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Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

DEPT. OF COMMERCE
AND CONSUMER AFFAIRS

2013 MAR 21 P 2:36

HEARINGS OFFICE

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DEPT. OF COMMERCE
AND CONSUMER AFFAIRS
STATE OF HAWAII

Attorneys for Department of Commerce
and Consumer Affairs

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of) PHA 2012-34-L
)
NEW ENGLAND COMPOUNDING)
PHARMACY, INC., dba NEW ENGLAND) SETTLEMENT AGREEMENT PRIOR TO
COMPOUNDING CENTER) FILING OF PETITION FOR DISCIPLINARY
) ACTION AND BOARD'S FINAL ORDER;
) EXHIBITS "1" – "8"
Respondent.)

248040108

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS'
REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"),
through its undersigned attorney, and Respondent NEW ENGLAND COMPOUNDING
PHARMACY, INC., dba NEW ENGLAND COMPOUNDING CENTER (hereinafter
"Respondent"), enter into this Settlement Agreement on the terms and conditions set forth
below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was permitted by the Board of Pharmacy (hereinafter the "Board") as a pharmacy under Miscellaneous Permit Number PMP 355. Permit Number PMP 355 was issued on or about January 13, 2004. The permit will expire on or about December 31, 2013.

2. Respondent's mailing address for purposes of this action is 697 Waverly Street, Framingham, Massachusetts 01702.

3. On or about October 3, 2012, pursuant to a Voluntary Surrender Agreement with the Massachusetts Board of Registration in Pharmacy, Respondent agreed to surrender its Massachusetts Pharmacy Registration (No. 2848) and agreed to recall and quarantine certain of its products.

4. A copy of the Massachusetts Order obtained from the website maintained by the Virginia Board of Pharmacy (as an attachment to Exhibit "4") is attached as Exhibit "1."

5. On or about October 3, 2012, the North Carolina Board of Pharmacy summarily suspended Respondent's North Carolina's pharmacy permit pursuant to an Order Summarily Suspending Permit.

6. A copy of the North Carolina Order obtained from the website maintained by the North Carolina Board of Pharmacy is attached as Exhibit "2."

7. On or about October 5, 2012, the Maryland Board of Pharmacy issued an Order for Summary Suspension *In the Matter of New England Compounding Center Permit No.: PO3113*, Maryland Board of Pharmacy Case No.: PI-13-057/13-457, in which the Maryland

Board of Pharmacy summarily suspended Respondent's permit to operate a pharmacy in the State of Maryland.

8. A copy of the Maryland Order obtained from the website maintained by the Maryland Board of Pharmacy is attached as Exhibit "3."

9. On or about October 6, 2012, the Virginia Board of Pharmacy suspended Respondent's registration to operate as a nonresident pharmacy pursuant to an Order of Mandatory Suspension.

10. A copy of the Virginia Order obtained from the website maintained by the Virginia Board of Pharmacy is attached as Exhibit "4."

11. On October 6, 2012, Respondent announced a recall of all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts.

12. On or about October 9, 2012, the Ohio State Board of Pharmacy summarily suspended Respondent's Ohio Terminal Distributor of Dangerous Drugs license pursuant to a Summary Suspension Order/Notice of Opportunity for Hearing.

13. A copy of the Ohio Order obtained from the website maintained by the Ohio State Board of Pharmacy is attached as Exhibit "5."

14. On or about October 15, 2012, the Tennessee Board of Pharmacy approved a Voluntary Surrender Agreement in which Respondent agreed to surrender its license to practice as a pharmacy in Tennessee.

15. A copy of the Tennessee Agreement obtained from the website maintained by the Tennessee Board of Pharmacy is attached as Exhibit "6."

16. On or about October 15, 2012, the Michigan Board of Pharmacy summarily suspended Respondent's Michigan pharmacy license.

17. On or about October 17, 2012, Respondent voluntarily surrendered its New Hampshire pharmacy registration.

18. On or about October 18, 2012, the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation approved a Consent Order in *Department v. New England Compounding Center*, No 2012-10295, in which Respondent agreed to the indefinite suspension of its Illinois pharmacy license.

19. A true and correct copy of the Illinois Order is attached as Exhibit "7."

20. On or about October 26, 2012, Respondent agreed to the voluntary relinquishment of its Florida pharmacy license.

21. On or about October 29, 2012, Respondent surrendered its Louisiana non-resident pharmacy license.

22. On or about November 5, 2012, the Texas State Board of Pharmacy agreed to the voluntary revocation of Respondent's Texas pharmacy license in Agreed Board Order #L-13-003, *In the Matter of New England Compounding Center (Pharmacy License #22866)*.

23. A true and correct copy of the Texas Order is attached as Exhibit "8."

24. Respondent did not report the above-described disciplinary actions to the Board within thirty (30) days.

25. In the interest of submitting this Settlement Agreement to the Board in a timely fashion, Petitioner and Respondent have agreed to stipulate to the above recitation of the actions

of pharmacy boards and other licensing authorities in other jurisdictions without attaching certified copies of such actions.

26. Petitioner and Respondent recognize that Respondent may have been subject to other actions by pharmacy boards and other licensing authorities in other jurisdictions that have not been expressly described in this Settlement Agreement.

27. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is represented by Paul Cirel, Esq., Collora, LLP, 100 High Street, 20th Floor, Boston, Massachusetts, 02110, who is authorized by Respondent to sign this Settlement Agreement on its behalf.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein permitted as a pharmacy by the Board acknowledges that Respondent is subject to penalties including but not limited to revocation, suspension or limitation of permits and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent admits that by failing to notify the Board of the disciplinary action taken by other jurisdictions as described in paragraphs A(3) through A(22) above, it violated Hawaii Revised Statutes ("HRS") §436B-19(15).

6. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

7. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2012-34-L.

8. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

C. TERMS OF SETTLEMENT:

1. Revocation of Permit. Respondent agrees to the voluntary revocation of Respondent's permit.

The revocation shall become effective immediately upon the approval of this Settlement Agreement by the Board. Respondent shall turn in all indicia of the permit to the Executive Officer of the Board within ten (10) days after receipt of notice that this Settlement Agreement has been approved.

Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to obtain a permit, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

2. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of pharmacies in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

3. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraph C.4 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

4. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

5. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

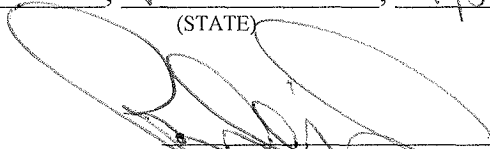
6. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement

Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

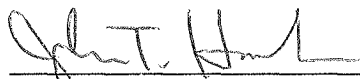
7. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: Boston, MA, 1/22/13.
(CITY) (STATE) (DATE)


PAUL CIREL, Representative of and Legal
Counsel for Respondent New England
Compounding Pharmacy, Inc., dba New England
Compounding Center


DATED: Honolulu, Hawaii, FEB - 7 2013.


JOHN T. HASSLER
PATRICK K. KELLY
Attorneys for Department of Commerce
and Consumer Affairs

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF NEW ENGLAND
COMPOUNDING PHARMACY, INC., dba NEW ENGLAND COMPOUNDING CENTER;
SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY
ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" – "8"; CASE NO. PHA 2012-34-L

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

MARK E. BROWN
Chairperson

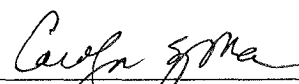

PATRICK ADAMS
Vice-Chairperson

GARRETT A. LAU



3/21/13
DATE


TODD INAFUKU


CAROLYN S. J. MA



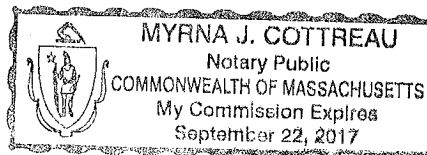
PVL 07/15/11

STATE OF Mass.)
) SS.
COUNTY OF Suffolk)

On this 22nd day of January, 2013, before me personally appeared
Paul Cirel, to me known to be the person described, and who executed the
foregoing instrument on behalf of New England Compounding Center as
its Attorney, and acknowledged that he/she executed the same as
his/her free act and deed.

Myrna J. Cottreau
Name: Myrna J. Cottreau
Notary Public, State of Mass.

My Commission expires: 9/22/2017



OCT 04 2012
ENFORCEMENT

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of
NEW ENGLAND
COMPOUNDING CENTER
Pharmacy Registration No. 2848

Docket No. PHA-2012-0204

VOLUNTARY SURRENDER AGREEMENT

The Board of Registration in Pharmacy (Board) and New England Compounding Center, a pharmacy licensed by the Board (Pharmacy Registration No. 2848), located at 697 Waverly Street in Framingham, Massachusetts (Pharmacy), do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the file of the Pharmacy that is maintained by the Board:

1. The parties enter into this Voluntary Surrender Agreement (Agreement) relating to matters pending before the Board as Docket No. PHA-2012-0204 (Complaint) concerning:
 - (a) an inspection conducted on October 2, 2012; and
 - (b) the sterility of certain drug products compounded and dispensed by the Pharmacy; specifically, methylprednisolone acetate.
2. The Pharmacy acknowledges and agrees to surrender Pharmacy Registration No. 2848 to the Board, effective October 3, 2012 (the Effective Date of the Agreement).
3. The parties acknowledge and agree that the period of Pharmacy license surrender shall continue until such time as the Board has determined that it is in the best interest of the public health and safety for the Pharmacy to resume operations.
4. The Pharmacy agrees to **immediately** commence recall procedures regarding **ALL in use date:**
 - (a) methylprednisolone acetate; and
 - (b) other drug products prepared for intrathecal administration.
5. The Pharmacy acknowledges and agrees that the **quarantine** of:
 - (a) methylprednisolone acetate (commenced September 26, 2012) shall continue in effect, in accordance with the **Quarantine Notice** issued by the Board on October 1, 2012; and
 - (b) all other drug products on Pharmacy premises shall immediately commence and be subject to the terms and conditions of the October 1, 2012 **Quarantine Notice**.
6. The Agreement and its contents shall be incorporated into the records maintained by the Board. The Agreement is a public record subject to disclosure to the public and equivalent state licensing boards.

