



Cutanea Life Sciences, Inc. Comprehensive Compliance Program

Cutanea engages in research, development, manufacture and marketing of dermatology products, including commercialization of those products. Cutanea strives for the highest standards of corporate conduct and is committed to establishing and maintaining an effective and comprehensive corporate compliance program. We have adopted a compliance program that addresses matters covered by the May 2003 publication “Compliance Program Guidance for Pharmaceutical Manufacturers” (“OIG Guidance”), which was developed by the United States Department of Health and Human Services Office of Inspector General (“OIG”). The OIG Guidance gives broad discretion to manufacturers in the development, design and definition of the scope of a compliance program.

Cutanea’s Comprehensive Compliance Program (“Compliance Program”) applies to our officers, employees and agents in their activities on behalf of Cutanea. Our Compliance Program’s purpose is to assist Cutanea in maintaining compliance with the laws, regulations and company policies, directives and guidance that apply to our products, to train our employees and agents on these matters and to prevent, detect and correct instances of non-compliance. Cutanea expects that our officers, employees and agents will comply with all applicable Cutanea policies and additional guidance, as well as the related laws, regulations and health plan program requirements. In the event that Cutanea becomes aware of non-compliance, we will investigate the matter and where appropriate, take disciplinary action, up to and including employee termination, and implement corrective measures to prevent future non-compliance.

Cutanea’s Compliance Program as described below is dynamic. We intend to regularly review and modify it to meet our evolving compliance needs. Accordingly, The Compliance Program may be amended or revised by Cutanea from time to time.



1. Leadership and Structure

Cutanea's Chief Compliance Officer, working with the Corporate Compliance Committee, has overall responsibility for oversight of Cutanea's Compliance Program. This includes oversight of the development and operation of the Compliance Program. The Chief Compliance Officer has been vested with the authority relating to compliance within the organization and shall exercise independent judgment concerning those matters. In this role, the Chief Compliance Officer reports directly to the Chief Executive Officer and also to the Board of Directors and makes reports to the Board concerning operation of the Compliance Program.

2. Written Standards

Cutanea has adopted a Code of Conduct which helps to guide our daily operations and reflects the unique business and regulatory environment in which we operate and which reflects our consideration of the OIG Guidance.

With regard to an annual spending limit, Cutanea has established guidance regarding appropriate interactions with health care professionals (HCP's). It is Cutanea's policy to substantially comply with the Pharmaceutical Research and Manufacturers of America (PhRMA) "Code of Interactions with Health Care Professionals," dated July 1, 2002, which includes limits on gifts, meals and other activities with HCP's.

For purposes of complying with the California Health and Safety Code Sections 119400 and 119402, Cutanea has established, commencing January 1, 2017, a maximum annual aggregate dollar limit of \$2,000 for gifts, promotional materials and/or activities provided to California health care professionals. This dollar limit represents a spending cap, not a goal or average, and typically the amount spent per physician is anticipated to be substantially less than this maximum amount. Waiver of the limit would require the approval of the Chief Compliance Officer.



In an attempt to assure that HCP's fully understand our products, Cutanea representatives may take time to explain the benefits and risks associated with them, as well as the relevant clinical efficacy studies and mechanisms of action, where appropriate. Some of these informational and educational presentations may take place during a modest meal to avoid taking HCP's away from important time with their patients.

Occasionally, Cutanea does provide medically relevant and patient oriented items to HCP's. Some examples include anatomical models, patient education charts and information that is useful for patients in understanding or managing their condition and/or treatment.

3. Education and Training of Cutanea's Personnel

A key element of our Compliance Program is education and training. Cutanea is committed to implementing programs to effectively communicate our policies and guidance to affected personnel on a timely basis. New personnel will receive such training as part of their initial training and existing personnel are expected to receive compliance training on at least an annual basis. Additionally, Cutanea will review and update its training programs periodically, as well as identify additional areas of training on an ongoing basis.

4. Internal Lines of Communication

We expect Cutanea employees, officers and agents to promptly report suspected, planned or actual violations of our policies and guidelines and/or laws which govern our business activities. We encourage communications with an employees' supervisor and/or senior team members or directly with the Chief Compliance Officer. If these individuals are not available or if the reporter prefers, reports of violations may be made on an anonymous basis to Cutanea's Compliance and Ethics Hotline which is toll free and available 24 hours a day, 7 days per week.



We also encourage our employees, officers and agents to ask questions about any activity when they are unclear about a potential violation or application of our Compliance Program. Questions may be posed through any of the established channels.

Acts of retaliation or retribution against an employee or officer who acts in good faith to report a potential, suspected, planned or actual violation or application of our policies and guidelines and/or laws which govern our activities are not permitted and will be dealt with accordingly.

5. Auditing and Monitoring

The Chief Compliance Officer is charged with developing a plan to audit and monitor compliance with company policies as part of Cutanea's Compliance Program. The audit and monitoring activities are intended to identify existing or potential problem areas and to enable the establishment of corrective measures to prevent further non-compliance. The nature, extent and frequency of our reviews, auditing and monitoring activities reflects changes in business practices new regulatory requirements and other considerations.

6. Hiring

Cutanea is committed to hiring employees who are aligned with the company's core values and whose actions reflect a high degree of integrity and ethics. Prior to their commencement of employment the company follows various procedures designed to engage only individuals who will uphold the company's ethical standards.

7. Responding to Potential Violations

Cutanea's Chief Compliance Officer will also review non-compliance reports and determine whether further investigation is warranted. Audit findings are also reported to the Chief Compliance Officer. When deemed necessary, the Chief Compliance officer will conduct an investigation into potentially non-compliance activity to determine whether a violation of Cutanea's policies and guidelines has occurred. The Chief Compliance Officer may engage outside experts or legal



counsel as required in evaluating reports, audit findings and conducting investigations.

8. Corrective Action

The Chief Compliance Officer also oversees the implementation of corrective measures in response to non-compliance with Cutanea's policies and guidelines. Corrective measures take into account the findings from various activities (including reports, investigations, audits and monitoring) and may include appropriate and consistently applied disciplinary action to individual actors. Such discipline may include termination of employment where warranted. Corrective measures may include enhancements to our policies, procedures, practices, training and internal controls with the intent of preventing future non-compliance.

DECLARATION OF COMPLIANCE

As part of Cutanea's continuing commitment to corporate compliance, Cutanea declares that, to the best of its knowledge, information and belief and based on good faith understanding of the statutory requirements of California Health and Safety Code sections 119400 and 119402, it has adopted a Comprehensive Compliance Program as mandated by this California law. During the period between January 1, 2017 and December 31, 2017, Cutanea believes it was in compliance with its Compliance Program and the above referenced statutes in all material respects.

Consistent with Cutanea's understanding of the California statute, this declaration is limited to those activities undertaken by Cutanea that are directed to California. Cutanea makes this declaration in good faith, in the absence of clarifying regulations or guidance from the State of California. This declaration reflects our consideration of the OIG Guidance, which gives broad discretion to manufacturers in the development, design and definition of the scope of compliance programs.



Copies of this declaration and the Compliance Program may be obtained by calling our toll free line at 1-844-780-8152.

Dated February 13, 2018