CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

The Commonwealth of Massachusetts

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Department of Public Health
Division of Health Professions Licensure
Board of Registration in Pharmacy
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MARYLOU SUDDERS
Secretary

EILEEN M. SULLIVAN
Acting Commissioner

VIA U.S. FIRST CLASS CERTIFIED MAIL,# 7012 3460 0002 3702 8832
RETURN RECEIPT REQUESTED

January 16, 2015

Kathryn M. Stalmack, Esq.
Polsinelli
161 N. Clark Street, Suite 4200
Chicago, IL 60601-1900

Re: In the Matter of New England Home Therapies, DS3486
Board of Registration in Pharmacy, Docket Nos. PHA-2014-0034 and PHA-2014-0240

Dear Attorney Stalmack:

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 New England Home Therapies 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 15, 2015, as stated on the signature page of the agreement.

A copy of this letter and the Agreement will remain in complaint file Docket Nos. PHA-2014-0034 and PHA-2014-0240. The file will be retained for no less than three (3) years in accordance with state public records laws.

In addition, Karen Fishman is responsible for monitoring compliance with any probation agreement that a pharmacy enters into with the Board. All correspondence and documentation in connection with this Probation Agreement should be directed to her at the Board's office listed above. You may also contact her at (617) 973-0951 with any questions regarding this matter.

If you have any questions regarding this matter, please contact me at (617) 973-0821. As New England Home Therapies attorney of record, the Board expects that you will notify your client of the Board's action and forward to them the enclosed copy of the Agreement. Thank you for your cooperation.

Sincerely,

Heather Engman, Board Counsel
Board of Registration in Pharmacy

Enclosure

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of	)	PHA-2014-0034
NEW ENGLAND	)	PHA-2014-0240
HOME THERAPIES	)	
Registration No. DS3486	)	
Expires December 31, 2015	)	

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and New England Home Therapies ("NEHT" or "Pharmacy"), DS3486, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the Pharmacy's record maintained by the Board:

1. The Pharmacy acknowledges that the Board opened Complaints against its Massachusetts pharmacy registration related to the conduct set forth in Paragraph 2, identified as PHA-2014-0034 and PHA-2014-0240.[1]

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

   a. On or about November 20, 2013, NEHT received environmental monitoring results that were above USP 797 action limits. NEHT did not report the abnormal environmental monitoring results to the Board as required by 247 CMR 6.15(7).

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

b. On or about November 20, 2013, NEHT ceased sterile compounding and performed renovations to its sterile compounding area. Specifically, NEHT altered the physical structure of the ante room and buffer rooms by installing a new door to the negative pressure buffer room, new door to the ante room, and a new pass through from the ante room to the buffer room. The renovations were completed on or about November 24, 2013. Following the renovations, NEHT "triple cleaned" its sterile compounding area and resumed sterile compounding activities on or about November 24, 2013. NEHT did not recertify its primary or secondary engineering controls following the alteration of the physical structure of the buffer rooms and ante room and prior to resumption of sterile compounding activities, in violation of USP 797.

c. On or about December 3, 2013, NEHT appeared before the Board to seek approval for renovations to its clean room.

d. NEHT failed to submit its bi-annual sterile compounding report on or before January 15, 2014, as required by 247 CMR 6.15(5).

e. In approximately early February 2014, NEHT again performed major service on and/or altered the physical structure of its buffer rooms and ante room. Specifically, NEHT installed a negative pressure buffer room, changed ceiling tiles, and performed fan maintenance. Following the renovations, the area was "triple cleaned." NEHT did not recertify its primary or secondary engineering controls after the major service and/or alteration of the physical structure of the sterile compounding area but before resumption of sterile compounding activities, in violation of USP 797.

f. On or about February 21, 2014, NEHT notified the Board that its construction was complete.