EXHIBIT "1"



7. The Board agrees that in return for the Pharmacy execution of this Agreement, the Board will not initiate proceedings pursuant to G.L. c. 94C, s. 14 and G.L. c. 112, s. 40; any and all other rights of the Board to take action within the scope of its authority are expressly reserved.
8. The Pharmacy understands and agrees that the decision to enter into this Agreement is a final act and is not subject to reconsideration or judicial review.
9. The Agreement is neither an admission of liability or wrongdoing.
10. The Pharmacy states that the Pharmacy has used legal counsel in connection with the decision to enter into this Agreement or, if the Pharmacy did not, that the Pharmacy had an opportunity to do so.
11. The Pharmacy and the duly authorized representative executing this Agreement on behalf of the Pharmacy, certifies that the representative has read this document entitled "Voluntary Surrender Agreement" and understands that, by executing this Agreement, the Pharmacy is waiving any and all right to a formal hearing at which the Pharmacy would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to provide testimony 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, President
Date: October 3, 2012

BOARD OF REGISTRATION
IN PHARMACY

James T. DeVita
James T. DeVita, R.Ph.
President
Date: October 3, 2012

Effective Date: October 3, 2012

Decision No. 3066

NORTH CAROLINA BOARD OF PHARMACY

In Re:)	
)	
)	ORDER SUMMARILY
New England Compounding Center)	SUSPENDING PERMIT
(Permit No. 08439))	

Pursuant to G.S. § 150B-3(c) and 21 N.C.A.C. 46 .2006(b), the North Carolina Board of Pharmacy ("Board"), vis Gene Minton, E. Lazelle Marks, Robert (Joey) McLaughlin, Jr., and Parker Chesson, find that the protection of the public health, safety and welfare requires emergency action. Accordingly, the Board hereby Summarily Suspends Permit No. 8439 issued to New England Compounding Center ("Respondent Pharmacy") located on 697 Waverly Street, Framingham, Massachusetts 01702, effective upon service of this Order. Respondent Pharmacy shall immediately cease any practice of pharmacy in North Carolina pending issuance by the Board of a Final Agency Decision, and shall not dispense, ship, mail or deliver any dispensed legend drugs into North Carolina.

Respondent Pharmacy may request a hearing on the charges against the permit by submitting a written request within sixty (60) days of service of this order, pursuant to 21 N.C.A.C. 46. 2004. Within sixty (60) days of receipt of a written request, the Board will issue a notice of hearing with respect to whether the summary suspension should be continued. That notice will advise Respondent Pharmacy of the date and time of the hearing, which will be set within the discretion of the Board. In the event that Respondent Pharmacy requests a hearing, this summary suspension remains in effect until the issuance of a further decision by the Board.

If Respondent Pharmacy does not request a hearing as set forth above, the Respondent Pharmacy waives the right to contest the Board's decision and the suspension imposed upon the

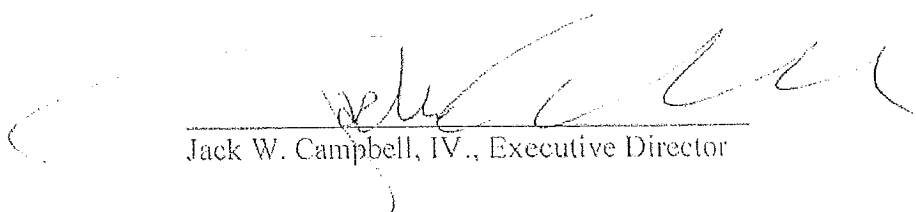
EXHIBIT "2"

permit by this order. However, the Respondent Pharmacy retains the right to file a written petition for reinstatement of the permit at any time following this order.

The Board will set a hearing at a time and place within its discretion and will rule on the petition for reinstatement in its discretion under its duty to consider the public health, safety and welfare.

By Order of the Board, this 30th day of October, 2012.

NORTH CAROLINA BOARD OF PHARMACY

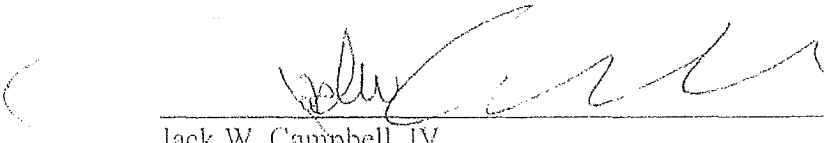


Jack W. Campbell, IV., Executive Director

CERTIFICATE OF SERVICE

I hereby certify that I caused a copy of the foregoing Order Summarily Suspending Permit No. 08439, to be served Respondent Pharmacy New England Compounding Center by Clinton R. Pinyan, Esq., as general counsel and agent for the Board:

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



Jack W. Campbell, IV
Executive Director
North Carolina Board of Pharmacy

IN THE MATTER OF

NEW ENGLAND COMPOUNDING CENTER

PERMIT No: P03113

Respondent-Pharmacy

BEFORE THE

MARYLAND BOARD

OF PHARMACY

CASE NO.: PI-13-057/13-457

ORDER FOR SUMMARY SUSPENSION

Pursuant to Md. State Govt. Code Ann. §10-226 (c) (2009 Repl.), the Maryland Board of Pharmacy (the "Board") hereby **SUMMARILY SUSPENDS** the permit to operate as a pharmacy in the State of Maryland issued to **NEW ENGLAND COMPOUNDING CENTER**, Permit Number P03113. (the "Respondent Pharmacy") under the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. §§ 12-101 et seq. (2009 Repl. Vol.). This Order is based on the following investigative findings, which the Board has reason to believe are true:

FINDINGS OF FACT

1. At all times relevant hereto, the Respondent-Pharmacy was authorized to operate a pharmacy in the State of Maryland. The Respondent-Pharmacy currently holds a permit to operate a pharmacy under permit number P03113. The Respondent-Pharmacy was first issued a permit on March 13, 2003, and its current permit will expire on December 31, 2013.

The statements regarding the Respondent Pharmacy are only intended to provide the Respondent Pharmacy with notice of the basis for the Board's action. They are not intended as, and do not necessarily represent a completed description of the evidence, either documentary or testimonial, to be offered against the Respondent Pharmacy in this matter.

