The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure
Office of General Counsel
239 Causeway Street, Suite 500, Boston, MA 02114

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VIA U.S. FIRST CLASS CERTIFIED MAIL,# 7012 3460 0003 3582 1199

January 16, 2014

Paul M. Garbarini
Attorney At Law
P.O. Box 1551
Northampton, MA 01061

Re: In the Matter of Lenox Village Pharmacy; DS3344; PHA 2012-0241

Dear Mr. Garbarini:

This letter acknowledges receipt by the Board of Registration in Pharmacy (Board) of a single signed original copy of the Consent Agreement for Reprimand (Agreement) between Lenox Village Pharmacy and the Board in resolution of the above-referenced complaint. The Board has now signed the Agreement, and submits a copy for your client's records. Please note carefully that the effective date of the Agreement is January 16, 2014, as stated on the signature page of the agreement.

A copy of this letter and the Agreement will remain in complaint file Docket No. PHA-2012-0241. The file will be retained for no less than three (3) years in accordance with state public records laws.

As the attorney of record for Lenox Village Pharmacy, the Board expects that you will notify your client of the Board's action and forward to him the enclosed copy of the Agreement. Thank you for your cooperation.

Sincerely,

Beth A. Oldmixon
Prosecuting Counsel

Enclosure

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION IN PHARMACY

In the Matter of)
Lenox Village Pharmacy)
Registration No. DS3344)
Expiration Date: December 31, 2013)

PHA-2012-0241

CONSENT AGREEMENT FOR REPRIMAND

The Massachusetts Board of Registration in Pharmacy ("Board") and Lenox Village Pharmacy ("Registrant" or "Lenox"), a Pharmacy licensed by the Board, Registration No. DS3344, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the Registrant's record maintained by the Board:

1. The Registrant acknowledges that the Board opened a complaint against its Massachusetts Pharmacy registration (registration[1]) related to the conduct set forth in paragraph 2, identified as Docket No. PHA-2012-0241 ("Complaint").

2. The Board and Registrant acknowledge and agree to the following facts:

   a. On or about October 18, 2012, Lenox, through its Manager of Record Richard P. Mole, submitted an Attestation of Compliance to the Board attesting that Lenox was engaged in the compounding of sterile preparations and attesting that all sterile compounding practices were in compliance with all Massachsuetts Board of Registration in Pharmacy regulations (247 CMR) and USP Standard <797> in the compounding of sterile preparations.

   b. Board investigators conducted an unannounced inspection of Lenox on or about December 11 & 12, 2012. During the inspection, Board investigators observed Lenox to be non-complaint with 247 CMR 9.01 and United States Pharmacopoeia ("USP") Standard <797> Pharmaceutical Compounding – Sterile Preparations, with regard to its compounding of sterile medications.

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

c. As a result of Lenox's non-compliance, on or about December 12, 2012, Lenox was notified to immediately cease the preparation and dispensing of sterile compounded medications, and quarantine all sterile compounded medications on Lenox's premises.

3. The Registrant agrees that the Board shall impose a **REPRIMAND** on its license based on the facts admitted in Paragraph 2, effective as of the date on which the Board signs this Agreement (Effective Date).

4. The Registrant agrees to refrain from all sterile compounding unless and until it receives written approval from the Board to resume the preparation and dispensing of sterile compounded medications. Board approval shall not be granted unless and until Registrant demonstrates, upon inspection by Board investigators, that it is fully compliant with United States Pharmacopeia standards pertaining to sterile compounding and all other state and federal laws and regulations pertaining to the practice of pharmacy.

5. Based on Registrant's agreement to refrain from sterile compounding unless and until it receives written approval from the Board to resume, **the Cease and Desist and Quarantine Notice dated December 12, 2012 is hereby rescinded.**

6. The Board agrees that in return for the Registrant's execution and successful compliance with all the requirements of this Agreement, the Board will not prosecute the Complaint.

7. The Registrant understands that it has a right to formal adjudicatory hearing concerning the Complaint and that during said adjudication it 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, G. L. c. 30A, and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01 *et seq.* The Registrant further understands that by executing this Agreement it is knowingly and voluntarily waiving its right to a formal adjudication of the Complaint.

