

## 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]

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## 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]

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## 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.*

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