

## DERMAVANT SCIENCES, INC.

### COMPREHENSIVE COMPLIANCE PROGRAM SUMMARY

#### INTRODUCTION:

Dermavant Sciences, Inc. (“Dermavant” or the “Company”) recognizes that compliance is essential to good business practices and that with the support of senior management, Dermavant employees at all levels should play an active role in the company’s compliance activities. Dermavant is committed to maintaining an effective compliance program that promotes ethical business conduct.

The Company has established a Comprehensive Compliance Program (“CCP”) structured around the seven elements outlined in the April 2003 *“Compliance Program Guidance for Pharmaceutical Manufacturers”* published by the United States Health and Human Services, Office of Inspector General (OIG Guidance). In developing the CCP, Dermavant has also considered applicable guidance provided by the Pharmaceutical Research and Manufacturers of America (PhRMA).

Dermavant’s CCP is designed to provide a mechanism for preventing, detecting and reporting any non-compliance with applicable laws and regulations and Company policies using the following elements:

1. Designation of a Chief Compliance Officer and Compliance Committee
2. Written standards of conduct, policies and procedures
3. Training and education
4. Open lines of communication
5. Monitoring and auditing
6. Responding to Potential Violations
7. Corrective action

As acknowledged by the OIG Guidance, implementing a CCP cannot guarantee that improper employee conduct will be eliminated in its entirety. It is Dermavant’s policy that all employees must comply with applicable laws and regulations as well as Company policies. If Dermavant becomes aware of violations of law or Company policy, the matter will be investigated and, if appropriate, disciplinary action will be taken and corrective measures will be implemented to prevent future violations.

Below is an overview of Dermavant’s CCP. This has been designed to fit Dermavant’s unique needs. Dermavant continuously assesses the effectiveness of its CCP to enable it to implement necessary adjustments or refinements.

#### **CCP Element One: Designation of a Chief Compliance Officer and Compliance Committee**

##### A. Compliance Officer

Compliance oversight will be the responsibility of the Chief Compliance Officer. The Chief Compliance Officer may appoint Assistant Compliance Officers and other delegates as

necessary to implement the CCP. Each Assistant Compliance Officer or other delegate will report directly to the Chief Compliance Officer on compliance matters.

The Chief Compliance Officer will act as the focal point the Company's CCP. The key functions of the Compliance Department will be coordination and communication with appropriate individuals or departments regarding the planning, implementation, enhancement and enforcement of the CCP. The Compliance Department's primary responsibilities will include:

- overseeing and monitoring implementation of the CCP;
- reporting on a regular basis to the Chief Executive Officer, Executive Leadership Team, Corporate Compliance Committee (discussed below), and Board Audit Committee on compliance matters and assisting these individuals or groups to establish methods to promote compliance with applicable requirements of the CCP;
- periodically revising the CCP, as appropriate, to respond to changes in Dermavant's needs and applicable legal requirements, identifying possible improvements in the CCP, or identifying systemic patterns of non-compliance;
- developing, coordinating, and participating in a multi-faceted educational and training program that focuses on the elements of the CCP, and seeking to ensure that all affected employees and management understand and comply with requirements of the CCP;
- ensuring that all Dermavant personnel including independent contractors and agents (particularly those agents and contractors who are involved in sales and marketing activities), are aware of the CCP's requirements especially with respect to sales and marketing activities, among other areas;
- coordinating personnel issues with Dermavant's Human Resources department to ensure that the List of Excluded Individuals/Entities has been checked with respect to all Dermavant personnel;
- coordinating monitoring and auditing activities;
- reviewing and, where appropriate, acting in response to reports of non-compliance received through established reporting mechanisms or otherwise brought to the Compliance Department's attention (*e.g.* as the result of an internal audit, corporate counsel, etc.);
- independently investigating and acting on matters related to compliance, including designing and coordinating internal investigations and any resulting corrective action with various Dermavant departments;
- participating with Dermavant's legal counsel in the appropriate reporting of any discovered violations of federal health care program requirements; and

- continuing the momentum and, as appropriate, revising and expanding the CCP after the initial implementation.

The Chief Compliance Officer has the authority to review all documents and other information relevant to compliance activities. The Chief Compliance Officer shall seek the advice of competent legal counsel where appropriate.

B. Compliance Committee

A Compliance Committee will be established to work with the Chief Compliance Officer and assist in the implementation of the CCP. The Compliance Committee will provide Dermavant with increased oversight in addition to that provided by the Chief Compliance Officer. The Compliance Committee will be composed of individuals with a variety of skills and personality traits. Committee members must demonstrate high integrity, good judgment, assertiveness, and an approachable demeanor, such that they have the respect and trust of Dermavant personnel. The Compliance Committee will strive to have at least one member from each of the following:

- Human Resources
- Regulatory Affairs
- Medical Affairs
- Finance
- Commercial
- Technical Operations
- Quality
- Legal

The Compliance Committee will meet as called by the Chief Compliance Officer, but at least on a quarterly basis.

**CCP Element Two: Written Standards of Conduct, Policies and Procedures**

The Company's Code of Business Conduct & Ethics requires that (1) all of our business dealings reflect high ethical standards and irreproachable personal integrity and (2) Dermavant personnel recognize and comply with applicable local, state and federal legal requirements.

