

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)
STUART LEVINE)
[REDACTED])
[REDACTED])

PHA-2013-0051

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and Stuart Levine ("Licensee"), PH16082, [REDACTED] do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the Licensee's record maintained by the Board:

1. Licensee acknowledges that a complaint has been opened by the Board against his Massachusetts pharmacy license related to the conduct set forth in Paragraph 2, identified as Docket No. PHA-2013-0051.¹
2. The Board and Licensee acknowledge and agree to the following facts:
 - a. Board investigators conducted an unannounced inspection of Village Fertility Pharmacy, DS89659, on or about November 26 & 27, 2012. The Licensee was the Manager of Record of Village Fertility at the time of the inspection and has been the Manager of Record since at least March 31, 2009. During the inspection, Board investigators observed deficiencies pertaining to the compounding of sterile medications, including violations of United States Pharmacopoeia ("USP") Chapter 797 standards. Additionally, investigators noted that Village Fertility was not appropriately licensed in states other than Massachusetts into which it shipped medications.
 - b. As described in 247 CMR 6.07, Licensee, as manager of record, was responsible for the operation of the Village Fertility pharmacy in compliance with 247 CMR 2.00 et seq. and applicable state and federal laws and regulations.

¹ The term "license" applies to both a current license and the right to renew an expired license.

c. As a result of the November 2012 inspection, Village Fertility was required to submit a plan of correction to the Board.

d. On or about February 20, 2013, Village Fertility informed the Board that it received a customer complaint of visible black particulate matter in vial of sterile compounded product. As a result, Board investigators inspected Village Fertility on or about February 21, 22, 25, and 28, 2013 ("February 2013 inspection"). The Licensee was the Manager of Record of Village Fertility at the time of the inspection February 2013 inspection.

e. During the February 2013 inspection, Board investigators observed Village Fertility to be non-compliant with 247 CMR 9.01 and United States Pharmacopoeia ("USP") Standard <797> Pharmaceutical Compounding - Sterile Preparations, with regard to its compounding of sterile medications. Additionally, Village Fertility acknowledges that, between at least November 2012 and February 2013, it shipped compounded sterile products into states in which it did not hold required non-resident licenses.

f. On or about April 26, 2013, the Board approved Village Fertility's written plan of correction dated April 2, 2013 to resume the compounding of low risk sterile products.

3. Licensee agrees that his pharmacist license shall be placed on PROBATION for 36 months ("Probationary Period"), commencing with the date on which the Board signs this Agreement ("Effective Date").
4. Licensee agrees to complete a certificate program in sterile compounding that is approved by the Board on or before December 31, 2013.
5. During the Probationary Period, the Licensee further agrees that he shall comply in all material respects with all laws and regulations governing the practice of pharmacy and the United States Pharmacopoeia.

6. Licensee agrees to refrain from all medium and high risk sterile compounding unless and until he, as manager of record of Village Fertility Pharmacy, receives written approval from the Board to resume the preparation and dispensing of medium and high risk sterile compounded medications. Board approval shall not be granted unless and until Village Fertility demonstrates, upon inspection by Board investigators, that it is fully compliant United States Pharmacopeia standards pertaining to medium and high risk sterile compounding and all other state and federal laws and regulations pertaining to the practice of pharmacy.
7. The Board agrees that in return for Licensee's execution and successful compliance with the requirements of this Agreement it will not prosecute the Complaint.
8. If the Licensee has complied to the Board's satisfaction with all the requirements contained in this Agreement, the Probationary Period will terminate 36 months after the Effective Date upon written notice to the Licensee from the Board².
9. If the Licensee does not materially comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint³ during the Probationary Period, the Licensee agrees to the following:
 - a. The Board may upon written notice to the Licensee, as warranted to protect the public health, safety, or welfare:
 - i. EXTEND the Probationary Period; and/or
 - ii. MODIFY the Probation Agreement requirements; and/or
 - iii. IMMEDIATELY SUSPEND the Licensee's pharmacist license.
 - b. If the Board suspends the Licensee's pharmacy license pursuant to Paragraph 9(a)(iii), the suspension shall remain in effect until:

² In all instances where this Agreement specifies written notice to the Licensee from the Board, such notice shall be sent to the Licensee's address of record.

³ The term "Subsequent Complaint" applies to a complaint opened after the Effective Date concerning acts, omissions, or events occurring after the Effective Date, which (1) alleges that the Licensee engaged in conduct that violates Board statutes or regulations, and (2) is substantiated by evidence, as determined following the complaint investigation during which the Licensee shall have an opportunity to respond.

- i. the Board provides Licensee written notice that the Probationary Period is to be resumed and under what terms; or
 - ii. the Board and Licensee sign a subsequent agreement; or
 - iii. the Board issues a written final decision and order following adjudication of the allegations (1) of noncompliance with this Agreement, and/ or (2) contained in the Subsequent Complaint.
10. Licensee agrees that if the Board suspends his pharmacist license in accordance with Paragraph 9, he will immediately return his current Massachusetts pharmacist license to the Board, by hand or certified mail. Licensee further agrees that upon said suspension, he will no longer be authorized to practice as a pharmacist in the Commonwealth of Massachusetts and shall not in any way represent himself as a pharmacist until such time as the Board reinstates his pharmacist license or right to renew such license.
11. Licensee understands that he has a right to formal adjudicatory hearing concerning the Complaint and that during said adjudication he would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to testify on his own behalf, to contest the allegations, to present oral argument, to appeal to the courts, and all other rights as set forth in the Massachusetts Administrative Procedures Act, M.G.L. c. 30A, and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01 et seq. The Licensee further understands that by executing this Agreement he is knowingly and voluntarily waiving its right to a formal adjudication of the Complaints.
12. The Licensee acknowledges that he has been represented by legal counsel in connection with the Complaint and this Agreement.
13. The Licensee acknowledges that after the Effective Date, the Agreement constitutes a public record of disciplinary action by the Board. The Board may forward a copy of this Agreement to other licensing boards, law enforcement entities, and other individuals or entities as required or permitted by law.

14. The Licensee certifies that he has read this Agreement. The Licensee understands and agrees that entering into this Agreement is a voluntary and final act and not subject to reconsideration, appeal or judicial review.

Walter Pyle 8/13/13
Witness (Sign and date)

Stuart Levine 8-13-13
Signature and Date
STUART LEVINE

Print Name
Stuart Levine

Margy Cittadino (HAE)
Margaret Cittadino
Associate Director
Board of Registration in Pharmacy

8-19-13
Effective Date of Probation Agreement

Fully Signed Agreement Sent to Licensee on 8-20-13 by
Certified
Mail No. 7012 3460 0001 7330 9743