

ANI PHARMACEUTICALS, INC. DECLARATION OF COMPLIANCE

ANI Pharmaceuticals, Inc. (ANI) declares that, to the best of its knowledge, and based on a good faith understanding of the statutory requirements of California Health and Safety Code §§ 119400 and 119402, as of June 2023, ANI believes that it is maintaining a comprehensive Compliance Program in compliance with the statutory requirements above.

ANI Compliance Program (January 21, 2023)

Commitment:

ANI is committed to establishing and maintaining a comprehensive and effective compliance program (“Compliance Program”) in accordance with the “Compliance Program Guidelines for Pharmaceutical Manufacturers” published by the Office of Inspector General, U.S. Department of Health and Human Services (“OIG Guidance”) and the Pharmaceutical Research and Manufacturers of America “Code on Interactions with Healthcare Professionals” (the “PhRMA Code”).

The fundamental elements of ANI's Compliance Program as it relates to sales and marketing activities in the United States are described below.

Compliance Program Overview

1. Governance

The Chief Compliance Officer, Rare Disease is responsible for developing, operating and monitoring this Compliance Program. The Chief Compliance Officer has direct access to the ANI Board of Directors and senior management and provides regular reports on the status of the Compliance Program.

ANI has established an internal Compliance Committee to advise the Chief Compliance Officer and assist in the implementation of the Compliance Program.

2. Written Standards

ANI has established written policies and procedures to ensure compliance with the OIG Guidance and the PhRMA Code. In addition to its Code of Ethics, ANI has policies, procedures and guidelines that outline the specific behaviors required for day-to-day operations and outline how ANI employees are expected to conduct their activities. Among other things, these policies, procedures and guidelines address potential risk areas such as those identified in the

OIG Guidance. ANI regularly evaluates its policies to ensure continued compliance with these rules.

3. Education and Training

All employees are required to receive compliance training applicable to their job function and responsibilities, which includes training on the Compliance Program and ANI policies. Annual healthcare compliance training is required of all employees, consultants and contractors who engage in, or support, commercial activities. ANI regularly reviews and updates its training programs to help ensure it continues to meet the educational needs of its employees.

4. Internal Lines of Communication

ANI strives to provide a work environment that encourages employees to communicate openly with management about all types of workplace issues without fear of retaliation or recrimination. To support this concept, ANI encourages employees to report suspected misconduct to any of the following resources:

- Their supervisor or manager, including any executive of an ANI function;
- Any business partner in Legal, Compliance, or Human Resources;
- The Chief Compliance Officer directly or via email; or
- An anonymous hotline toll-free telephone number and website. This telephone line is operated by an independent firm who will forward reported concerns to ANI Compliance Office.

5. Auditing and Monitoring

ANI recognizes that auditing and monitoring are critical to maintaining the effectiveness of a Compliance Program. The subject of auditing and monitoring assessments, as well as the extent and frequency of the reviews, may vary according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations, and are scaled to address the size, organizational structure and operations of ANI. As appropriate, auditing and monitoring results will help guide training and communication and ANI's risk-assessment process.

6. Responding to Potential Violations

The purpose of the Compliance Program is to prevent and detect violations of law or company policy. As the OIG Guidance recognizes, however, the implementation of such a program cannot guarantee that improper employee conduct will be eliminated. Nonetheless, it is ANI's expectation that ANI personnel will comply with the Compliance Program, and the policies established in support of such program. If ANI becomes aware of violations of law or company policy, those matters will be promptly investigated and, where appropriate, disciplinary action

will be taken and corrective measures implemented to address potential gaps and prevent future violations.

7. Corrective Action Procedures

A key element of the Compliance Program is to provide clear disciplinary policies that set out the consequences of violating the law or company policies. After investigation of a reported or detected issue, the company will assess whether disciplinary action is appropriate, and whether a violation is in part due to gaps in policies, practices, training or internal controls, and act to prevent future violations.

A copy of this document and/or ANI's written Declaration of the Company's adherence to the Comprehensive Compliance Program described above can be obtained by calling 1-800-434-1121.