



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

MITT ROMNEY
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KERRY HEALEY
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SECRETARY

CHRISTINE C. FERGUSON
COMMISSIONER

Board of Registration In Pharmacy
239 Causeway Street, 5th Floor
Boston, MA 02114

October 04, 2004.

Barry J. Cadden, R.Ph.
Manager of Record
New England Compounding Center
697 Waverly Street
Framingham, MA 01702

RE: Docket Number DS-03-055/ PH-03-066/ New England Compounding Center (Lic. No. 2848) and Barry Cadden, R.Ph., License No. 21239

Dear Mr. Cadden:

The Board has voted to resolve the above-referenced case by offering you a consent agreement to resolve issues related to the above-referenced matter.

Please be advised that if you choose not to enter into the Agreement, the Board will proceed to a formal hearing, pursuant to G.L. c. 30A.

Please return both copies of the Agreement to the Board at your earliest convenience but no later than within ten (10) days of their receipt. The Board will then sign them and an executed copy will be returned to you.

Please contact Associate Director James D. Coffey at 617-727-6095 if you have any questions regarding this matter.

Sincerely,

Charles R. Young, R.Ph.
Executive Director
Board of Registration In Pharmacy

Enc.

By Certified Mail 7003 1010 0003 3509 7959

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of
NEW ENGLAND
COMPOUNDING CENTER
Registration No. 2848
BARRY J. CADDEN, R.Ph.
License No. 21239

DOCKET NOS. DS-03-055
PH-03-066

CONSENT AGREEMENT

The Board of Registration in Pharmacy ("Board") and NEW ENGLAND COMPOUNDING CENTER (Pharmacy Registration No. 2848), located at 697 Waverly Road, in Framingham, Massachusetts ("Registrant"), and BARRY J. CADDEN, R.Ph. ("Licensee") Pharmacist License No. 21239 and Manager of Record of Registrant, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the file of Registrant which is maintained by the Board:

1. The parties enter into this Consent Agreement ("Agreement") to resolve disputed matters arising out of the complaints pending against Registrant and Licensee, respectively, as Docket Nos. DS-03-055 and PH-03-066 ("Complaints").
2. The Registrant agrees that this Agreement has been entered into as a result of an adverse event complaint report investigated by the U.S. Food and Drug Administration alleging that Registrant, while the Licensee was Manager of Record, failed to comply with accepted standards in compounding a certain order for methyprednisolone acetate preservative free 80mg/ml suspension.
3. Accordingly, the Registrant agrees to the following:
 - a. The conduct described in Paragraph 2. above constitutes professional misconduct warranting disciplinary action by the Board pursuant to G.L. c. 112, § 61 and 247

CMR 9.01(1);

- b. The Registrant and Licensee are hereby REPRIMANDED by the Board and the Registrant's pharmacy registration and Licensee's pharmacist license are hereby placed on probation for a minimum three (3) year period (the "Probationary Period"), commencing on the date this Consent Agreement is executed by the Board; and
- c. The Registrant and Licensee agrees that during the Probationary Period:
 - 1) Registrant's manager of record shall be required to develop and implement written policies and procedures to provide for and insure that USP Guidelines are followed and the Registrant performs in accordance with USP Guidelines and 247 CMR;
 - 2) Registrant's manager of record shall be required to update standard operating procedures on a quarterly basis
 - 3) Registrant may be inspected by the Board;
 - 4) Registrant will keep a written report of each adverse event reported and make such reports available for review by the Board upon request during inspections;
 - 5) Registrant will provide an after business hours telephone number for consumer use and have written protocols for after business services; and
4. Registrant and Licensee acknowledge that the Registrant and Licensee must apply in writing to the Board for termination of the Probationary Period and that termination of the Probationary Period shall be granted only if all of the conditions set forth above in Paragraph 3.c. have been met. The Board may request a conference to discuss the merits of such request.
5. This Agreement and its contents shall be incorporated into the records maintained by the Board. This Agreement and its contents are matters of public record, and are subject to disclosure without limitation to the public and equivalent state licensing boards.
7. The Board agrees that in return for the execution and fulfillment of the requirements of this Agreement by the Registrant and Licensee, the Board will not advance the prosecution of the Registrant and Licensee pursuant to the Complaint; any and all other rights of the Board to take action within the scope of its authority are expressly reserved.
8. The Registrant and Licensee understand and agree that the failure to accept the terms of this Agreement shall nullify the representations contained herein, and permit the Board to initiate formal adjudicatory action under the State Administrative Procedure Act, G.L. c. 30A, and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.00 *et. seq.*
9. The Registrant and Licensee understand and agree that the decision to enter into this Agreement and to accept the terms and conditions herein described is a final act and is not subject to reconsideration or judicial review.

10. The Registrant and Licensee state legal counsel has been consulted in connection with the decision to enter into this Agreement and if not, that there was an opportunity to do so.
11. The Registrant and Licensee certify this document entitled "Consent Agreement" has been read. The Registrant and Licensee understand that, by executing this Agreement, the Registrant and Licensee are waiving any right to a formal hearing with rights 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 court in the event of an adverse ruling, and all other rights set forth in G.L. c. 30A and 801 CMR 1.01 *et seq.*

**NEW ENGLAND
COMPOUNDING CENTER**

By: _____
Barry J. Cadden, R.Ph.
Director of Pharmacy

Date: _____

Barry J. Cadden, R.Ph.
Manager of Record
Date: _____

**BOARD OF REGISTRATION
IN PHARMACY**

By: _____
James T. DeVita, R.Ph.
President

Effective Date: _____

Board Dec. No.
Cert Mail No: 7003 1010-0003 3509 7959