

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is made and entered into this ____ day of February, 2023 between the United States of America ("United States"), acting by and through the United States Attorney's Offices for the Southern District of Florida and the Southern District of Texas on behalf of the Drug Enforcement Administration ("DEA"), Woodfield Distribution, LLC ("WDSrx") and Adam Runsdorf ("Runsdorf") (collectively "the Parties").

RECITALS

1. WDSrx is a DEA registrant located and doing business in the Southern District of Florida and in the Southern District of Texas. WDSrx is owned and operated by Adam Runsdorf. WDSrx is located at 951 Clint Moore Rd, Boca Raton, FL 33487 and at 1113 Gillingham Lane, Suite A, Sugar Land, Texas, 77530.

2. WDSrx is registered with DEA and was assigned the following unique DEA Numbers:

- a. RW0518932;
- b. RW0407076;
- c. RW0413548;
- d. RW0433653;
- e. RW0483317;
- f. RW0502218; and
- g. RW0502814.

authorizing WDSrx to distribute, import, export and destroy controlled substances as required by and in conformity with the Controlled Substances Act, 21 U.S.C. §§ 801-904, ("the CSA").

3. The Drug Enforcement Administration ("DEA") is the component agency of the United States Department of Justice primarily responsible for administering the CSA and is vested with the responsibility for investigating violations of the Act. The CSA regulates persons and companies that manufacture, distribute and dispense controlled substances in order to

prevent diversion. The CSA aims to protect the public's health and safety from dangers posed by highly addictive or dangerous controlled substances that are diverted into the illicit market, while also ensuring that patients have access to pharmaceutical controlled substances for legitimate medical purposes. Entities that dispense controlled substances are required to have a valid DEA registration number and are referred to as "registrants." Among other preventive measures, DEA registrants must comply with various recordkeeping requirements. Remedies resulting from violations of the CSA or its regulations (21 C.F.R. §1300.01 *et seq.*) include civil penalties.

4. WDSrx and Runsdorf acknowledge that their distributorship facilities were required to operate in accordance with the statutory and regulatory provisions of the CSA and its implementing regulations.

5. The United States contends that it has certain civil penalty claims against WDSrx and Runsdorf for the conduct of its distributor warehouses between 2017 and 2021 ("Covered Time Period"), and that WDSrx and Runsdorf are subject to monetary penalties as provided in 21 U.S.C. § 842(c). The specific conduct the United States alleges by WDSrx and Runsdorf is set forth in Attachment 1 of the United States' Statement of Covered Conduct ("Covered Conduct.")

6. This Agreement is neither an admission of liability by Defendants except to the extent admitted in Runsdorf's guilty plea, nor a concession by the United States that its claims are not well founded.

7. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties have reached a full and final understanding pursuant to the Terms and Conditions below.

TERMS AND CONDITIONS

1. WDSrx and Runsdorf shall pay the sum of **TWO MILLION FOUR HUNDRED SEVENTY-FIVE THOUSAND DOLLARS (\$2,475,000.00)** (the "Settlement Amount") to the United States as follows:

- a. the sum of **One Million, Seven Hundred and Twenty-Five Thousand Dollars (\$1,725,000)** to the U.S. Attorney's Office for the Southern District of Florida, and
- b. the sum of **Seven Hundred and Fifty Thousand Dollars (\$750,000.00)** to the U.S. Attorney's Office for the Southern District of Texas,

by electronic funds transfer pursuant to written instructions provided by each office no later than ten (10) business days after the Effective Date of this Agreement.

2. Should WDSrx and Runsdorf fail to perform as stipulated herein, the United States reserves the right to rescind this agreement and seek the maximum penalties provided under the law against them for all violations of the CSA.

3. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon WDSrx and Runsdorf's full payment of the Settlement Amounts, the United States releases WDSrx and Runsdorf from any civil monetary claim the United States has asserted or could assert for the Covered Conduct under Title 21 U.S.C. § 842(c) (including attorney's fees, costs, and expenses of every kind of however denominated).

