

Kowa Pharmaceuticals America, Inc. California Declaration of Compliance

Kowa Pharmaceuticals America, Inc ("KPA") has adopted a Comprehensive Compliance Program in accordance with California Health and Safety Code, § 119402. KPA's Comprehensive Compliance Program is in accordance with the April 2003 "Compliance Program Guidance for Pharmaceutical Manufacturers" developed by the United States Department of Health and Human Services Office of Inspector General (OIG) and incorporates policies that comply with the Pharmaceutical Research and Manufacturers of America "Code on Interactions with Healthcare Professionals" as revised from time to time.

KPA is committed to ensuring compliance with its company policies and with applicable laws and regulations. The Comprehensive Compliance Program represents KPA's commitment to the highest standards of corporate conduct. The OIG Guidance acknowledges that the implementation of a compliance program, such as the Comprehensive Compliance Program, cannot ensure that improper employee conduct will never occur. Nonetheless, KPA expects and requires its employees to abide by KPA's Code of Conduct and the other policies described in its Comprehensive Compliance Program.

KPA declares, to the best of its knowledge and based on its good faith understanding of the statutory requirements that KPA is in compliance with Comprehensive Compliance Program and Chapter 8, Part 15, Division 104 of the California Health and Safety Code.

KPA has set the annual aggregate limit on covered promotional expenditures at \$3,000 per covered medical or healthcare professional for annual periods commencing on September 1, 2008. This limit may be revised by KPA from time to time. The foregoing limit does not represent any usual, customary, average, or typical amount for medical or healthcare professionals.

KPA exempts certain expenditures from this limit based upon a good faith understanding of California Health & Safety Code §§ 119400-119402 and the PhRMA Code. Such exemptions include:

- Drug samples given to physicians and healthcare professionals intended for free distribution to patients;
- Financial support for continuing medical education forums;
- Financial support for health educational scholarships;
- Payments made for legitimate professional services provided by a healthcare or medical professional that are provided at the fair market value for the services rendered; and
- Documents, informational or educational brochures, and other items that inform medical or healthcare professionals about KPA products provide scientific and educational data, support medical research and education, or enhance a patient's understanding or management of a disease state or disorder.

This program became effective as of September 1, 2008 and was last reviewed March 2014. KPA will assess its Comprehensive Compliance Program at least annually.