EXHIBIT ³

2. The Respondent-Pharmacy is located at 697 Waverly Street, Frammingham, Massachusetts 01702 and, until recently, was permitted to distribute prescription medications in all 50 states.

3. On or about October 3, 2012, the Respondent-Pharmacy voluntarily ceased operation after a fungal meningitis outbreak was traced to a steroid produced at the facility.

4. As of October 2012, at least thirty five people in six states have become ill from the steroid and five people have died, including one person in Maryland.

5. The Respondent-Pharmacy voluntarily surrendered its Massachusetts Pharmacy permits.

6. On or about October 4, 2012, the North Carolina Board of Pharmacy issued an order summarily suspending the Respondent-Pharmacy's permit to practice pharmacy.

7. Based on the above-investigative findings, the Board has a basis to charge the Respondent-Pharmacy for violating the following.

Md. Health Occ. Code Ann. § 12-403

(f) A nonresident pharmacy shall:

(4) Maintain at all times a valid, unexpired permit to conduct a pharmacy in compliance with the laws of the state in which it is located[.]

Md. Health Occ. Code Ann. § 12-409

(b) Non-resident pharmacy. (1) A nonresident is subject to the disciplinary actions stated in this subsection.

(2) The Board may fine a nonresident pharmacy in accordance with § 12-410 of this subtitle or deny, revoke, or suspend the permit of a nonresident pharmacy for any violation of § 12-403 (d) through (g) of this subtitle.

CONCLUSIONS OF LAW

Based on the foregoing, the Board concludes as a matter of law that the public health, safety or welfare imperatively requires emergency action, pursuant to Md. St. Gov't. Code Ann. § 10-226(c)(2) (2009 Repl. Vol.)

ORDER

Based on the foregoing, it is therefore this 5th day of October 2012, by a majority vote of a quorum of the State Board of Pharmacy, by authority granted to the Board by Md. St. Gov't. Code Ann. §. 10-226(c)(2) (2009 Repl. Vol.), hereby:

ORDERED that the permit issued to the Respondent Pharmacy to operate a pharmacy in the State of Maryland under Permit Number P03113 is hereby **SUMMARILY SUSPENDED**; and be it further

ORDERED that the Respondent Pharmacy shall return its wall certificate and wallet sized permit to the Board, within five days of the date this Order is signed by the Board, and be it further

ORDERED, that this document constitutes a final Order of the Board and is therefore a public document for purposes of public disclosure, as required by Md. State Gov't Code Ann. § 10-617(h) (2009 Repl. Vol. and 2011 Supp.).


LaVerne G. Nassea, Executive Director
Maryland Board of Pharmacy

NOTICE OF AN OPPORTUNITY FOR A HEARING

In accordance with the Act and the Administrative Procedures Act Md. State Govt. Code Ann. §§ 10-201 *et seq.*, the Board hereby notifies the Respondent-Pharmacy of an opportunity for a non-evidentiary Show Cause hearing to show cause why the Board should lift the summary suspension. The Respondent-Pharmacy must request a hearing in writing **WITHIN THIRTY (30) DAYS** of service of this Notice. The written request must be made to:

LaVerne Naasea, Executive Director
Maryland Board of Pharmacy
4201 Patterson Avenue 21215
(410) 764-4755

with copies mailed to:

Tracie Orlove Fruman, Assistant Attorney General
Administrative Prosecutor
Office of the Attorney General
300 West Preston Street, Room 201
Baltimore, Maryland 21201

Linda Bethman, Assistant Attorney General
Board Counsel
Office of the Attorney General
300 West Preston Street, Room 302
Baltimore, Maryland 21201

If a request for a Show Cause hearing is made, a hearing will be scheduled before the Board.

VIRGINIA:

BEFORE THE BOARD OF PHARMACY

IN RE: NEW ENGLAND COMPOUNDING CENTER
NONRESIDENT PHARMACY
Registration No.: 0214-000687

ORDER OF MANDATORY SUSPENSION

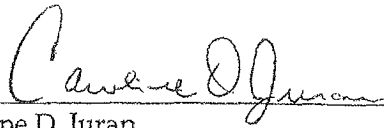
In accordance with the provisions of § 54.1-3434.3 of the Code of Virginia (1950), as amended ("Code"), I, Caroline D. Juran, Executive Director, Virginia Board of Pharmacy, received and acted upon evidence that the New England Compounding Center voluntarily surrendered permit #2848, to operate as a pharmacy in the State of Massachusetts pursuant to a Voluntary Surrender Agreement effective October 3, 2012. A copy of the facility's Voluntary Surrender Agreement is attached to this Order and is marked as Commonwealth's Exhibit No. 1.

WHEREFORE, by the authority vested in the Executive Director of the Virginia Board of Pharmacy, pursuant to § 54.1-3434.3 of the Code, it is hereby ORDERED that the registration of New England Compounding Center to operate as a nonresident pharmacy in the Commonwealth of Virginia be, and hereby is, suspended.

Upon entry of this Order, the registration of New England Compounding Center will be recorded as suspended and no longer current. Should New England Compounding Center seek reinstatement of its registration pursuant to § 54.1-3434.3, it shall be responsible for any fees that may be required for the reinstatement and renewal of its registration prior to issuance of its registration to resume operation as a nonresident pharmacy in the Commonwealth of Virginia.

Pursuant to § 2.2-4023 and § 54.1-2400.2 of the Code, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public inspection and copying upon request.

