based on internal pilot testing of the survey instrument at the agency.

Dated: April 24, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–6461 Filed 4–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Research Review Subcommittee of the 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 the Subcommittee: Research Review Subcommittee of the 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 on May 19, 2006, from 8 a.m. to 4:30 p.m.

Location: Hilton Hotel, Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

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.

Agenda: On May 19, 2006, the subcommittee will listen to presentations about the research program at the Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER). The program is intended to provide dynamic, responsive, cutting edge research to contribute to OVRR's regulatory mission and facilitate development of safe and effective biological products. The subcommittee will discuss the program and make recommendations to the Vaccines and Related Biological Products Advisory Committee at a future open meeting of the full committee. Information regarding CBER's scientific program is outlined in its Strategic Plan of 2004 and is available to the public on the Internet at: *http://www.fda.gov/cber/inside/mission.htm*. Information regarding FDA's Critical Path to New Medical Products is available to the public on the Internet at: *http://www.fda.gov/oc/initiatives/criticalpath/*.

Procedure: On May 19, 2006, from 8 a.m. to 1 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 by May 12, 2006. Oral presentations from the public will be scheduled between approximately 12 p.m. to 1 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 12, 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.

Closed Committee Deliberations: On May 19, 2006, from 2 p.m. to 4:30 p.m., the meeting will be closed to the public. 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) and to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4). The subcommittee will discuss internal research programs in the Office of Vaccines Research and Review, CBER.

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 Christine Walsh or Denise Royster 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 21, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–6508 Filed 4–28–06; 8:45 am]

BILLING CODE 4160–01–S

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). The meeting will be open 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 on May 18, 2006, from 9 a.m. to 4:45 p.m.

Location: Hilton Hotel, Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

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.

Agenda: The committee will hear presentations and make recommendations on the safety and efficacy of GARDASIL (Human Papillomavirus [Types 6,11,16,18] Recombinant Vaccine) manufactured by Merck.

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 11, 2006. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral

presentations should notify the contact person before May 11, 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 Christine Walsh or Denise Royster 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 24, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–6509 Filed 4–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0401]

Guidance for Industry and Food and Drug Administration Staff: Compliance With the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices.'' The Medical Device User Fee and Modernization Act 2002 (MDUFMA), as amended by the Medical Device User Fee Stabilization Act of 2005 (MDUFSA), requires that FDA issue guidance identifying the circumstances in which the name, abbreviation, or symbol of the manufacturer of an original device is not ''prominent and conspicuous.'' MDUFSA requires that FDA issue guidance no later than 180 days after the date of enactment (August 1, 2005).

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 on a 3.5'' diskette of the guidance document entitled ''Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices'' 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: Casper E. Uldriks, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0106.

SUPPLEMENTARY INFORMATION:

I. Background

MDUFMA (Public Law 107–250) amended section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352) to require a device, or an attachment to the device, to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer. This labeling provision applied to all devices and all device manufacturers.

On August 1, 2005, MDUFSA (Public Law 109–43) amended section 502(u) of the act by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Therefore, section 502(u) of the act, as amended by MDUFSA, no longer sets forth requirements for original equipment manufacturers, unless they also reprocess SUDs. Under the amended provision, if an original device or an attachment to it does not prominently and conspicuously bear the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, the manufacturer who reprocesses the SUD may identify itself using a detachable label on the packaging of the device.

Section 2(c)(2) of MDUFSA requires that FDA issue guidance not later than 180 days after the date of its enactment to identify the circumstances under which the identifying mark of a manufacturer of an original device is not ''prominent and conspicuous,'' as used in section 502(u) of the act. On October 11, 2005, FDA issued draft guidance describing the circumstances under which the agency would not consider a manufacturer's mark to be prominent and conspicuous. FDA received several comments on the draft guidance, all of which were considered in finalizing the guidance.

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 ''Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices.'' 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

To receive '' Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices'' by fax, 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 (1217) 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,