

**COMMONWEALTH OF MASSACHUSETTS**

**NOTICE OF THE REGULARLY SCHEDULED MEETING OF THE  
BOARD OF REGISTRATION IN PHARMACY**

December 3, 2013  
239 Causeway Street ~ Room 417 A&B  
Boston, Massachusetts 02114

**AGENDA**

Time	#	Item	Exhibits	Staff Contact
8:30	I.	<b>CALL TO ORDER</b>		
8:35	II.	<b>APPROVAL OF AGENDA</b>		
8:40	III.	<b>ADOPTION OF REMOTE PARTICIPATION PER OPEN MEETING LAW (M.G.L. ch. 30A, s. 20(d) and 940 CMR 29.10)</b>		
8:45	IV.	<b>EXECUTIVE SESSION</b>  1. Approval of prior executive session minutes in accordance with M.G.L. ch.30A, § 22(f) for sessions held during the September 10, 2013, October 1, 2013 and November 5, 2013 meetings.		<b>CLOSED SESSION</b>
8:50	V.	<b>ADJUDICATORY SESSION (M.G.L. ch. 30A, § 18)</b>		<b>CLOSED SESSION</b>
8:55	VI.	<b>M.G.L. c. 112, § 65C SESSION COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY</b>		<b>CLOSED SESSION</b>
9:55	VII.	<b>APPROVAL OF BOARD MINUTES</b>  1. Draft Minutes for the October 1, 2013 Meeting of the Board of Registration in Pharmacy, Regular Session	Minutes	V. Berg
10.00	VIII.	<b>REPORTS</b>  1. Applications approved pursuant to Licensure Policy 13-01 2. Plans of Correction reviewed pursuant to Enforcement Policy 13-02	Reports	M. Cittadino H. Engman

10:10	IX.	<p><b>FILE REVIEW</b></p> <ol style="list-style-type: none"> <li>1) PHA-2012-0258 Pharmacy Corporation of America</li> <li>2) PHA-2013-0061 Jeffrey Lynch PH24722</li> <li>3) PHA-2013-0072 Richard Mancini PH22198</li>   <li>4) PHA-2012-0131, Rogers Pharmacy DS14170</li> <li>5) PHA-2013-0005, Kenneth Minty, PH17282</li> <li>6) PHA-2013-0004, Jon Cincotta, PT139</li>   <li>7) PHA-2012-0105, Kristen Richard, PH27014</li> <li>8) PHA-2012-0106, Rite Aid 10092, DS 2886</li>   <li>9) PHA-2013-0077, Edward Lynsky, PH15346</li>   <li>10) SA-INV-2643, CVS 1855, DS2901</li> <li>11) SA-INV-2944, CVS 2283, DS2844</li> <li>12) SA-INV-2870, CVS 973, DS3426</li> <li>13) SA-INV-2429, CVS 2325, DS2850</li> <li>14) SA-INV-2939, CVS 993, DS1755</li> <li>15) SA-INV-3051, Mura Pharmaceuticals, WD369</li> <li>16) SA-INV-2730, Louis &amp; Clark 572, DS2543</li> <li>17) SA-INV-2884, Walgreens 4358, DS2873</li> <li>18) SA-INV-3077, Walgreens 3469, DS2593</li> <li>19) SA-INV-3034 Costco Pharmacy 333, DS3211</li> </ol>		
11:30	X.	<b>BREAK</b>		

