



**April 24, 2007**

**Re: FDA Guideline for Industry: Complementary & Alternative Medicine Products and Their Regulation by the Food & Drug Administration**

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

The Association for Applied Psychophysiology and Biofeedback (AAPB), our sister organization the International Society for Neurofeedback and Research (ISNR), and the Biofeedback Certification Institute of America (BCIA) are writing in response to the FDA's efforts to regulate biofeedback devices as part of the larger effort to regulate complementary and alternative medicine (CAM) devices.

AAPB is a voluntary professional society with a 33-year history of advancing the development, dissemination, and utilization of knowledge about biofeedback to improve health. ISNR, also a voluntary professional society with a 15-year history, has major interests involving biofeedback with a specialty in EEG Biofeedback (neurofeedback, EEG activity). BCIA is the certification body for the clinical practice of biofeedback. Both AAPB and ISNR endorse BCIA certification as the standard in the field. Collectively, these groups represent the largest, longest-standing organizations dedicated to practice, research, and education in biofeedback.

The organizations mentioned herein have a longstanding commitment to the ethical and efficacious use of biofeedback instrumentation/devices. We care deeply about how such devices are used and the claims made for any application deemed to be "biofeedback." Hence, as the FDA moves forward in regulating CAM devices, we would welcome the opportunity to work collaboratively with you in creating definitions that appropriately and adequately identify biofeedback and non-biofeedback devices.

Sincerely,

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