UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of **Tick Klock Drug, LLC** **DEA Certificates of Registration:** **AJ0986250 & FT2564638**	RE-22-2062

MEMORANDUM OF AGREEMENT

This Memorandum of Agreement (the "Agreement") between the United States Department of Justice, Drug Enforcement Administration ("DEA" and/or "Government") and Tick Klock Drug, LLC (herein "Tick Klock Drug") reflects the full and final administrative settlement between the parties regarding DEA Certificates of Registration ("COR") AJ0986250 and FT2564638 and any new applications or future DEA Registrations.

I. BACKGROUND

1. Tick Klock Drug is currently registered with the DEA as a Retail Pharmacy with authority to handle controlled substances in Schedules II-V under Registration AJ0986250, with registered address at 109 S. Main Street, Colfax, WA 99111. Tick Kock Drug is also currently registered with DEA as a Retail Pharmacy with authority to handle controlled substances in Schedules II-V under Registration FT2564638, with registered address at 109 S Main Street, Colfax, WA 99111.
2. Tick Klock Drug, located in Colfax, Washington, is a retail pharmacy that, since 1966, has been owned by the Johnson Family. In January 2023, Nathan Johnson, a pharmacist licensed in Washington State, and Kim Johnson, purchased Tick Klock Drug from Nathan's parents Mark and Robyn Johnson. Tick Klock Drug dispenses prescription medications, including controlled substances.

3. In order to protect the public and public health, the Controlled Substances Act, 21 U.S.C. §§ 801 et seq., and implementing regulations promulgated by the DEA (hereinafter collectively "the CSA"), places duties and responsibilities on medical professionals to ensure that controlled substances are prescribed, dispensed, and used for medically appropriate purposes and in a safe manner. Under the CSA, the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. 21 C.F.R. § 1306.04. Accordingly, by law, a pharmacy has a corresponding responsibility to ensure that prescriptions are legitimate and medically appropriate. *Id.*

4. Additionally, the Combat Methamphetamine Epidemic Act of 2005 (CMEA) and implementing regulations impose limitations on the amount of pseudoephedrine and other scheduled listed chemical products that a pharmacy may sell over a 30-day period. Pseudoephedrine, sold under the brand name Sudafed, is a decongestant that can be used to manufacture methamphetamine, a Schedule II controlled substance, and commonly abused street drug. The CMEA also requires pharmacies to maintain records, to train employees concerning safe dispensing and sale of pseudoephedrine, and to annually certify compliance with CMEA requirements and regulations.

II. SPECIFIC EXAMPLES OF ALLEGED CONDUCT

At times, between July 1, 2017, and July 6, 2022, Tick Klock Drug committed violations of the Act, including, but not limited to, the following examples:

5. During this period, Tick Klock Drug failed to keep accurate records of its controlled substances, in violation of 21 CFR § 1304.21(a). The DEA's audit in July 2022 found discrepancies in inventory records of the following controlled substances:

    - Carisoprodol 350mg, a Schedule IV Controlled Substance; and
    - Alprazolam 2mg, a Schedule IV Controlled Substance.

6. Tick Klock Drug failed to conduct a physical count of their Carisoprodol and other schedule III-V drugs when the container holds more than 1,000 tablets, in violation of 21 CFR § 1304.11(e)(6)(ii).
7. Tick Klock Drug failed to create a record of the number of units in each commercial container and the number of commercial containers on their biennial inventory, in violation of 21 CFR § 1304.11(e)(iii)(C)&(D).
8. Tick Klock Drug failed to maintain copies of their subscriber agreements, in violation of 21 CFR § 1311.60(c).
9. Tick Klock Drug failed to create a record of the year in which a Power of Attorney was executed, in violation of 21 CFR § 1305.05(c).
10. Tick Klock Drug failed to create and maintain their Schedule III-V invoices in a manner that separated them from the non-controlled substances, in violation of 21 CFR § 1304.04(h)(3).
11. Tick Klock Drug failed to record the date of receipt for its Schedule III-V controlled substances acquired from other persons, in violation of 21 CFR § 1304.22(c).
12. At times, between January 1, 2022 and July 6, 2022, Tick Klock Drug and its pharmacists and employees did not always appropriately exercise its corresponding responsibility in filling prescriptions for controlled substances. At times, Tick Klock Drug filled prescriptions written by physicians or other medical providers that contained "red flags", i.e., indicia of fraud, drug-seeking, lack of medical necessity, potential for abuse or health risk, or potential for diversion, without appropriately resolving those red flags prior to dispensing. These red flags included patients for whom Tick Klock Drug filled prescriptions for a potentially dangerous and medically-inappropriate combination of an opioid, a benzodiazepine, and a muscle relaxant known as the "holy trinity".