g. Board investigators conducted an inspection of NEHT on February 24, 2014 and observed multiple sterile compounding deficiencies. Deficiencies observed on February 24, 2014 include but are not limited to the following:

i. Media fill Hycon Lot YM were not incubated at the correct temperature;

ii. Molding on window of east side wall in need of repair and re-caulking;

iii. Pre-filters to at least two primary engineering controls ("PEC") were visibly soiled;

iv. Magnahelic gauges to positive pressure and negative pressure buffer rooms were not functioning properly;

v. Pass through was not equipped with an interlock system and the Pharmacy did not have a policy and procedure pertaining to a pass through without an interlock system;

vi. Three PECs lacked magnahelic pressure gauges;

vii. PEC in negative pressure buffer room had a cracked glass barrier shield;

viii. Door between ante room and buffer room left open by staff during course of inspection;

ix. Tube sealer ACS-152 located in buffer room was visibly contaminated;

x. Buffer room ceiling had visible cracks;

xi. NuAire Hood 51823XV had finger prints and smudges on its underside;

xii. Viable air sampling was not performed during December 2013 certification;

xiii. Epoxy observed on Edgeguard TPN PEC grill; and

xiv. Pharmacy did not have a policy and procedure for cleaning refrigeration condensation plates in the ante room.

h. During the February 24, 2014 inspection, Board investigators became aware of the sterile compounding deficiencies described in Paragraphs 2a – e. As a result, the Board issued a Notice to Cease and Desist all sterile compounding on February 26, 2014.

i. On or about September 22 – 24, 2014 Board investigators visited NEHT and observed the ante room sink to have a leak in the drainage pipe. Board investigators further observed a bucket containing bleach under the sink to collect the drips. NEHT became aware of the leak on or about September 16, 2014 but failed to remedy the leak in a timely manner.

3. The Pharmacy agrees that its registration shall be placed on PROBATION for one (1) year ("Probationary Period"), commencing with the date on which the Board signs this Agreement ("Effective Date").

4. During the Probationary Period, the Pharmacy agrees that it shall comply in all material respects with all laws and regulations governing the practice of pharmacy and the United States Pharmacopeia.

5. During the Probationary Period, the Pharmacy further agrees that it shall comply with all of the following requirements to the Board's satisfaction:

a. NEHT agrees to conduct non-viable and viable air sampling at least one time per month. The viable air samples shall test for the presence of both fungus and bacteria. NEHT shall utilize a third party vendor to conduct non-viable and viable air sampling;

b. NEHT agrees to conduct surface sampling at least one time per month. The surface samples shall test for the presence of both fungus and bacteria. NEHT shall utilize a third party vendor to conduct surface sampling;

c. NEHT agrees to deliver a scanned copy of all actionable and non-actionable non-viable air, viable air, and surface sampling results to abnormalresults@massmail.state.ma.us no later than four hours after receipt of said results from the third party vendor(s);

d. NEHT agrees to ensure that all current compounding personnel, including pharmacists who oversee compounding, successfully complete a Certificate Program in sterile compounding before March 31, 2015. The Certificate Program shall consist of at least 20 contact hours of continuing education in the area of sterile compounding with no more than 10 contact hours obtained through home study;

e. NEHT agrees to ensure that all future compounding personnel, including pharmacists who oversee compounding, successfully complete a certificate program in Sterile Compounding within six months of employment at NEHT. The Certificate Program shall consist of at least 20 contact hours of continuing education in the area of sterile compounding with no more than 10 contact hours obtained through home study;

f. NEHT agrees to ensure that all compounding personnel, including pharmacists who oversee compounding, successfully complete media fill tests upon initial employment and at least once every six months thereafter. The media fill tests shall consist of three media fill tests per day for three consecutive days in a manner that represents the most challenging type of compounding performed. Compounding personnel shall complete media fill tests at the same time gloved fingertip/thumb sampling is performed, as applicable. NEHT shall provide to the Board within 30 days of the Effective Date a detailed methodology for media fills that includes the media used to conduct the test. NEHT shall notify the Board within four hours of receipt of any positive media fill test by sending an email to abnormalresults@massmail.state.ma.us;

g. NEHT agrees to ensure that all compounding personnel, including pharmacists who oversee compounding, successfully complete gloved fingertip/thumb sampling of both hands upon initial employment and at least once every month. Compounding personnel shall complete gloved fingertip/thumb sampling at the same time media fill testing is performed, as applicable. NEHT shall notify the Board within four hours of receipt of any positive gloved fingertip/thumb test by sending an email to abnormalresults@massmail.state.ma.us;

h. NEHT agrees to create and maintain hood logs for each compounding hood. Each time sterile compounding is performed, NEHT compounding personnel shall record the following information in the hood log: (1) the date; (2) the start time and end time; and (3) the name and volume of compounded sterile product prepared; and (4) the name of the individual who performed the compounding;

