

V. Responsiveness Criteria

Each application submitted will be screened to determine whether it was received by the closing date and time. Applications received by the closing date and time will be screened for completeness and conformity with the requirements outlined in Sections III and IV of this Notice and the Program Announcement. Only complete applications that meet these requirements will be considered for funding.

VI. Application Review Information

Not Applicable.

VII. Agency Contacts

Direct inquiries regarding programmatic issues to U.S. Department of Health and Human Services, Administration on Aging, Office for American Indian, Alaskan Native and Native Hawaiian Programs, Washington, DC 20201, telephone: (202) 357-3501.

Dated: October 18, 2007.

Josefina G. Carbonell,

Assistant Secretary for Aging.

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BILLING CODE 4154-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Endocrinologic and Metabolic 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). The meeting will be open to the public.

Name of Committees:

Nonprescription Drugs Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee.

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

Date and Time: The meeting will be held on December 13, 2007, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/ Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is 301-589-5200.

Contact Person: Diem-Kieu Ngo, 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, 301-827-7001, FAX: 301-827-6776, e-mail: diem.ngo@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), codes 3014512541 and 3014512536. 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 committees will evaluate data submitted by Merck & Co., Inc., to support the over-the-counter use of MEVACOR (lovastatin) 20 milligrams (mg) a day to help lower cholesterol which may prevent a first heart attack.

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 2007 and 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 November 29, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.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 November 15, 2007. 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 November 16, 2007.

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 Diem-Kieu Ngo 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: October 17, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7-20855 Filed 10-22-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products 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: Vaccines and Related Biological Products 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 by teleconference on November 14, 2007, from 1 p.m. to approximately 4:30 p.m.

Location: National Institutes of Health, Building 29B, Conference Rooms A/B, Bethesda, MD. This meeting will be held by teleconference. The public is welcome to attend the meeting at the specified location where

a speaker phone will be provided. Public participation in the meeting is limited to the use of the speaker phone in the conference room. Important information about transportation and directions to the National Institutes of Health (NIH) campus, parking, and security procedures is available on the Internet at <http://www.nih.gov/about/visitor/index.htm>. Visitors must show two forms of identification, one of which must be a government issued photo identification such as a Federal employee badge, driver's license, passport, green card, etc. If you are planning to drive to and park on the NIH campus, you must enter at the South Dr. entrance of the campus which is located on Wisconsin Ave. (the Medical Center Metro entrance), and allow extra time for vehicle inspection. Detailed information about security procedures is located at <http://www.nih.gov/about/visitorsecurity.htm>. Due to the limited available parking, visitors are encouraged to use public transportation.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD, 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512391. 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 November 14, 2007, the committee will meet in open session to hear updates of the research programs in: (1) The Laboratory of Method Development, Division of Viral Products, Center for Biologics Evaluation and Research, FDA and (2) the Laboratory of Mycobacterial Diseases & Cellular Immunology, Division of Bacterial Parasitic & Allergenic Products, Center for Biologics Evaluation and Research, FDA.

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 2007 and scroll down to the appropriate advisory committee link.

Procedure: On November 14, 2007, from 1 p.m. to approximately 3:30 p.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 November 7, 2007. Oral presentations from the public will be scheduled between approximately 2:30 p.m. and 3:30 p.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 30, 2007. 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 31, 2007.

Closed Committee Deliberations: On November 14, 2007, from approximately 3:30 p.m. to 4:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of intramural research programs and make recommendations regarding personnel staffing decisions.

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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.

Dated: October 17, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0401]

Guidance for Industry, Food and Drug Administration, and Foreign Governments; Fiscal Year 2008 Medical Device User Fee Small Business Qualification and Certification; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "FY 2008 Medical Device User Fee Small Business Qualification and Certification." This guidance explains how a business headquartered in the United States or headquartered in a foreign nation may respectively qualify as "small business" under the medical device user fee provisions of the Federal Food, Drug, and Cosmetic Act (the act). A "small business" may pay certain medical device user fees at a substantial discount from the standard (full) fee rates and may obtain a one-time fee waiver for its first premarket application (a premarket approval application (PMA), biologics license application (BLA), product development protocol (PDP), or premarket report (PMR)).

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 "FY 2008 Medical Device User Fee Small Business Qualification and Certification" 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.