

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the United States Drug Enforcement Administration (“DEA”) (collectively, the “United States”), and Novel Laboratories, Inc. (“Novel”), through their authorized representatives. The United States and Novel are collectively referred to as “the Parties.”

RECITALS

A. At all relevant and material times, Novel is located at 400 Campus Drive in Somerset, New Jersey 08873. Novel is registered with the DEA under DEA # RN0355809.

B. The United States contends that it has certain civil claims against Novel arising from its violations of the Controlled Substances Act (“CSA”).

C. The United States contends that, between January 1, 2019, and August 31, 2021, Novel committed record-keeping violations involving approximately 7.7 kg hydrocodone, 3.1 kg oxycodone, and 30 kg Temazepam, in violation of 21 USC §842(a)(5). This conduct is referred to below as the “Covered Conduct.”

D. This settlement agreement is neither an admission of liability by Novel nor a concession by the United States that its claims are not well founded. 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:

TERMS AND CONDITIONS

1. Novel shall pay to the United States a total civil penalty in the sum of two million two hundred fifty thousand dollars (\$2,250,000.00) within 14 days of the Effective Date of this Agreement, as defined in Paragraph 17 below (the “Settlement Agreement”). Novel shall be subject to payment of interest accrued at a rate of 4.83% per annum for any amount not paid within 14 days of the Effective Date of this Agreement.

2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below and conditioned upon the United States’ receipt of the Settlement Amount plus interest due under Paragraph 1, the United States releases Novel from any civil or administrative monetary claim that the United States has for the Covered Conduct under the Controlled Substances Act. Nothing in this Paragraph precludes the Department of Justice or DEA from taking action against entities or persons, or for conduct or practices, for which claims have been reserved in Paragraph 3 below.

3. Notwithstanding the release given in Paragraph 2 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. 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; and
- f. Any liability of individuals.

4. Novel waives and shall not assert any defenses Novel 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. 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 Internal Revenue laws, Title 26 of the United States Code.

5. Novel fully and finally releases 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 Novel has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. Novel agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Novel shall encourage, and agrees not to impair, the cooperation

of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Novel further agrees to furnish to the United States, upon request and upon service of an administrative subpoena or other official notice, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf, after the Effective Date of this Agreement.

7. This Agreement is binding on Novel's successors, transferees, heirs, and assigns.

8. Except as provided in Paragraph 6, this Agreement is intended to be for the benefit of the Parties only, and by this Agreement the Parties do not release any claims against any other person or entity, except as otherwise stated in this Agreement.

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

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 and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or

compulsion.

12. This Agreement is governed by the laws of the United States. The exclusive venue for any dispute relating to this Agreement is the United States District Court for the District of New Jersey. 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.

13. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

14. The undersigned represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

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

16. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

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

THE UNITED STATES OF AMERICA

PHILIP R. SELLINGER
United States Attorney

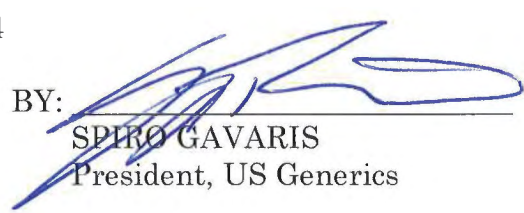
Dated: April 9, 2024

BY: **JORDANN
CONABOY**
JORDANN R. CONABOY
Assistant United States Attorney
United States Attorney's Office
District of New Jersey

Digitally signed by
JORDANN CONABOY
Date: 2024.04.09 18:04:49
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NOVEL LABORATORIES, INC.

Dated: April 9, 2024

BY: 
SPIRO GAVARIS
President, US Generics