

**KADMON PHARMACEUTICALS, LLC**  
**Comprehensive Compliance Program<sup>1</sup>**  
**State of California**

Kadmon Pharmaceuticals, LLC (“KPL”) is committed to the highest standards of corporate citizenship and ethical conduct and complying with all applicable laws and regulations in its marketing, promotional, educational and research activities. Accordingly, for purposes of complying with the State of California’s requirement that pharmaceutical companies implement and maintain a Comprehensive Compliance Program regarding the sales and marketing of its products, KPL has established a Comprehensive Compliance Program that is consistent with the “Compliance Program Guidance for Pharmaceutical Manufacturers” published in April 2003 by the Office of Inspector General of the United States Department of Health and Human Services (the “OIG Guidance”) and the updated “Code on Interactions with Healthcare Professionals” effective January 2009 adopted by the Pharmaceutical Research and Manufacturers of America.

**I. OVERVIEW OF COMPREHENSIVE COMPLIANCE PROGRAM**

KPL’s Comprehensive Compliance Program includes the following:

1. **Compliance Officer and Compliance Committee.** KPL has designated a Compliance Officer who is charged with the responsibility for operating and monitoring the Comprehensive Compliance Program and with the authority to report directly to KPL’s Board of Directors and President and CEO. In addition, a Compliance Committee has been established. Members of the Compliance Committee will meet on an ad hoc basis to review policies and procedures, resolve compliance issues and serve as a body to review complaints or questions. This Committee will include as members KPL’s Compliance Officer, a representative from KPL’s Human Resource Department and a member(s) of KPL’s Board of Directors.
2. **Written Policies and Procedures.** As part of its Comprehensive Compliance Program, KPL has established written policies and procedures applicable to all employees that interact with healthcare professionals and other product customers. These policies and procedures are provided to all appropriate employees and are available both electronically and in written form from the Compliance Officer or KPL’s Human Resource Department.
3. **Conducting Effective Training and Education.** KPL requires regular compliance training for all applicable employees on the policies and procedures established as part of the Comprehensive Compliance Program. Employees are required to sign an acknowledgement after the receipt of the policies and procedures and applicable training.
4. **Developing Effective Lines of Communication.** KPL has established an open line of communication for employees to contact the Compliance Officer and report compliance questions and concerns to management and the Board of Directors. Employees are provided a mechanism to report questions and concerns anonymously via email.
5. **Conducting Internal Monitoring and Auditing.** KPL will use audits and other techniques to monitor compliance and identify risks. Internal monitoring and auditing are critical components of KPL’s Comprehensive Compliance Program. KPL employees at all levels are responsible for reporting potential compliance issues of which they become aware.
6. **Enforcing Compliance Obligations.** KPL’s Comprehensive Compliance Program and policies and procedures include a clear description of disciplinary standards, including the potential for termination as a result of non-compliance.

<sup>1</sup> This Comprehensive Compliance Program, as well as the underlying policies and procedures, are intended to satisfy certain legal and reporting requirements, including, but not limited to, Nev. Rev. Stat. § 639 (Marketing Code of Conduct) and Cal. Code, Health & Safety § 119400 *et seq* (Comprehensive Compliance Program).

- 7. Investigating and Responding to Reports of Non-Compliance.** All incidents requiring investigation by the Compliance Officer will be addressed promptly and presented to the Compliance Committee. Any corrective action will take place in a timely fashion and where necessary, offenses shall be reported to relevant governmental authorities.

## **II. ANNUAL SPENDING LIMIT**

As required by California Health & Safety Code sections 119400-119402, with specific reference to the provision of “gifts, promotional material, or items or activities” that a pharmaceutical company may provide to an individual medical or healthcare professional, KPL has established an aggregate, annual dollar limit of \$2,500 on promotional items and/or meals directed to an individual medical or healthcare professional who resides or practices in the State of California. The limit represents a maximum amount and is not necessarily a usual, customary, average or typical amount for medical or healthcare professional and may be revised in the future as appropriate.

## **III. DECLARATION OF COMPLIANCE**

KPL declares that, to the best of its knowledge, and based on its good faith understanding of the statutory requirements, it has developed a Comprehensive Compliance Program that is consistent with California Health & Safety Code sections 119400-119402. Accordingly, to the best of its knowledge, KPL declares that it is in compliance with its Comprehensive Compliance Program and California Health & Safety Code sections 119400-119402.

As recommended in the OIG Guidance, KPL has developed a Compliance Program tailored to the size, organizational structure and resources of its company. While the OIG Guidance recognizes that even an effective compliance program may not completely eliminate all misconduct by individuals, KPL’s Comprehensive Compliance Program is reasonably designed to prevent and detect violations. The expectation of KPL is that all directors, officers and employees will adhere to its Comprehensive Compliance Program. KPL’s Comprehensive Compliance Program is dynamic, and in order to address evolving compliance needs, KPL will assess its Comprehensive Compliance Program at least annually and as part of this assessment, KPL may modify aspects of its Program to enhance the Program’s effectiveness.

Copies of this summary of the Comprehensive Compliance Program and declaration are available on KPL’s website at [www.kadmon.com](http://www.kadmon.com) or by calling the following toll-free number 1-800-405-8506.