FOR THE BOARD



Caroline D. Juran
Executive Director

ENTERED: October 5, 2012

EXHIBIT "4"

OCT 04 2012

ENFORCEMENT

SUFFOLK COUNTY

COMMONWEALTH OF MASSACHUSETTS

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)
NEW ENGLAND)
COMPOUNDING CENTER)
Pharmacy Registration No. 2848)

Docket No. PHA-2012-0204

VOLUNTARY SURRENDER AGREEMENT

The Board of Registration in Pharmacy (Board) and New England Compounding Center, a pharmacy licensed by the Board (Pharmacy Registration No. 2848), located at 697 Waverly Street in Framingham, Massachusetts (Pharmacy), do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the file of the Pharmacy that is maintained by the Board:

1. The parties enter into this Voluntary Surrender Agreement (Agreement) relating to matters pending before the Board as Docket No. PHA-2012-0204 (Complaint) concerning:
 - (a) an inspection conducted on October 2, 2012; and
 - (b) the sterility of certain drug products compounded and dispensed by the Pharmacy; specifically, methylprednisolone acetate.
2. The Pharmacy acknowledges and agrees to surrender Pharmacy Registration No. 2848 to the Board, effective October 3, 2012 (the Effective Date of the Agreement).
3. The parties acknowledge and agree that the period of Pharmacy license surrender shall continue until such time as the Board has determined that it is in the best interest of the public health and safety for the Pharmacy to resume operations.
4. The Pharmacy agrees to **immediately** commence recall procedures regarding **ALL in use date:**
 - (a) methylprednisolone acetate; and
 - (b) other drug products prepared for intrathecal administration.
5. The Pharmacy acknowledges and agrees that the **quarantine** of:
 - (a) methylprednisolone acetate (commenced September 26, 2012) shall continue in effect, in accordance with the **Quarantine Notice** issued by the Board on October 1, 2012; and
 - (b) all other drug products on Pharmacy premises shall immediately commence and be subject to the terms and conditions of the October 1, 2012 **Quarantine Notice**.
6. The Agreement and its contents shall be incorporated into the records maintained by the Board. The Agreement is a public record subject to disclosure to the public and equivalent state licensing boards.



7. The Board agrees that in return for the Pharmacy execution of this Agreement, the Board will not initiate proceedings pursuant to G.L. c. 94C, s. 14 and G.L. c. 112, s. 40; any and all other rights of the Board to take action within the scope of its authority are expressly reserved.
8. The Pharmacy understands and agrees that the decision to enter into this Agreement is a final act and is not subject to reconsideration or judicial review.
9. The Agreement is neither an admission of liability or wrongdoing.
10. The Pharmacy states that the Pharmacy has used legal counsel in connection with the decision to enter into this Agreement or, if the Pharmacy did not, that the Pharmacy had an opportunity to do so.
11. The Pharmacy and the duly authorized representative executing this Agreement on behalf of the Pharmacy, certifies that the representative has read this document entitled "Voluntary Surrender Agreement" and understands that, by executing this Agreement, the Pharmacy is waiving any and all right to a formal hearing at which the Pharmacy would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to provide testimony 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, President
Date: October 3, 2012

BOARD OF REGISTRATION
IN PHARMACY

James T. DeVita
James T. DeVita, R.Ph.
President
Date: October 3, 2012

Effective Date: October 3, 2012

Decision No. 3066



OHIO STATE BOARD OF PHARMACY

77 South High Street, Room 1702; Columbus, OH 43215-6126

-Equal Opportunity Employer and Service Provider-

TEL: 614/466-4143

E-MAIL: exec@bop.state.oh.us

FAX: 614/752-4836

TTY/TDD: Use the Ohio Relay Service: 1-800/750-0750

URL: <http://www.pharmacy.ohio.gov>

SUMMARY SUSPENSION ORDER/NOTICE OF OPPORTUNITY FOR HEARING

October 9, 2012

New England Compounding Center
c/o Barry Cadden, Responsible Pharmacist
697 Waverly Street
Framingham, MA 01702

Dear Mr. Cadden,

In accordance with Section 3719.121(B) of the Ohio Revised Code, the Board has determined that there is clear and convincing evidence that the continuation of your professional practice presents a danger of immediate and serious harm to others. The reasons for the Board's action are that you have committed any and/or all of the following acts:

(1) Records of the Board of Pharmacy indicate that your facility was originally licensed in the State of Ohio on January 17, 2008, and is currently licensed to practice pharmacy in the State of pursuant to Sections 4729.27 and 4729.55 of the Ohio Revised Code and Rule 4729-5-11 of the Ohio Administrative Code).

(2) The New England Compounding Center has provided intrathecal methylprednisolone acetate injections that allegedly resulted in a fungal meningitis outbreak that have affected people in nine (9) states, leaving eight (8) people dead. These allegedly contaminated products were administered to approximately 430 people in Ohio. Further, the North Carolina Board of Pharmacy summarily suspended your permit (No. 8439) to practice pharmacy in that state on October 3, 2012 as a result of these same facts.

YOU ARE HEREBY NOTIFIED that Section 3719.121(B) of the Ohio Revised Code states, in pertinent part:

(B) If the board under which a person has been issued a license. . . determines that there is clear and convincing evidence that continuation of the person's professional practice. . . presents a danger of immediate and serious harm to others, the board may suspend the person's license, . . . without a prior hearing.