4. Notwithstanding the release given in paragraph 3 of this Agreement, or any other term of this Agreement, the following claims 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. Except as explicitly stated in this Agreement, any administrative liability,

- 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;
- f. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;
- g. Any liability of individuals; or
- h. Any liability of individuals (including current or former directors, officers, employees, agents, or shareholders of WDSrx and Runsdorf) who receive written notification that they are the target of a criminal investigation (as defined in the United States Attorneys' Manual), are indicted or charged, or who enter into a plea agreement, related to the Covered Conduct.

5. Nothing in this Agreement shall prevent, preclude, limit, or prejudice the right of the United States to enforce the CSA by commencing a civil or administrative action against WDSrx and Runsdorf for violations of the CSA unrelated to the Covered Conduct or which occur after the Covered Time Period.

6. The obligations imposed upon WDSrx and Runsdorf pursuant to this Agreement are in addition to, and not in derogation of, all requirements imposed upon them pursuant to all applicable federal, state and local laws and regulations, including, but not limited to, the requirements set forth in the CSA.

7. WDSrx and Runsdorf waive and shall not assert any defenses WDSrx and Runsdorf may have to any criminal prosecution or administrative action 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. Nothing in this paragraph or any other provision of this Agreement constitutes an

agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

9. WDSrx and Runsdorf agree that any and all costs they have, will or may incur, in connection with this matter—including payment of the Settlement Amounts under this Agreement, attorneys' fees, costs of investigation, negotiation, past and future compliance efforts, and remedial action—shall be unallowable costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) for government contracting accounting and for purposes of any government reimbursement program.

10 WDSrx and Runsdorf fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that WDSrx and Runsdorf have asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

11. 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.

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

13. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

14. This Agreement is governed by the laws of the United States. The exclusive

jurisdictions and venue for any dispute relating to this Agreement is the United States District Court for the Southern District of Florida and the United States District Court for the Southern District of Texas. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

15. This Agreement and the Attachment constitute the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

16. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

17. This Agreement is binding on WDSrx and Runsdorf's successors, transferees, heirs, and assigns.

18. All parties consent to the United States' disclosure of this Agreement and Attachment, and information about this Agreement, to the public.

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

20. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

Mark A. Lavine
Assistant United States Attorney
Southern District of Florida

DATED: 08/02/2023

BY: Jill D. Venezia
Jill D. Venezia
Assistant United States Attorney
Southern District of Texas

WOODFIELD DISTRIBUTION, LLC

DATED: 7/31/23

BY: ARB
Adam Runsdorf
President
Woodfield Distribution, LLC

ADAM RUNSDORF

DATED: 7/31/23

BY: ARB
Adam Runsdorf

DATED: _____

BY: _____

Jill O. Venezia
Assistant United States Attorney
Southern District of Texas

WOODFIELD DISTRIBUTION, LLC

DATED: 7/31/23

BY:  _____

Adam Runsdorf
President
Woodfield Distribution, LLC

ADAM RUNSDORF

DATED: 7/31/23

BY:  _____

Adam Runsdorf

ATTACHMENT 1

UNITED STATES' STATEMENT OF COVERED CONDUCT

The United States contends that it has grounds to pursue civil monetary claims against WDSrx and Runsdorf based on the conduct of the DEA Registrants listed in Recital 2 of the Agreement which occurred during the Covered Time Period:¹

1	21 CFR § 1301.72(b)(8)(ii)	Failure to obtain permission in advance, in writing, from the DEA to store non-controlled substances in the controlled substances cage, as required by Title 21 CFR § 1301.72(b)(8)(ii).
2	21 CFR § 1301.74(b)	Failure to design and operate a system to report suspicious controlled substance order, as required by Title 21 CFR § 1301.74(b).
3	21 CFR § 1301.74(c)	Failure to design and operate a system to report suspicious controlled substance order, as required by Title 21 CFR § 1301.74(b).
4	21 CFR § 1304.04(f)	Failure to maintain separate records for controlled substances, as required by Title 21 CFR § 1304.04(f).
5	21 CFR § 1304.11(a)	A controlled substances audit revealed a failure to maintain complete and accurate controlled substance records, as required by Title 21 CFR § 1304.11(a).
6	21 C.F.R. § 1304.11(a)	Failure to indicate on the Biennial Inventory whether it was taken at the Beginning of Business or Close of Business, as required by 21 C.F.R. § 1304.11(a).
7	21 C.F.R. § 1304.11(a)	WOODFIELD's Biennial Inventory for the reverse distributor registration was not annotated as being taken at beginning of business or close of business as required by Title 21 C.F.R. § 1304.11(a).

