

a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1697 to identify the draft guidance you are requesting. To receive "Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Approval (PMA) and Premarket Notification [510(k) Submissions]," 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 Please use the document number 1698 to identify the draft guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available at <http://www.regulations.gov>.

#### V. Paperwork Reduction Act of 1995

These draft guidances contain information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501-3520) (the PRA). The collections of information addressed in these draft guidance documents have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB No. 0910-0120), premarket approval applications (21 CFR part 814, OMB No. 0910-0231), investigational device exemptions (21 CFR part 812, OMB No. 0910-0078), and humanitarian use devices (21 CFR part 814, OMB No. 0910-0332). The labeling provisions addressed in the "Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Notification [510(k) Submissions]" draft guidance have been approved by OMB under OMB No. 0910-0485.

#### VI. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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: October 15, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9-25233 Filed 10-20-09; 8:45 am]

**BILLING CODE 4160-01-S**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2009-D-0473]

##### Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Cardiac Allograft Gene Expression Profiling Test Systems; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the special controls guidance document entitled "Class II Special Controls Guidance Document: Cardiac Allograft Gene Expression Profiling Test Systems." This guidance document describes a means by which cardiac allograft gene expression profiling test systems may comply with the requirement of special controls for class II devices. It includes recommendations for validation of performance characteristics and recommendations for product labeling. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule codifying the classification of cardiac allograft gene expression profiling test systems into class II (special controls), and establishing this guidance document as the special control for this device.

**DATES:** Submit electronic or written comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled "Class II Special Controls

Guidance Document: Cardiac Allograft Gene Expression Profiling Test Systems" 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 to <http://www.regulations.gov>. Submit written comments concerning this guidance 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:

Kellie B. Kelm, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5625, Silver Spring, MD 20993, 301-796-6145.

##### SUPPLEMENTARY INFORMATION:

##### I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule codifying the classification of cardiac allograft gene expression profiling test systems into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)) and establishing this guidance document as the special control for cardiac allograft gene expression profiling test systems classified under that regulation. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the 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), request FDA to classify the device under the criteria set forth in section 513(a)(1). 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. Under this authority, on August 26, 2008, FDA by order classified into class II, subject to this special control guidance document, the XDx AlloMap Test.

## II. Significance of Special Controls Guidance Documents

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 cardiac allograft gene expression profiling test systems classified under § 862.1163 (21 CFR 862.1163). In order to be classified as a class II device under § 862.1163, a cardiac allograft gene expression profiling test system must comply with the requirement of special controls; manufacturers must address the issues requiring special controls as identified in the guidance documents, either by following the recommendations in the guidance documents 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. To receive "Class II Special Controls Guidance Document: Cardiac Allograft Gene Expression Profiling Test Systems," 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 1686 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available at <http://www.regulations.gov>.

## IV. Paperwork Reduction Act of 1995

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule establishing as special controls for the cardiac allograft gene expression profiling test systems the guidance document that is the subject of this notice. The preamble to that rule

addresses the application of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) to the information collection provisions referenced in this guidance document.

## V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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: October 9, 2009.

### Jeffrey Shuren,

*Acting Director, Center for Devices and Radiological Health.*

[FR Doc. E9-25313 Filed 10-20-09; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meeting

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 meeting.

The meeting 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 material, 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:* Center for Scientific Review Special Emphasis Panel; BSPH Member Conflict Applications.

*Date:* October 23, 2009.

*Time:* 3:30 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Mark P. Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301-435-1775, [rubertm@csr.nih.gov](mailto:rubertm@csr.nih.gov).

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

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 13, 2009.

### Jennifer Spaeth,

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-25269 Filed 10-20-09; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center on Minority Health and Health Disparities; Notice of Closed Meeting

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 meeting.

The meeting 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 material, 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 Center on Minority Health and Health Disparities Special Emphasis Panel; Conference Grant Review.

*Date:* November 10, 2009.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Prabha L. Atreya, Ph.D., Chief, Office of Scientific Review, National Center on Minority Health and Health Disparities, 6707 Democracy Boulevard, Suite 800, Bethesda, MD 20892, (301) 594-8696, [atreyapr@mail.nih.gov](mailto:atreyapr@mail.nih.gov).

Dated: October 14, 2009.

### Jennifer Spaeth,

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-25287 Filed 10-20-09; 8:45 am]

**BILLING CODE 4140-01-P**