.

JURISDICTION

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.

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

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

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1	8. Section 4300.1 of the Code states: The expiration cancellation for faiture or even in a state of the state		
2	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,		
3	ine placement of a license on a retired status or the voluntary summerder of a		
4	license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.		
5	STATUTORY PROVISIONS		
6	9. Section 4022 of the Code states:		
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8	Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:		
9	(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.		
11	(b) Any device that hears the statement: "Caution: federal law matrix of the		
12	device to sale by or on the order of a ""Rx only " or words of similar increased		
13	the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.		
14	(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.		
15 16	10. Section 4113, subdivision (c) of the Code states: "The pharmacist-in-charge shall be		
{	responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining		
17 18	to the practice of pharmacy."		
19	11. Section 4127.7 of the Code states:		
20	On or after July 1, 2005, a pharmacy shall compound sterile injectable products		
21	from one of more nonsterine ingredients in one of the following environments:		
22	(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.		
23	(b) An ISO class 5 cleanroom.		
24	(c) A barrier isolator that provides an ISO class 5 environment for compounding.		
25	12. Section 4301 of the Code states in pertinent part:		
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27	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		
28	misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:		
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Accusation

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

(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.

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

Any person who has been denied a license or whose license has been revoked 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 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, member, officer, director, associate, or partner had knowledge or knowingly 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:

(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 years.

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

14. Health and Safety Code section 110390 states:

It is unlawful for any person to disseminate any false advertisement of any food, drug, device or cosmetic. An advertisement is false if it is false or misleading in any particular.

.15. Health and Safety Code section 110403 states in pertinent part that:

It is unlawful for any person to advertise any drug or device represented to have any effect in any of the following conditions, disorders, or diseases:

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(aa) sexual impotence.

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Accusation

1	16. Health and Safety Code section 110405 states:
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3	An advertisement that is not unlawful under Section 110390 is not unlawful under Section 110403 if it is disseminated only to members of the medical, dental, pharmaceutical, or veteringry professions, sectors and sectors of the medical dental,
4	of these professions, or is disseminated only for the number of the scientific periodicals
	education by persons not commercially interested, directly or indirectly, in the sale of drugs or devices.
5	REGULATORY PROVISIONS
6	17. California Code of Regulations, title 16, section 1735(a):
7	states in pertinent part:
8	"Compounding" means any of the following activities occurring in a
9	licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:
10	(1) Altering the dosage form or delivery system of a drug
11	(2) Altering the strength of a drug
12	(3) Combining components or active ingredients
13	(4) Preparing a drug product from chemicals or bulk drug substances
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15	18. California Code of Regulations, title 16, section 1735.2(h) states:
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17	(h) Every compounded drug product shall be given an expiration date
18	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
19	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,
20	unless a longer date is supported by stability studies of finished drugs or compounded
21	drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
22	Jacomente en me responsible pllamlacist.
23	19. California Code of Regulations, title 16, section 1735.8 states:
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25	(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor
26	and ensure the integrity, potency, quality, and labeled strength of compounded drug products.
27	(b) The quality assurance plan shall include written procedures for verification,
28	monitoring, and review of the adequacy of the compounding process and shall also include written documentation of review of those processes by qualified pharmacy
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personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

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20. California Code of Regulations, title 16, section 1751.7(a)(4) states:¹

(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

COST RECOVERY

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

DRUGS

21 22. <u>Testosterone Pellets</u> and <u>Testosterone/Anastrozole Pellets</u> are Schedule III controlled
 substances pursuant to Health and Safety Code section 11056(f)(30) and dangerous drugs
 pursuant to Business and Professions Code section 4022.

24 23. <u>Estradiol Pellets</u> are dangerous drugs pursuant to Business and Professions Code
 25 section 4022.

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 ¹ California Code of Regulations, title 16, section 1751.8(a)(4), in effect at the time of the
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FACTUAL ALLEGATIONS

24. At all relevant times herein, Respondent Joseph Grasela was the Pharmacist-in-Charge of Respondent University Compounding Pharmacy.

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25. From 2012 through the present, Respondents have compounded and sold testosterone pellets, testosterone/anastroloze pellets and estradiol pellets, sterile injectable products, for use in the treatment of symptoms arising from Andropause and Menopause for implementation in the human body.

8 26. On the internet in 2012, Respondents advertised and represented that their 9 testosterone pellet therapy was "[c]onvenient and effective" and provided "continuous relief 10 from the symptoms of Andropause," including "loss of morning erection," "stronger libido" and 11 "stronger erections." This advertisement was disseminated to the general public.

