

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 15, 2011.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Vice President) 33 Liberty Street, New York, New York 10045-0001:

1. *FNBNY Bancorp, Inc. and Modern Capital Holdings LLC*, both in New York, New York; to become bank holding companies by acquiring 100 percent of the voting shares of Madison National Bancorp, Inc., and Madison National Bank, both in Hauppauge, New York.

In connection with this application, Modern Capital Holdings LLC, New York, New York, also has applied to acquire 24.9 percent of the voting shares of The Upstate National Bank, Lisbon, New York.

Board of Governors of the Federal Reserve System, July 15, 2011.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 2011-18283 Filed 7-19-11; 8:45 am]

**BILLING CODE 6210-01-P**

## 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) review the urgent 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/bhpradvisory/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 1-888-391-9505, 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](mailto: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](mailto:nhatot@hrsa.gov).

Dated: July 14, 2011.

**Reva Harris,**

*Acting Director, Division of Policy and Information Coordination.*

[FR Doc. 2011-18254 Filed 7-19-11; 8:45 am]

**BILLING CODE 4165-15-P**

## 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.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**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

days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the FD&C Act, FDA has determined, under 21 CFR 10.115(g)(2), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Thus, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying focused ultrasound stimulator systems for aesthetic use into class II (special controls) under section 513(f)(2) of the FD&C Act.

## II. Significance of Guidance

FDA believes that adherence to the recommendations described in this guidance document, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of focused ultrasound stimulator system for aesthetic use classified under 878.4590 (21 CFR Part 878). In order to be classified as a class II device under 878.4590, an ultrasound stimulator for aesthetic use must comply with the requirements of special controls; a manufacturer must address the issues requiring special controls as identified in the guidance, either by following the recommendations in the guidance document or by some other means that provides equivalent assurances of safety and effectiveness.

## III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use," you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1701 to identify the guidance you are requesting

## IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR Part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR Part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR 56.115 have been approved under OMB control number 0910-0130; the collections of information in 21 CFR 50.23 have been approved under OMB control number 0910-0586; the collections of information in 21 CFR Part 58 have been approved under OMB control number 0910-0119; and the collections of information in 21 CFR Part 801 have been approved under OMB control number 0910-0485.

## V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 15, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

[FR Doc. 2011-18280 Filed 7-19-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose

confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Stem Cells.

*Date:* July 27, 2011.

*Time:* 9 a.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

*Contact Person:* Raul A. Saavedra, PhD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223, [saavedrr@ninds.nih.gov](mailto:saavedrr@ninds.nih.gov).

This notice is being published less than 15 days prior to the meeting due to timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Rare Diseases.

*Date:* August 2, 2011.

*Time:* 9 a.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

*Contact Person:* Raul A. Saavedra, PhD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223, [saavedrr@ninds.nih.gov](mailto:saavedrr@ninds.nih.gov).

This notice is being published less than 15 days prior to the meeting due to timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Epilepsy Genetic Centers Without Walls.

*Date:* August 5, 2011.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Amalfi Hotel, 20 West Kinzie Street, Chicago, IL 60654.

*Contact Person:* William C. Benzing, PhD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-0660, [Benzingw@mail.nih.gov](mailto:Benzingw@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)