## ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement or MOA") is entered into as of this 28<sup>th</sup> day of March (hereinafter the "Effective Date") by and between the United States Department of Justice, Drug Enforcement Administration (hereinafter "DEA") and The Harvard Drug Group, LLC (hereinafter "Harvard Drug") (each a "Party" and collectively, the "Parties").

## I. APPLICABILITY

This Agreement shall be applicable to Harvard Drug and all Harvard Drug DEAregistered facilities except where explicitly indicated.

#### II. BACKGROUND

WHEREAS, on June 10, 2010, the DEA, by then-Deputy Administrator, Michele M. Leonhart, issued an Order to Show Cause Immediate Suspension of Registration, which was served by the DEA on June 15, 2010, ("DEA Order") at the Harvard Drug Livonia, Michigan distribution center located at 31778 Enterprise Drive, Livonia, Michigan 48150 (the "Livonia Facility");

WHEREAS, Harvard Drug also operates a distribution center located at 5110 West 74<sup>th</sup> Street, Indianapolis, Indiana 46268 ("Indianapolis Facility"), which Indianapolis Facility was not the subject of the DEA Order;

WHEREAS, the DEA Order alleged, among other things, that the Livonia Facility failed to report suspicious orders and to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain Harvard Drug customers;

WHEREAS, on June 18, 2010, the Parties entered into a Consent Order Modifying June 10, 2010 Order to Show Cause Immediate Suspension Order ("District Court Order") modifying the DEA Order such that Harvard Drug may continue to distribute schedule III, IV, and V drugs at the Livonia facility and requiring the Parties to "commence and work diligently towards a global resolution of the issues raised in the DEA Order;"

WHEREAS an administrative hearing has been scheduled in this matter, and is pending before Administrative Law Judge Wing;

WHEREAS, the Parties believe that the continued cooperation between the Parties to reduce the potential for diversion is in the public interest, including but not limited to sharing of information related to the distribution of controlled substances; and



WHEREAS, the Parties believe that a settlement in this matter is in the public interest and desire to settle and resolve all outstanding claims and/or issues with respect to the DEA Order and allegations.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, and for other good and valuable consideration, and intending to be legally bound hereby, the Parties hereto agree as follows:

## III. GENERAL TERMS

- 1. <u>Intention of Parties to Effect Settlement</u>. In order to avoid the uncertainty and expense of litigation, the Parties agree to resolve this matter according to the Terms and Conditions below.
- 2. <u>No Admission or Concession</u>. This Agreement is neither an admission by Harvard Drug of liability or of any allegations made by DEA in the DEA Order and investigations, nor a concession by DEA that its allegations in the DEA Order and investigations are not well-founded.
- 3. <u>Covered Conduct</u>. For purposes of this Agreement, "Covered Conduct" shall mean the following:
  - (A) the conduct alleged in the DEA Order;
- (B) the conduct alleged in the DEA Prehearing Statement dated July 19, 2010, and in the Supplemental Prehearing Statement on Behalf of the Government dated December 28, 2010; and,
- (C) the alleged failure of Harvard Drug to detect and report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b) on or before the Effective Date of the Agreement.
- 4. <u>DEA Representative</u>. For purposes of this Agreement, the DEA Representative shall be the Chief, Pharmaceutical Investigations Section, Operations Division, DEA Headquarters.
- 5. <u>Harvard Drug Representative</u>. For purposes of this Agreement, the Harvard Drug Representative shall be Samir Shah, Vice President, Regulatory.

