

Annual Declaration of Compliance – California Health and Safety Code § 119402

Braeburn Inc. (“Braeburn”) is committed to meeting the highest standards of ethics in its corporate conduct. To that end, and in accordance with the requirements of California Health and Safety Code § 119402, Braeburn has adopted a Comprehensive Compliance Program (“CCP”) that is in accordance with the “Compliance Program Guidance for Pharmaceutical Manufacturers” issued by the Department of Health and Human Services Office of Inspector General in 2003 (“HHS-OIG Guidance”). As part of its CCP, Braeburn has established an annual per-practitioner spending limit for certain promotional activities directed toward healthcare professionals practicing in California. Braeburn declares that, to the best of its knowledge and based on a good faith understanding of the requirements of the statute, it is in compliance with its CCP and with California Health and Safety Code § 119402, in all material aspects.

Consistent with the HHS-OIG guidance, Braeburn has adopted a CCP that is designed to fit the size and structure of Braeburn and is regularly reviewed to ensure that the CCP still meets applicable legal and ethical requirements. In particular, the CCP is designed to meet requirements that are applicable to a pharmaceutical manufacturer and has included in its CCP policies for compliance with the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals (“PhRMA Code”).

Braeburn’s CCP consists of seven key elements, as described in further detail in Braeburn’s Compliance Program Overview and in other policies and procedures adopted by Braeburn:

- Leadership responsibility for compliance operations
- Written policies and procedures for compliance with applicable laws and regulations
- Education and training of Braeburn personnel on compliance
- Enabling communication and investigation of potential misconduct
- Responding effectively to violations, including through appropriate discipline
- Regular monitoring of compliance
- Continued development and refinement of the compliance program

A copy of this declaration and/or Braeburn’s CCP may be obtained by calling 1-610-467-8680 and dialing 0 for the receptionist. You may also submit questions or request copies by writing to Braeburn, 450 Plymouth Rd, Suite 400, Plymouth Meeting, PA 19462.