

State of California Compliance Program Declaration

As part of our commitment to compliance, Tris Pharma has developed and implemented a Compliance Program consistent with the HHS OIG Compliance Program Guidance for Pharmaceutical Manufacturers (“OIG Guidance”) and the PhRMA Code on Interactions with Healthcare Professionals (“PhRMA Code”). Tris Pharma declares, based on its good faith understanding and to the best of its knowledge, that Tris Pharma is in substantial compliance with its Comprehensive Compliance Program and the requirements of California Health and Safety Code §§ 119400-119402. This declaration is based upon information available to Tris Pharma.

Tris Pharma has set the annual aggregate limit on covered promotional expenditures in California at \$2,000 per covered medical or healthcare professional. This limit may be revised by Tris Pharma from time to time. It is important to note that this annual dollar limit is an upper limit and is not an accurate representation of the average value of gifts, promotional materials, items or activities that Tris Pharma may provide generally to a healthcare professional.

The annual limit excludes the value of certain expenditures based upon a good faith understanding of California Health & Safety Code sections 119400-119402. Such excluded expenditures include:

- *Drug samples provided to healthcare professionals intended for free distribution to patients;*
- *Financial support for continuing medical education forums;*
- *Financial support for health educational scholarships;*
- *Payments for legitimate professional services, including professional speaking, advising, consulting, training or market research services, that are based on the fair market value of the services provided, and;*
- *Documents, informational or educational brochures, and other items that inform medical or healthcare professionals about Tris Pharma 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.*

A description of Tris' Corporate Compliance Program, including the Company's written declaration and certification of compliance with California SB 1765, can be requested by calling Tris Pharma directly at 732-647-3984.

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