11:45	XI.	<p><b>APPLICATIONS</b></p> <ol style="list-style-type: none"> <li>1. <b>New England Home Therapies (DS3486)</b> 337 Turnpike Road, Southborough Renovation/Expansion to include new negative pressure chemotherapy (hazardous drug) compounding room</li> <li>2. <b>AcariaHealth Pharmacy</b> 260 E Fordham Road, Suite E, Wilmington, MA. New Community Pharmacy Application</li> <li>3. <b>Open Source Pharmaceuticals Inc.</b> 1208A VFW Parkway, Suite 202, West Roxbury New Wholesale Distributor Application</li> <li>4. <b>NeedleTech Products, Inc</b> John L. Dietsch Blvd., North Attleboro New Wholesale Distributor Application</li> </ol>	Applications and supporting documents	M. Cittadino
1:00	XII.	<p><b>FLEX SESSION</b></p> <ol style="list-style-type: none"> <li>1. Elections</li> <li>2. Review of Licensing Policy 13-05: Staff Action to Identify License Applications Requiring Good Moral Character Evaluation</li> <li>3. Topics for upcoming meetings</li> </ol>		
1:30	XIII.	<p><b>ADJOURNMENT</b></p>		

COMMONWEALTH OF MASSACHUSETTS  
BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE REGULARLY SCHEDULED MEETING  
239 Causeway Street, Fourth Floor ~ Room 417A  
Boston, Massachusetts 02114

Tuesday, December 3, 2013

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**Board Members Present**

James T. DeVita, RPh, President  
Anita Young, RPh, EdD, Secretary  
Jane F. Franke, RN, MHA  
Patrick M. Gannon, RPh, MS, FABC  
Anthony Perrone, RPh, MD, MBA  
Edmund Taglieri, RPh, MSM, NHA  
Richard Tinsley, MBA, MEd  
Joanne Trifone, RPh

**Board Members Not Present**

Karen Ryle, RPh, President-Elect  
(remote log-in for election vote)

**Board Staff Present**

David Sencabaugh, RPh, Executive Director  
Margaret Cittadino, MEd, Associate Director  
Heather Engman JD, MPH, Board Counsel  
Vita P. Berg, JD, Board Counsel  
Leo McKenna, RPh, PharmD, QA Coordinator  
Samuel Penta, RPh, Investigator Supervisor  
William E. Frisch, Jr., RPh, Investigator  
Carolyn Reid, Administrative Assistant  
Joseph Sceppa, RPh, Consultant

**Board Staff Not Present**

Cheryl Lathum, RPh, PharmD, Investigator

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TOPIC:

**I. CALL TO ORDER**

DISCUSSION: A quorum of the Board was present. J. DEVITA chaired the meeting and asked if anyone in the audience was recording the meeting; no one indicated that they were recording the meeting.

ACTION: At 8:35 a.m. J. DEVITA, President, called the December 3, 2013, meeting of the Board of Registration in Pharmacy to order.

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...TOPIC:

**II. APPROVAL OF AGENDA**

DISCUSSION: Board members reviewed the tentative agenda. V. BERG announced that certain items will be deferred to the January Meeting (Item IX, File Review 10, 12, 14, 18, 19). There are no reports for this month (Item VIII.)

ACTION: Motion by, P. GANNON, seconded by A. YOUNG, and voted unanimously to approve the agenda with the above changes.

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TOPIC:

**III. ADOPTION OF REMOTE PARTICIPATION PER OPEN MEETING LAW (M.G.L. ch.30a, § 20(d) and 94 CMR 29.10)**

DISCUSSION: V. BERG briefly reviewed the laws and regulations that allow for a board member who is not physically present at the location of a board meeting to participate in the meeting via telecommunications. The Board chair may permit a member to participate remotely in specific instances, as described in the laws and regulations. One caveat is that the remote participant(s) do not count towards quorum. A quorum has to be comprised of those physically present. The Board chair would approve and announce the remote participant(s). All votes conducted while a member was participating remotely need to be by roll call. The Board must formally adopt this practice by vote before any remote participation takes place.

ACTION: Motion by J. TRIFONE seconded by P. GANNON and voted unanimously to adopt remote participation as allowed by law and regulation.

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TOPIC:

**IV. EXECUTIVE SESSION**

DISCUSSION: None

ACTION: Motion by E. TAGLIERI seconded by J. FRANKE and passed by unanimous roll call vote to enter into the Executive Session at 8:43 a.m. J. DEVITA: yes; J. TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; J. FRANKE: yes; P. GANNON: yes; A. PERRONE: yes; R. TINSLEY: yes.

