

**SETTLEMENT AND RELEASE AGREEMENT
AND
ADMINISTRATIVE MEMORANDUM OF AGREEMENT**

This Settlement and Release Agreement and Administrative Memorandum of Agreement (“Agreement”) is entered into this 1st day of April 2009, by and between the United States Department of Justice, Drug Enforcement Administration (“DEA”) and Masters Pharmaceutical, Inc., an Ohio corporation (“Masters”), (each a “Party” and collectively the “Parties”).

BACKGROUND

1. Masters is registered with DEA as a distributor of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention Act of 1970, 21 U.S.C. § 801 et seq., (“CSA” of “the Act”).
2. On October 17, 2008, DEA issued an Order to Show Cause to Masters, with respect to its distribution facility located at 11930 Kemper Springs, Cincinnati, Ohio 45240. (Appendix A)
3. The Order to Show Cause referenced above alleges, among other things, that Masters failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels as evidenced by sales to certain customers of Masters.
4. DEA also alleges that Masters failed to report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b) .
5. 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.

STIPULATION AND AGREEMENT

The facts alleged in the Order to Show Cause, if proven at an administrative hearing, could constitute grounds for revoking Masters’ DEA registration. Masters alleges that it has presented to the DEA evidence that, if proven at an administrative hearing, would demonstrate that Masters’ continued registration is in the public interest. In lieu of continuing adversarial proceedings Masters and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties’ belief that a settlement in this administrative matter is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, all outstanding administrative claims and/or issues with respect to the alleged failure of Masters to detect and report suspicious orders and the alleged failure of Masters to maintain adequate controls against the diversion of controlled substances on or prior to April 1, 2009, including but

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not limited to the conduct described in the Order to Show Cause, and all outstanding claims and or issues with respect to the allegations set forth in paragraphs 3 and 4 above. The parties further believe that the terms and conditions of this settlement as set forth below represent a complete, just, and equitable resolution of this administrative matter.

2. No Admission or Concession. This Agreement is neither an admission by Masters of liability or of the veracity of any allegation made by DEA in the Order to Show Cause, this Agreement or any investigation, nor a concession by DEA that its allegations in the Order to Show Cause and investigations are not well-founded.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following:

- a. the conduct alleged in the Order to Show Cause (Appendix A);
- b. the alleged failure of Masters to maintain adequate controls against the diversion of controlled substances, on or prior to April 1, 2009, at its distribution facility;
- c. the alleged failure of Masters to detect and report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b) on or before April 1, 2009.

II. Terms and Conditions

1. Obligations of Masters.

- a. Masters agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders that exceed established thresholds and meet other criteria as determined by Masters will be reviewed by a Masters employee trained to detect suspicious orders for the purposes of determining whether (i) such orders should not be filled and reported to the DEA or (ii) based on a detailed review, the order is not suspicious and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels. Orders identified as suspicious will be reported to the DEA as discussed in subsection II(1)(c). This compliance program shall apply to the current and any future Masters distribution centers registered with the DEA in the United States and its territories and possessions. Masters 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. On a monthly basis, Masters shall provide DEA Headquarters with a report of all sales transactions of controlled substances, carisoprodol, and tramadol through Electronic Data Interchange in a format mutually and reasonably agreed upon by the Parties. The data shall be due by the 15th of each month for the previous month's report. This information will be reconciled in the manner that

