COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of	
LOUIS AND CLARK DRUG, Inc.	Docket Nos. DS-08-060
Pharmacy Registration Nos. 2365	DS-08-053
3244	DS-08-059
1563	DS-08-117
2543	DS-08-120

CONSENT AGREEMENT

The **Board of Registration in Pharmacy** ("Board") and **Louis and Clark Drug, Inc.**, a Massachusetts corporation registered by the Board as owner and operator of certain pharmacies licensed by the Board; specifically, pharmacies licensed by the Board to operate at:
(a) Two Medical Center Drive, Springfield, MA 01095 (Pharmacy Registration No. 1563);
(b) 300 Birnie Street, Springfield, MA 01107 (Pharmacy Registration No. 3244);
(c) 471 Breckwood Boulevard, Springfield, MA 01109 (Pharmacy Registration No. 2365); and
(d) 490 Page Boulevard, Springfield, MA 011094 (Pharmacy Registration No. 2543)
(Louis and Clark Drug, Inc. and the pharmacies listed sometimes being hereinafter being collectively referred to as "Registrant" or the "Pharmacies"), do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the files maintained by the Board:

1. The parties enter into this Consent Agreement ("Agreement") to resolve disputed matters arising out of complaints pending against Registrant as Docket Nos. DS-08-053, DS-08-059, DS-08-060, DS-08-117 and DS-08-120 ("Complaints").

2. Registrant acknowledges the occurrence of the medication errors alleged in the Complaints; as more specifically described below:

a. On or about April 9, 2007, Registrant (Pharmacy Registration No. 2543) improperly filled a prescription for a patient by dispensing Trihexphenidyl 5mg (blister pack) rather than Trifluoperazine 5mg as prescribed (Docket No. DS-08-117); and

b. On various dates from on or about August 2007 through January 2008, Registrant (Pharmacy Registration No. 2543) improperly labeled (interchange) prescriptions for a patient wherein medications were identified as "fiber therapy" and "antidiarrhea therapy" (Docket No. DS-08-120).

3. Registrant acknowledges that Board Investigators performed inspections of Registrant, as described below, and observed multiple statutory and regulatory violations pertaining to the practice of pharmacy, including, but not limited to:

a. **Pharmacy Registration No. 2365** ("Pharmacy")

(1) 247 CMR 9.01(14) – Perpetual inventory of Schedule II medications was not available for inspection.
Pharmacy failed to maintain a perpetual inventory of each Schedule II controlled substance received, dispensed or disposed of, with reconciliations performed at least once every ten days.

(2) 247 CMR 6.07(1)(i) – Biennial inventory was not available for inspection.
Pharmacy failed to reconcile an inventory of controlled substances in Schedules II, III, IV and V, based upon federal biennial inventory requirements (21 CFR §1304.11).

(3) 247 CMR 6.01(5)(a) 4. and (5)(a)5., 6.01(5)(b) and 9.01(3) - United States Pharmacopoeia (USP) standards.
Pharmacy did not comply withUSP standards in failing to:
a) store internal and external medications separately;
b) maintain necessary equipment (balance);
c) to provide necessary and appropriate storage space for medications and maintain equipment necessary to conduct the practice of pharmacy accordance with USP.

(4) 247 CMR 6.01(5)(a)7. and 6.02(1) – Appropriate sanitary appliances, including suitable sink required in prescription area; the pharmacy shall be kept in a clean and sanitary manner.
Pharmacy had cleaning products stored with internal and external compounding supplies.
Compounding area was a multipurpose area containing food and cleaning supplies.

(5) 247 CMR 9.01(10) – Pharmacist shall not dispense expired or outdated drugs.
Pharmacy had expired/expired drugs on the premises.

(6) 247 CMR 9.01(5) – Pharmacist is responsible for the proper preservation and security of all drugs in the pharmacy, including proper refrigeration and storage.
Pharmacy refrigerator had inadequate convection; refrigerated storage was inadequate for the amount of product stored.

(7) 247 CMR 9.01(1) – Pharmacist shall conduct professional activities in accordance with all federal, state and municipal laws and regulations; 9.01(10) - Pharmacist shall not dispense expired, outdated or otherwise substandard drugs to any person or entity who is not licensed or legally authorized to receive such drugs, and 9.01(17) – Pharmacist shall not purchase drug samples of the purpose of compounding, dispensing or in any way reselling these samples.
Pharmacy continued "pilot project" dispensing Schedule VI medication samples to clinic patients after expiration Board authorization.

b. **Pharmacy Registration Nos. 2365, 3244 and 1563**

247 CMR 6.03 (1) – Manager of record change required to be promptly submitted to the Board.
Pharmacies failed to submit "Change of Manager" applications to the Board in a timely manner.

