

California 2019 Compliance Policy and Declaration

NOTICE: This information is provided pursuant to the requirements of California Health & Safety Code §§ 119400 – 119402 (“California Compliance Law”), which requires pharmaceutical companies doing business in California to adopt and make available on the company’s website a comprehensive compliance program (“CCP”). This law is in accordance with the Office of Inspector General (OIG) May 2003 publication of the “Compliance Program Guidance for Pharmaceutical Manufacturers” (“OIG Compliance Guidance”) and policies for compliance with the Pharmaceutical Research and Manufacturers of America (“PhRMA”) July 2008 “Code on Interactions with Health Care Professionals” (“PhRMA Code”). The PhRMA Code became effective January 2009.

I. INTRODUCTION

Romark L.C. (“Romark”) is committed to compliance with applicable laws, regulations, and industry standards. Romark has developed a CCP in accordance with applicable laws, regulations, and industry standards, which is required by California Compliance Law. In addition, Romark has implemented and maintains a website (www.romark.com) and phone number (877) 925-4642 to facilitate communication and requests for information related to California State requirements. This is a summary document and does not include all of the numerous policies and practices that comprise Romark’s CCP.

II. OVERVIEW OF COMPLIANCE PROGRAM

1. Written Code of Conduct

Romark’s Code of Conduct is distributed to all workers (employees and non-employees who perform work regularly at Romark) upon commencement of their working relationship and whenever changes are made to the Code.

2. Written Policies and Procedures

Romark has written policies to assure substantial compliance with the applicable laws, regulations and industry standards governing the marketing and promotion of our products. These policies govern activities involving communication with healthcare professionals about the appropriate use of our products and activities involving the advancement of scientific and educational activities supporting medical research and education (grants, charitable contributions, research, and third-party scientific and educational conferences).

Romark representatives may occasionally offer a modest meal as part of an educational presentation or a business discussion. Venues that feature entertainment or recreation, and attendance by spouses or guests, are not permitted.

Romark has set an annual aggregate dollar limit on gifts and promotional materials and activities provided to healthcare professionals at \$2,500.00 per covered healthcare professional. It is the policy of Romark not to provide entertainment (e.g., sporting events, golf outings, concerts, etc.) to healthcare professionals.

3. Assigned Compliance Officer

Romark’s Compliance Officer is empowered with appropriate authority to exercise independent judgment and has free and unencumbered access to senior management and the Romark board of directors. Our Compliance Officer is responsible for developing, operating, and monitoring the CCP. Our Compliance

Officer oversees Romark's Compliance Committee, which is comprised of the Compliance Officer and members of the company's management team.

4. Training

Romark's compliance training and education programs increase awareness of the legal and ethical implications of abiding by our Code of Conduct and related policies, and making sound and ethical business decisions.

New employees receive compliance training at the time of hire and annually thereafter, which covers applicable guidelines governing Romark's CCP. Employees are trained on the consequences of failure to comply with the requirements of Romark's CCP.

5. Communication

Romark fosters effective lines of communication by encouraging open and candid discussion between management and employees regarding any compliance concern. Romark has also adopted confidentiality and non-retribution/non-retaliation policies. Romark employees are encouraged to raise compliance questions or report compliance concerns to their manager, the Legal Department or to the Compliance Officer. Employees also have the option to make anonymous reports regarding potential compliance violations using the Romark Compliance Hotline.

6. Auditing, Monitoring and Investigating

Romark self-assesses and periodically audits its compliance with its CCP. Romark will conduct an investigation of matters that are brought to the company's attention in order to ensure the consistent application of Romark's standards.

Romark requires a prompt and diligent response to questions, concerns, and reports of potential violations of the company's compliance program, including its standards regulating the marketing and promotion of its products. Actions in response to detected problems may include improving policies, procedures, training, communication and monitoring or may require disciplinary action to prevent future violations.

7. Enforcement and Disciplinary Guidelines

Romark will take disciplinary action, up to and including discharge/termination, in response to violation of the CCP.

III. DECLARATION FOR CALIFORNIA COMPLIANCE LAW

As part of Romark's ongoing efforts in the area of compliance, we have developed a CCP that is designed to comply with applicable laws, regulations, and industry standards relating to the marketing and promotion of our products.

As of the date of this Declaration, to the best of our knowledge, and based upon our good faith interpretation of the requirements of Cal. Health & Safety Code §§ 119400 – 119402, Romark is in substantial compliance with the requirements of these provisions and with our CCP.

As recognized by the OIG Compliance Guidance, even an effective compliance program cannot eliminate the possibility that one or more individual employees engage in conduct that would be considered

improper. Accordingly, this declaration is not intended and should not be construed to imply that the Romark has not identified any individual instances in which an employee has or may have violated one or more provisions of its CCP. In such situations, Romark takes reasonable and appropriate remedial or corrective action in a manner consistent with its CCP.

Last updated: May 22, 2019