

## **GALDERMA LABORATORIES, L.P. COMPLIANCE PROGRAM**

### **INTRODUCTION:**

Galderma Laboratories, L.P. (“Galderma” or the “Company”) recognizes that compliance is central to good business practices, and that with the support of senior management, Galderma employees at all levels should play an active role in the company’s compliance activities. Galderma has a strong commitment to establishing and maintaining an effective compliance program that promotes ethical business conduct. To help put this commitment into action, the company has established a comprehensive compliance program (the “Program”) 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 Program, Galderma has also considered applicable guidance provided by the Pharmaceutical Research and Manufacturers of America (PhRMA), the American Medical Association (AMA), the Advanced Medical Technology Association (AdvaMed), and the American Osteopathic Association (AOA) as well as the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Galderma’s Program is designed to provide a mechanism for preventing, detecting and reporting any non-compliance with applicable laws and regulations as well as company policies using the following elements:

1. The designation of a 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. Investigation
7. Corrective action

As acknowledged by the OIG Guidance, implementing a Program cannot guarantee that improper employee conduct will be eliminated in its entirety. It is Galderma’s policy that all employees must comply with applicable laws and regulations as well as company policies. If Galderma 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 Galderma’s Compliance Program. This has been designed to fit Galderma’s unique needs. Galderma continuously assesses the effectiveness of its Program to enable it to implement necessary adjustments or refinements.

### **Program Element One: Compliance Officer and Compliance Committee**

#### **A. Compliance Officer**

Compliance oversight will be the responsibility of the Compliance Officer, who will be designated by the President and General Counsel of Galderma. The Compliance Officer will report directly to the General Counsel, President and/or Management Committee of Galderma on all compliance matters. The Compliance Officer may

appoint Assistant Compliance Officers and other delegates as necessary to implement the Program. Each Assistant Compliance Officer or other delegate will report directly to the Compliance Officer on compliance matters.

The Compliance Officer will act as the focal point for all compliance activities. The key functions of the Compliance Officer will be coordination and communication with appropriate individuals or departments regarding the planning, implementation, enhancement and enforcement of the Program. The Compliance Officer's primary responsibilities will include:

- overseeing and monitoring implementation of the Program;
- reporting on a regular basis to the General Counsel, President and/or Management Committee and Compliance Committee (discussed below) on compliance matters and assisting these individuals or groups to establish methods to promote compliance with applicable requirements of the Program;
- periodically revising the Program, as appropriate, to respond to changes in Galderma's needs and applicable legal requirements, identifying possible improvements in the Program, 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 Program, and seeking to ensure that all affected employees and management understand and comply with requirements of the Program;
- ensuring that all Galderma personnel including independent contractors and agents (particularly those agents and contractors who are involved in sales and marketing activities), are aware of the Program's requirements especially with respect to sales and marketing activities, among other areas;
- coordinating personnel issues with Galderma's Human Resources department to ensure that the List of Excluded Individuals/Entities has been checked with respect to all Galderma personnel;
- assisting Galderma's internal auditors in coordinating internal compliance review and monitoring activities;
- reviewing and, where appropriate, acting in response to reports of non-compliance received through established reporting mechanisms or otherwise brought to the Compliance Officer'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 Galderma departments;
- participating with Galderma'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 Program after the initial implementation.

The Compliance Officer may have other responsibilities for Galderma but will be afforded the time to devote adequate and substantive time and attention to compliance functions. The Compliance Officer has the authority to review all documents and other information relevant to compliance activities. The 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 Compliance Officer and assist in the implementation of the Program. The Compliance Committee will provide Galderma with increased oversight in addition to that provided by the 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 Galderma personnel. The Compliance Committee will strive to have at least one member from each of the following departments:

- Regulatory Affairs
- Sales
- Medical
- Marketing
- Finance
- Managed Care

In the event that the Compliance Officer is not an individual from the Legal Department, an individual from the Legal Department must be on the Compliance Committee.

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

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

The Program includes a system of policies that set forth the Company's highest level principles, to ensure compliance with applicable laws and regulations, and support good business practices by Galderma.

Galderma's Charter of Ethics and U.S. Compliance Code of Conduct require that all of our business dealings reflect high ethical standards and irreproachable personal integrity and that Galderma personnel recognize and comply with applicable local, state and federal legal requirements.

The OIG Guidance addresses several areas of potential risk for pharmaceutical companies and suggests that companies develop compliance policies in these areas: data integrity pertaining to government reimbursement, kickbacks or other illegal

renumerations, and distribution of drug samples. Galderma has implemented policies addressing each of these areas, as well as many others.

In addition, with respect to business activity in California, per California SB 1765, Galderma has established a specific annual dollar limit on gifts, promotional materials, or other items that Galderma may provide to a healthcare professional. This annual dollar limit is \$2,500.00 and reflects dollars expended in association with programs designed to inform prescribing healthcare professionals about Galderma products and the disease state these products help treat. Galderma provides a declaration of its adoption of California Health Safety & Code 119400-119402 on its corporate website.

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

The most effective and efficient method of ensuring compliance is a well-formulated training and educational program. A compliance training and education program that includes training for appropriate Galderma personnel will be implemented. These education programs will be mandatory (in some circumstances) and will be targeted for specific audiences. Training will be conducted at the beginning of employment with Galderma and periodically during employment tenure as needed.

Examples of education topics may include:

- Government and private payer reimbursement principles;
- 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 Program by Galderma personnel.

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

The Program 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 Program will facilitate a method for Galderma personnel to report potential violations to the Compliance Officer.

The Program's system for meaningful and open communication will include the following:

- Requesting all Galderma 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;
- Establishing a hotline with a user-friendly process for effectively reporting possible non-compliance with the Program;

- Establishing processes that make efforts to maintain the anonymity of the person(s) involved in reporting potential non-compliance with the Program and the person(s) involved in the alleged conduct (while the Compliance Officer 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 Program or Company policy.

The Compliance Officer will also communicate results of investigations to any and/or all appropriate persons involved with the alleged non-compliance with the Program, including the General Counsel, President and/or Management Committee as deemed necessary. The Compliance Officer will also preserve any information that may be associated with the alleged activity.

**Program Element Five: Monitoring and Auditing**

Galderma's Program 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.

**Program Element Six: Investigation**

When Galderma 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 Program, include disciplinary action up to and including termination of employment.

**Program Element Seven: Corrective Action**

The Program provides for enforcement and disciplinary provisions, which are necessary to add credibility and integrity to this compliance initiative. Galderma 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 Galderma 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 Program, failure to comply with applicable law or regulations, and other types of non-compliance with the Program threaten Galderma's status as a reliable, honest, and trustworthy participant in the pharmaceutical industry. Detected but uncorrected misconduct can endanger the reputation and legal status of Galderma. Consequently, upon receipt of reasonable indications of suspected noncompliance, it is important that the Compliance Officer immediately investigate the allegations to determine whether a material violation of applicable law or the requirements of the Program 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 Program, a report and repayment to the government, and/or a referral to criminal and/or civil law enforcement authorities.

Copies of Galderma's U.S. Compliance Program may be obtained by calling 1-800-313-9958 or emailing [usdfw.compliance@galderma.com](mailto:usdfw.compliance@galderma.com).

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