¹ Capitalized terms and acronyms shall have the meaning ascribed to them in the Settlement Agreement.

8	21 C.F.R. § 1304.11(a)	WOODFIELD's Initial Inventories for the exporter registration were not annotated as being taken at beginning of business or close of business as required by Title 21 C.F.R. § 1304.11(a).
9	21 C.F.R. § 1304.11(e)(3)(ii)(B)	Failure to document the finished form for all controlled substances listed on the Biennial Inventory as required by Title 21 C.F.R. § 1304.11(e)(3)(ii)(B).
10	21 C.F.R. § 1304.21(a)	An audit was unable to be conducted due to WOODFIELD's failure to maintain records of controlled substances received and distributed. Failure to maintain a complete and accurate record of each controlled substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed, of as required by Title 21 (C.F.R.), § 1304.21(a).
11	21 C.F.R. § 1304.21(a)	An audit of controlled substances resulted in discrepancies due to WOODFIELD's failure to maintain complete and accurate records of each controlled substance as required by Title 21 C.F.R. § 1304.21(a).
12	21 C.F.R. § 1304.21(a)	An audit was unable to be conducted due to WOODFIELD's failure to maintain records of controlled substances received and distributed. Failure to maintain a complete and accurate record of each controlled substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of as required by Title 21 C.F.R. § 1304.21(a).
13	21 C.F.R. § 1304.21(e)	Failure to maintain DEA Form 41's for several dates that controlled substances were destroyed as required by Title 21 C.F.R. § 1304.22(e)(2)(ii) and 1304.21 (e).
14	21 C.F.R. § 1304.22(a)(2)(v)	Failure to indicate the date received and the amount of controlled substances received on Import Declarations (DEA Form 236's) as required by Title 21 C.F.R. § 1304.22 (a)(2)(v) and § 1304.22 (d).

15	21 C.F.R. § 1304.22(a)(2)(vii)	Failure to maintain records of the Schedule 3-5 controlled substances transferred from the Importer DEA registration, DEA number RW0413548 to WOODFIELD's Distributor registration, DEA number RW0407076, as required by Title 21 C.F.R. § 1304.22 (a)(2)(vii).
16	21 C.F.R. § 1304.22(b)	Failure to indicate the date received, and the name, address, and registration number of the person from whom the units were acquired, on their official form documenting the receipt of returned controlled substances, Return Authorizations, as required by 21 C.F.R. § 1304.22(b).
17	21 C.F.R. § 1304.22(b)	Failure to maintain a complete and accurate record of the quantity of controlled substances received in regards to Schedule 3-5 controlled substances received by WOODFIELD's Distributor registration, DEA number RW0407076, from WOODFIELD's Importer registration, DEA number RW0413548, as required by 21 C.F.R. § 1304.22(b).
18	21 C.F.R. § 1304.22(d)	Failure to indicate the date received and the amount of controlled substances received on Import Declarations (DEA Form 236's) as required by Title 21 C.F.R. § 1304.22 (a)(2)(v) and § 1304.22 (d).
19	21 C.F.R. § 1304.22(d)	Failure to maintain records of Schedules 3-5 controlled substances transferred from the Distributor DEA registration number RW0407076, to WOODFIELD's Exporter DEA registration RW0518932 as required by Title 21 C.F.R. § 1304.22(d).
20	21 C.F.R. § 1304.22(e)(2)(i)	Failure to document the DEA number of the customer on Schedule 3-5 controlled substance purchase records, as required by Title 21 C.F.R. § 1304.22(e)(2)(i).
21	21 C.F.R. § 1304.22(e)(2)(ii)	Failure to maintain DEA Form 41's for several dates that controlled substances were destroyed as required by Title 21 C.F.R. § 1304.22(e)(2)(ii) and 1304.21 (e).