## IV. TERMS AND CONDITIONS

## 1. Obligations of Harvard Drug.

- (A) Harvard Drug agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the federal Controlled Substances Act ("CSA") and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders that exceed thresholds and other criteria established by Harvard Drug to identify orders of interest will be reviewed by a Harvard Drug employee, trained to detect suspicious orders, for the purposes of determining whether: (i) such orders should be not filled and reported to the DEA; or (ii) based on a detailed review, the order is for a legitimate purpose and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels. Orders identified as suspicious by Harvard Drug will be reported to the DEA within two business days. This compliance program shall apply to all current and future Harvard Drug distribution centers registered with the DEA in the United States and its territories and possessions. Harvard Drug acknowledges and agrees that the obligations undertaken in this subparagraph do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.
- (B) All current and future Harvard Drug distribution centers registered with the DEA and authorized to distribute controlled substances of finished pharmaceutical products to retail pharmacies shall provide DEA Headquarters with a monthly report of all Schedules II through V controlled substance domestic sales transactions through an Electronic Data Interchange in a format mutually and reasonably agreed upon by the Parties. The report will be due by the 15th of each month for the previous month. This information will be based on raw sales data and will not be reconciled in the manner that Automation of Reports and Consolidated Orders System ("ARCOS") data is reconciled, nor does this requirement supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the data provided in this report shall be a true and correct copy of the raw transaction data at the time that the data is transmitted to the DEA and acknowledge that the report does not contain any adjustments or corrections that would normally be part of a distributor's reconciliation of its business records. The Parties agree that the report does not otherwise constitute the basis for Harvard Drug's compliance with recordkeeping and reporting requirements or its requirement to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA or applicable DEA regulations. The Parties also agree that such report is not currently required under the CSA or DEA regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5), however, failure to file such a report may be considered a breach of this MOA. The Parties agree that, to the extent that such a report becomes a requirement under the CSA or DEA regulations, then



Harvard Drug will be subject to such a requirement. Barring any such requirement under the CSA or DEA regulations, Harvard Drug shall, under the terms of this MOA, begin transmitting information for all controlled substances within 60 days of the Effective Date of the Agreement. The obligations contained in this paragraph shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination of the obligations contained in this paragraph.

- (C) Harvard Drug shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that Harvard Drug shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until directed otherwise in writing by DEA Headquarters. DEA agrees to notify all of the DEA Field Offices within 30 days of the Effective Date of this Agreement that Harvard Drug will no longer be required to provide suspicious order reports or any other type of reports regarding excessive purchases of controlled substances to the DEA Field Offices and that this Agreement shall supersede any DEA regulatory requirements to report suspicious orders to DEA Field Offices directly. The obligations contained in this paragraph shall be and remain in full force and effect from the Effective Date of this Agreement, and thereafter shall remain in full force and effect unless terminated and revoked by DEA with thirty (30) days written notice.
- (D) Harvard Drug agrees to a one-year suspension of its authority to distribute Schedule II through V controlled substances at its Livonia Facility, DEA registration number RG0131499, as it applies to Schedule II through V controlled substances. This suspension shall not apply to or affect in any way Harvard Drug's authority (i) to distribute, or operations involving List I Chemical products at or from the Livonia Facility, which are authorized under a separate DEA chemical registration to be issued by the DEA, or (ii) receipt or shipment of controlled substances pursuant to Harvard Drug's DEA exporter registration, number RT0350772. The one-year suspension shall take effect commencing on the Effective Date of this Agreement. With the exception of its obligations under the CSA and 21 C.F.R. §1301.74(b), Harvard Drug further understands that during the one-year suspension of its Livonia facility it cannot directly or indirectly participate in any order, sale, purchase, or distribution of controlled substances pursuant to its DEA registration number RG0131499 to any of its customers regardless of their affiliation with the Livonia facility. However, such restriction shall not apply to Harvard Drug's business offices and staff, wherever located, related to the management and administrative roles and responsibilities on the ordering, sale, purchase and distribution of controlled substances related to Harvard Drug's other DEA registered facilities.
- (E) Harvard Drug agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders is hereby rescinded and is of no legal effect with respect to Harvard Drug's obligations to detect and report suspicious orders in accordance with 21 C.F.R. §1301.74(b).

