COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of NEW ENGLAND COMPOUNDING CENTER Registration No. [redacted] BARRY J. CADDEN, R.Ph. License No. [redacted]	Docket Nos. DS-03-055 PH-03-066 DS-05-040

CONSENT AGREEMENT

The Board of Registration in Pharmacy ("Board") and **NEW ENGLAND COMPOUNDING CENTER ("NECC")** (Pharmacy Registration No. [redacted]), located at 697 Waverly Road, in Framingham, Massachusetts ("Registrant"), and **BARRY J. CADDEN**, R.Ph. ("Licensee") Pharmacist License No. [redacted] 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 files of Registrant and Licensee which are 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, PH-03-066 and DS-05-040 ("Complaints").

2. The Registrant, Licensee and the Board stipulate and agree that this Agreement is in settlement of complaints relating to an adverse event complaint report investigated by the United States Food and Drug Administration for methyprednisolone acetate preservative free 80 mg/ml suspension, and concerning the dispensing of Trypan Blue without a valid prescription ("the Complaints").

3. The Registrant, Licensee and the Board acknowledge that this Agreement is a nondisciplinary agreement not reported to the National Association of State Boards of Pharmacy or other outside report agencies, except that the Licensee's failure to fulfill the requirements of paragraph 5 may result in the imposition of discipline by the Board.

4. In order to resolve these matters without further proceedings before the Board, the Registrant, the Licensee, and the Board agree that on the date of the execution of this Agreement by the Board ("Effective Date") the Board will order that the Licensee be placed on **Probation for a Period of One (1) Year**, and the probation order will be

Stayed for one (1) year from the Effective Date of this Agreement ("the Stay").

5. The Registrant and the Licensee agree as follows:

(a) Within 45 days from the Effective Date of this Agreement, the Registrant and Licensee shall provide documentation satisfactory to the Board that Board-approved evaluator: Pharmacy Support, Inc. ("PSI" or "Evaluator"), at the expense of the Registrant and Licensee, has conducted an inspection of and prepared a written report analyzing Registrant's compounding practices and compliance with United States Pharmacopeia Standard 795 – Non-Sterile Compounding Procedures and USP Standard 797 – Sterile Compounding Procedures, in accordance with 247 CMR 9.01(3)("USP Standards"), with any recommendations for revisions to practice for compliance with USP Standards ("the First Report"). The inspection shall include consideration of, but not be limited to:

i. Sterile Environmental Design
ii. Quality Assurance Program
iii. Media Fills (operator qualification/process validation)
iv. Environmental Monitoring
v. Cleaning and Sanitizing Program
vi. Training Records
vii. Process Control
viii. Equipment
ix. Finished Preparation Testing
x. Adverse Event Records

(b) The Registrant and Licensee will arrange for the Evaluator to provide a copy of the First Report as described in Paragraph 5(a) directly to the Board within fourteen days of the inspection.

(c) The Registrant and Licensee will implement all recommendations made by the Evaluator within 90 days of the Effective Date of this Agreement. The Registrant and Licensee must petition and receive the approval of the Board to exempt or postpone implementation of any particular recommendation.

(d) Within six months of the Effective Date of this Agreement, the Registrant and Licensee shall provide documentation satisfactory to the Board that the Evaluator, at the expense of the Registrant and Licensee, has conducted a second inspection of Registrant and prepared a written report after an analysis as described in Paragraph (5) above, and further, as to whether the recommendations made by the Evaluator in the First Report have been implemented ("the Second Report").

(e) The Registrant and Licensee will arrange for the Evaluator to provide a copy of the Second Report as described in Paragraph 5(d) directly to the Board within fourteen days of the inspection.

(f) The Registrant and Licensee will update Standard Operating Procedures on a biannual

basis.

(g) The Registrant and Licensee will keep a written report of each adverse event reported and make such reports available for review by the Board upon request.

6. If the Registrant and Licensee successfully complete the requirements of paragraph 5, its registration and his license will **not** be placed on probation.

7. If the Registrant and the Licensee fail to successfully complete the requirements of paragraph 5, the Stay will be withdrawn by the Board and the Board's order of **Probation for a Period of One (1) Year** ("Probation") will be imposed upon the Registrant and Licensee without the necessity of additional proceedings pursuant to G. L. c. 30A. The terms and conditions of Probation will be determined by the Board at that time and may include, but not be limited to practice restrictions, monitoring conditions, appearances before the Board, and continuing education and training.

8. 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.

9. 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 Complaints; any and all other rights of the Board to take action within the scope of its authority are expressly reserved.

10. 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.*

11. 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.

12. 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.

13. 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
Barry J. Cadden, R.Ph.
Director of Pharmacy

Date: 1/5/06

Barry J Cadden
Barry J. Cadden, R.Ph.
Manager of Record
Date: 1/5/06

BOARD OF REGISTRATION IN PHARMACY

By: Karen Ryle
Karen Ryle, R.Ph., M.S.
President

Effective Date: 1/10/06

Board Dec. No. 1210, 1211
Cert Mail No.