

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss.

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)
Epicur Pharma) Docket No.: PHA-2024-0095
License No. NO00051)
Exp: December 31, 2025)

CONSENT AGREEMENT FOR REPRIMAND

The Massachusetts Board of Registration in Pharmacy (Board) and Epicur Pharma (Outsourcing Facility or Licensee), an outsourcing facility licensed by the Board, license no. NO00051, 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. The Outsourcing Facility acknowledges the Board opened a Complaint against its Massachusetts outsourcing facility license related to the conduct set forth in Paragraph 2, identified as docket number PHA-2024-0095 (Complaint).
2. The Licensee and the Board agree to resolve this Complaint without making any admissions or findings and without proceeding to a formal adjudicatory hearing. The Complaint alleges the following:
 - a. On April 2, 2024, the FDA issued a Warning Letter (MARCS-CMS 677624) to the Licensee for failing to meet the conditions to register as an outsourcing facility under Section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) and deficiencies in practices for producing drug products intended or expected to be sterile which put patients at risk.
3. The Board and Licensee acknowledge and agree that based upon the information described in Paragraph 2 the Board could find the Licensee in violation of 247 Mass. Code Regs. 10.03(l)(v) warranting disciplinary action by the Board under Mass. Gen. Laws ch. 112, §§ 42A, 61 and 247 Mass. Code Regs. 10.03(l)(v).
4. The Licensee agrees that the Board shall impose a REPRIMAND on its license based on the facts described in Paragraph 2, effective as of the date on which the Board signs this Agreement (Effective Date).
5. The Board agrees that in return for the Licensee's execution and successful compliance with all the requirements of this Agreement, the Board will not prosecute the Complaint.

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6. The Licensee understands that it has a right to formal adjudicatory hearing concerning the Complaint and that during said adjudication the Licensee would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to testify on its 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, Mass. Gen. Laws ch. 30A, and the Standard Adjudicatory Rules of Practice and Procedure, 801 Mass. Code Regs. 1.01 *et seq.* The Licensee further understands that by executing this Agreement the Licensee is knowingly and voluntarily waiving its right to a formal adjudication of the Complaint.
7. The Licensee acknowledges that it has been at all times represented by Counsel or otherwise free to seek and use legal counsel in connection with the Complaint and this Agreement.
8. The Licensee acknowledges that after the Effective Date, the Agreement constitutes a public record of disciplinary action by the Board subject to the Commonwealth of Massachusetts' Public Records Law, Mass. Gen. Laws ch. 4, § 7. 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.
9. 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.
10. The individual signing this Agreement certifies that they are authorized to enter into this Agreement on behalf of the Licensee, and that they have read this Agreement.

3/17/25
Date


(signature)

Michael J. Godek, R.Ph.
(print name)
Michael J. Godek, R.Ph.
Executive Director
Board of Registration in Pharmacy

03/17/2025

Effective Date of Reprimand Agreement

Fully Signed Agreement Sent to Licensee on March 19, 2025 by Certified Mail
No. 9589 0710 5270 1211 6864 00

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