The CCP also includes a system of Compliance Manuals that set forth the Company's standards and rules to ensure compliance with applicable healthcare laws and regulations and to support ethical business practices by Dermavant. These Compliance Manuals clearly set out the consequences for violations of the law or company policy. Although each situation is considered on a case-by-case basis, the Company will consistently undertake appropriate disciplinary action to address inappropriate conduct and deter future violations.

In addition, with respect to business activity in California, per California SB 1765, Dermavant has established a specific annual dollar limit on gifts, promotional materials, or other items that Dermavant may provide to a healthcare professional. This annual dollar limit is \$2,000.00 and

reflects dollars expended in association with programs designed to inform healthcare professionals about Dermavant products and the disease state these products help treat. Dermavant provides a declaration of its adoption of California Health Safety & Code 119400-119402 on its corporate website.

### **CCP Element Three: Training and Education**

The most effective and efficient method of ensuring compliance is a well-formulated training and educational curriculum. Dermavant has implemented a compliance training and education curriculum. These training sessions will be mandatory and will be targeted for specific audiences. Training will be conducted at the beginning of employment with Dermavant and periodically during employment tenure as needed.

Examples of education topics may include:

- General prohibitions on paying or receiving remuneration to induce referrals;
- Acceptable sales and marketing promotional guidelines;
- Prescription Drug Marketing Act requirements;
- Security and privacy of confidential patient information; and
- Duty to report misconduct.

The above list of educational topics is not exhaustive, or all encompassing. Rather it should be viewed as a starting point. Other topics will be offered as deemed necessary and/or required to ensure compliance with the CCP by Dermavant personnel.

### **CCP Element Four: Open Lines of Communication**

The CCP encourages the use of a resource phone line, e-mails, written memoranda, newsletters, and other forms of information exchange, including access to supervisors, to maintain open lines of communication. The CCP will facilitate a method for Dermavant personnel to report potential violations to the Compliance Department.

The CCP's system for meaningful and open communication includes the following:

- Requesting and encouraging all Dermavant employees to report conduct that a reasonable person would, in good faith, believe to be in violation of applicable requirements of the Federal Health Care Programs;
- A toll-free hotline, available 24-hours a day, 7-days a week with a user-friendly process for effectively reporting possible non-compliance with the CCP or other suspected illegal or unethical activity;
- Processes that make efforts to maintain the anonymity of the person(s) involved in reporting potential non-compliance with the CCP and the person(s) involved in the alleged conduct (while the Compliance Department will strive to maintain the anonymity of a reporting employee's identity, it also needs to be clear that there may be

a point at which the individual's identity may become known or may have to be revealed in certain instances, e.g. to further the investigation).

- Ensuring that there is no retaliation for reporting conduct that a reasonable person acting in good faith would have believed to be a violation of the law, the CCP or Company policy.

The Compliance Department will also communicate results of investigations to any and/or all appropriate persons involved with the alleged non-compliance with the CCP, including the Chief Legal Officer, Chief Executive Officer and/or Leadership Team as deemed necessary. The Compliance Department will also preserve any information that may be associated with the alleged activity.

#### **CCP Element Five: Monitoring and Auditing**

Dermavant's CCP includes monitoring and auditing that evaluate whether there are policies and procedures addressing risk areas, whether the policies and procedures have been implemented and communicated, and whether the policies and procedures were followed. The areas for monitoring and auditing are reviewed and updated to reflect evolving compliance concerns, which may arise due to new laws, new regulatory requirements, or circumstances identifying new risk areas. The results of monitoring and auditing activities may be used as a basis for adapting and improving existing compliance policies, procedures, and training.

#### **CCP Element Six: Responding to Potential Violations**

When Dermavant believes that an employee has violated a law or Company policy, it investigates the matter and takes appropriate disciplinary action in order to address the violation and prevent future violations. The consequences for violations of Company policy, including those identified in the CCP, include disciplinary action up to and including termination of employment.

#### **CCP Element Seven: Corrective Action**

The CCP provides for enforcement and disciplinary provisions, which are necessary to add credibility and integrity to this compliance initiative. Dermavant will consistently undertake appropriate disciplinary action across the Company in order for the disciplinary policies to have the required deterrent effect. Intentional and material non-compliance will subject transgressors to significant sanctions. Such sanctions could range from oral warnings to suspension, termination or other sanctions, as appropriate. Disciplinary action also may be appropriate where failure to detect a violation is attributable to a Dermavant employee's negligence or reckless conduct. Each situation must be considered on a case-by-case basis, taking into account all relevant factors, to determine the appropriate response.

Violation of the CCP, failure to comply with applicable law or regulations, and other types of non-compliance with the CCP threaten Dermavant's status as a reliable, honest, and trustworthy participant in the pharmaceutical, medical device, and cosmetic industries. Detected but uncorrected misconduct can endanger the reputation and legal status of Dermavant. Consequently, upon receipt of reasonable indications of suspected noncompliance, it is

important that the Compliance Department immediately investigate the allegations to determine whether a material violation of applicable law or the requirements of the CCP have occurred and, if so, take decisive steps to correct the problem. The exact mechanics of the investigation will vary according to the circumstances, but the review should be detailed enough to identify the root cause of the problem. As appropriate, the investigation may include a corrective action CCP, a report and repayment to the government, and/or a referral to criminal and/or civil law enforcement authorities.

Copies of the Company's Comprehensive Compliance Program may be obtained by calling 1-8-DERMAVANT or emailing [help.compliance@dermavant.com](mailto:help.compliance@dermavant.com).

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