UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
NEW JERSEY FIELD DIVISION
NEWARK DIVISION OFFICE

IN THE MATTER OF:
NOVEL LABORATORIES, INC.

MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("MOA") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and Novel Laboratories, Inc. (each a "Party" and collectively the "Parties").

APPLICABILITY

This MOA shall be applicable to Novel Laboratories, Inc. ("Novel" or the "company"), which is registered with the DEA as a Manufacturer under DEA #RN0355809. The company is located at 400 Campus Dr, Somerset, NJ 08873 and has been registered as a manufacturer since July 16, 2007.

BACKGROUND

The DEA has alleged certain violations of the Controlled Substances Act during an investigation of Novel in 2021, as follows:

Investigative Findings

1. During the on-site inspection of Novel, completed between June 28, 2021 and July 28, 2021, an accountability audit was conducted on multiple controlled substances. The audit period chosen was December 31, 2021, close of business to June 28, 2021, beginning of business. Of the audited controlled substances, the investigators uncovered three (3) accountability discrepancies that could not be explained by routine manufacturing process variations.

   The following three controlled substances, in Active Pharmaceutical Ingredient (API) and bulk capsule form, stood out for the degree of discrepancy:

Controlled Substance	Difference	%Difference
Oxycodone (API)	- 3.10 kg	-2.27%
Temazepam 15mg (capsules)	+14.69 kg	+1.77%
Temazepam 30mg (capsules)	- 16.13 kg	-1.95%

For the temazepam, measured during the bulk encapsulation phase of production, the API of the temazepam 15mg tablets was over 14.69kg (1.77%) and the API of the temazepam 30mg tablets was short 16.13kg (1.95%). The diverging results at the same production phase but in opposite directions could not be explained by the company. At the time of the inspection and in a subsequent letter, dated August 12, 2021, the company responded that these discrepancies are most likely attributable to either their initial or closing inventory being completed incorrectly. Such discrepancies are a violation of **Title 21 CFR § 1304.11(a),** which states, **"Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location."**

The oxycodone API was short 3.1kg (2.27%), which is a loss of controlled substance prior to entering any of the manufacturing phases. The oxycodone API, which had not been used in a production batch, was still unaccounted for after several months and had not been rectified in physical form or by records as of November 1, 2021. If the discrepancy is not the result of a similar record-keeping violation, noted above, then alternatively such loss is a violation of **Title 21 CFR § 1301.71(a)**, which states, **"All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances…".**

2. Additionally, during the investigation, investigators found approximately 894 individual bottles of retained samples, belonging to the Quality Assurance and Quality Control departments, stored within the vault which failed to provide effective controls to guard against theft and diversion of controlled substances. The controlled substances were not properly sealed to disclose potential tampering and were stored on the ground floor of the vault, therefore increasing the possibility of theft or loss in violation of **Title 21 CFR § 1301.71(a)**, which states, **"All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances…".** The assorted containers also lacked the proper labels to indicate the substance name, drug schedule, quantity, or strength, in violation of **Title 21 CFR § 1302.03(b)** which states, **"Each manufacturer shall print upon the labeling of each controlled substance distributed by him the symbol designating the schedule in which such controlled substance is listed."**

3. Further, during the investigation, investigators found multiple paper drums stored within the vault and labeled as containing acetaminophen, a non-controlled substance. The company advised they were re-purposed paper drums used to store assorted controlled substances, to include Schedule II, awaiting destruction. Upon inspection, each drum contained a specific type of controlled substance and from the various stages of the manufacturing process set aside as waste and destined for destruction. The drums lacked the proper labeling and did not include the symbol for the Schedule of controlled substances contained therein, in violation of **Title 21 CFR § 1302.03(b)** which states, **"Each manufacturer shall print upon the labeling of each controlled substance distributed by him the symbol designating the schedule in which such controlled substance is listed."** Further, the controlled substances were not properly labeled to disclose the presence of a controlled substance within the drum, therefore increasing the possibility of theft or loss in violation of **Title 21 CFR § 1301.71(a)**, which states, **"All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances…".**

4. Finally, while not a subject of the on-site inspection referenced above, on July 26, 2019, Novel identified and reported to DEA an unaccounted for loss of 7.698 kgs of hydrocodone bitartrate API. Novel submitted a DEA Form 106 on July 29, 2019 and a letter dated July 30, 2019, discussing the results of its investigation. While Novel did not report any evidence of diversion, Novel was unable to document the reason for the discrepancy in the inventory.