Automation of Reports and Consolidated Orders System (ARCOS) data is reconciled. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for Masters' compliance with recordkeeping and reporting requirements under the CSA or applicable DEA regulations. The Parties agree that such report is not 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). Masters shall begin transmitting this information for all controlled substances no later than 90 days after the Parties have mutually agreed upon a format and as soon as practicable for carisoprodol and tramadol. 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. Masters 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 contrary to DEA regulations, Masters shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA agrees to notify all of the DEA Field Offices within thirty days of the Effective Date of this Agreement that Masters will no longer be required to provide suspicious order reports or any other type of report 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. 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 days written notice.
- d. Masters agrees that within 180 days of the Effective Date of this Agreement it will review distributions of oxycodone, hydrocodone, alprazolam, and phentermine to retail pharmacy customers and physicians for the 18-month period immediately preceding the execution of this Agreement and identify any current customer whose purchases of oxycodone, hydrocodone, alprazolam, and phentermine exceeded the thresholds or met other criteria established in its compliance program on the date of such review. To the extent it has not otherwise done so, Masters shall conduct an investigation for each customer where such review reveals purchasing patterns substantially deviating from the normal purchasing patterns observed by Masters for that customer, and take appropriate action as required by this Agreement, DEA regulations and other procedures established under Masters' compliance program.
- e. Masters' policy and procedure is to cooperate with the government in any investigation. Masters agrees to reasonably cooperate with DEA, the United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting Masters' customers for alleged violations or

activities related to the Covered Conduct unless such matters would affect the rights or obligations of Masters 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 Masters or its employees of any constitutional rights or rights that the company 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.

- f. Masters agrees to pay to the United States of America under 21 U.S.C. § 842(c) for violations of 21 U.S.C. § 842(a)(5) the amount of \$500,000 in settlement of claims or potential claims for civil penalties made by the United States of America for failing to report suspicious orders of controlled substances. Payment of said amounts shall be made by Masters in the amount indicated and as directed by the United States Attorneys' Office set forth in Appendix B, Paragraph 13. Masters agrees to execute the Settlement Agreement at Appendix B simultaneously 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, and to fully pay said amount according to the time frames set forth in Appendix B, paragraph 13.
- g. Any material breach by Masters of subsections II(1)(a)-(h) of this Agreement by Masters 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 Masters' DEA certificate(s) of registration

2. Obligations of DEA.

- a. At Master' request, DEA shall provide diversion prevention and awareness training, as practicable, to retail pharmacy industry members and Masters employees at Masters trade shows, or at Masters internal training sessions, and through written materials. The frequency and content of such training shall be at DEA's sole discretion.
- b. 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 subsection II(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.
- c. On a date mutually agreed upon by the parties that shall be within 180 days of the Effective Date of this Agreement, DEA shall conduct a review of the functionality of Master' diversion compliance program ("Compliance Review") at Masters'

distribution center. DEA shall also review the investigatory files maintained by Masters of the customers serviced by the distribution center. DEA shall notify Masters no less than 48 hours prior to commencing the Compliance Review, and DEA shall issue a Notice of Inspection to Masters upon commencement of the Compliance Review. During the course of the Compliance Review, if requested, Masters shall provide DEA with information in a form reasonably agreed to by the Parties related to the sales of controlled substances, non-controlled drugs, and listed chemicals from the Effective Date of Agreement to the date of the Compliance Review. At the conclusion of the Compliance Review, DEA shall conduct an exit interview with appropriate Masters representatives to provide DEA's preliminary conclusions regarding the Compliance Review. The parties agree that, at Masters' option, Masters may be represented by counsel at such Compliance Review and that DEA shall neither object to nor limit the number of counsel present at such Compliance Review.

