

## **SETTLEMENT AGREEMENT**

This Settlement Agreement (“Agreement”) is entered into this 1st day of April 2009, by and between the United States Department of Justice, through the United States Attorney’s Office for the Southern District of Ohio (“United States”) and Masters Pharmaceutical, Inc., an Ohio corporation, (“Masters”) (each a “Party” and collectively the “Parties”).

### **RECITALS**

1. Masters is in the business of distributing branded and generic prescription drugs, as well as over-the-counter medications, to retail pharmacies throughout the United States. In furtherance of this business objective, Masters operates a distribution facility in the Cincinnati, Ohio.
2. Masters holds a Certificates of Registration issued by the Drug Enforcement Administration (“DEA”) authorizing it to distribute controlled substances from its distribution facility
3. Masters is required to operate its distribution facility in accordance with the statutory and regulatory provisions of the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* (“the CSA”).
4. Masters’ distribution facility supplies prescription medications, including controlled substances, to retail pharmacies and other health care providers throughout the United States.
5. DEA is the Department of Justice component agency primarily responsible for administering the CSA and is vested with the responsibility of investigating CSA violations.
6. The Attorney General, through the United States Attorneys, has primary authority to bring civil actions to enforce the CSA. *See* 21 U.S.C. § 871 *and* 28 C.F.R. § 0.55(c).
7. Hydrocodone, phentermine and alprazolam are medications whose manufacture,

distribution, sale and possession are regulated by DEA under the CSA. This includes a requirement to report customer orders for controlled substances that are suspicious as the term is defined under 21 C.F.R. §1301.74(b).

8. 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), including Masters’ sales, from 2005 through 2008, of over 4,199,465 dosage units of controlled substances to illegally operating Internet pharmacies, and Masters’ failure to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);
  - b. the alleged failure generally of Masters to maintain adequate controls against the diversion of controlled substances, on or before April 1, 2009, at its distribution facility;
  - c. the alleged failure generally 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.
9. By entering into this Agreement, Masters does not admit to the violations alleged as a result of any DEA investigation, or to any violation of law, liability, fault, misconduct, or wrongdoing.
10. At all times relevant to the activity alleged in these Recitals and Attachments, the CSA (21 U.S.C. § 842(c)(1)) authorized the imposition of a civil penalty of up to \$25,000 for most violations of Section 842, but, violations of § 842(a)(5) (record keeping and reporting violations) are subject to a civil penalty of up to \$10,000 for each violation.
11. To avoid the delay, expense, inconvenience, and uncertainty of litigation of these claims, the Parties agree to settle, compromise, and resolve all existing or potential claims for civil penalties the United States may have against Masters under § 842 of the CSA based on the Covered Conduct as further described in Paragraphs 13 and 14 below.

12. This Agreement is neither an admission of liability by Masters nor a concession by the United States that its claims are not well founded. In consideration of the mutual promises, covenants, and obligations set forth in this Agreement, the Parties agree as follows:

**TERMS AND CONDITIONS**

13. Masters shall pay to the United States the sum of Five Hundred Thousand Dollars (\$500,000) (the "Settlement Amount"), with \$350,000 of the Settlement Amount due within thirty (30) days of the effective date of this Agreement, \$100,000 of the Settlement Amount due one year from the date of the \$350,000 payment, and \$50,000 of the Settlement Amount due two years from the date of the \$350,000 payment, payable by electronic funds transfer to the United States Attorney's Office, Southern District of Ohio, pursuant to instructions provided by the United States. Masters may make any of the payments described above in advance of their respective due dates without penalty.

14. In consideration of the undertakings by Masters, the United States agrees to settle and relinquish all claims for civil penalties it may have under 21 U.S.C. § 842 against Masters, its shareholders, officers, directors, attorneys and employees for possible violations of the CSA, and the regulations promulgated thereunder, based on the Covered Conduct.

15. Masters fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which it has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the investigation, prosecution and settlement of this matter.

16. Notwithstanding any term of this Agreement, specifically reserved and excluded from its

scope and terms as to any entity or person are the following:

- A. Any potential criminal liability;
- B. Any criminal, civil or administrative claims arising under Title 26, U.S. Code (Internal Revenue Service);
- C. Any administrative liability, including mandatory exclusion from any federal programs;
- D. Any liability to the United States for any conduct other than that covered by the release in Paragraph 14; and
- E. Any claims based on such obligations as are created by this Agreement.

17. Masters acknowledges that its DEA-registered facility is required to comply with the controlled substance record keeping and reporting requirements of the CSA, as modified by the Parties in a separate Settlement and Release Agreement and Administrative Memorandum of Agreement dated April 1, 2009. Masters represents that it has taken good-faith actions to detect and prevent diversion including agreeing to implement the policies and procedures that are the subject of an administrative settlement agreement between it and DEA.

18. Masters agrees that any and all costs it has or will incur in connection with this matter -- including payment of the Settlement Amount under this Agreement, attorney's fees, costs of investigation, negotiation, and remedial action -- shall be unallowable costs for government contract accounting and for Medicare, Medicaid, TriCare, and FEHBP reimbursement purposes.

19. This Agreement is not intended by the Parties to be, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein.

20. This Agreement shall be governed by the laws of the United States. If a dispute arises under this Agreement between Masters and the Office of the United States Attorney signing this

Agreement, exclusive jurisdiction and venue shall lie in the Southern District of Ohio, and to the extent that state law applies to the dispute, the law of the State of Ohio shall apply.

21. The Parties agree that this Agreement does not constitute evidence or an admission by any person or entity, and shall not be construed as an admission by any person or entity, with respect to any issue of law or fact.

22. This Agreement constitutes the entire agreement between the Parties and cannot be amended except in writing and when signed by all the Parties to this Agreement.

23. Masters acknowledges that its authorized representatives have read this Agreement and understand that as of its effective date, it will be a matter of public record.

24. Each person who signs this Agreement in a representative capacity warrants that he or she is fully authorized to do so.

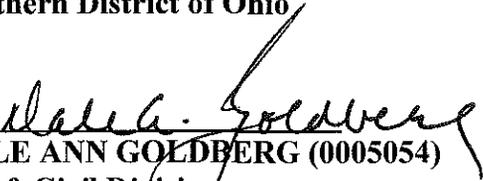
25. This Agreement shall become effective (i.e., final and binding) on the date of signing by the last signatory (the "Effective Date"). It may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same agreement. The government agrees to notify Masters immediately when the final signatory has executed this Agreement.

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

By:   
\_\_\_\_\_  
**DENNIS SMITH  
President**

Dated: \_\_\_\_\_  
**On Behalf of the United States of America:**

**GREGORY G. LOCKHART  
United States Attorney  
Southern District of Ohio**

  
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**DALE ANN GOLDBERG (0005054)  
Chief, Civil Division**

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Dated: \_\_\_\_\_

Dated: 4/28/2009