- (F) Harvard Drug agrees that within 180 days of the Effective Date of this Agreement, it will have completed a review of all of its customers that have purchased oxycodone, hydrocodone, alprazolam and phentermine from the Livonia Facility in the 12-month period immediately preceding the June 18, 2010 Order Modifying the June 10, 2010 Order to Show Cause Immediate Suspension Order and will identify any current customer whose purchases of controlled substances are shown by that review to have exceeded the thresholds established in its compliance program. To the extent it has not already done so, Harvard Drug shall conduct an investigation for each customer where such review reveals purchasing patterns substantially deviating from the normal purchasing patterns, and take appropriate action as required by this Agreement, DEA regulations and other procedures established under Harvard Drug's compliance program including its Suspicious Order System (SOS).
- (G) Harvard Drug's policy and procedure is to cooperate with the government in investigations. Harvard Drug agrees to reasonably cooperate with DEA, the United States Attorney's Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting Harvard Drug's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of Harvard Drug in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by the DEA or other law enforcement authorities. However, nothing in this paragraph shall be construed as a waiver by Harvard Drug or its employees of any right, privilege or immunity, including constitutional rights or rights that the company has or would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.
- (H) Harvard Drug agrees to execute the Settlement Agreement with the U.S. Department of Justice through the U.S. Attorney's Office ("USAO") for the Eastern District of Michigan in conjunction with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph.
- (I) Any material breach by any Harvard Drug DEA-registered facility of Section IV, paragraphs 1.(A)-(G) of this Agreement after the Effective Date of this Agreement may be a basis upon which DEA can issue an Order to Show Cause seeking the revocation of Harvard Drug's DEA certificate(s) of registration for that facility.

## 2. Obligations of DEA.

- (A) DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as required under 21 C.F.R. § 1301.74(b) and described in Section IV, paragraph 1(C) of this Agreement. DEA agrees that this procedure is consistent with DEA regulatory requirements and hereby waives the regulatory requirement to report suspicious orders of controlled substances to the DEA Field Division Offices.
- (B) DEA agrees and acknowledges that neither the CSA, DEA regulations, nor the terms of this Agreement establish a requirement that reporting of a suspicious order means that a customer be designated as a suspicious customer that would de facto require the suspension of all orders or sales of other controlled substances to such customer. Harvard Drug acknowledges, however, that it is required under 21 C.F.R. §1301.74(b) to "design and operate a system to disclose to the registrant suspicious orders of controlled substances."
- (C) DEA agrees that any request made by DEA or any of its employees that Harvard Drug continue to sell controlled substances to customers for an order that Harvard Drug has determined to be suspicious shall be made in writing to the designated Harvard Drug Representative.
- (D) Within 180 days but not earlier than 90 days of the Effective Date of this Agreement, the DEA shall inspect the functionality of Harvard Drug's diversion compliance ("Compliance Inspection") at the Livonia Facility and Indianapolis Facility. DEA shall also inspect the investigatory files maintained by Harvard Drug of the customers serviced by the Livonia Facility and Indianapolis Facility. DEA shall notify Harvard Drug no less than 48 hours prior to commencing the Compliance Inspection. DEA shall issue a Notice of Inspection to Harvard Drug upon commencement of the Compliance Inspection. During the course of the Compliance Inspection, if requested, Harvard Drug shall provide DEA with information related to the sales of controlled substances, non-controlled drugs, and listed chemicals from Effective Date of Agreement to the date of the Compliance Inspection. DEA reserves the opportunity to conduct appropriate interviews of Harvard Drug employees during the Compliance Inspection under terms and conditions established by DEA; however, nothing in this Agreement shall require an employee to be interviewed by DEA or otherwise constitute a waiver of an employee's rights. DEA also reserves the opportunity to review Harvard Drug's Standard Operating Procedures during such Compliance Inspection. At the conclusion of the Compliance Inspection, DEA shall conduct an exit interview with an appropriate Harvard Drug representative to provide DEA's preliminary conclusions regarding the Compliance Inspection. The Parties agree that, at Harvard Drug's option, the Company may be represented by counsel at such Compliance Inspection and interview(s) with employees.



