

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.

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.

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.*

[FR Doc. E7-20854 Filed 10-22-07; 8:45 am]

BILLING CODE 4160-01-S

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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.

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> or <http://www.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**  
Joseph V. Puleo, Center for Devices and

Radiological Health (HFZ-220), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3150, ext. 116, e-mail: [joseph.puleo@fda.hhs.gov](mailto:joseph.puleo@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

“FY 2008 Medical Device User Fee Small Business Qualification and Certification” explains how a business headquartered in the United States or headquartered in a foreign nation may

qualify as “small business” under the medical device user fee provisions of the act (21 U.S.C. 301). 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 PMA, BLA, PDP, or PMR). The following fees apply for fiscal year (FY) 2008:

Application Type	FY 2008	
	Standard Fee	Small Business
Premarket application (PMA, BLA, PDP, or PMR)	\$185,000	\$46,250
Panel-track PMA supplement	\$138,750	\$34,688
BLA efficacy supplement	\$185,000	\$46,250
180-day PMA supplement	\$27,750	\$6,938
Real-time PMA supplement	\$12,950	\$3,238
510(k) premarket notification	\$3,404	\$1,702
30-day notice	\$2,960	\$1,480
513(g) request	\$2,498	\$1,249
Periodic reporting on a class III device	\$6,475	\$1,619
Establishment registration	\$1,706	

To qualify as a “small business,” the business must have “gross receipts or sales” of no more than \$100 million in the most-recent tax year, including the “gross receipts or sales” of all of the business’ affiliates (see sections 738(d)(2)(A) and (e)(2)(A) of the act (21 U.S.C. 379j(d)(2)(A) and (e)(2)(A))). An affiliate is defined by section 737(12) of the act (21 U.S.C. 379i(12)) as a business entity that has a relationship with a second business entity if, directly or indirectly—

“(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.”

A business headquartered in the United States must demonstrate that it meets the \$100 million threshold by submitting a certified copy of its most-recent Federal (U.S.) income tax return. A business headquartered outside the United States must demonstrate that it meets the \$100 million threshold by submitting a National Taxing Authority Certification from the foreign equivalent of the U.S. Internal Revenue Service. Under the guidance, both U.S. and foreign businesses should provide FDA with contact information, identify all of

their affiliates, and certify that the information they provide to FDA is complete and accurate.

FDA is making this final guidance document immediately available. Prior public participation is not feasible because it implements statutory requirements that require immediate implementation. This guidance is necessary to help effect such implementation.

**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 FY 2008 medical device user fee small business qualification and certification. 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 “FY 2008 Medical Device User Fee Small Business Qualification and Certification,” you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov)

to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 2008 to identify the guidance you are requesting.

Persons interested in obtaining a copy of the guidance may 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 USC 3501–3520). The collections of information in this guidance were approved under OMB control number 0910–0613 (approval expires April 16, 2008).

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in Form FDA 3602 have been approved under OMB Control No. 0910–0508 (approval expires January 31, 2010).

**V. 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.

Dated: October 18, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 07–5226 Filed 10–18–07; 3:08 pm]

**BILLING CODE 4160–01–S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Heart, Lung, and Blood Institute; Notice of Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting 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 would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Heart, Lung, and Blood Advisory Council.

*Date:* October 30, 2007.

*Open:* 8 a.m. to 12 p.m.

*Agenda:* To discuss program policies and issues.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

*Closed:* 1 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

*Contact Person:* Stephen Mockrin, PhD, Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7100, Bethesda, MD 20892, (301) 435–0260.

*mockrins@nhlbi.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to administrative errors.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: [www.nhlbi.nih.gov/meetings/index.htm](http://www.nhlbi.nih.gov/meetings/index.htm), where an agenda and any additional information for the meeting will be posted when available.

(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 Institutes of Health, HHS)

Dated: October 18, 2007.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 07–5252 Filed 10–22–07; 8:45 am]

**BILLING CODE 4140–01–M**

**DEPARTMENT OF THE INTERIOR****Bureau of Land Management****DEPARTMENT OF AGRICULTURE****Forest Service**

[NV–912–07–1220PA–006F]

**Notice of Public Meeting: Recreation Subcommittee Meeting of the Bureau of Land Management, Nevada, Sierra Front-Northwestern Great Basin, Northeastern Great Basin and Mojave-Southern Great Basin Resource Advisory Councils**

**AGENCIES:** Bureau of Land Management, Interior and Forest Service, Agriculture.

**ACTION:** Recreation Subcommittee Meeting.

**SUMMARY:** In accordance with the Federal Lands Recreation Enhancement Act of 2004 (FLREA), the Recreation Subcommittee will hold a meeting to finalize draft protocol and guidelines and to discuss membership needs for fiscal year 2008.

**DATES:** Wednesday, November 14, 2007, from 1 p.m. to 3 p.m. A public comment period will begin at 2:30 p.m.

**ADDRESSES:** Meeting place will be the Bureau of Land Management, Carson City Field Office, 5665 Morgan Mill Road, Carson City, Nevada.

**FOR FURTHER INFORMATION CONTACT:** Doran Sanchez, Chief, Office of Communications, (775) 861–6586, or Barbara Keleher, Outdoor Recreation Planner, (775) 861–6628, at the BLM Nevada State Office, 1340 Financial Blvd., Reno, Nevada.

**SUPPLEMENTARY INFORMATION:** The Federal Lands Recreation Enhancement Act (REA; Pub. L. 108–447), enacted on December 8, 2004, directs the Secretaries of the Interior or Agriculture, or both, to establish Recreation Resource Advisory Committees to provide advice and recommendations on recreation fees and fee areas in each State or region for Federal recreational lands and waters managed by the Bureau of Land Management (BLM) or Forest Service. The law allows the agencies to use existing Resource Advisory Councils (RACs) or to establish new Recreation RACs. For Nevada, a recreation subcommittee of three existing RACs has been designated to perform Recreation Resource Advisory Committee responsibilities pertaining to both BLM and Forest Service managed Federal lands and waters per the national interagency agreement between BLM and the Forest Service. This subcommittee will recommend new