Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC. The meeting will be open to the public; however, seating is limited and pre-registration is encouraged (see below).

FOR FURTHER INFORMATION CONTACT: Roberta Lavin, Office of Human Services Emergency Preparedness and Response, e-mail *roberta.lavin@acf.hhs.gov* or (202) 401–9306.

SUPPLEMENTARY INFORMATION: The National Commission on Children and Disasters (henceforth ''the Commission'') is a commission that shall independently conduct a comprehensive study to examine and assess the needs of children as they relate to preparation for, response to, and recovery from all hazards, building upon the evaluations of other entities and avoiding unnecessary duplication by reviewing the findings, conclusions, and recommendations of these entities. The Commission shall then submit a report to the President, the Secretary of Health and Human Services, and the Congress on the Commission's independent and specific findings, conclusions, and recommendations to address the needs of children as they relate to preparation for, response to, and recovery from all hazards, including major disasters and emergencies. The Commission implements the intent of Congress as expressed in The Consolidated Appropriations Act, 2008 (Pub. L. 110–161), Division G, Title VI, (henceforth ''the Act'') signed into law on December 26, 2007, authorizing funds for a body performing the functions here assigned to the Commission.

The Commission will hear presentations on and discuss: (1) The Department of Health and Human Services' efforts to support the needs of children in disaster situations; (2) the Federal Emergency Management Administration's efforts to support the needs of children in disaster situations; (3) White House perspectives on the Administration's efforts to support the needs of children in disaster situations; and (4) plans for future work of the Commission.

The meeting will be open to the public; however, seating is limited and pre-registration is encouraged. To pre-register, please e-mail *carol.apelt@acf.hhs.gov* with ''Meeting Registration'' in the subject line, or call Carol Apelt at (202) 205–4618 by 5 p.m. EST, October 9, 2008. Registration must include your name, affiliation, phone number. If you require a sign language interpreter or other special assistance, please call Carol Apelt at (202) 205–4618 as soon as possible and no later than October 6, 2008.

Dated: September 24, 2008.

Charles Keckler,

Deputy Assistant Secretary for Policy for Children and Families.

[FR Doc. E8–22939 Filed 9–29–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0270] (formerly Docket No. 2007N–0357)

Medical Device User Fee and Modernization Act; Notice to Public of Web Location of 2009 Proposed Guidance Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the Web location where the agency will post a list of guidance documents the Center for Devices and Radiological Health (CDRH) is considering for development in fiscal year (FY) 2009. In addition, FDA has established a docket where stakeholders may provide comments and/or draft language for those topics as well as suggestions for new or different guidances.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written comments 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: Deborah A. Wolf, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–2350.

SUPPLEMENTARY INFORMATION:

I. Background

During negotiations over the reauthorization of the Medical Device User Fee and Modernization Act (MDUFMA), FDA agreed, in return for additional funding from industry, to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. These commitments include annually posting a list of guidance documents that CDRH is considering for development and providing stakeholders an opportunity to provide comments and/or draft language for those topics, or suggestions for new or different guidances. This notice announces the Web location of the list of guidances (see § 10.115(c)(1) (21 CFR 10.115(c)(1))) on which CDRH is intending to work over the next FY. We note that the agency is not required to issue every guidance on the list, nor is it precluded from issuing guidance documents that are not on the list. The list includes topics that currently have no guidance associated with them, topics where updated guidance may be helpful, and topics for which CDRH has already issued level 1 drafts that may be finalized following review of public comments. We will consider stakeholder comments as we prioritize our guidance efforts.

FDA and CDRH priorities are subject to change at any time. Topics on this and past guidance priority lists may be removed or modified based on current priorities. We also note that CDRH's experience over the years has shown that there are many reasons CDRH staff does not complete the entire annual agenda of guidances it undertakes. Staff are frequently diverted from guidance development to other activities, including review of premarket submissions or postmarket problems. In addition, the Center is required each year to issue a number of guidances that it cannot anticipate at the time the annual list is generated. These may involve newly identified public health issues as well as special control guidance documents for de novo classifications of devices. It will be helpful, therefore, to receive comments that indicate the relative priority of different guidance topics to interested stakeholders.

Through feedback from stakeholders, including draft language for guidance documents, CDRH expects to be able to better prioritize and more efficiently draft guidances that will be useful to industry and other stakeholders. This will be the second annual list CDRH has posted. FDA intends to update the list each year.

FDA invites interested persons to submit comments on any or all of the guidance documents on the list. FDA has established a specific docket (see docket number found in brackets in the heading of this document) where comments about the FY 2009 list, draft language for guidance documents on those topics, and suggestions for new or different guidances may be submitted. FDA believes this docket is an

important tool for receiving information from interested parties and for sharing this information with the public. Similar information about planned guidance development is included in the annual agency-wide notice issued by FDA under its good guidance practices (§ 10.115(f)(5)). The CDRH list, however, will be focused exclusively on device-related guidances and will be made available on FDA's Web site prior to the beginning of each FY from 2008 to 2012.

To access the list of the guidance documents CDRH is considering for development in 2009, visit the FDA Web Site at *http://www.fda.gov/cdrh/mdufma/guidance/agenda/fy09.html*.

II. Request for 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. Comments submitted to this docket may include draft guidance documents that stakeholders have prepared for FDA's consideration.

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: September 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–22911 Filed 9–29–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Antiviral Drugs 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Antiviral Drugs 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 October 30, 2008, from 9 a.m. to 1 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 1750 Rockville Pike, Rockville, MD, 301–468–1100.

Contact Person: Paul Tran, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–6793, FAX: 301–827–6776, e-mail: *paul.tran@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512531. 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: The meeting will be open to the public from 8 a.m. to 9 a.m., unless public participation does not last that long, from 9 a.m. to 1 p.m., the meeting will be closed to permit discussion of current and future advances on antiviral drugs which will include the review of trade secret and/or confidential information.

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/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: On October 30, 2008, from 8 a.m. to 9 a.m., the meeting is open to the public. 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 October 16, 2008. Oral presentations from the public will be scheduled between approximately 8 a.m. and 9 a.m. 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 October 7, 2008. 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 October 8, 2008.

Closed Committee Deliberations: On October 30, 2008, from 9 a.m. to 1 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). During this session, the committee will be updated on current and future advances on antiviral drugs.

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 Paul Tran 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/oc/advisory/default.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: September 19, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–22912 Filed 9–29–08; 8:45 am]

BILLING CODE 4160–01–S