FOR FURTHER INFORMATION CONTACT: Robert A. Phillips, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3666.

SUPPLEMENTARY INFORMATION:

I. Background

An FFDM system is a device intended to be used to produce full field digital x-ray images of the breast. This generic type of device may include one or more of the following: digital mammography software, full field digital image receptor, acquisition workstation, and signal analysis programs. Mammographic x-ray producing equipment (x-ray generator, x-ray control, x-ray tube, collimator, beam filter, and breast compression system) and display accessories are regulated under 21 CFR 892.1710, 21 CFR 892.2040, and 21 CFR 892.2050 as class II devices (special controls). The FFDM system device is currently in class III and subject to premarket approval requirements (section 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e)).

At a public meeting on May 23, 2006, the Radiological Devices Panel (the Panel) unanimously recommended that the FFDM system be reclassified from class III to class II (special controls). The Panel also recommended that class II with a special controls guidance document would provide reasonable assurance of the safety and effectiveness of the device. FDA considered the Panel's recommendations, and elsewhere in this issue of the **Federal Register**, FDA is proposing to reclassify the FFDM system into class II. If the reclassification rule is finalized, FDA intends that this draft guidance document will serve as the special control for this device.

Following the effective date of any final reclassification rule based on the proposal, any firm submitting a premarket notification (510(k)) for an FFDM system would need to address the issues covered in the special controls draft guidance document. However, the firm need only show that its device meets the recommendations of the draft guidance document or in some other way provides equivalent assurances of safety and effectiveness.

II. Significance of Guidance

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, if finalized, will represent the agency's current thinking on the FFDM system. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Class II Special Controls Guidance Document: Full Field Digital Mammography System,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number (1616) 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

This draft guidance document 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, 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**), 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments and submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: May 21, 2008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8–12119 Filed 5–29–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0366] (formerly Docket No. 2007D–0234)

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin; 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: Tissue Adhesive for the Topical Approximation of Skin.'' This guidance document describes a means by which tissue adhesive for the topical approximation of skin may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to reclassify these device types from class III into class II (special controls).

DATES: Submit written or electronic 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: Tissue Adhesive for the Topical Approximation of Skin'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr.,

Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: George J. Mattamal, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3619.

SUPPLEMENTARY INFORMATION:

I. Background

Tissue adhesive for the topical approximation of skin devices are intended for topical closure of surgical incisions, including laparoscopic incisions, and simple traumatic lacerations that have easily approximated skin edges. Tissue adhesives for topical approximation of skin may be used in conjunction with, but not in place of, deep dermal stitches. This device is currently in class III and subject to premarket approval requirements (section 515 of the Federal Food, Drug, and Cosmetic Act (act); 21 U.S.C. 360e).

On August 25, 2006, at a public meeting of FDA's General and Plastic Surgery Devices Panel (the Panel), the Panel unanimously recommended that the tissue adhesive for the topical approximation of skin device be reclassified from class III into class II and recommended that a guidance document, which the Panel thought should include several voluntary consensus standards, be the special control for the device type. FDA considered the Panel's recommendations and, in the **Federal Register** of July 3, 2007 (72 FR 36398), published a proposed rule to reclassify the tissue adhesive for the topical approximation of skin device into class II. In addition, FDA issued a draft class II special controls guidance document entitled ''Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin'' to support the proposed reclassification.

Following publication of the draft guidance, four comments on the guidance were submitted to the FDA. We considered the suggestions and made appropriate revisions, including consideration of the comments on testing the applicator. FDA is now identifying the guidance document entitled ''Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin'' as the guidance document that will serve as the special control for this device type.

The guidance document provides a means by which the tissue adhesive for the topical approximation of skin device may comply with the requirement of special controls for this class II device. Following the effective date of the final reclassification rule, any firm submitting a premarket notification (510(k)) for a tissue adhesive for the topical approximation of skin device will need to address the issues covered in the special controls guidance document. However, the firm need only show that its device meets the recommendations of the guidance document or in some other way provides equivalent assurances of safety and effectiveness. This guidance supersedes the guidance entitled ''Cyanoacrylate Tissue Adhesive for the Topical Approximation of Skin - Premarket Approval Applications (PMAs),'' dated February 13, 2004.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on ''Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

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: Tissue Adhesive for the Topical Approximation of Skin,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1630 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

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 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

V. 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: May 21, 2008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8–12072 Filed 5–29–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Alternative Medicine; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 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 for Complementary and Alternative Medicine Special Emphasis Panel, CAM Approaches in the Management of HIV Disease and Its Complications.

Date: June 24, 2008.

Time: 9:30 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Jeanette M. Hosseini, PhD, Scientific Review Officer, Office of Scientific Review, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 594–9096, *jeanetteh@mail.nih.gov.*

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel, Training and Education.

Date: July 1–2, 2008.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Blvd., Bethesda, MD 20817.

Contact Person: Laurie Friedman Donze, PhD, Scientific Review Officer, Office of Scientific Review, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, 301–402–1030, *donzel@mail.nih.gov.*

Dated: May 22, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–12044 Filed 5–29–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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: Communication Disorders Review Committee.

Date: June 19, 2008.

Time: 10 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: The Westin Washington, DC, 1400 M Street, NW., Washington, DC 20005.

Contact Person: Shiguang Yang, DVM, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Activities, NIDCD, NIH, 6120 Executive Blvd., Suite 400C, Bethesda, MD 20892, 301–435–1425, *yangshi@nidcd.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: May 22, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–12046 Filed 5–29–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 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 Institute of Mental Health Special Emphasis Panel; Center for Genomic Studies on Mental Disorders.

Date: June 23, 2008.

Time: 1 p.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: Vinod Charles, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6151, MSC 9606, Bethesda, MD 20892–9606, 301–443–1606.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; IDSC Review.

Date: July 10, 2008.

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

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.

Contact Person: Megan Libbey, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6148, MSC 9609, Rockville, MD 20852, 301–402–6807, *libbeym@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)