- d. The Compliance Review will be deemed satisfactory unless DEA determines that the facility being inspected 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 after April 1, 2009; or (iii) failed to meaningfully investigate new or existing customers regarding the customer's legitimate need to order or purchase controlled substances. The Compliance Review shall be deemed "not satisfactory" if DEA provides written notice with specificity to Masters on or before 220 days from the Effective Date of this Agreement, stating that Masters failed to meet any of the requirements in either subsections II(2)(d)(i), (ii), or (iii) of this Agreement. DEA shall not find the Compliance Review "not satisfactory" unless the failure(s) are sufficient to provide DEA with a factual and legal basis for issuing an Order to Show Cause under 21 U.S.C. § 824(a) against the inspected facility. In the event that DEA provides such written notice of a Compliance Review Failure, DEA shall meet and confer with Masters within 48 hours regarding such a finding. DEA shall consider remedial measures that Masters has instituted in determining whether the Compliance Review is satisfactory. A finding of "satisfactory" does not otherwise express DEA's approval of Masters' compliance program.
- e. DEA shall execute this Agreement only upon obtaining a fully executed copy of the Settlement Agreement at Appendix B.
- f. 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 Masters' entry into this Agreement; all actions taken by Masters pursuant to this Agreement; any remedial actions taken by Masters to address the alleged or perceived violative conduct; and the compliance history of Masters.
- g. DEA represents that it has reviewed its records for investigations or inspections, initiated or conducted prior to April 1, 2009, which may allege that Masters 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 Masters to DEA on or before April 1, 2009, for indications that Masters 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 (other than conduct in Appendix B, Paragraph 8) occurring before April 1, 2009, for civil penalty proceedings under to 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. Masters and DEA agree that upon the execution of this Agreement, DEA and Masters shall file a joint motion with the DEA Administrative Law Judge to terminate all pending administrative proceedings.

4. Release by DEA. In consideration of the fulfillment of the obligations of Masters under this Agreement, DEA hereby agrees to:

- a. Release Masters, together with its shareholders, officers, directors, employees, successors, attorneys and assigns (collectively, the "Released Parties") from any administrative claims within DEA's enforcement authority for the conduct alleged in the Order to Show Cause and this Agreement; and
- b. Refrain from filing any administrative claims against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823, 824 and 842, based on the Covered Conduct.

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 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, civil, or criminal proceedings with respect to the Covered Conduct 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 Masters' request, DEA agrees to disclose the terms of this Agreement to any other law enforcement agency and will represent that Masters' compliance with this Agreement adequately addressed the administrative and civil allegations raised by DEA as defined in the Covered Conduct. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

5. Release by Masters. Masters fully and finally releases DEA, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Masters has asserted, could have asserted, or may assert

Masters Pharmaceutical, Inc.
Attn: Dennis Smith
11930 Kemper Springs Drive
Cincinnati, Ohio 45240

With a Copy to:

Richard T. Lauer
Robbins, Kelly, Patterson & Tucker
7 West 7th Street, Suite 1400
Cincinnati, Ohio 45202

7. Disclosure. Masters and DEA may each disclose the existence of this Agreement and information about this Agreement to the public. In any such communication, DEA agrees that it will: (a) not suggest or allege that Masters or its employees were involved in any criminal conduct; (b) not suggest or allege that Masters intentionally violated any state, federal or local law; (c) affirmatively state that Masters cooperated fully with DEA's investigation; and (d) affirmatively state that Masters has agreed to continue to cooperate with DEA in reducing the unlawful diversion of controlled substances.

8. 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.

9. Authorizations. The individuals signing this Agreement on behalf of Masters represent and warrant that they are authorized by Masters 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.

10. Choice of Law and Venue. This Settlement Agreement and Release 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 subsections II(2)(a-d) of this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the Masters distribution facility(s) at issue is located. 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 Settlement and Release Agreement as of the date written above.

**On Behalf of Masters Pharmaceuticals, Inc.
11930 Kemper Springs Drive
Cincinnati, Ohio 45240**

By: 

Dennis Smith
President

Dated: 4-1-09

**On Behalf of the United States Department of Justice,
Drug Enforcement Administration**

~~By: _____
Michele M. Leonhart
Acting Administrator
Drug Enforcement Administration~~

~~Dated: _____~~

~~By: _____
Wendy H. Goggin
Chief Counsel
Drug Enforcement Administration~~

~~Dated: _____~~

SEE AMENDED SIGNATURE PAGE (attached)

**On Behalf of the United States Department of Justice,
Drug Enforcement Administration**

By: _____ 4/21/09

James Gelchof
Diversion Program Manager
Drug Enforcement Administration
Detroit, Michigan 48226