WHEREFORE, PURSUANT TO SECTION 3719.121(B) OF THE OHIO REVISED CODE, YOU ARE HEREBY NOTIFIED THAT YOUR REGISTRATION AND LICENSE TO PRACTICE PHARMACY IN THE STATE OF OHIO ARE HEREBY SUSPENDED. YOU SHALL IMMEDIATELY CEASE ANY PRACTICE OF PHARMACY IN THE STATE OF OHIO. This suspension shall remain in effect until such time as the Board issues a final adjudication order.

EXHIBIT "5"

YOU ARE HEREBY FURTHER ADVISED that Section 4729.57 of the Ohio Revised Code provides in pertinent part:

(A) The State Board of Pharmacy may suspend, revoke, or refuse to renew any license issued to a terminal distributor of dangerous drugs pursuant to section 4729.54 of the Revised Code, or may impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Ohio Revised Code for a similar offense or one thousand dollars if the acts committed have not been classified as an offense by the Revised Code, for any of the following causes:

(1) Making any false material statements in an application for a license as a terminal distributor of dangerous drugs;

(2) Violating any rule of the board;

(3) Violating any provision of this chapter;

(4) Violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code;

(5) Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code;

(6) Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this division prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor;

(7) Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in Section 4729.55 of the Revised Code.

(8) Except as provided in division (B) of this section:

(a) Waiving the payment of all or any part of a deductible or copayment that an individual, pursuant to a health insurance or health care policy, contract, or plan that covers the services provided by a terminal distributor of dangerous drugs, would otherwise be required to pay for the services if the waiver is used as an enticement to a patient or group of patients to receive pharmacy services from that terminal distributor;

(b) Advertising that the terminal distributor will waive the payment of all or any part of a deductible or copayment that an individual, pursuant to a health insurance or health care policy, contract, or plan that covers the pharmaceutical services would otherwise be required to pay for the services.

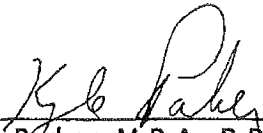
YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the Ohio State Board of Pharmacy, if you request such a hearing within thirty (30) days of the time of the mailing of this notice.

IF YOUR FACILITY DESIRES A HEARING, such request shall be mailed to the State Board of Pharmacy, 77 South High Street, Room 1702, Columbus, Ohio 43215-6126. YOUR REQUEST MUST BE IN WRITING, AND MUST BE RECEIVED IN THE OFFICE OF THE OHIO STATE BOARD OF

PHARMACY ON OR PRIOR TO THE THIRTIETH (30TH) DAY FOLLOWING THE MAILING DATE OF THIS NOTICE. You may appear at such hearing in person, by or with your attorney, or you may present the facility's position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against the facility.

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the thirtieth (30th) day following the mailing of this notice, the Ohio State Board of Pharmacy, upon consideration of the aforementioned allegations against your facility, may take action without such a hearing.

BY ORDER OF THE STATE BOARD OF PHARMACY



Kyle W. Parker, M.B.A., R.Ph.
Executive Director

KWP/vlf (D-121009-268)

Registered Mail/Return Receipt
RE 663 138 435 US

c: Sean M. Culley, Assistant Attorney General

BEFORE THE TENNESSEE BOARD OF PHARMACY

IN THE MATTER OF:

NEW ENGLAND COMPOUNDING CENTER,
LICENSE NUMBER 00004144
697 WAVERLY STREET
FRAMINGHAM, MA 01702

)
)
) COMPLAINT NO. 201200215
)
)

VOLUNTARY SURRENDER AGREEMENT

The Division of Health Related Boards of the Tennessee Department of Health ("Division"), by and through the Office of General Counsel, and Respondent, New England Compounding Center ("NECC" or "Respondent") do hereby stipulate and agree as follows:

I. Authority and Jurisdiction

The Tennessee Board of Pharmacy ("Board") regulates and supervises pharmacies, pharmacists, pharmacy technicians, and pharmaceutical manufacturers, wholesalers, and distributors licensed to practice pursuant to the Tennessee Pharmacy Practice Act (See "Practice Act" located at Tennessee Code Annotated section 63-10-101, *et seq.*), including the discipline of licensees, as well as those who are required to be licensed, who violate the Practice Act and the Rules promulgated by the Board. (See Tenn. Comp. R.&Regs. § 1140-01-.01, *et seq.*) The Board enforces the Practice Act to promote and protect the health, safety and welfare of the public; accordingly, it is the policy of the Board to require strict compliance with the law and to apply the law to preserve the quality of pharmacy care provided in Tennessee.

II. Stipulations of Fact

1. At all times pertinent herein, Respondent has been licensed by the Board as a pharmacy in the state of Tennessee, having been granted license number 00004144 on February 15,

EXHIBIT "6"

2005.

2. On or about October 3, 2012, Respondent voluntarily surrendered its pharmacy license in its home state of Massachusetts. The Surrender Agreement states that it relates to: (a) an inspection conducted on October 2, 2012; and (b) the sterility of certain drug products compounded and dispensed by the Pharmacy; specifically, methylprednisolone acetate.
3. Tennessee Code Annotated section 4-5-320(c) grants the Board the authority to summarily suspend a license if it finds that the public health, safety, or welfare require emergency action.
4. Tennessee Code Annotated section 63-10-305 and Tenn. Comp. R. & Regs. 1140-1-.08 grant the Board the authority to revoke, suspend, or impose other lawful disciplinary action, including a civil penalty for any violation of any laws relating to drugs or to the practice of pharmacy and/or the Board's rules.
5. Tennessee Code Annotated section 63-10-305(7) grants the Board the authority to suspend, revoke, or refuse to issue a license to a licensee that has had its license to practice pharmacy suspended or revoked by another state for disciplinary reasons.
6. Rule 1140-01-.08(3)(a)(3) of the Rules of the Tennessee Board of Pharmacy provides that every out-of-state pharmacy also licensed in Tennessee must maintain at all times a current permit, license, or registration to conduct the pharmacy in compliance with the laws of the state in which the pharmacy is located.

