

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is made and entered into by and between the United States of America, acting through the United States Department of Justice and the Drug Enforcement Administration (“DEA”) (collectively, the “United States”); and Maida Pharmacy, Inc. (“Maida”) (hereafter Maida and the United States are the “Parties”), through their authorized representatives.

RECITALS

A. Maida Pharmacy is a retail and compounding pharmacy located at 121 Massachusetts Avenue, Arlington MA. Maida is a DEA registrant with assigned Certificate of Registration No. AM1910175.

B. Each DEA registrant is required to conduct its operation in accordance with the Controlled Substances Act, 21 U.S.C. § 801, *et seq.* (the “Act”), and the regulations promulgated thereunder. Failure to keep an accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of is a violation of the Act and DEA regulations. 21 U.S.C. § 827(a)(3); 21 C.F.R. §§ 1304.21, 1304.22(c), § 1317.05. To comply with the Act and DEA regulations, for example, registrants are required to maintain an accurate biennial inventory. 21 C.F.R. § 1304.11(c). The CSA provides for civil penalties for registrants that violate these recordkeeping requirements.

C. The DEA is the Department of Justice agency primarily responsible for enforcing the Act and is vested with the responsibility of investigating violations of the Act.

D. The United States Attorney General, through the United States Attorney’s Office, has primary authority to bring civil actions to enforce the Act. *See* 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

E. Maida admits, acknowledges, and accepts responsibility for the following facts:

a. On February 8, 2023, DEA inspected Maida and audited its inventory.

Twenty-one of twenty-three controlled substances the DEA audited showed differences between the amount Maida listed in its inventory compared to the amount investigators were able to account for during the audit. Maida did not provide records showing that within the last two years it conducted its biennial inventory, as required by the regulations.

b. Maida did not keep complete and accurate records of all the controlled substances it purchased from manufacturers or that it distributed. Some of the receipts in Maida's possession did not contain all information required under the Act, such as the name or initials of the individual who dispensed the substance.

c. Maida employees disposed of Ketamine by placing it curbside in trash bags left outside of the pharmacy to be picked up by the municipal trash service for Arlington, instead of destroying it as required by DEA regulations. Maida did not have records demonstrating how many controlled substances were expired, damaged, defective, or awaiting proper disposal.

The foregoing conduct is referred to as the "Covered Conduct."

F. The United States contends that it has claims for civil monetary penalties and injunctive relief against Maida under the Controlled Substances Act and its implementing regulations based upon the covered conduct.

In consideration of the mutual promises and obligations of this Agreement, the Parties agree, and covenant as follows:

TERMS AND CONDITIONS

1. As set forth below, Maida shall pay to the United States the sum of twenty-five thousand dollars (\$25,000), plus interest at a rate of 4.375% per annum from December 15, 2023, and continuing through the date of payment (the "Settlement Amount"), of which none is restitution.

2. Maida shall make payment of the Settlement Amount pursuant to written instructions to be provided by the Office of the United States Attorney for the District of Massachusetts, no later than fourteen days after the Effective Date of this Agreement.

3. No later than five business days after the Effective Date of this Agreement, Maida and the DEA will enter into the three-year Memorandum of Agreement ("MOA") that is attached as Exhibit A.

4. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, and conditioned upon Maida complying with Paragraph 3, the United States releases Maida (including its predecessors, current and former parents, divisions, subsidiaries, and assigns) from any civil or administrative claims the United States has, could have, or may assert in the future, related to the Covered Conduct under the Act and associated DEA regulations.

5. Notwithstanding the release given in Paragraph 4 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;

- c. Any administrative liability or enforcement right, including the suspension and debarment rights of any federal agency, other than the DEA, as to the Covered Conduct;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement; or
- f. Any liability of any individuals.

6. The United States reserves the right to seek injunctive relief pursuant to 21 U.S.C. § 843(f) if Maida fails to pay the Settlement Amount or comply with the obligations of the MOA.

7. Maida waives and shall not assert any defenses it may have to any criminal prosecution relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

8. Maida releases the United States and its agencies, officers, agents, employees, and servants from any claims (including for attorneys' fees, costs, and expenses of every kind and however denominated) that Maida has asserted, could have asserted, or may assert in the future against the United States or its agencies, officers, agents, employees, or servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

9. The obligations imposed upon Maida pursuant to this Agreement and the MOA are in addition to, and not in derogation of, all requirements imposed upon Maida pursuant to all applicable federal, state, and local laws and regulations, including but not limited to the

requirements set forth in Title 21 of the United States Code and the regulations promulgated thereunder.

10. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

11. Each Party represents that it freely and voluntarily enters into this Agreement without any duress or compulsion.

12. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity.

13. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. This Agreement shall be deemed to have been drafted by all Parties to this Agreement and, therefore, shall not be construed against any Party for that reason in any subsequent dispute.

14. The Agreement, including the MOA, contains the entire agreement between the Parties regarding the alleged claims at issue herein. The Agreement may be amended only by a writing signed by both Parties.

15. This Agreement is binding on Maida's successors, transfers, and assigns.

16. The undersigned represents and warrant that they are fully authorized to execute this Agreement on behalf of the Parties.

17. This Agreement may be executed in counterparts, each of which constitutes an original and both of which constitute one and the same agreement, but shall become final and binding only upon signing by both Parties.

18. The Parties may execute this Agreement via facsimile and/or by portable document format (.pdf), both of which shall be deemed the equivalent of an original signature.

19. The Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public, except that Maida's DEA Registration Number shall be redacted and not disclosed to the public.

20. This Agreement shall become effective on the date of the signature of the last signatory to the Agreement ("Effective Date of this Agreement").

THE UNITED STATES OF AMERICA

DATED: 4/8/24

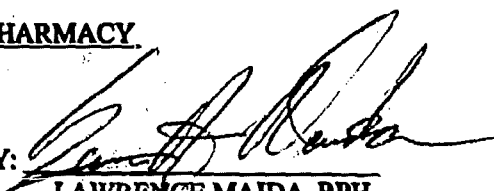
BY: JULIEN MUNDELE Digitally signed by JULIEN MUNDELE
Date: 2024.04.08
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JULIEN M. MUNDELE
Assistant U.S. Attorney
United States Attorney's Office
District of Massachusetts

DATED: 4/8/24

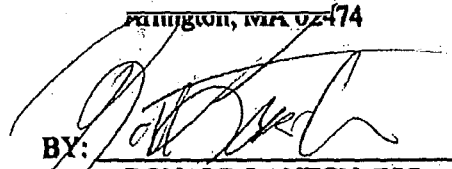
BY: Stephen Belleau Digitally signed by Stephen Belleau
Date: 2024.04.08
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STEPHEN P. BELLEAU
Acting Special Agent in Charge
Drug Enforcement
Administration New England
Field Division

MAIDA PHARMACY

DATED: 4/4/24

BY: 
LAWRENCE MAIDA, RPH
Owner/Pharmacist
121 Massachusetts Ave
Framington, MA 02474

DATED: 4/4/24

BY: 
RONALD LANTON, ESQ.
Counsel for Maida Pharmacy