

## **Corporate Compliance Program (CCP) for Pharmaceutical Products**

### **INTRODUCTION**

At Sigma-Tau we value integrity and this is at the core of the way we conduct business. Compliance with the U.S. healthcare laws and rules that govern our interactions with customers and our communications about our products demonstrates our commitment to integrity. Compliance also builds trust with patients, healthcare professionals, institutional purchasers, and the government. To assure such compliance, Sigma-Tau has adopted the policies in its Corporate Code of Conduct for Pharmaceutical Products designed, implemented, and enforced with the purpose of preventing and detecting of unethical activity and activity that violates federal, state, and local laws. Starting June 30, 2005 Sigma-Tau made its declaration of compliance with the posting of the Corporate Compliance Program (CCP) on the corporate web site. The Corporate Code of Conduct for Pharmaceutical Products and the Corporate Compliance Program (CCP) for Pharmaceutical Products documents are available on the Sigma-Tau corporate web site. For more information and copies of the documents, visit [www.sigma-tau.com](http://www.sigma-tau.com).

### **COMPLIANCE WITH CALIFORNIA HEALTH & SAFETY CODE SECTION 119402**

The Corporate Code of Conduct for Pharmaceutical Products and the Corporate Compliance Program (CCP) for Pharmaceutical Products have been developed in accordance with the "Program Guidance for Pharmaceutical Manufacturers" published by the Office of the Inspector General of the US Department of Health and Human Services in April 2003, and requires compliance with the "Code on Interactions with Healthcare Professionals" effective January 1, 2009, as adopted by the Pharmaceutical Research and Manufacturers of America.

#### **California Health & Safety Code**

As required by California Health & Safety Code section 119402, with specific reference to the provision of "gifts, promotional material, or items or activities" that a pharmaceutical company may provide to an individual medical or healthcare professional, Sigma-Tau has established an aggregate annual dollar limit of \$1,200 for each medical or healthcare professional in the State of California for the 12 month period beginning July 1, 2005. Drug samples for free distribution to patients, financial support for health education scholarships, financial support for continuing education and payments for professional services are exempt from this limit pursuant to section 119402. It should be noted that this dollar limit is a maximum only.

To the best of our knowledge, Sigma-Tau is in material compliance with our Corporate Code of Conduct for Pharmaceutical Products and the Corporate Compliance Program (CCP) for Pharmaceutical Products and California Health & Safety Code section 119402.

The following toll-free number is available to you in order to obtain a copy or copies of the Comprehensive Compliance Program (CCP) for Pharmaceutical Program and where written declaration of compliance can be obtained.

**Sigma-Tau Pharmaceuticals, Inc.**  
**Corporate Compliance Group**  
**9841 Washingtonian Blvd., Ste 500**  
**Gaithersburg, MD 20878**  
**Telephone: 301- 948-1041**  
**U.S. Toll-free number: 800-775-8581, Option 5**