13. Additionally, between July 1, 2017 and July 8, 2022, Tick Klock Drug violated the CMEA by: (1) failing to certify compliance with the CMEA and implementing regulations; (2) failing to prominently display required warning notices; (3) failing to obtain all purchaser signatures for sales of pseudoephedrine, including for sales by Tick Klock Drug employees; and (4) selling pseudoephedrine in amounts that exceeded maximum allowable quantities.

14. Tick Klock Drug has cooperated and indicates that it intends to continue to cooperate with the United States' investigation. Further, Tick Klock Drug has undertaken, and agrees to continue to undertake, corrective actions and proactive steps in order to address and prevent the recurrence of the conduct set forth in Paragraphs 5 through 13.

15. The United States contends that it has certain civil and administrative claims under the Controlled Substances Act, Chapter 21, United States Code, and its implementing regulations against Tick Klock Drug, as further set forth above. That conduct, and the United States' claims and allegations that Tick Klock Drug violated 21 U.S.C. § 842(a)(2), and regulations promulgated thereunder, and that therefore are liable for an assessment of civil penalties for each violation, pursuant to 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5, are hereinafter referred to as the " Covered Conduct."

16. While Tick Klock Drug agrees to, admits, and wishes to accept responsibility for the factual recitations in Paragraphs 5 through 13 above, this Agreement is not an admission of legal liability by Tick Klock Drug. Tick Klock Drug acknowledges and understands that it had and continues to have the obligation to comply with the Controlled Substance Act, Chapter 21, United States Code, the CMEA, and the regulations promulgated thereunder. Tick Klock Drug represents that it will comply with these obligations from this point further and further represents that it has taken additional steps to ensure its compliance with those requirements, and with Washington state law, going forward.

17. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

III. TERMS & CONDITIONS

18. Tick Klock Drug agrees the factual recitations in in Paragraphs 5 through 13, would provide the DEA sufficient grounds to seek an Order to Show Cause to deny, restrict, or revoke the DEA Certificate of Registration numbers AJ0968250 and FT2564638.

19. Tick Klock Drug and the DEA are entering into this Agreement to give Tick Klock Drug the opportunity to demonstrate or achieve compliance with all legal requirements relating to Tick Klock Drug's DEA Certificate of Registrations.

20. Tick Klock Drug represents that it had an opportunity to seek the advice of counsel prior to entering into this Agreement, and it has full knowledge of the events described herein. Tick Klock Drug further represents and agrees that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

21. Tick Klock Drug acknowledges that the specific conduct alleged in Paragraphs 5 through 13 constitute violations of the CSA and CMEA and represents that it will use its best efforts to ensure full compliance with the CSA and CMEA alone with the terms and conditions set forth in this Agreement. Tick Klock Drug understands that this Agreement provides it with an opportunity to correct its alleged prior conduct.

22. Tick Klock Drug shall pay a Civil Penalty pursuant to the Act to resolve any and all civil claims arising from the Covered Conduct. The Civil Penalty shall be in the amount of $20,000 ("Civil Penalty"). Tick Klock Drug shall execute a Settlement Agreement with the United States Department of Justice, which shall be entered into by the U.S. Attorney's Office for the Eastern District of Washington.