- (E) The Compliance Inspection will be deemed "satisfactory" unless DEA determines that the Indianapolis facility has: (i) failed to maintain effective controls against diversion regarding the distribution of any controlled substance; (ii) failed to detect and report to DEA suspicious orders of controlled substances; (iii) failed to meaningfully investigate new or existing customers regarding the customer's legitimate need to order or purchase controlled substances; or, (iv) the Livonia facility has violated any terms of this MOA. DEA shall find a Compliance Inspection "satisfactory," unless the failure(s) described with specificity are sufficient to provide a factual and legal basis for issuing an Order to Show Cause under 21 U.S.C. § 824(a) against one or more of the inspected facilities. In the event that DEA finds the Compliance Inspection "unsatisfactory" for reasons set forth in (i) – (iv) of this paragraph, or identifies other violations that are not consistent with the public interest, or that such violations do not involve criminal offenses, DEA will provide a written Compliance Deficiency Notice to Harvard Drug describing the violation(s). DEA shall meet and confer with Harvard Drug within five business days regarding its findings set forth in the Compliance Deficiency Notice. DEA shall provide Harvard Drug with the opportunity to cure any deficiency identified in the Compliance Deficiency Notice within 30 days after Harvard Drug's receipt thereof. Harvard Drug agrees to provide DEA with a written notice of the actions taken to cure the deficiency. Thereafter, DEA agrees to provide Harvard Drug with a written notice within ten business days acknowledging that any deficiency has been cured. Subject to the provisions set forth in this paragraph, nothing shall preclude DEA from issuing an Order to Show Cause and/or Immediate Suspension Order at any time against one or more of Harvard Drug's DEA-registered locations or at a future location should the DEA determine that there is a sufficient factual and legal basis to do so.
- (F) DEA shall also consider remedial measures that Harvard Drug has instituted in determining whether the Compliance Review is satisfactory. A finding of "satisfactory" does not otherwise express DEA's approval, certification or accreditation of the compliance program implemented.
- (G) In the event that DEA discovers information that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider Harvard Drug's entry into this Agreement; all actions taken by Harvard Drug pursuant to this Agreement; any remedial actions taken by Harvard Drug to address the alleged or perceived violative conduct; and the compliance history of Harvard Drug.
- (H) Upon the completion of the Compliance Inspection and barring no other legal action against any of Harvard Drug facilities DEA will remove the suspension of the DEA registration, number RG0131499, for the Livonia Facility one year from the Effective Date of this Agreement. DEA shall also issue a final decision on the request for approval of the Livonia Facility vault previously submitted to the DEA Detroit Field Office. In the event that Harvard Drug has not satisfied DEA in regard to the

Compliance Inspection within one year of the Effective Date of this Agreement Harvard agrees to continue its suspension at the Livonia Facility until the matter is resolved by mutual agreement of the Parties.

- (I) Upon Harvard Drug's submission of a timely application for renewal of its DEA registration for the Livonia Facility, DEA agrees to renew Harvard Drug's DEA registration number RG0131499 for the Livonia Facility on its scheduled expiration date, November 30, 2010. Harvard Drug acknowledges that the renewed registration shall remain subject to the registration suspension provisions as provided in Section IV, paragraph 1(D).
- (J) DEA represents that it has reviewed its records for investigations or inspections initiated or conducted prior to the Effective Date of this Agreement, which may allege that Harvard Drug failed to report suspicious orders as required by 21 C.F.R. § 1301.74(b). DEA further represents that it has reviewed reports and records submitted by Harvard Drug to DEA on or before the Effective Date of the Agreement for indications that Harvard Drug may have failed to report suspicious orders as required by 21 C.F.R. § 1301.74(b). DEA has not referred and agrees to not refer any conduct occurring before the Effective Date of this Agreement for civil penalty proceedings under 21 U.S.C. § 842(a)(5) that would be based on the Covered Conduct, to any other agency within the Department of Justice.

## 3. Joint Obligations of the Parties.

- (A) Harvard Drug and DEA agree that upon the execution of this Agreement, DEA and Harvard Drug shall file a joint motion with the DEA Administrative Law Judge to terminate all pending administrative proceedings against Harvard Drug.
- (B) Harvard Drug and DEA agree to execute this Agreement in conjunction with the execution of a full and final Settlement Agreement with the U.S. Department of Justice through the USAO for the Eastern District of Michigan of all liability for civil penalties which arises in connection with the Covered Conduct.