8. The Registrant acknowledges that it has been at all times free to seek and use legal counsel in connection with the Complaint and this Agreement.

9. The Registrant 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, G.L. 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.

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

Witness (sign and date)
1/10/14

Joseph G. Martragono 01/10/14
Lenox Village Pharmacy
(sign and date)

Print Name: Joseph G. Martragono

1/16/2014
Effective Date of Reprimand Agreement

~~Margaret Cittadino~~ David Sencabaugh
~~Associate Director~~ Executive Director
Board of Registration in Pharmacy

Fully Signed Agreement Sent to Registrant on January 16, 2014 **by Certified Mail No.** 7012 3460 0003 3582 1199

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of LENOX)
VILLAGE PHARMACY)
5 Walker Street,)
Lenox, MA 01240)

PHA-2012-0241

CEASE AND DESIST AND QUARANTINE NOTICE

1. Lenox Village Pharmacy ("Lenox") is hereby notified to IMMEDIATELY CEASE AND DESIST engaging in the compounding of sterile medications and the distribution of compounded sterile medications.

2. This Notice is issued pursuant to the authority of the Department of Public Health ("Department") through the Board of Registration in Pharmacy ("Board") and the Division of Food and Drugs, pursuant to M.G.L. c. 94, § 189A, M.G.L. c. 94C, §§ 13 and 14, M.G.L. c. 112, §§ 39 and 42A, and Board Regulation 247 CMR 10.08, related to observed pharmacy practices and conditions at Lenox, Pharmacy Registration No. DS3344, located at 5 Walker Street, Lenox, Massachusetts.

3. Lenox was observed to be non-compliant with the requirements of Board regulations, including but not limited to 247 CMR 9.01 and United States Pharmacopoeia ("USP") Standard <797> Pharmaceutical Compounding – Sterile Preparations, with regard to its preparation of sterile medications.

4. Lenox must immediately cease the preparation and dispensing of compounded sterile medications (Schedules II through VI), unless otherwise specifically permitted in Paragraph 7 below. Lenox must immediately QUARANTINE all compounded sterile medications on Lenox premises, unless otherwise specifically permitted in Paragraph 7 below, including the following:

   ALL (1) compounded sterile medications (Schedules II through VI) located on Lenox premises; (2) sterile medications and pharmaceuticals contained in opened or sealed manufacturer stock bottles or other type of manufacturer packaging on Lenox premises; and (3) any sterile "compounded" medications prepared for dispensing and stored at Lenox.

5. Pursuant to this Notice, no dispensing of sterile compounded medications (Schedules II through VI) or any sterile "compounded" controlled substances may occur without the express approval of the Department. No disposition may be made of ANY of the above-referenced controlled substances subject to this QUARANTINE NOTICE without the express approval of the Department. An EMBARGO ORDER may be issued by the Department, pursuant to M.G.L. c. 94C, § 13, if necessary. Removal or

disposition of the above-described articles without permission from the Department shall be subject to applicable statutory and regulatory penalties.

6. Lenox may not resume the compounding or dispensing of sterile medications without the express approval of the Department. Lenox shall conduct an orderly transition of patient care and pharmacy related compounding services.

7. Lenox may compound and dispense one four day supply of Neosporin Irrigation for one long term patient on or before December 14, 2012.

8. In accordance with 247 CMR 10.08, a hearing limited to the determination of the necessity of this Notice shall be afforded to the licensee within 21 days of the issuance of this Notice.

9. Direct questions to Samuel Penta, Board Investigator, 617-973-0888, or Madeleine Biondolillo, M.D., Director, Bureau of Health Care Safety and Quality, Department of Public Health 617-753-8100.

BOARD OF REGISTRATION IN PHARMACY

James T. DeVita

James T. DeVita, R.Ph
President
Effective Date: December 12, 2012

Richard P. Mole RPh Date: 12/12/12

Acknowledgement of receipt by Lenox Time: 5:51PM

Print Name: Richard P. Mole RPh