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EXECUTIVE SESSION (8:43 – 8:47 a.m.)

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TOPIC:

**V. ADJUDICATORY SESSION**

DISCUSSION: None

ACTION: Motion by J. TRIFONE seconded by E. TAGLIERI and passed by unanimous roll call vote to enter into the Executive Session at 8:47 a.m. J. DEVITA: yes; J. TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; J. FRANKE: yes; P. GANNON: yes; A. PERRONE: yes; R. TINSLEY: yes.

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ADJUDICATORY SESSION (8:47 – 8:50 a.m.)

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TOPIC:

**VI. M.G.L. c. 112, § 65C SESSION**

DISCUSSION: None

ACTION: Motion by E. TAGLIERI seconded by J. TRIFONE and passed by unanimous roll call vote to enter into M.G.L. c. 112, § 65C Session at 8:38 a.m. J. DEVITA: yes; J. TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; J. FRANKE: yes; A. PERRONE: yes; R. TINSLEY: yes.

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M.G.L. c. 112, § 65C SESSION (8:50 – 10:28 a.m.)

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BREAK (10:28 – 10:42 a.m.)

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TOPIC:

**VII. APPROVAL OF BOARD MINUTES**

October 1, 2013 Regularly Scheduled Meeting

DISCUSSION: V. BERG presented the minutes of the October 1, 2013 Regularly Scheduled Meeting.

ACTIONS: Motion by J. TRIFONE, seconded by A. YOUNG, and voted unanimously, to approve the minutes of the October 1, 2013 Regularly Scheduled Meeting, with minor changes.

TOPIC:

**VIII. REPORTS**

**1. Applications approved pursuant to Licensure Policy 13-01**

DISCUSSION: M. CITTADINO indicated that the report would be deferred until the January meeting.

ACTION: So noted.

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**VIII. REPORTS**

**2. Plans of Correction reviewed pursuant to Enforcement Policy 13-02**

DISCUSSION: H. ENGMAN indicated that there were no Plans of Correction to report.  
ACTION: So noted.

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TOPIC:

**IX. FILE REVIEW**

1. Pharmacy Corporation of America (DS3599), PHA-2012-0258
2. Jeffrey Lynch (PH24722), PHA-2013-0061
3. Richard Mancini (PH22198), PHA-2013-0071

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. As a result of a Board inspection, this Pharmacy Corporation of America in Brockton received a Cease and Desist order from the Board on 12/28/2012.

The Rhode Island Board of Pharmacy notified the MA Board that an inspection of the Warwick facility revealed that at the direction of Jeffrey Lynch (MOR, Brockton) and Richard Mancini (MOR Warwick), six (6) MA licensed pharmacy technicians from the Brockton PCA prepared sterile products at the Warwick, Rhode Island PCA from 12/28/13 to 1/4/2013 without being licensed in Rhode Island.

The Brockton facility subsequently received prepackaged medications from a non-licensed wholesaler, and subsequently dispensed them to a patient.

This is a complex case and the Board was unsure of which compounded products were involved, how it relates to the Cease and Desist order, the sections of 247 CMR, and who made the collective decision to relocate personnel.

ACTION: Motion by J. DEVITA, seconded by P.GANNON, and voted unanimously, to table the matter until additional information could be obtained

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TOPIC:

**IX. FILE REVIEW**

4. **Rogers Pharmacy** (DS14170), PHA-2012-0131
5. **Kenneth Minty** (PH17282), PHA-2013-0005
6. **Jon Cincotta** (PT139), PHA-2013-0004

DISCUSSION:

W. FRISCH presented the above-referenced matter to the Board. This complaint by a nurse involves transposed blister pack packaging of Zyprexa (olanzapine) 10 & 20 mg. The error was caught and corrected. No incorrect medications were administered.

Pharmacy technician Jon Cincotta incorrectly packaged both blister packs simultaneously. Pharmacist/MOR Kenneth Minty checked the blister packs but did not catch the errors.