4. Accordingly, Registrant agrees:

a. that the improper dispensing and regulatory violations described in Paragraphs 2 and 3 constitutes conduct warranting disciplinary action by the Board, pursuant to M.G.L. c.112, §§ 42A and 61 and 247 CMR 9.01(1), 10.03(1)(a); and 10.03(1)(b);

b. that the Pharmacies are hereby placed on PROBATIONARY STATUS for a minimum one year period commencing on the Effective Date of the Agreement ("Probationary Period"). Termination of the Probationary Period regarding each of the Pharmacies shall be governed by Paragraph 4 of the Agreement;

c. to submit a copy of updated policies and procedures regarding pharmacy security and accountability of controlled substances for each of the Pharmacies to the Board for review, approved by a duly authorized officer of Registrant or Richard Hoeckh, current Director of Pharmacy, within thirty (30) days of the Effective Date of the Agreement;

d. to submit a certification of completion of the corrective action described to the Board as having been implemented by Registrant, signed under the pains and penalties of perjury by a duly authorized officer of Registrant, within thirty (30) days of the Effective Date of the Agreement;

e. to develop a Pharmacy Regulatory Compliance Plan for the purpose of evaluating current Pharmacy compliance with relevant federal and state statutes and regulations ("Plan") in the below listed areas. The Plan shall include, at a minimum:

(1) a comprehensive assessment of Pharmacy systems and procedures to ensure compliance with federal and state statutes and regulations in the below listed pharmacy operation areas; and

(2) implementation of measures necessary to correct noncompliance and the development and implementation of systems to:

i. conduct regular inspections and annual self-audits of Pharmacy operations for the purposes of ensuring patient safety and maintaining Pharmacy compliance with relevant federal and state statutes and regulations;

ii. track Pharmacy compliance with relevant federal and state statutes and regulations; and

iii. establish "Return to Compliance" plans for noncompliance identified during inspections and self audits;

f. to provide written confirmation to the Board, within ten (10) days of the Effective Date of the Agreement, that the current Manager of Record at each Louis and Clark Drug Store, Inc. pharmacy in the Commonwealth has completed a Board "Self-Inspection Form". Each Manager of Record must complete a Self-Inspection Form (signed and dated) and maintain a copy of the form on pharmacy premises, readily retrievable at Board request, for a minimum period of two years from the Effective Date of the Agreement;

g. to provide written confirmation to the Board, within fifteen (15) days of the Effective Date of the Agreement, that the current Manager of Record at each Louis and Clark Drug Store, Inc. pharmacy in the Commonwealth has completed the Institute for Safe Medication Practices "Medication Safety Self-Assessment for Community/Ambulatory Pharmacy". Each Manager of Record must complete a Self-Inspection Form (signed and dated) and maintain a copy of the form on pharmacy premises, readily retrievable at Board request, for a minimum period of two years from the Effective Date of the Agreement; and

h. That Pharmacy representatives, as requested by the Board, shall appear before the Board to review and assess Pharmacy operations and compliance with the Agreement, the Plan, and relevant federal and state statutes and regulations. The Pharmacy shall provide specific information and documentation to the Board during the Probationary Period as may be requested to determine compliance of Pharmacy operations with the Agreement, the Plan, and federal and state statutes and regulations.

5. Registrant hereby acknowledges and agrees that petitions for termination of the Probationary Period with respect to each of the Pharmacies shall be reviewed by the Board in accordance with the following requirements:

a. written request shall be submitted to the Board requesting termination of the Probationary Period; and
b. full compliance with all terms and conditions of the Agreement and meeting all other requirements for licensure.

6. This Agreement shall be incorporated into the records maintained by the Board. This Agreement and its contents are matters of public record subject to disclosure to the public and equivalent state licensing boards.

7. The Board agrees that in return for execution of this Agreement, the Board will not advance the prosecution of Registrant pursuant to the Complaints; any and all other rights of the Board to take action within the scope of its authority are expressly reserved.

8. Registrant understands and agrees that, at any time during the Probationary Period, upon a determination by the Board of any violation of any of the terms and conditions of this Agreement, or any violation of the applicable laws, rules and regulations governing the practice of pharmacy, provided the Registrant has been provided an opportunity to respond to the determination of vioaltion, the Board may suspend the registration of the respective pharmacy without the requirement of further proceedings pursuant to G.L. c. 30A for a period of time and upon such conditions as deemed necessary by the Board.

9. Registrant acknowledges and agrees that should any of the Pharmacies be found to have violated any of the statutes and/or regulations governing the practice of pharmacy for conduct occurring during the Probationary Period, the Board may consider the conduct described herein and more fully described in the Complaints in determining an appropriate sanction for the subsequent offense.

10. Registrant acknowledges and agrees that the decision to enter into the Agreement and to accept the terms and conditions herein described is a final act and is not subject to reconsideration or judicial review.

11. Registrant acknowledges that legal counsel was consulted in connection with the decision to enter into the Agreement or, if not, that Registrant had an opportunity to do so.

12. Registrant acknowledges that by executing this Agreement, Registrant is waiving the right to a formal hearing at which Registrant would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to offer 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*. Registrant states that in executing this document entitled "Consent Agreement", Registrant understands and agrees that it is knowingly and voluntarily waiving its right and the right to a formal hearing and to all of the above-listed rights.

Louis and Clark Drug, Inc.
By and on behalf of
Pharmacy Registration Nos. 2365
3244
1563
2543

By: Chad G Mutter

Title: President

Date: 8-21-2009

BOARD OF REGISTRATION IN PHARMACY

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

Effective Date: 9/2/09

Dec. Nos. 1712 / 1713 / 1711 / 1957 / 1958