

Discovery Laboratories, Inc. Compliance Program and Marketing Code of Conduct*

Introduction

Discovery Laboratories, Inc. (“**Discovery Labs**”) is committed to the highest standards of corporate citizenship and ethical conduct, and continually strives to create a corporate culture that embodies these values in every aspect of its business. Discovery Labs has established a Compliance Program and Marketing Code of Conduct (the “**Compliance Program**”) structured around the seven elements outlined in the April 2003 Compliance Program Guidance for Pharmaceutical Manufacturers, published by the United States Department of Health and Human Services, Office of Inspector General (“**OIG Guidance**”), as well as various applicable state and local laws.

Discovery Labs’ Compliance Program is designed to prevent and detect violations of ethical norms, legal and regulatory requirements, and company policy. While the implementation of a compliance program cannot eliminate improper conduct altogether, Discovery Labs expects that its employees will act in accordance with the Compliance Program. Discovery Labs continuously re-evaluates and adapts its Compliance Program as needs change.

Compliance Program Overview

- 1. Leadership and Structure.** Discovery Labs’ compliance officer is Mary B. Templeton, Senior Vice President and General Counsel. Ms. Templeton reports directly to the Chief Executive Officer. Ms. Templeton is in a position to effect change within the organization and to exercise independent judgment.
- 2. Written Standards and Annual Spending Limit.** Discovery Labs’ written compliance standards are set forth in three primary sets of documents: (1) the Code of Conduct, (2) Policies and Standard Operating Procedures (collectively “**Policies**”); and (3) the Employee Handbook. Together, these documents adopt the core principles set forth in the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals (“**PhRMA Code**”) and reinforce the requirement that every employee conduct business according to the highest standards of corporate citizenship and ethical conduct.

* This Compliance Program description and the underlying programs and policies are intended to satisfy certain legal and reporting requirements, including but not limited to Nev. Rev. Stat. § 639 (Nevada Marketing Code of Conduct); Cal. Code, Health & Safety § 119400 *et seq* (California Comprehensive Compliance Program); and 105 CMR 970.000 (Massachusetts Marketing Code of Conduct). Discovery Labs declares to the best of our knowledge, we are in compliance with our Compliance Program as described and the requirements of the California Health and Safety Code §§ 119400-119402.

Annual Spending Limit – For purposes of complying with California Health and Safety Code §§ 119400-02, Discovery Labs has established a “specific annual dollar limit on gifts, promotional materials, or items or activities that [Discovery Labs] may give or otherwise provide to an individual medical or healthcare professional.” This annual dollar limit is one thousand dollars (\$1,000.00) and primarily reflects dollars that may be expended in association with programs designed to inform healthcare professionals about Discovery Labs’ products and associated disease states.¹ This annual dollar limit is an *upper* limit, and Discovery Labs anticipates that the *average* value of such spending would be significantly lower than the limit set forth above. Discovery Labs will evaluate this limit on an annual basis, and reserves the right to modify the limit as necessary.

3. Education and Training. Discovery Labs educates and trains employees on its Compliance Program through sessions developed and conducted primarily by the Legal Department. Discovery Labs’ incorporates a mixture of live training sessions with an opportunity for question-and-answer, computer-based training, and self study.

4. Internal Lines of Communication. Discovery Labs is committed to creating and maintaining open lines of communication between management and employees. All employees, whether seeking answers to questions or reporting potential instances of fraud and abuse, should know to whom to turn and will be able to do so without fear of retribution. To that end, the company has adopted open-door and non-retaliation policies, and has also instituted an ethics and compliance hotline.

5. Auditing and Monitoring. Discovery Labs’ compliance efforts include activities to monitor, audit, and evaluate compliance with the company's policies and procedures. For example, management is responsible for reviewing and approving employee expense reports to foster compliance. In accordance with the OIG Compliance Program Guidance, the nature of Discovery Labs’ auditing and monitoring may vary according to a number of factors, including new regulatory requirements, changes in business practice, and other considerations.

6. Responding to Potential Violations. Adherence to Discovery Labs’ Code of Conduct, Policies, and Employee Handbook is a condition of employment at Discovery Labs. Violations of an employee's obligations under these mandatory documents can subject an employee to serious disciplinary measures, including possible termination of employment. Although each suspected violation of a company policy is considered on a case-by-case basis, Discovery Labs undertakes efforts to ensure consistent and appropriate disciplinary action.

¹ This annual dollar limit does not include certain amounts associated with drug samples, financial support for continuing medical education and certain educational scholarships, or legitimate professional services or consulting agreements. *See* Cal. Code, Health & Safety § 119402(d). It is Discovery Labs’ intent to comply with other applicable state laws that may set different or lower spending thresholds in certain circumstances or jurisdictions.

7. Corrective Action Procedures. As part of its Compliance Program, Discovery Labs undertakes internal investigations and, when necessary, corrective actions. In accordance with the OIG Guidance, the exact nature and of the internal investigation varies according to the circumstances. Upon conclusion of an internal investigation, corrective action and preventative measures are determined and implemented as appropriate.

To request a copy of the Discovery Labs Compliance Program description, please call (866) 901-3726.