Terms and Conditions

In addition to executing a Settlement Agreement of a civil fine (Attached), the Parties agree to a resolution of this matter through this MOA, which represents a final and complete administrative resolution of this matter related to the alleged violations set forth above. This MOA is neither an admission of liability by Novel nor a concession by DEA that its claims are not well founded. In the interest of ensuring compliance with Title 21 of the United States Code and the regulations promulgated thereunder, Novel and the DEA agree to the following:

5. Novel Laboratories, Inc. represents that the firm has consulted with legal counsel prior to entering into this MOA. The company further represents that this MOA is voluntarily entered into without any degree of duress or compulsion. Nothing in this MOA shall be construed as a waiver by Novel or its employees of any rights that the company would have as a party to a matter involving litigation with the government or a third party, including, without limitation, attorney- client or attorney work product privileges.

6. In consideration of the fulfillment of Novel's obligations under this Agreement and subject to the provisions in Paragraph 11 below, DEA agrees to fully, finally and forever release Novel, including its officers, directors, employees, successors, and assigns from any other administrative claims within DEA's enforcement authority for the conduct set forth in this MOA; however, DEA or any other government agency may use evidence of the conduct in any proceeding, provided the subject of the proceeding is not itself the conduct described in this MOA. The conduct above may be used, for example, to prove repeated violations of the CSA or other applicable law.

7. Novel will report any and all thefts or significant losses to DEA in writing via DEA Form 106 for controlled substances or DEA Form 107 for listed chemicals within 24 hours of discovery. Novel will then conduct or cause to be conducted an internal investigation on any and all such losses involving controlled substances and List 1 chemicals and provide to the DEA the results of its internal investigation. Such results will be provided to the DEA within 90 days of discovery pursuant to an amended DEA Form 106/107. For purposes of this clause, Novel will make a change to its standard operating procedures, defining for itself what "significant" means. Novel will provide a copy of its modified standard operating procedures that incorporate this clause within 90 days of executing this MOA, and DEA may cause Novel to adopt a more restrictive definition.

8. Within 90 days of executing this MOA, Novel will conduct or cause to be conducted a complete and accurate inventory of all controlled substances on-hand in compliance with the requirements found in Title 21 CFR § 1304.11, 1304.11 (c), 130411(e)(1), 1304.21, and 1304.22(a). The inventory will include all stocks of controlled substances, in all forms, to include active pharmaceutical ingredients, reference standards, in-process material, samples, waste, and finished products, including substances which are possessed for research or commercial products. The inventory will be provided to DEA in an accurate, complete and readily retrievable format within 90 days of executing this MOA. A uniform format of weighing and measuring gross, tare and net weights will be used as a standard operating procedure across all controlled substances and List 1 chemicals. Upon completion of the comprehensive inventory of all controlled substances and list 1 chemicals, noted above, the company will provide to DEA a separate list of all on-hand inventory designated as waste and set for destruction. The separate list will be forwarded to DEA at least 15 days before arranging for destruction through a reverse distributor.

9. In addition to complying with all required state, local, and federal regulations, Novel will implement or cause to be implemented a comprehensive training program for all employees with access to controlled substances. The training will instruct on the requirements of the Code of Federal Regulations and all applicable company generated standard operating procedures. The company will report to the DEA within 90 days of the execution of this MOA what steps have been taken to ensure compliance.

10. Novel agrees that the terms and provisions of this MOA shall be executed in good faith.

11. Novel agrees that any breach or violation of any term of this MOA may be grounds for DEA to seek to revoke Novel's DEA registration and may therefore result in administrative action. Additionally, nothing in this MOA shall be construed as a waiver on the part of DEA to utilize any other grounds for revocation or denial of any additional DEA registration associated with Novel, nor shall it be construed as a waiver of any defense or reservation of rights by Novel.

12. The terms of this MOA will not establish any precedent and will not be used as a basis by Novel Laboratories, Inc. or any representative to seek or justify similar terms in any other matter.

13. Novel agrees that they will not seek to modify or terminate any term of this MOA in any forum, other than with the DEA, prior to the completion of the term of this MOA. Further, Novel Laboratories, Inc. agrees that modification of the MOA may only be made in writing and upon agreement of both Parties.

The obligations contained in this MOA remain in full force and effect for a period of three (3) years, effective upon the date of its signing by the last signatory hereto.

On behalf of Novel Laboratories, Inc.:

April 3, 2024

Thomas A. Ghignone, Esquire
Senior Vice President
Legal Affairs & Corporate Secretary
Lupin, Inc.

Date

April 4, 2024

John A. Gilbert, Jr., Esquire
Attorney
Hyman, Phelps & McNamara, P.C.

Date

On behalf of the United States Department of Justice, Drug Enforcement Administration:

April 4, 2024

Robert J. Slavkovsky
Diversion Program Manager
New Jersey Field Division
Drug Enforcement Administration

Date

THOMAS PREVOZNIK Digitally signed by THOMAS PREVOZNIK Date: 2024.04.04 15:22:38 -04'00'

Thomas W. Prevoznik
Assistant Administrator
Diversion Control Division
Drug Enforcement Administration

Date