i. NEHT agrees to obtain an HVAC assessment, performed by a third party vendor, at each recertification period. The HVAC assessment shall include evaluation of air intake, air supply, duct work, differential pressures, returns, HEPA filtration efficiency, air flow dynamics, and the opinion of the HVAC engineer regarding the performance of the system;

j. NEHT agrees to conduct training for all current compounding personnel, including pharmacists who oversee compounding, regarding proper operation of the pass through. Within 7 days of this agreement NEHT will provide the Board with attestation from all current compounding personnel, including pharmacists who oversee compounding, that training has been completed;

k. NEHT agrees to ensure that all future compounding personnel, including pharmacists who oversee compounding, receive training for proper operation of the pass through. NEHT will ensure this documentation is made available to the Board upon the Board's request;

l. NEHT agrees to implement and maintain a change control policy and procedure that details the manner in which the pharmacy manages change, including renovations, installation of equipment, and above action limit environmental monitoring results that require cessation of compounding;

m. NEHT agrees to implement a policy and procedure for the recall of sterile compounded products required by improper compounding, above action limit environmental monitoring results, and/or positive personnel monitoring results;

n. NEHT agrees to maintain a detailed procedure and plan to maintain patient continuity of care in the event NEHT cannot compound and/or dispense sterile compounded medications; and

o. NEHT agrees to maintain a policy and procedure to ensure all personnel are trained on a proper escalation process in the absence of the Manager of Record (MOR) for proper adjudication of matters requiring MOR attention.

6. During the Probationary Period, the Pharmacy further agrees that it shall NOT:

a. Engage in any in any high-risk level sterile compounding; or

b. Extend Beyond Use Dates for any product beyond USP 797, as indicated in the table below.

	Room Temp	Cold Temp	Frozen
Low Risk	48 hours	14 days	45 days
Medium Risk	30 hours	9 days	45 days
High Risk	24 hours	3 days	45 days

7. The Board agrees that in return for the Pharmacy's execution and successful compliance with the requirements of this Agreement it will not prosecute the Complaint.

8. If the Pharmacy has complied to the Board's satisfaction with all the requirements contained in this Agreement, the Probationary Period will terminate **one (1) year** after the Effective Date upon written notice to the Pharmacy from the Board[2].

9. If the Pharmacy does not comply with the terms of this Agreement, or if the Board opens a Subsequent Complaint[3] during the Probationary Period, the Pharmacy agrees to the following:

a. The Board may upon written notice to the Pharmacy, 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 Pharmacy's registration.

b. If the Board suspends the Pharmacy's registration 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 Pharmacy from the Board, such notice shall be sent to the Pharmacy'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 Pharmacy engaged in conduct that violates Board statutes or regulations, and (2) is substantiated by evidence, as determined following the complaint investigation during which the Pharmacy shall have an opportunity to respond.

i. the Board provides the Pharmacy written notice that the Probationary Period is to be resumed and under what terms; or

ii. the Board and the Pharmacy 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. The Pharmacy agrees that if the Board suspends its registration in accordance with Paragraph 9, it will immediately return its current Massachusetts registration to the Board, by hand or certified mail. The Pharmacy further agrees that upon said suspension, it will no longer be authorized to operate as a pharmacy in the Commonwealth of Massachusetts and shall not in any way represent itself as a pharmacy until such time as the Board reinstates registration or right to renew such registration.

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

12. The Pharmacy acknowledges that it has been represented by legal counsel in connection with the Complaints and this Agreement.

13. The Pharmacy 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 Pharmacy understands and agrees that entering into this Agreement is a voluntary and final act and not subject to reconsideration, appeal, or judicial review.

15. The individual signing this Agreement certifies that he/she is authorized to enter into this Agreement on behalf of the Pharmacy, and that he/she has read this Agreement.

Witness (sign and date) 1-13-15

Signature and Date 1-13-15

Kathryn Stalmack, Attorney for NGHT
Print Name

David Sencabaugh, R. Ph.
Executive Director
Board of Registration in Pharmacy

1-15-15
Effective Date of Probation Agreement

Fully Signed Agreement Sent to Registrant on 1-16-15 **by Certified Mail No.** 7012 3460 0002 3702 8832