22	21 C.F.R. § 1304.33(b)	Failure to report a year-end inventory of all controlled substances on-hand for 2016 to the DEA Automated Reports and Consolidated Orders System (ARCOS) Unit, as required by 21 C.F.R. § 1304.33(b).
23	21 C.F.R. § 1304.33(b)	Failure to report a year-end inventory of all controlled substances on hand for 2017 to the DEA ARCOS Unit as required by Title 21 C.F.R. § 1304.33(b).
24	21 C.F.R. § 1304.33(d)(2)	Failure to present data to the ARCOS Unit in such a manner as to identify the particular trade name of the product for which the report is being made, as required by 21 C.F.R. § 1304.33(d)(2).
25	21 C.F.R. § 1304.33(d)(2)	Failure to correctly report controlled substance transactions to the Drug Enforcement Administration's (DEA) Automation of Reports and Consolidated Orders System (ARCOS) as required by Title 21, C.F.R. § 1304.33(d)(2).
26	21 C.F.R. § 1305.03	Failure to maintain DEA Form 222's documenting returned or damaged Schedule 2 controlled substances which were transferred to WOODFIELD's reverse distributor, DEA registration number RW0433653, as required by 21 C.F.R. § 1305.03.
27	21 C.F.R. § 1305.12(a)	Failure to prepare and execute DEA Form 222's to document the receipt of schedule 2 controlled substances from WOODFIELD's Texas Distributor registration, DEA number RW0502218, as required by 21 C.F.R. § 1305.12(a).
28	21 C.F.R. § 1305.12(a)	Failure to prepare and execute DEA Form 222's to document the receipt of returned Schedule 2 controlled substances, as required by 21 C.F.R. § 1305.12(a).
29	21 C.F.R. § 1305.13(a)-(f)	Failure to maintain DEA Form 222's for the receipt of Schedule 2 controlled substances transferred from WOODFIELD's Distributor registration, DEA number RW0407076 to WOODFIELD's Reverse Distributor registration, DEA number RW0433653

		in violation of Title 21 C.F.R. § 1305.13(a)-(f).
30	21 CFR § 1305.13(b)	Failure to timely fulfill DEA-222 controlled substance orders within 60 days of executing the DEA Form-222, as required by Title 21 CFR § 1305.13(b).
31	21 C.F.R. § 1305.13(b)	Failure to indicate the date shipped and quantity of controlled substances shipped on DEA Form 222's, as required by 21 C.F.R. § 1305.13(b).
32	21 CFR § 1305.13(d)	Failure to make and send a copy of DEA-222 Forms to the DEA by the close of the month, as required by Title 21 CFR § 1305.13(d).
33	21 C.F.R. § 1305.13(e)	Failure to indicate the date received and the amount of controlled substances received on Official Order Forms (DEA Form 222's), as required by 21 C.F.R. § 1305.13(e).
34	21 C.F.R. § 1305.13(e)	Failure to document the date received and/or amount received on several DEA Form 222's (Schedule 2 Order Forms) as required by Title 21 C.F.R. § 1305.13(e).
35	21 C.F.R. § 1305.22(d)	Failure to create a record of the quantity of each item shipped and the date shipped, when filling an electronic order, as required by 21 C.F.R. § 1305.22(d).
36	21 C.F.R. § 1305.22(g)	Failure to indicate the date received and quantity of controlled substances received on their primary record of receipt for CSOS orders, as required by 21 C.F.R. § 1305.22(g).
37	21 CFR § 1312.11(a)	Enabling a non-DEA Registrant to "cause the importation" of controlled substances, a violation of Title 21 CFR § 1312.11(a).
38	21 CFR § 1312.14	Failure to import controlled substances to the final listed location, as required by Title 21 CFR § 1312.14.
39	21 CFR § 1317.05(b)	Failure to properly secure and promptly deliver expired controlled substances to the registered location of a DEA Reverse Distributor, as required by Title 21 CFR § 1317.05(b).