

## **XANODYNE COMPLIANCE PROGRAM**

### **CALIFORNIA COMPLIANCE DECLARATION**

Xanodyne is committed to maintaining an effective compliance program in accordance with the Compliance Program Guidance for Pharmaceutical Manufacturers published by the Officer of Inspector General of the United States Department of Health and Human Services (the "OIG Guidance"). A compliance program is one of the key components of our commitment to the highest standards of corporate conduct. The compliance program adopted by Xanodyne is intended to adhere to the OIG Guidance, as well as the Pharmaceutical Research and Manufacturers of America (PhRMA) "Code on Interactions with Healthcare Professionals" (the "PhRMA Code").

Effective July 1, 2005, California law [Cal. Health & Safety Code §119402 (SB 1765)], requires certain pharmaceutical companies doing business in California to make available their program for compliance with applicable federal and state laws and industry standards regulating the marketing and promotion of their products. In addition, California law requires pharmaceutical companies to establish annual dollar limits on items and promotional materials given to healthcare professionals. Each company must publish an annual statement declaring its compliance with the law.

Xanodyne is committed to complying with the OIG Guidance and the PhRMA Code. Our current policies support adherence to the voluntary guidelines that California law will now enforce. Xanodyne will enhance its existing policies and programs to cover the formal annual dollar limits required by the law and begin monitoring performance against those limits.

#### **Annual Spending Limit per California Medical and Health Care Professional**

Xanodyne sales professionals may occasionally provide items to health care professionals designed for the education of patients or healthcare professionals. These items will be of reasonable value and provided in accordance with the provisions of the PhRMA Code and other applicable Company policies but in no event shall any one item exceed \$100 in value. In addition, Xanodyne sales professionals may occasionally offer modest meals as part of an educational presentation or in connection with Xanodyne's efforts to advance the professionals' understanding of the efficacy, safety, and benefits of Xanodyne's approved products. Xanodyne has established an annual limit of \$1,000 per individual health care professional for meals and patient or practice-related items. As part of its annual review of its compliance program, Xanodyne may revise this annual limit in the future, but any revisions will be consistent with the OIG Guidance, PhRMA Code, and best industry practices to ensure regulatory compliance.

Consistent with Xanodyne's understanding of the California law, Xanodyne excludes certain items and payments in determining whether the annual limit has been met. Xanodyne's annual dollar limit, as of the date of this declaration, does not include the value of:

- Drug samples provided to individual healthcare professionals intended for free distribution to patients.

- Financial support of independent education, including continuing medical education forums.
- Financial support for health education 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.
- Items, including but not limited to patient educational brochures, anatomical instruction sheets, diaries or other materials to track medical information, provided to patients by their physician with the purpose of enhancing patients' understanding or management of a disease state or disorder.

### **Annual Declaration for Purposes of California Health & Safety Code, §§ 119400-119402**

As part of its ongoing efforts in the area of compliance, Xanodyne maintains a compliance program that is designed to comply with applicable federal and state laws related to the marketing and promotion of our products. To our knowledge as of the date of this declaration, Xanodyne is, in all material respects, in compliance with California Health & Safety Code, §§ 119400-119402.

Copies of this summary and declaration may be obtained by contacting Xanodyne's Chief Compliance Officer at the following toll-free number: 877-926-6396.