ACTION:

4) & 5). Motion by J. FRANKE, seconded by P. GANNON, and voted unanimously, to defer action to a time when these complaints can be combined with other cases involved with blister pack packaging.

6) Motion by J. DEVITA, seconded by A. YOUNG, and voted unanimously to refer this matter to the Office of Prosecution for the issuance of an Order to Show Cause. The motion further authorized, in the alternative, resolution with a consent agreement for stayed probation with terms requiring that Mr. Cincotta successfully complete two contact hours of continuing education in medication safety.

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**TOPIC:**

**IX. FILE REVIEW**

7. **Kirsten Richard** (PH27014), PHA-2012-0105
8. **Rite Aid #10092** (DS2886), PHA 2012-0106

**DISCUSSION:**

W. FRISCH presented the above-referenced matter to the Board. This complaint involved the incomplete removal/obliteration of a prior patient's identification information by pharmacist Kristen Richard, thereby violating HIPAA regulations. The plan of correction included check to ensure that any prior label has been removed before affixing the new label.

**ACTION:**

7) Motion by E. TAGLIERI, seconded by A. YOUNG, and voted unanimously, to refer this matter to the Office of Prosecution for the issuance of an Order to Show Cause. The motion further authorized, in the alternative, resolution with a consent agreement for stayed probation with terms requiring that Ms. Richard provide proof that staff have been trained in HIPAA regulations.

8) Motion by A. YOUNG, seconded by E. TAGLIERI, and voted unanimously, to refer this matter to the Office of Prosecution for the issuance of an Order to Show Cause. The motion further authorized, in the alternative, resolution with a consent agreement for stayed probation with terms requiring that that Rite Aid provide proof that staff have been retrained with respect to returning products to stock and HIPAA regulations.

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**TOPIC:**

**IX. FILE REVIEW**

9. **Edward Linsky** (PT7549), PHA-2012-0260

**DISCUSSION:**

S. PENTA presented the above-referenced matter to the Board. The Georgia Board of Pharmacy notified MA Board that Mr. Linsky, registered in both states, had entered into a consent order with the Georgia Board for dispensing the longer acting Novolin 70/30 for a Novolog 70/30 prescription.

**ACTION:** Motion by J. TRIFONE, seconded by A. YOUNG, and voted unanimously, that a letter be sent to the registrant indicating that should he want to practice again in Massachusetts this matter would have to be resolved be for reactivation of his license.

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**TOPIC:**

**IX. FILE REVIEW**

11. **CVS 2283** (DS2844), SA-INV-2944

**RECUSAL:** J. DEVITA recused himself and was not present during the discussion or votes for these matters.

**DISCUSSION:**

W. FRISCH presented the above-referenced matter to the Board. The pharmacy dispensed 13 tablets of Vicodin (hydrocodone 5 mg/acetaminophen 500 mg) rather than the 18 tablets that had been prescribed. The original and corrected count were



verified by the patient's representative, also a nurse. Pharmacy staff has been retrained to double-count prescriptions for controlled substances.

ACTION: Motion by E. TAGLIERI, seconded by J. TRIFONE, and voted unanimously, to dismiss the complaint without prejudice due to insufficient evidence.

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**TOPIC:**

**IX. FILE REVIEW**

**13. CVS 2325 (DS2850), SA-INV-2429**

RECUSAL: J. DEVITA recused himself and was not present during the discussion or votes for these matters.

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. A consumer indicated that this pharmacy refused to refill a prescription for a cholesterol-lowering medication.

The prescription had been filled at a Caremark (mail order) pharmacy (phone number on prescription label), yet had not been received.

The MOR counseled the technician on handling similar situations.

ACTION: Motion by J. TRIFONE, seconded by P. GANNON, and voted unanimously, to dismiss the complaint without prejudice.

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**TOPIC:**

**IX. FILE REVIEW**

**15. Muro Pharmaceuticals (WD369), SA-INV-3051**

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. The inappropriate repackaging and distribution of tadalafil (Cialis) and sildenafil (Viagra) was incorrectly attributed to Muro Pharmaceuticals in MA.