IV. Stipulated Disposition

7. The Stipulations of Fact are sufficient to establish that the Board may initiate a disciplinary proceeding against Respondent under Tennessee Code Annotated section 63-10-305(7).
8. Respondent understands the rights found in the Practice Act and the Uniform

Administrative Procedures Act (See Tenn. Code Ann. §§ 4-5-101 thru 4-5-404), including the right to a hearing to contest the Stipulations of Fact, the right to appear personally and by legal counsel, the right to confront and to cross-examine witnesses who would testify against Respondent, the right to testify and to present evidence on Respondent's own behalf, as well as to the issuance of subpoenas to compel the attendance of witnesses and the production of documents, as well as the right to appeal for judicial review of an adverse action.

9. For the purpose of avoiding the costs and uncertainties of further administrative action with respect to this cause, Respondent agrees to the **VOLUNTARY SURRENDER** of its license to practice as a pharmacy in the state of Tennessee.
10. Respondent understands this **VOLUNTARY SURRENDER** has the same effect as a **REVOCATION** and is a formal disciplinary action.
11. Respondent understands that although it makes no admission of liability or wrongdoing by voluntarily surrendering its pharmacy license, the Board retains the right to bring an action against Respondent for the assessment of civil penalties for the reasons set forth in Tennessee Code Annotated section 60-10-305 and Rule 1140-01-.08(3)(a)(3) of the Rules of the Tennessee Board of Pharmacy.
12. By entering into this Agreement, Respondent understands and agrees that the decision to enter into this Agreement is a final act and is not subject to reconsideration or judicial review.
13. The parties hereto agree that Respondent makes no admission of liability or wrongdoing.
14. A violation of this Voluntary Surrender Agreement shall constitute a separate violation of the Tennessee Pharmacy Practice Act located at Tennessee Code Annotated section 63-10-101, *et seq.*, and constitutes grounds for further disciplinary action by the Board.

15. Respondent states that it has used legal counsel in connection with the decision to enter into this Agreement or, if it did not, Respondent had an opportunity to do so.
16. This Agreement and its contents shall be incorporated into the records maintained by the Board. In addition, this Agreement is a public record subject to disclosure to the public and equivalent licensing boards.

By: Bang Peder
New England Compounding Center,
Respondent
Pharmacy License No. 00004144

By: Paul Cirel
Paul Cirel, Esq.
Attorney for Respondent
100 High Street
Boston, Mass. 02110-2321

Dated: 10/12/12

Dated: 10/12/12

By: Andrew Holt
Andrew Holt, Pharm.D.
Executive Director
Tennessee Board of Pharmacy

By: John R. Smith
John R. Smith
Chief Deputy General Counsel
Tennessee Department of Health
220 Athens Way, Suite 210
Nashville, TN. 37243
(615) 532-7179
john.r.smith@tn.gov

Dated: 10/15/12

Dated: 10/15/12

Approval by the Board

Upon the agreement of the parties and the record as a whole, this Voluntary Surrender Agreement was approved by a majority of a quorum of the Tennessee Board of Pharmacy at a public meeting of the Board and signed this 15th day of October, 2012.

Brenda Warren
Brenda Warren, Pharm. D.
Chairperson
Tennessee Board of Pharmacy

STATE OF ILLINOIS
ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION

DEPARTMENT OF FINANCIAL AND PROFESSIONAL)	
REGULATION, DIVISION OF PROFESSIONAL REGULATION)	
of the State of Illinois,	Complainant)
)	
v.)	No. 2012-10295
)	
NEW ENGLAND COMPOUNDING CENTER)	
License No. 054-016977,	Respondent)

CONSENT ORDER

The Illinois Department of Financial and Professional Regulation, Division of Professional Regulation (hereinafter the "Department") by Scott A. Golden, its attorney, and NEW ENGLAND COMPOUNDING CENTER, Respondent, agree to the following:

STIPULATIONS

NEW ENGLAND COMPOUNDING CENTER is licensed as a pharmacy in the State of Illinois, holding License No. 054-016977. Said license is presently in active status. At all times material to the matters set forth in this Consent Order, the Department had jurisdiction over the subject matter and parties to this Consent Order.

Respondent, an out-of-state pharmacy, dispensed compounded products into the State of Illinois which have been recalled after patients who were administered the same drugs in other states were diagnosed with fungal meningitis. During October 2012, Respondent voluntarily surrendered its license in several states including in Massachusetts where it is located.

The allegation(s) as set forth herein, if proven to be true, would constitute grounds for discipline of Respondent's license as pharmacy in the State of Illinois on the authority of 225 ILCS 85/30(a)(2) (2011); Ill. Admin. Code tit. 68, §1330.40(a)(2) (2010); and 225 ILCS 85/30(a)(8) (2011).

Respondent has been advised of the right to have the pending allegations reduced to written charges, the right to a hearing, the right to contest any charges brought, and the right to administrative review of any Order resulting from a hearing. Respondent knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by either the Illinois State Board of Pharmacy or the Director of the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation. Respondent acknowledges that it has entered into this Consent Order freely and of its own will without threat or coercion by the Department or any person. Respondent acknowledges that the Department attorney may be requested to communicate with the Illinois State Board of Pharmacy or the Director of the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation in furtherance of the approval of this Consent Order.

