Romania, Russia, Turkey, and Ukraine on December 29, 2005; Nigeria on February 8, 2006; India on February 22, 2006; Egypt on February 27, 2006; Niger on March 2, 2006; Albania, Azerbaijan, Cameroon, and Burma (Myanmar) on March 15, 2006; Israel on March 20, 2006; Afghanistan on March 21, 2006; and Jordan on March 29, 2006.

On April 3, 2006, OIE reported confirmation of highly pathogenic avian influenza H5N1 in guinea fowl in Burkina Faso. USDA added Burkina Faso to their ban on April 5, 2006. At this time, HHS/CDC is adding Burkina Faso to its current embargo. This action is effective on April 10, 2006, and will remain in effect until further notice.

SUPPLEMENTARY INFORMATION:

Background

An outbreak of avian influenza subtype H5N1 in guinea fowl has been reported at Gampéla, Kadiogo province, Burkina Faso.

Introduction of birds infected with highly pathogenic avian influenza H5N1 into the United States could lead to outbreaks of disease among birds and among the human population, a significant public health threat. Banning the importation of all avian species from affected countries is an effective means of limiting this threat. HHS/CDC is therefore taking this action to reduce the likelihood of introduction or spread of influenza A H5N1 into the United States.

Immediate Action

Therefore, pursuant to 42 CFR 71.32(b), HHS/CDC is amending the February 4, 2004, order to add Burkina Faso to the list of countries subject to the order's embargo of birds and products derived from birds. All other portions of the February 4, 2004, order, as further amended on March 10, 2004; September 28, 2004; December 29, 2005; February 8, 2006; February 22, 2006; February 27, 2006; March 2, 2006; March 15, 2006; March 20, 2006; March 21, 2006; and March 29, 2006, shall remain in effect until further notice.

Dated: April 13, 2006.

Julie Louise Gerberding,

Director, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

[FR Doc. E6–5841 Filed 4–18–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 2, 2006, from 8:30 a.m. to 3:30 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184, ext. 176, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512521. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make a recommendation on the reclassification of the noninvasive bone growth stimulator indicated for the treatment of established nonunion fractures acquired secondary to trauma and as an adjunct to the treatment of lumbar spinal fusion surgery for one or two levels.

Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panel* (click on ''Upcoming CDRH Advisory Panel/Committee Meetings'').

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 19, 2006. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:45 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 19, 2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shirley Meeks at 240–276–0450, ext. 105, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 12, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–5783 Filed 4–18–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. 2005D–0195

Guidance for Industry and FDA Staff; The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9.'' This guidance document is intended to assist facilities and their personnel in meeting the Mammography Quality Standards Act (MQSA) final regulations.

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 ''The Mammography Quality Standards Act Final Regulations:

Modifications and Additions to Policy Guidance Help System #9'' 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 301–443–8818. 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.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Charles Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Drive., Rockville, MD 20850, 301–594–3332

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 15, 2005 (70 FR 41043), FDA issued a notice of availability for, and an opportunity for public comment on, ''The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9'' draft guidance. During the public comment period, 6 respondents submitted a total of 38 comments. In addition, the National Mammography Quality Assurance Advisory Committee reviewed the draft guidance during its September 26 to 27, 2005, meeting and provided additional comments. FDA reviewed and considered all the comments, and in response FDA has modified the draft guidance as follows by:

1. Further clarifying Small Field Digital Mammography (SFDM) requirements,
2. Adding the phrase ''final interpretation quality'' to the section on retention and transfer of Full Field Digital Mammography (FFDM) images,
3. Clarifying that FFDM images used for final interpretation contain certain identifying information,
4. Clarifying under what circumstances the 8 hours of new mammographic modality training can be included as part of other initial interpreting physician requirements,
5. Further clarifying the table describing acceptability of the American Registry of Radiologic Technologists (ARRT(M)) certificate,
6. Modifying the guidance regarding the testing of single use cushion pads,
7. Modifying the table listing medical physicist involvement in certain FFDM repairs,
8. Clarifying the conditions under which electronic Quality Control test data may be retained.

This document provides guidance on the following issues:

1. Definitions of final interpretation and lossless and lossy digital compression,
2. Use of Small Field Digital Mammography (SFDM) image receptors,
3. Clarification relating to reestablishing processor operating levels,
4. Impact of the Health Insurance Portability and Accountability Act (HIPAA) requirements on certain MQSA activities,
5. Retention of medical outcomes audit records,
6. Steps to take when patients do not wish to receive their lay summaries,
7. Combining medical reports,
8. The effect of film digitization and compression of Full Field Digital Mammography (FFDM) digital data on retention, transfer, and interpretation of mammographic images,
9. Clarification of continuing education requirements,
10. Use of foreign-trained physicians,
11. Use of the ARRT(M) certificate to meet certain radiologic technologist requirements,
12. Quality Control testing when using cushion pads on compression devices,
13. Medical physicist involvement in certain FFDM repairs,
14. Use of printers and monitors that were not specifically approved as part of an FFDM unit,
15. Digitization of paper records and personnel documents.

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 the issues described in the previous paragraphs. 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

In order to receive ''The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1538 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. 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 on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 this guidance were approved under OMB control number 0910–0580.

V. Comments

Interested persons may submit to the Division of Dockets Management (See **ADDRESSES**), written or electronic comments regarding this document at any time. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 10, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–5785 Filed 4–18–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Research Projects (R01s).

Date: May 2, 2006.

Time: 8 a.m. to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

Contact Person: Irina Gordienko, PhD, Scientific Review Administrator, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892, 301–435–0725, *gordieni@nhlbi.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.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Research Project-Cooperative Agreements (U01s).

Date: May 9, 2006.

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

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Shelley S. Sehnert, PhD, Scientific Review Administrator, Review Branch, NIH/NHLBI, 6701 Rockledge Drive, Room 7206, Bethesda, MD 20892–7924, 301–435–0303, *ssehnert@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Continuing Education Training Grants (T15s).

Date: May 11, 2006.

Time: 8 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Rina Das, PhD, Scientific Review Administrator, Review Branch, NHLBI, National Institutes of Health, 6701 Rockledge Drive, Room 7200, Bethesda, MD 20892, 301–435–0297, *dasr2@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Institutional National Research Service Award (T32).

Date: May 19, 2006.

Time: 2:30 p.m. to 4 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: Charles Joyce, PhD, Scientific Review Administrator, Review Branch, NHLBI, National Institutes of Health, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892, 301–435–0288, *cjoyce@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Education Projects (R25s).

Date: May 22, 2006.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Rina Das, PhD, Scientific Review Administrator, Review Branch, NHLBI, National Institutes of Health, 6701 Rockledge Drive, Room 7200, Bethesda, MD 20892, 301–435–0297, *dasr2@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institute of Health, HHS)

Dated: April 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–3701 Filed 4–18–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 contact proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Synthesis and Distribution of Opioid and Related Peptides.

Date: May 2, 2006.

Time: 1:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Eric Zatman, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, (301) 435–1438.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, International Drug Abuse Researcher E-Learning Program.

Date: May 3, 2006.

Time: 9:30 a.m. to 11 a.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, (301) 435–1439, *lf33c.nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Wearable Wireless PDA Peripheral for Research.

Date: May 10, 2006.

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

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Eric Zatman, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, (301) 435–1438.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Developmental Awards, and Research Scientist Awards; 93.278, Drug abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)