## 4. Release by DEA.

- (A) In consideration of the fulfillment of the obligations of Harvard Drug under this Agreement, DEA agrees to:
  - (i) Fully, finally and forever release Harvard Drug, including its officers, directors, members, employees, successors, assigns or past or current equity owners (direct and indirect) and members, directors, and employees of the foregoing, ("Harvard Drug Released Parties") from any other administrative or

civil claims within DEA's enforcement authority for the Covered Conduct except as outlined in this Agreement; and

- (ii) Refrain from filing any administrative claims against Harvard Drug Released Parties within DEA's enforcement authority based on the Covered Conduct, to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the Effective Date of this Agreement, and the review of the reports and records Harvard Drug submitted to DEA prior to that date.
- (B) Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Harvard Drug Released Parties for non-Covered Conduct. Further, nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof ("law enforcement agency"), from initiating administrative or civilproceedings based on the Covered Conduct, under statutes and regulations other than the CSA and DEA regulations, and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any law enforcement agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At Harvard Drug's request, DEA agrees to disclose the terms of this Agreement to any other law enforcement agency and will represent that Harvard Drug's compliance with this Agreement adequately addressed the administrative allegations raised by DEA as defined in the Covered Conduct. This release is applicable only to the Harvard Drug Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.
- 5. Release by Harvard Drug. Harvard Drug fully, finally and forever releases the United States of America, its agencies, employees, servants, and agents ("Government Released Parties") from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Harvard Drug has asserted, could have asserted, or may assert in the future against the Government Released Parties related to the Covered Conduct, or any term covered in this Agreement and the United States' investigation and prosecution thereof.
- 6. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Harvard Drug) are the following:
  - (A) Any potential criminal liability;



- (B) Any civil liability not released in the Settlement Agreement which Harvard Drug has agreed to execute with the U.S. Department of Justice through the U.S. Attorneys' Offices for the Eastern District of Michigan in connection with the Covered Conduct;
- (C) Any administrative liability, including mandatory exclusion from any federal programs, which is not released by this Agreement;
- (D). Any criminal, civil or criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
- (E) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct defined in Section III of this Agreement; or
  - (F) Any claims based upon such obligations as are created by this Agreement.

## V. MISCELLANEOUS

- 1. <u>Binding on Successors</u>. This Agreement is binding on Harvard Drug, and its respective successors, heirs, transferees, and assigns.
- 2. <u>Costs</u>. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Harvard Drug Released Parties and Government Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.
- 4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. The Parties represent that this Agreement is entered into with advice of counsel and knowledge of the events described herein. The Parties further represent that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

- 5. Execution of Agreement. This Agreement is effective (i.e., final and binding) as of the Effective Date of this Agreement and shall remain in effect for a period of three years from the Effective Date except that the releases described in paragraphs IV.4.A and IV.5 shall continue ad infinitum.
- 6. <u>Notices.</u> All communications and notices pursuant to Section IV, paragraphs (2)(D) through (F) of this Agreement to Harvard Drug shall be made in writing to Robert Brown, in-house counsel.
- 7. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.
- 8. <u>Authorizations</u>. The individuals signing this Agreement on behalf of Harvard Drug represent and warrant that they are authorized by Harvard Drug to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.
- 9. Choice of Law and Venue. This Agreement shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties under this Agreement will be the United States District Court for the Eastern District of Michigan, Southern Division. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement as of the date written above.

## THE HARVARD DRUG GROUP, LLC

By		
	e P. Haas xecutive Officer	
Dated: _	4-12-11	<u> </u>

# THE UNITED STATES DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION

Michele M. Leonhart

Administrator

Drug Enforcement Administration

Dated:

Бу. \_

Wendy H. Goggin

Chief Counsel

Drug Enforcement Administration

Dated: