DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Risk Communication 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: Risk Communication 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 February 25, 2010, from 8 a.m. to 5 p.m. and February 26, 2010, from 8 a.m. to 2 p.m.

Location: The Hilton Hotel, 8727 Coleville Rd, Silver Spring, MD 20910

Contact Person: Lee L. Zwanziger, Office of the Commissioner, rm. 14–90, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2895, FAX: 301–827–4050, e-mail: RCAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732112560. Please call the Information Line for up-to-date information on this meeting. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency’s Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On February 25 and 26, 2010, the committee will discuss strategies and lessons from a selection of the FDA’s previously issued communications, emphasizing communications challenges. Examples, selected for illustrative purposes only, will be drawn from communications about issues in broad areas such as biologics, drugs, medical devices, regulatory actions, and veterinary products. For more specific agenda information, please visit the following Web site and scroll down to the appropriate advisory committee link (http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm), or call the FDA Advisory Committee Information Line as detailed in the previous paragraph. FDA intends to make agenda information available at both locations no later than 15 days before the meeting.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee link.

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 on or before February 17, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on February 25, 2010, and 10:30 to 11:30 a.m. on February 26, 2010. Those desiring to make formal oral presentations should notify the contact person 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 on or before February 17, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 18, 2010.

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 Lee Zwanziger at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

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

Dated: January 26, 2010.

Jill Hartzler Warner, Acting Associate Commissioner for Special Medical Programs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Workshop on Pediatric Neurological and Neurocognitive Assessments for Cardiovascular Devices; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled “Workshop on Pediatric Neurological and Neurocognitive Assessments for Cardiovascular Devices.” The purpose of the public workshop is to solicit information from clinicians, academia, professional societies, other government agencies, and industry on various neurological and neurocognitive assessments for pediatric patients implanted with cardiovascular devices. The information gathered in this and future workshops will help to develop future guidance for the administration of these assessments.

Date and Time: The public workshop will be held on March 25, 2010, from 8 a.m. to 5 p.m. Participants are encouraged to arrive early to ensure time for parking and security screening before the meeting. Security screening will begin at 7:30 a.m. and check-in will begin at 8 a.m.
Location: The public workshop will be held at the Food and Drug Administration, White Oak Campus, Bldg. 2, Central Shared Use Building, rm. 2047, 10903 New Hampshire Ave., Silver Spring, MD 20903.

Contact Person: Sonna Patel-Raman, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, rm. 1255, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301–796–6335, FAX: 301–847–8115, e-mail: sonna.patel@fda.hhs.gov.

Registration: Registration and seating will be on a first-come, first-served basis and discussion preference will be afforded to clinical research investigators involved in pediatric clinical device trials, health care givers, and patient advocates. E-mail your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by February 25, 2010. There is no registration fee to attend the public workshop. Early registration is recommended because seating is limited. There will be no onsite registration.

Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible. If you need special accommodations due to a disability, please contact Sonna Patel-Raman by February 25, 2010.

SUPPLEMENTARY INFORMATION: The goal of the workshop is to understand and review the current clinical practices for these assessments in the pediatric population and to discuss options for standardized practices that may be used and validated during pediatric device trials. There are several neurological and neurocognitive assessments used in adults and pediatric patients. However, a lack of sufficient data and validated measures, due to the limited pediatric population, has restricted growth in the field. Several peer-reviewed journal articles acknowledge that there are no standards for the type of test administered or the frequency of the assessments. A standardized practice for evaluating this critical area will benefit the pediatric cardiovascular device community by providing a clear understanding of safety and effectiveness of these devices in the pediatric population. Assessments that demonstrate a real clinical benefit can provide useful information to patients, their families, and the clinical communities when weighing the risk involved. Invited experts will address the types of pediatric cardiovascular devices being developed, with a particular focus on mechanical circulatory support, current types of clinical assessments used in the pediatric population, and challenges that face this community. After each presentation, there will be a short question and answer session allowing workshop participants to interact with the speaker. A concluding session will allow for additional interactions with speakers.

Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at http://www.fda.gov/Medical Devices/NewsEvents/Workshops Conferences/default.htm.

Transcripts: Please be advised that as soon as a transcript is available, it can be obtained in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857. A transcript of the public workshop will be available on the Internet at http://www.fda.gov/MedicalDevices/News Events/WorkshopsConferences/default.htm.


Jeffrey Shuren,
Director, Center for Devices and Radiological Health.

FOR FURTHER INFORMATION CONTACT: Victoria Vargas, Ginnie Mae, 451 7th Street, SW., Room B–133, Washington, DC 20410; e-mail: victoria.vargas@hud.gov; telephone—(202) 475–6752; fax—(202) 485–0225 (this is not a toll-free number); the Ginnie Mae Web site at http://www.ginniemae.gov for other available information.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Ginnie Mae Multiclass Securities Program Documents (Forms and Electronic Data Submissions).

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Notice of Proposed Information Collection: Comment Request; Ginnie Mae Multiclass Securities Program Documents (Forms and Electronic Data Submissions)

AGENCY: Office of the President of Government National Mortgage Association (Ginnie Mae), HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments Due Date: April 5, 2010.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Leroy McKinney, Jr., QDAM, Information Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L’Enfant Plaza Building, Room 800a, Washington, DC 20410; e-mail Leroy.McKinney.jr@hud.gov; telephone (202) 708–5564. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. McKinney.