27. On or about April 23, 2012, Respondents chose an expiration date of 365 days for the
testosterone pellets compounded with a cholesterol base, rather than a stearic acid base, without
possessing a written justification for the chosen expiration date or substantiated studies of
finished drugs or compounded drug products which used the same components and packaging
showing a longer date was supported.

From April 23, 2012 to the present, including after the filing of an accusation alleging 17 28. a violation of Business and Professions Code section 4127.7, Respondents have and continue to 18 compound (i.e., combined components or active ingredients) sterile injectable products, i.e., 19 testosterone pellets, estradiol pellets and testosterone/anastrozole pellets from non-sterile 20 ingredients, but failed to perform the compounding in either: (a) an ISO class 5 laminar airflow 21 hood within an ISO class 7 cleanroom with a positive air pressure differential relative to the 22 adjacent areas; (b) an ISO class 5 cleanroom or (c) a barrier isolator that provides an ISO class 5 23 environment for compounding. 24

25 29. In August and September 2015, the Federal Drug Administration conducted
26 inspections of University Compounding Pharmacy and issued a Form 483 against University
27 Compounding Pharmacy, making such observations as University Compounding Pharmacy
28 "failed to thoroughly conduct out of specification investigations with respect to sterility failure

found in three different batches of drug products," University Compounding Pharmacy's "aseptic processing areas are deficient regarding the system for monitoring environmental conditions," and University Compounding Pharmacy's "procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process."

FIRST CAUSE FOR DISCIPLINE

(Labeling Without Proper Expiration Dates for Sterile Injectable Drugs)

30. Respondents are subject to disciplinary action under Code section 4301(o), for violating title 16, California Code of Regulations, sections 1735.2(h) and 1751.7(a)(4) in that they labeled testosterone pellets, compounded in a cholesterol base with an expiration date of 365 days in the future, without possessing either a written justification for that chosen expiration date or substantiated studies of finished drugs or compounded drug products using the same components and packaging showing a longer date was supported, as set forth in paragraphs 22 through 29, which are incorporated herein by reference.

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SECOND CAUSE FOR DISCIPLINE

(Failure to Compound Sterile Injectable Drugs in Authorized Environment)

17 31. Respondents are subject to disciplinary action under Code section 4301(o), for
18 violating Business and Professions Code section 4127.7 in that from April 2012 through the
19 present, they compounded sterile injectable drugs, i.e., testosterone pellets, estradiol pellets and
20 testosterone/anastroloze pellets in an environment which was not authorized by law, as set forth
21 in paragraphs 22 through 29, which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(False Advertising)

32. Respondents are subject to disciplinary action under Code section 4301(j), for
violating Health and Safety Code sections 110390 and 110403 in that Respondents represented
and advertised an unapproved drug therapy, as having an effect on sexual impotence to the
general public, as set forth in paragraphs 22 through 29, which are incorporated herein by
reference.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

Respondents are subject to disciplinary action under Code section 4301 for 33. unprofessional conduct in that they engaged in the activities described in paragraphs 22 through 29 above, which are incorporated herein by reference.

OTHER MATTERS

34. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number 8 PHY 45621 and Sterile Compounding License Number LSC 99018 issued to University RX 9 Specialist, doing business as University Compounding Pharmacy, they shall be prohibited from 10 serving as a manager, administrator, owner, member, officer, director, associate, or partner of a 11 licensee for five years if Pharmacy Permit Number PHY 45621 and Sterile Compounding 12 License Number LSC 99018 are placed on probation or until Pharmacy Permit Number PHY 13 45621 and Sterile Compounding License Number LSC 99018 are reinstated if they are revoked. 14 35. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit 15 Number PHY 45621 and Sterile Compounding License Number LSC 99018 issued to University 16 RX Specialist, doing business as University Compounding Pharmacy, while Joseph Grasela has 17 been an officer and owner and had knowledge of or knowingly participated in any conduct for 18 which the licensee was disciplined, Joseph Grasela shall be prohibited from serving as a 19 manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 20 five years if Pharmacy Permit Number PHY 45621 and Sterile Compounding License Number 21 LSC 99018 are placed on probation or until Pharmacy Permit Number PHY 45621 and Sterile 22 Compounding License Number LSC 99018 are reinstated if they are revoked. 23

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Pursuant to Code section 4307, if discipline is imposed on Pharmacist License 36. No. RPH 40868 issued to Joseph Grasela, Joseph Grasela shall be prohibited from serving as a 25 manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 26 five years if Pharmacist License Number RPH 40868 is placed on probation or until Pharmacist 27 License Number RPH 40868 is reinstated if it is revoked. 28

DISCIPLINARY CONSIDERATIONS 2 To determine the degree of discipline, if any, to be imposed on Respondents, 37. 3 Complainant alleges: 4 On or about June 27, 2006, the Board issued Citation number CI 2005 31081 a. 5 against University RX Specialist, dba University Compounding Pharmacy for violating California 6 Code of Regulations, title 16, sections 1716 and 1764 and Civil Code section 56.10 in that it 7 filled a prescription in an improper amount and shipped drugs to the wrong address. It paid the 8 fine on or about July 18, 2006. 9 Ь. On or about July 30, 2010, the Board issued Citation number CI 2009 43472 10 against University RX Specialist, dba University Compounding Pharmacy for violating California 11 Code of Regulations, title 16, section 1751.7 in that it failed to conduct end product pyrogen 12 testing on all sterile injectable products compounded for non-sterile ingredients and failed to 13 conduct end product pyrogen testing on certain stock solutions which were made of non-sterile 14 ingredients. It paid the fine on or about August 18, 2010. 15 On or about January 28, 2010, the Board issued Citation number CI 2008 38495 16 c. against Joseph Grasela for violating California Code of Regulations, title 16, section 1715 in that 17 he failed to complete a current hospital pharmacy self-assessment. He paid the fine on or about 18 December 14, 2010. 19 20 d. On or about July 30, 2010, the Board issued Citation number Cl 2010 45194 21 against Joseph Grasela for violating California Code of Regulations, title 16, section 1751.7 in that he failed to conduct end-product pyrogen testing on all sterile injectable products 22 compounded for non-sterile ingredients and failed to conduct end-product pyrogen testing on 23 24 certain stock solutions which were made of non-sterile ingredients. He paid the fine on or about August 18, 2010. 25 PRAYER 26 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, 27 and that following the hearing, the Board of Pharmacy issue a decision: 28

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Accusation

Revoking or suspending Pharmacy Permit Number PHY 45621, issued to University
 RX Specialist, doing business as University Compounding Pharmacy;

2. Revoking or suspending Sterile Compounding License Number LSC 99018, issued to University RX Specialist, doing business as University Compounding Pharmacy;

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3. Revoking or suspending Pharmacist License Number RPH 40868, issued to Joseph
Grasela;

Prohibiting University RX Specialist, doing business as University Compounding 4. 7 Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, 8 or partner of a licensee for five years if Pharmacy Permit Number PHY 45621 and Sterile 9 Compounding License Number LSC 99018 are placed on probation or until Pharmacy Permit 10 Number PHY 45621 and Sterile Compounding License Number LSC 99018 are reinstated if 11 Pharmacy Permit Number PHY 45621 and Sterile Compounding License Number LSC 99018 12 issued to University RX Specialist, doing business as University Compounding Pharmacy are 13 revoked; 14

5. Prohibiting Joseph Grasela from serving as a manager, administrator, owner, member,
 officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number
 PHY 45621 and Sterile Compounding License Number LSC 99018 are placed on probation or
 until Pharmacy Permit Number PHY 45621 and Sterile Compounding License Number LSC
 99018 are reinstated if Pharmacy Permit Number PHY 45621 and Sterile Compounding License
 Number LSC 99018 issued to University RX Specialist, doing business as University
 Compounding Pharmacy are revoked;

6. Prohibiting Joseph Grasela from serving as a manager, administrator, owner,
member, officer, director, associate, or partner of a licensee for five years if Pharmacist License
Number RPH 40868 is placed on probation or until Pharmacist License Number RPH 40868 is
reinstated if Pharmacist License Number RPH 40868 issued to Joseph Grasela is revoked;
Ordering University RX Specialist doing business as Lipivareity Compound.

7. Ordering University RX Specialist, doing business as University Compounding
 Pharmacy and Joseph Grasela to pay the Board of Pharmacy the reasonable costs of the

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investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; Taking such other and further action as deemed necessary and proper. 8. DATED: VIRGINIAMEROL Executive Officer Board of Pharmacy Department of Consumer Affairs State of California Complainant SD2012704307 81196205.docx

Accusation