



## **Collegium Pharmaceutical Statement regarding compliance with California Health and Safety Code § 119402**

**NOTICE: This information is provided pursuant to the requirements of California Health & Safety Code, Section 119402, which requires pharmaceutical companies doing business in California to make available their Compliance Program and to provide annual written declaration of their adherence to the requirements of the Compliance Program.**

California Health & Safety Code, Section 119402, (“California Compliance Law”) requires pharmaceutical companies to adopt a “Comprehensive Compliance Program” in accordance with the requirements set forth in the April 2003 “Compliance Program Guidance for Pharmaceutical Manufacturers” (“OIG Guidance”) published by the United States Department of Health and Human Services Office of Inspector General (“OIG”). Further, the California Compliance Law requires manufacturers to include in their Comprehensive Compliance Program policies for compliance with the Pharmaceutical Research and Manufacturers of America (“PhRMA”) “Code on Interactions with Health Care Professionals” (“PhRMA Code”). The California Compliance Law further states that companies shall institute limits on gifts and incentives to health care professionals and requires that companies declare annually, in writing, their compliance with their Comprehensive Compliance Program as well as the requirements of the California Compliance Code. Companies are also required to make available to the public both their annual declaration and the provisions of their Comprehensive Compliance Program via their website and a toll-free telephone number.

### **Annual Declaration (June 2017)**

As stated in its Compliance Program, Collegium is committed to conducting its business ethically and in compliance with applicable laws. To the best of its knowledge and based on a good faith understanding of the applicable statutory requirements, Collegium has established a Comprehensive Compliance Program that meets the requirements set forth in California Health & Safety Code, Sections 119400-119402. Collegium's Compliance Program is tailored to the size, organizational structure and resources of Collegium and has been developed to meet the issues addressed by the above-referenced California Law. By making this declaration, Collegium is not asserting that it can prevent individual employees from improper conduct and/or otherwise violating the standards set forth in its Comprehensive Compliance Program.

Collegium has established procedures to identify potential violations and will discipline employees as necessary. As of the date of this declaration, such procedures are in place and will be reassessed periodically and no less frequently than on an annual basis. Thus, subject to the limitations described above, Collegium declares that, based upon its current tracking and monitoring systems, Collegium is, in all material respects, in compliance with the Compliance Program and with the established annual spending limits. As recognized by the OIG Compliance Program Guidance, even an effective compliance program cannot eliminate the possibility that one or more individual employee engages in conduct that would be considered improper. Accordingly, this declaration is not intended and should not be construed to imply that Collegium has not identified any individual instances in which an employee has or may have violated one or more provisions of its Compliance Program. In such situations, Collegium takes reasonable and appropriate remedial or corrective action in a manner consistent with its Compliance Program.



Collegium Pharmaceutical, Inc. (“Collegium”) has established a comprehensive Compliance Program in accordance with the OIG Guidance and has put in place policies to foster compliance with the requirements of the PhRMA Code. In addition, as part of its Comprehensive Compliance Program, Collegium has established a specific annual aggregate dollar limit of \$2,500 for the following items: 1) meals provided in connection with informational presentations or scientific exchange; 2) educational items intended to enhance patient care (excluding items of minimal monetary value and/or of no independent value (e.g. printed advertising, reimbursement fact sheets)) and items for the benefit of and distribution to patients/care givers. This amount does not include the value of pharmaceutical drug samples or co-pay cards, grants for medical education, medical scholarships, professional service or consulting fees, patient education materials, and approved scientific reprints. This limit may be revised by Collegium from time to time. The foregoing limit does not represent a usual, customary, average or typical amount for medical or health care professionals. This annual aggregate limit is based on an estimate of the maximum value of gifts, promotional materials and other items or activities as defined herein that a California medical or health care professional may receive in one year.

**For a written copy of the Compliance Program description or this Declaration, call 1-866-384-4277.**