DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL).

Dates and Times: October 4, 2011, 11 a.m. to 3 p.m., E.D.T.

Place: Webinar Format.

Status: The meeting will be open to the public.

Purpose: The members of the ACICBL will begin the planning required to develop the legislatively mandated 12th Annual Report to the Secretary of Health and Human Services and the Congress. The meeting objectives are to: (1) Focus on a relevant topic that will enhance the mission of the Title VII training programs; (2) develop an outline that will inform the development of the 12th Annual Report; (3) identify issues related to the training programs; and (4) identify resources that will address gaps and further strengthen the outcomes from these efforts.

Agenda: The ACICBL agenda includes an opportunity for each member to offer ideas for the upcoming report, along with identifying consultants in specific areas who could provide expert testimony. The staff writer provided by the Health Resources and Services Administration (HRSA), Bureau of Health Professions, will offer a strategy for outlining the upcoming report. The agenda will be available 2 days prior to the meeting on the HRSA Web site (http://www.hrsa.gov/advisorycommittees/bhpadvisory/acicbl/acicbl.html). Agenda items are subject to change as priorities dictate.

Supplementary Information: Requests to make oral comments or provide written comments to the ACICBL should be sent to Dr. Joan Weiss, Designated Federal Official at the contact information below. Written comments can be provided before and after the meeting. Individuals who plan to participate on the webinar should register at least one day prior to the meeting using the following webinar information: https://hrsa.connectsolutions.com/e94041221/event/registration.html. The conference call-in number is 1–888–391–0505, using the participant pass code ACICBL.

For Further Information Contact: Anyone requesting information regarding the ACICBL should contact Dr. Joan Weiss, Designated Federal Official within the Bureau of Health Professions, Health Resources and Services Administration, in one of three ways: (1) Send a request to the following address: Dr. Joan Weiss, Designated Federal Official, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 9–36, 5600 Fishers Lane, Rockville, Maryland 20857; (2) call (301) 443–6950; or (3) send an e-mail to jweiss@hrsa.gov. In the absence of Dr. Weiss, CAPT Norma J. Hatot, Senior Nurse Consultant, can be contacted via telephone at (301) 443–2681 or by e-mail at nhatot@hrsa.gov.

Dated: July 14, 2011.

Reva Harris, Acting Director, Division of Policy and Information Coordination.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA—2011–D–0500]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled, “Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use.” This guidance document describes a means by which focused ultrasound stimulator systems for aesthetic use may comply with the requirement of special controls for class II devices. This guidance document is being immediately implemented as the special control for focused ultrasound stimulator systems for aesthetic use, but it remains subject to comment in accordance with the Agency’s good guidance practices.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Richard Felten, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1436, Silver Spring, MD 20993–0002, 301–796–6392.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document will serve as the special control for focused ultrasound stimulator systems for aesthetic use. Section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(2)) provides that any person who submits a premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) for a device that has not previously been classified, may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the FD&C Act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the FD&C Act. FDA shall, within 60