ACTION: Motion by P. GANNON, seconded by A. YOUNG, and voted unanimously, to close the staff assignment.

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**TOPIC:**

**IX. FILE REVIEW**

**16. Louis & Clark (DS2543), SA-INV-2730**

DISCUSSION:

W. Frisch presented the above-referenced matter to the Board. Complainant believes that a blister pack of medication contained Vitamin B-12, rather than Vitamin B-6 which had been prescribed. The size, color, and shape of the tablets was different. The complainant could not recall the name of the technician that took the call or the person who received the returned medication. An internal incident report was not generated as the pharmacy was unable to identify an individual who received the call or returned medication.

ACTION: Motion by P. GANNON, seconded by J. TRIFONE, and voted unanimously to open a complaint and to refer this matter to the Office of Prosecution for the issuance of an Order to Show Cause. The motion further authorized, in the alternative, resolution of the Complaint with a consent agreement for stayed probation with terms that the pharmacy pharmacy show evidence by policy which addresses the

management of alleged medication errors when notified by a customer; keeping evidence on hand for 2 years, policy 247 CMR 15, and completed inservicing of staff.

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**TOPIC:**

**IX. FILE REVIEW**

**17. Walgreens #4358 (DS2873), SA-INV-2884**

RECUSAL: J. TRIFONE recused herself and was not present for the discussion or vote.

DISCUSSION:

S. Penta presented the above-referenced matter to the Board. Complainant was unable to obtain a refill for Xalatan eye drops as the insurer did not accept the calculated day of supply.

The patient and the pharmacy made numerous calls to the prescriber's office and insurer to resolve the issue. After 6 days the issue was resolved.

ACTION: Motion by P. GANNON, seconded by A. YOUNG, and voted unanimously, to close the staff assignment with no discipline warranted.

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**X. BREAK (12:25 – 12:33 p.m.)**

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**TOPIC:**

**XI. APPLICATIONS**

**A. Applications for Expansion**

**1. New England Home Therapies (DS3486), 337 Turnpike Road, Southborough, MA**

DISCUSSION: Kimberly Gould (MOR) presented pharmacy plans and blueprint to expand the facility and create a negative pressure compounding room to prepare hazardous medications (chemotherapy).

ACTION: Motion by A. YOUNG, seconded by P. GANNON, and voted unanimously to approve the application, pending a successful re-inspection.

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**TOPIC:**

**XI. APPLICATIONS**

**B. Applications for a New Store**

**1. AcariaHealth Pharmacy, 260 E Fordham Road, Suite E, Wilmington, MA**

RECUSAL: S. PENTA recused himself and was not present during the discussion or votes for these matters.

DISCUSSION: Jo Stewart (MOR) and Matt Engels, President of Operations presented the application for a new community pharmacy. It would be a specialty pharmacy, located in an industrial park, specializing in disease states such as multiple sclerosis, hepatitis C, oral oncology therapies, and infertility treatments. At a later date, the pharmacy may request approval to prepare sterile compounded products (USP <797>), and plan to request Medicaid provider status after a year.

Two waivers were requested; 1) to stock medications for only certain diseases, 247 CMR 9.01(15) and 2) not to be required to compound sterile (USP <797>) and non-sterile (USP <795>) products.

ACTION: Motion by P. GANNON, seconded by A. YOUNG, and voted unanimously to approve this application, and waiver requests, pending a successful inspection.

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TOPIC:

**XI. APPLICATIONS**

**C. Applications for License as a Wholesale Distributor**

**1. Open Source Pharmaceuticals, 1208A VFW Parkway, West Roxbury, MA**

DISCUSSION: Andrew Rogers, Operations Manager, and David Zeiger, Pharmacy Consultant presented the application to the Board. Open Source Pharmaceuticals would distribute non-federally controlled (Schedule VI) pharmaceuticals. They plan to specialize in items which are in short supply (ASHP or FDA website). They would maintain minimal inventory, purchasing oversupply from pharmacies and other wholesalers and then shipping primarily to hospital pharmacies. They referred to a 5% rule, but could not identify the source.

