

# **Jubilant HollisterStier Comprehensive Compliance Program (CCP)**

## **Comprehensive Compliance Program (CCP) Statement**

Jubilant HollisterStier (JHS) is committed to complying with all applicable laws, regulations and industry standards and to conducting business in an ethical manner. Our sales and marketing activities are intended to enhance the practice of medicine, benefit patients, and not interfere with the independent judgment of health care professionals (HCPs).

With this in mind, Jubilant HollisterStier established our Comprehensive Compliance Program (CCP) in accordance with Compliance Program Guidance for Pharmaceutical Manufacturers published by the U.S. Department of Health and Human Services Office of Inspector General (OIG Guidance, 2003), which our policy consistent with the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Health Care Professionals (PhRMA Code). Our CCP is in alignment with Federal reporting regulations (Physician Payments Sunshine Provision (§ 6002) of the Patient Protection and Affordable Care Act (Pub. L. No. 11-148), and State Bills (SB's) that establish annual spending limits on promotional marketing materials and on items of value given to HCPs (for example: California State Bill (SB 1765, effective July 1, 2005, California SB 790, effective January 1, 2019, Minnesota Statute 151.461 (1993), Vermont (2012), and others). It is also in alignment with regulations which require a written code of conduct for practices which govern the marketing and sale of products, and require a comprehensive training program to regularly educate sales and marketing personnel, (e.g., Nevada State Bill (NVA.B.128) effective October 1, 2007).

## **Our Comprehensive Compliance Program includes the following, but is not limited to:**

- Policies, and procedures that are continually assessed and updated as needed to comply with current State and Federal laws, regulations and guidances. Our compliance program guides our interactions with healthcare professionals (HCPs) and healthcare organizations, and is designed to prevent, detect and remediate violations of law, regulations and company policies, as well as to promote an ethical culture within our company.
- A Compliance Committee whose function is deliberation of noncompliance and legal issues, and any related disciplinary decisions. The Compliance Committee consists of:
  - A Regulatory Compliance Officer with authority to report significant issues directly to the CEO and to the Board of Directors, who is responsible for developing, implementing, operating and monitoring the effectiveness of our compliance program.
  - The CEO and President of HollisterStier Allergy, the executive member of the Compliance Committee
  - Senior management representatives including Human Resources, Sales Operations and Finance.
  - Compliance support staff that regularly monitor new State and Federal regulations, sales marketing activity, and the ongoing status of compliance with this program.

- Quarterly audits of in-service meals, samples etc., provided to HCPs by our Sales Professionals in the course of conducting business and valuable product training, are performed to assure our sales and marketing staff are compliant with State and Federal regulations.
- Investigation of all suspected non-compliance offenses are documented, reported and prompt corrective action is taken as warranted.
- A “Corporate Code of Conduct” that articulates Jubilant HollisterStier’s expectations and commitment to compliance by management, employees and agents.
- Adoption of the “Code on Interactions with Healthcare Professionals” developed by the PhRMA (Pharmaceutical Research and Manufacturers of America) which incorporates applicable legal standards and principles of health care.
- Effective, ongoing training, education and certification programs for our employees. Sales and Marketing employees receive training to ensure that they have a good understanding of our marketing compliance policies and of the legal framework governing sales activities.
- Enforcement of standards with well-publicized disciplinary guidelines.

### **Jubilant HollisterStier (JHS) Marketing Practices**

Individual State laws dictate the actual dollar limit that may be spent annually on a medical or Healthcare Professional, and in some states, all meals/transfers of value are prohibited. JHS has set an annual spending limit (maximum amount) to a cumulative annual dollar limit of **\$1800.00** per Medical and Healthcare Professional (HCP). Exception: The annual limit for an individual medical or HCP in California is **\$250.00** per year (per SB 790, effective January 1, 2019).

Jubilant HollisterStier will revise this limit as needed to meet State and Federal requirements. The annual spending limit **includes** following example items:

- The value of gifts and promotional materials, (modest meals and learning activities) that are provided by Jubilant HollisterStier to HCPs in connection with the promotion of our Allergy product line.
- Medically-relevant items (\$25.00 or less per item) such as: Physician desk reference books, medical textbooks or anatomical models, provided occasionally to the physician, primarily for the benefit of the patient.
- Modest banquet meals and receptions, provided at CME meetings, etc., in connection with JHS’s efforts to advance the individual HCPs knowledge in regard to patient safety, efficacy and the benefits of Jubilant HollisterStier’s Allergy product line.

The annual spending limit **does not include** the following expenditures:

- Drug and medical device samples provided to physicians or HCPs intended for the patient’s benefit.
- Financial support for continuing medical education (CME) programs.

- Payment for legitimate professional services that are based on the fair market value of the services provided, and any meals or expenses associated with the provision of such services;
- Miscellaneous items of minimal value such as diaries, physician and patient educational materials that are provided to the HCP with the purpose of enhancing the patient's knowledge of the disease state, disorder and treatment directions.

### **Compliance Declaration**

Based on a good faith understanding of the requirements of Section 119402 of the California Health & Safety Code, Jubilant HollisterStier declares that, to the best of our knowledge, our Comprehensive Compliance Program addresses the California statutory requirements for inclusion of policies that encompass the OIG Guidance and PhMRA Code and limits on gifts, payments and incentives to health professionals. Jubilant HollisterStier also hereby declares that we are, in all material respects, in compliance with our Comprehensive Compliance Program as of July 2022.

We recognize that compliance is a dynamic concept that must be adapted to the specific characteristics of the individual company. With this in mind, our compliance program is monitored regularly to prevent and detect misconduct.

Jubilant HollisterStier's Compliance Program (CCP) is re-assessed at least annually, and may be modified periodically, to enhance program effectiveness and to better address, detect and prevent improprieties.

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This declaration is available on our Jubilant HollisterStier Allergy website, 24 hours a day. A printed copy may also be obtained by dialing: 1 (800) 495-7437 (Customer Service).