

approximately 1,400, audit reports to be submitted.

Because FDA expects that the vast majority of manufacturers who will participate in the Voluntary Audit Report Submission Program will be manufacturers certified by Health Canada under ISO 13485:2003, FDA expects the number of reports to be submitted from manufacturers certified by regulatory systems established by other founding GHTF members to be minimal. For purposes of calculating the reporting burden, FDA estimates that approximately 10 percent of total audit reports submitted under this program will be from these other manufacturers. Because 90 percent of the audit reports are expected to be submitted by manufacturers certified by Health Canada (approximately 1,400 audit reports as calculated previously in this document), the total number of audit reports FDA expects to receive in a year is 1,556, or approximately 1,600 audit reports.

FDA estimates from past experience with the Electronic Submission Gateway system, WebTrader, that the first year to set up the account and to receive the verification certificate takes approximately 40 hours. This burden may be minimized if the Respondent

already has an established account in WebTrader for other electronic submissions to FDA but FDA is assuming that all respondents to this new pilot program will be setting up a WebTrader account for the first time in the first year. For subsequent years, the estimate burden hours are estimated at 1 hour to renew the yearly required verification certification.

FDA further estimates that the gathering, scanning, and submission of the audit reports, certificates, and related correspondence would take approximately 2 hours utilizing the eSubmitter system.

Therefore, the first year will include 40 hours for the WebTrader system plus 2 hours for the eSubmitter submission process, resulting in 42 hours per response for the first year. For both the second and third years, it is estimated that only 1 hour will be necessary for the WebTrader system plus the 2 hours for the eSubmitter submission process, resulting in 3 hours per response each year thereafter.

The draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in

21 CFR part 820 have been approved under OMB control number 0910–0073 and the collections of information for the Inspection by Accredited Persons Program have been approved under OMB control number 0910–0569.

In the **Federal Register** of May 20, 2010 (75 FR 28257), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment which was related to the PRA reporting burden.

The comment stated that the reporting burden hours may be too low for the first submission and may take less time for subsequent submissions. In addition, this comment stated that the number of reports anticipated to be submitted may be a high estimate by a factor of 10. FDA appreciates the consideration of burden hours by the comment. The comment, however, did not provide any data to assist FDA to adjust the burden hours for the submission. Absent baseline information at this time, FDA will review the submissions during the pilot period and modify the burden to respondents accordingly.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN

	No. of respondents	No. of responses per respondent per year	Total annual responses	Average burden per response (in hours)	Total hours	Capital and operating and maintenance costs
First year .....	1,600	1	1,600	142	67,200	2,016,000
Second year (recurring) .....	1,600	1	1,600	3	4,800	48,000
Third year (recurring) .....	1,600	1	1,600	3	4,800	48,000
Totals .....					76,800	2,112,000

<sup>1</sup>Respondent may already have a valid WebTrader account established for other FDA electronic submissions.

There are capital, start-up, operating, or maintenance cost associated with this information collection. The costs are \$30 per year to establish and maintain the Electronic Submission Gateway verification certificate.

Dated: July 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2011–N–0478]

#### General and Plastic Surgery Devices Panel of the Medical Devices 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:* General and Plastic Surgery Devices Panel of the Medical Devices 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 August 30 and 31, 2011, from 8 a.m. to 6 p.m.

*Addresses:* FDA is opening a docket for public comment on this document. The docket will open for public comment on July 7, 2011. The docket will close on August 26, 2011. Interested persons may submit electronic or written comments regarding this document. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets

Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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.

*Location:* Hilton Washington DC North/Gaithersburg, Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

*Contact Person:* Margaret McCabe-Janicki, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring, MD 20993-0002, 301-796-7029, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. 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 August 30 and 31, 2011, the committee will discuss and make recommendations on postmarketing issues related to silicone gel-filled breast implants. This meeting is regarding the discussion of different innovative methodological approaches to the conduct of postmarket studies regarding silicone gel breast implants. Additionally, the panel will discuss key long-term safety issues associated with silicone gel breast implants in the real-world setting.

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 August 24, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 3 p.m. on August 30, 2011, and between approximately 8 a.m. and 10 a.m. on August 31, 2011. Those individuals interested in making 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 August 15, 2011. 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 August 17, 2011.

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 AnnMarie Williams, Conference Management Staff, 301-796-5966, 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/AboutAdvisoryCommittees/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: June 23, 2011.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2011-16952 Filed 7-6-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### Design of Clinical Trials for Systemic Antibacterial Drugs for the Treatment of Acute Otitis Media; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop regarding the design of Clinical Trials for Systemic Antibacterial Agents for the Treatment of Acute Otitis Media. This public workshop is intended to provide information for and gain perspective from health care providers, patients and patient advocacy organizations, academia, and industry on various aspects of the design of clinical trials. The input from this public workshop will help in developing topics for further discussion.

*Dates and Times:* The public workshop will be held on September 7, 2011 from 8:30 a.m. to 5 p.m.

*Location:* The public workshop will be held at the Crowne Plaza, 8777 Georgia Ave., Silver Spring, MD 20910, 301-589-0800. Seating is limited and available only on a first-come, first-served basis.

*Contact Persons:* Christine Moser or Ramou Mauer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6193, Silver Spring, MD 20993-0002, 301-796-1300.

*Registration:* Registration is free for the public workshop. Interested parties are encouraged to register early. Seating will be available on a first-come, first-served basis. To register electronically, e-mail registration information (including name, title, firm name, address, telephone, and fax number) to [Otitisworkshop@fda.hhs.gov](mailto:Otitisworkshop@fda.hhs.gov). Persons without access to the Internet may call 301-796-1300 to register. Persons needing a sign language interpreter or other special accommodations should notify Christine Moser or Lori Benner (see *Contact Persons*) at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** FDA is announcing a public workshop regarding scientific considerations in the design of clinical trials of antibacterial agents for the treatment of acute otitis media (middle ear infection). Discussions will focus on