ACTION: Motion by J. DEVITA, seconded by A. YOUNG, to take this application under advisement.

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TOPIC:

**XI. APPLICATIONS**

**C. Applications for License as a Wholesale Distributor**

**2. NeedleTech Products, 452 John L. Dietsch Boulevard, North Attleboro, MA**

Matter deferred upon request of applicant.

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TOPIC:

**XII. FLEX SESSION**

**1. Elections – by roll call vote**

J. DEVITA approved and announced that President-Elect would join the meeting remotely to participate in the election process.

a. President-Elect:

- P. GANNON votes: E. TAGLIERI, J. FRANKE, P. GANNON, A. PERRONE, R. TINSLEY

- A. YOUNG votes: J. DEVITA, K. RYLE, J. TRIFONE, A. YOUNG

P. GANNON will be the new President-Elect.

b. Secretary:

- J. TRIFONE votes: J. DEVITA, J. TRIFONE, A. YOUNG

- E. TAGLIERI votes: K. RYLE, E. TAGLIERI, J. FRANKE, P. GANNON, R. TINSLEY, A. PERRONE

E. TAGLIERI will be the new Secretary.

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**2. Review of Licensure Policy 13-05: Staff Action to Identify License Applications Requiring Good Moral Character Evaluation**

V. BERG distributed a draft of proposed licensure policy 13-05. The policy attempts to identify those areas where no discretion of the Board would be necessary.

The Board will explore the possibility of a single Board member making a recommendation to the full Board.

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**3. Topics for Upcoming Meetings**

- a. Best Practices for filling prescriptions using blister pack packaging (J. TRIFONE)
- b. Addressing the “days’ supply” issue for certain topical medications (P. GANNON)
- c. CPE Monitor and Statements of credit; guidance to registrants (A. YOUNG)
- d. “Road Map” of upcoming issues that the Board will need to consider (J. DEVITA)

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TOPIC:

XIII. ADJOURNMENT

DISCUSSION: None

ACTION: Motion by P. GANNON, seconded by E. TAGLIERI, and voted unanimously to adjourn at 1:47 p.m.

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LIST OF EXHIBITS USED DURING THE MEETING

1. Preliminary Agenda for the December 3, 2013 Regularly Scheduled Meeting.
2. Draft Minutes of the October 1, 2013 Regularly Scheduled Meeting
3. Investigative Report in the Matter of Pharmacy Corporation of America, DS3599, PHA-2012-0258, Jeffrey Lynch, PH24722, PHA-2013-0061, Richard Mancini, PH22198, PHA-2013-0072.
4. Investigative Report in the Matter of Rogers Pharmacy, DS14170, PHA-2012-0131, Kenneth Minty, PH17282, PHA-2013-0005, Jon Cincotta, PT139, PHA-2013-0004
5. Investigative Report in the Matter of Kristen Richard, PH27014, PHA-2012-0105, Rite Aid #10092, DS2886, PHA-2012-0106
6. Investigative Report in the Matter of Edward Linsky, PH15346, PHA-2013-0077
7. Investigative Report in the Matter of CVS #2283, DS2844, SA-INV-2944
8. Investigative Report in the Matter of CVS #2325, DS2850, SA-INV-2429
9. Investigative Report in the Matters of Muro Pharmaceuticals, WD369, SA-INV-3051
10. Investigative Report in the Matter of Louis & Clark #572, DS2543, SA-INV-2730
11. Investigative Report in the Matter of Walgreens #4358, DS2873, SA-INV-2884
12. Application for approval of expansion: New England Home Therapies, DS3486
13. Application for new community pharmacy: AcariaHealth Pharmacy
14. Application for new wholesale distributor: Open Source Pharmaceuticals
15. Proposed Licensure Policy 13-05, Staff Action to Identify Individual Registration Applications requiring Good Moral Character evaluation

Respectfully submitted,

David Sencabaugh, RPh, Executive Director