Respondent and the Department have agreed, in order to resolve this matter, that Respondent be permitted to enter into a Consent Order with the Department, providing for the imposition of disciplinary measures which are fair and equitable in these circumstances and which are consistent with the best interests of the people of the State of Illinois.

This Consent Order shall in no event be construed as or deemed to be evidence of or an admission on the part of the Respondent. Further, this Consent Order is entered into by the Respondent solely for the purpose of avoiding the expense and anxiety of a protracted hearing process and shall not be construed as an admission of the truth of any fact set forth above, and further, if this matter were to proceed to a hearing, Respondent would deny any wrongdoing.

CONDITIONS

WHEREFORE, the Department, through Scott A. Golden, its attorney, and NEW ENGLAND COMPOUNDING CENTER, Respondent, agree:

A. The pharmacy license of NEW ENGLAND COMPOUNDING CENTER, License No. 054-016977, shall be INDEFINITELY SUSPENDED. Said action, although taken in lieu of the voluntary surrender of Respondent's license, shall be considered disciplinary action.

B. Should Respondent petition for the restoration of its Illinois pharmacy license, Respondent shall have the burden to show by competent evidence:

1. That Respondent's licenses have been restored to practice in all states where it holds licensure, including but not limited to its home state of Massachusetts;
2. That Respondent is not under investigation by federal, state or local authorities related or unrelated to the above;
3. That Respondent knows of no pending civil litigation or criminal prosecution against Respondent arising out of the aforementioned conduct;
4. That Respondent has complied with all of the provisions of this Consent Order;
5. That Respondent has complied with all statutory requirements for renewal or reinstatement, including but not limited to payment of all necessary fees and completion of all appropriate forms; and
6. That Respondent warrants the public trust.

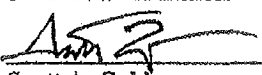
C. Upon notice of the effective date of this Consent Order, Respondent shall send to the Department all current indicia of licensure, including all copies of wall certificates and wallet cards. Said certificates will be retained by the Department during the period of suspension. Respondent shall send said certificates of licensure to the Department:

Illinois Department of Financial and Professional Regulation
Attn: Probation Compliance Unit
9511 Harrison Street, Suite LL50
Des Plaines, Illinois 60016

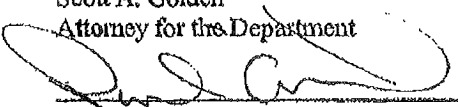
- D. Any violation by Respondent of the terms and/or conditions of this Consent Order shall be grounds for the Department to immediately file a Complaint to revoke or otherwise discipline Respondent's license to practice as a pharmacy in the State of Illinois.
- E. This Consent Order shall become effective immediately upon signing and approval by the Director of the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation.

DIVISION OF PROFESSIONAL REGULATION
of the State of Illinois

10/18/12
DATE


Scott A. Golden
Attorney for the Department

10/18/12
DATE


New England Compounding Center, by its representative,
Respondent

10/17/12
DATE


Paul R. Cirel
Attorney for Respondent

10/18/12
DATE


Philip P. Burgess, R.Ph.
Chairperson, Illinois State Board of Pharmacy

per authorization

THIS CONSENT ORDER IS APPROVED IN FULL:

DATED THIS 18th DAY OF October, 20 12.

ILLINOIS DEPARTMENT OF FINANCIAL AND
PROFESSIONAL REGULATION
OF THE STATE OF ILLINOIS
SUSAN J. GOLD, ACTING SECRETARY
DIVISION OF PROFESSIONAL REGULATION


JAY STEWART
DIRECTOR

Case No. 201210295
License No. 034016977

AGREED BOARD ORDER #L-13-003

RE: IN THE MATTER OF
NEW ENGLAND COMPOUNDING
CENTER
(PHARMACY LICENSE #22866)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy ("Board") the matter of pharmacy license number 22866 issued to New England Compounding Center, ("Respondent"), 697 Waverly Street, Framingham, Massachusetts 01702.

The Board received a request from Paul Cirel, Representative of New England Compounding Pharmacy, Inc. and Legal Counsel, for and on behalf of Respondent, which indicated Respondent had chosen to voluntarily revoke the pharmacy license issued to Respondent.

Pursuant to the request for revocation, it was agreed among the parties that Respondent shall comply with the requirements set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD


THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that effective upon the entry of this Order, pharmacy license number 22866 held by Respondent, shall be revoked and of no further force and effect.

EXHIBIT "8"

And it is so Ordered.

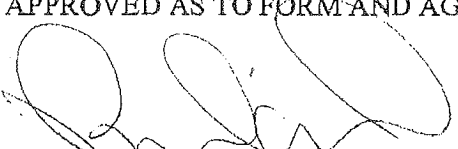
THIS ORDER IS A PUBLIC RECORD.

Signed and entered by the Executive Director on behalf of the Texas State Board of Pharmacy on
this 5th day of November, 2012.



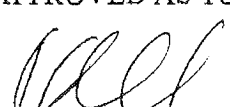
Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:



Paul Cirel, Representative of New England Compounding Pharmacy, Inc.
and Legal Counsel, for and on behalf of New England Compounding Center

APPROVED AS TO FORM:



Kerstin E. Arnold, General Counsel
Texas State Board of Pharmacy