Payment of the Civil Penalty shall be made in accordance with the terms and conditions of the Settlement Agreement.

23. Tick Klock Drug shall abide by all federal, state, and local laws and regulations relating to controlled substances, including without limitations the requirements set forth in 21 USC 801 *et seq.* and the regulations promulgated thereunder.

24. Tick Klock Drug shall provide DEA access to Tick Klock Drug's practice at the discretion of DEA, via a Notice of Inspection, during regular business hours. Tick Klock Drug will provide any and all records kept in the usual course of medical treatment (including patient records, etc.) requested by DEA without having to obtain any formal administrative requests such as warrants or subpoenas.

25. Tick Klock Drug agrees to cooperate with all state licensing authorities, including the Washington State Pharmacy Quality Assurance Commission. Tick Klock Drug agrees to report any disciplinary actions taken against any of its licenses to the DEA – Seattle Field Division, 300 Fifth Avenue, Suite 1300, Seattle, Washington, 98014 in writing and by certified mail, within seven business (7) calendar days of discovery.

26. Tick Klock Drug shall provide, for twelve (12) months, the DEA with a quarterly physical inventory of all controlled substances in its possession, custody, or control. Each inventory shall comply with the requirements of 21 CFR § 1304.11.

    Tick Klock Drug shall conduct quarterly physical inventories as follows:

    a. August 1, 2023 (Beginning of Business (BOB)) through October 31, 2023 (Close of Business (COB));

    b. November 1, 2023 (BOB) through January 31, 2024 (COB);

    c. February 1, 2024 (BOB) through April 30, 2024 (COB); and

    d. May 1, 2024 (BOB) through July 31, 2024 (COB).

Tick Klock Drug shall provide a copy via certified mail to the DEA – Seattle Field Division, 300 Fifth Avenue, Suite 1300, Seattle, Washington, 98014, within seven (7) business days after the completion of each quarterly inventory.

27. Tick Klock Drug agrees that all physical inventories completed at its registered location shall be signed by at least two (2) staff members, with one (1) person being the Pharmacist.

28. Tick Klock Drug shall provide each of its employees and managers with comprehensive training on compliance with the CSA and CMEA. Such training shall include, but not be limited to, the following:

    a. methods for the detection and prevention of diversion of controlled substances;

    b. evaluation of prescription to determine legitimacy;

    c. corresponding responsibility; and

    d. record keeping.

29. Tick Klock Drug shall maintain a training log subject to inspection by the DEA. The log shall list each individual who received training, training instructor(s), the date and duration of that training, and the subject matter addressed in the training. New employees shall receive training within thirty (30) calendar days of the start of employment. For the next twelve (12) months Tick Klock Drug agrees to provide a copy via certified mail to the DEA – Seattle Field Division, 300 Fifth Avenue, Suite 1300, Seattle, Washington, 98014, within seven (7) business days after the completion of each trained employee.

30. Tick Klock Drug agrees that employees shall not fill controlled substance prescriptions for themselves, and employees shall not sell scheduled listed chemical products to themselves.

31. Tick Klock Drug agrees to maintain and follow policies and procedures to meet controlled substance record keeping and dispensing requirements under the CSA.

32. Tick Klock Drug agrees to periodically review and update its policies and procedures relating to controlled substances to align with current drug trends and red flag behaviors in pharmaceutical industry.

33. Tick Klock Drug agrees to comply with obligations under 21 CFR § 1306.04 (a): "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."

34. Tick Klock Drug understands that it must resolve any red flags present on a prescription prior to dispensing controlled substances, and that the resolution of the red flags must be documented.

35. For the duration of this Agreement, Tick Klock Drug shall limit their sales of scheduled listed chemical products to 7.5 grams per each individual within a 30 day period.

36. DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under the CSA. DEA is taking no action by entering into this Agreement that can be interpreted to be directly or indirectly endorsing or approving the system that Tick Klock Drug is currently utilizing to meet its obligations under the CSA and the implementing regulations. Going forward, DEA's actions in fulfilling the oversight of Tick Klock Drug under this Agreement shall not be construed or interpreted to be directly or indirectly endorsing or approving the system. DEA expects Tick Klock Drug, like all registrants, to provide effective controls and procedures to guard against theft and diversion of controlled substances, per 21 CFR § 1301.71(a). If Tick Klock Drug's system proves to be ineffective in meeting its obligations, it will not be a valid defense in any legal action for Tick Klock Drug to claim that it was employing a system that was known to or disclosed to the DEA.

37. Tick Klock Drug agrees to contact the DEA, in writing, of any theft or significant loss of any controlled substances within one (1) business day of discovery and complete a DEA Form-106, as required under 21 CFR § 1301.74 (c). Tick Klock Drug must not use a DEA Form-106 for the general purpose of adjusting discrepancies in inventory.

38. Tick Klock Drug agrees that, for any and all future applications made in the next twenty (20) years, for a DEA Certificate of Registration (including applications for renewal or Modification of Registration), Tick Klock Drug shall provide a "yes" response to any question regarding whether Tick Klock Drug has ever had action taken against a federal controlled substances registration. Tick Klock Drug agrees to provide a truthful explanation of the circumstances and the existence of this Agreement to the DEA Seattle Field Division (or any other relevant DEA Office). Tick Klock Drug agrees that any future DEA Certificate of Registration issued prior to the expiration of this Agreement, regardless of practice location, shall be restricted as described in this Agreement for the period described in this Agreement.

39. Both the DEA and Tick Klock Drug may disclose this Agreement to third parties.

40. Tick Klock Drug understands and agrees that any violations of this Agreement may result in the initiation of proceedings to suspend or revoke its DEA Certificate of Registrations. In the event that such future administrative proceedings become necessary, nothing in this Agreement shall be construed as a waiver on the part of DEA to utilize any of the allegations as stated in this Agreement during such future administrative proceedings against Tick Klock Drug.

41. This Agreement represents the full and complete agreement of the Parties hereto. No other promises or agreements will be binding unless placed in writing and signed by both Parties.

42. The terms of this Agreement will not establish any precedent and will not be used as a basis by Tick Klock Drug to seek or justify similar terms in any other matter.

43. By executing this Agreement, Tick Klock Drug agrees to waive all rights to seek judicial review or to challenge or contest the validity of any terms or conditions of this Agreement.

44. This Agreement may be executed in multiple original counterparts, each of which shall constitute an original document, and all of which in the aggregate shall constitute one and the same agreement.

45. The person signing this Agreement on behalf of DEA represents that he, she, or they is/are duly authorized to act on behalf of DEA and that the authority to sign this Agreement has been properly delegated to him/her/they. Should any applicable legal requirements change and render the obligations of this Agreement in violation of applicable law, Tick Klock Drug shall be permitted to modify its compliance practices accordingly. Tick Klock Drug and DEA may each disclose the existence of the Agreement and information about this Agreement to the public without restriction.

46. Tick Klock Drug and the DEA agree that this Agreement shall become effective upon its complete execution by all parties. This Memorandum of Agreement shall remain in effect until the DEA notifies Tick Klock Drug that DEA has received and accepted the quarterly inventory for the period of May 1, 2024 (BOB) through July 31, 2024 (COB), mentioned in Section II above.

FOR TICK KLOCK DRUG:

Tick Klock Drug — Date: 7/28/23

Tick Klock Drug Attorney — Date: July 31, 2023

FOR THE DRUG ENFORCEMENT ADMINISTRATION:

A/DPM Craig Tom for

CRAIG TOM Digitally signed by CRAIG TOM Date: 2023.07.31 09:32:30 -07'00'

Date: _____

Robert A. Saccone
Acting Diversion Program Manager
Seattle Field Division

Date: 7.31.2023

David F. Reames
Special Agent in Charge
Seattle Field Division