TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
860.133	11	1	11	500	5,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on current trends, FDA anticipates that 11 petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a reclassification petition, have consulted and advised manufacturers on these requirements and have reviewed the documentation submitted.

Dated: September 13, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–24237 Filed 9–16–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2874]

Development of Guidance Documents for Medical Devices Regulated by the Center for Biologics Evaluation and Research; Stakeholders Input Under FDA Modernization Act of 1997; Public Meeting and Teleconference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and teleconference entitled ''Development of Guidance Documents for Medical Devices Regulated by the Center for Biologics Evaluation and Research-Stakeholders Input Under FDA Modernization Act of 1997.'' The goals of the public meeting and teleconference are to explain to stakeholders the process and development of medical device guidance documents under good guidance practices (GGP's) and how to participate in both processes and to give stakeholders the opportunity to provide input on what they think the Center for Biologics Evaluation and Research's (CBER's) priorities should be regarding medical devices regulated by CBER. The agency is also requesting comments prior to the meeting, from stakeholders on proposals of priorities for development of guidance documents related to CBER-regulated medical devices.

DATES: The meeting will be held on November 15, 1999, 1 p.m. to 4 p.m. (Eastern Time). The teleconference will be held on the same day. See Table 1 in section III of this document for the scheduled times and locations of the teleconference. The deadline for registration for the meeting or teleconference is November 8, 1999. Comments are requested before the meeting by October 1, 1999, or after the meeting by December 15, 1999.

ADDRESSES: The meeting will be held at the Masur Auditorium, National Institutes of Health, 9000 Rockville Pike, Bldg. 10, Bethesda, MD. See Table 1 in section III of this document for the scheduled locations of the teleconference. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Melanie N. Whelan, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3841, FAX 301–827–3079, or e-mail ''Whelan@CBER.FDA.GOV''.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 406(b) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (21 U.S.C. 393(f) and (g)), CBER held a series of public meetings to discuss its statutory obligations under FDAMA for biologics. The meetings were held in Washington, DC, on August 14, 1998 (63 FR 39877, July 24, 1998); in Oakland, CA, on August 28, 1998; in Bethesda, MD, on December 1, 1998 (63 FR 58743, November 2, 1998); and in San Francisco, CA, and Boston, MA, on April 28, 1999 (64 FR 13804, March 22, 1999). The FDA Pacific Regional Office sponsored a grassroots meeting on September 15, 1998 (63 FR 42052, August 6, 1998), in Irvine, CA, with the biotechnology industry.

At some of the earlier public meetings, a recurring theme was dissatisfaction with the handling of medical devices regulated by CBER. Important concerns were related to CBER procedures and standards for medical device products similar to products regulated by the Center for Devices and Radiological Health (CDRH). In response to these concerns, CBER developed the Device Action Plan in order to facilitate the implementation of the device provisions of FDAMA and to ensure consistency of policy and procedures between CBER and CDRH. CBER announced the completed Device Action Plan at the CBER Stakeholders Meetings held in San Francisco, CA, and Boston, MA, on April 28, 1999 (64 FR 13804, March 22, 1999). The following issues have been outlined in the Device Action Plan: (1) Compliance and team biologics issues (application of certain good manufacturing practices (GMP's) and compliance policy), (2) enhancing communication with industry and within FDA, (3) coordination with CDRH, and (4) improvement of device review performance. The Device Action Plan has been posted on the CBER web site at ''http://www.fda.gov/cber/dap/dap.htm''.

The public meeting and teleconference will be gathering information on all medical devices including those regulated under the Federal Food, Drug, and Cosmetic Act and those licensed under the Public Health Service Act. The public meeting and teleconference announced in this notice is intended to: (1) Explain to stakeholders the process and development of medical device guidance documents under GGP's and how they can participate in both processes, and (2) give stakeholders the opportunity to provide input on what they think CBER's priorities should be regarding the development of guidance documents related to medical devices regulated by CBER.

In preparation for the November 15, 1999, public meeting, FDA is soliciting comments from stakeholders on proposals of priorities for development

of guidance documents related to medical devices regulated by CBER.

II. Comments

Written comments should be identified with the docket number found in brackets in the heading of this document and submitted to the Dockets Management Branch (address above). All comments should be identified with the docket number found in brackets in the heading of this document. Stakeholders are encouraged to submit their written comments by Friday, October 1, 1999, in order to have the comments addressed at the meeting. Written comments may also be submitted after the meeting to the Dockets Management Branch (address above) by December 15, 1999. Two copies of any comments should be submitted, except that individuals may submit one copy. Received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

III. Scheduled Meetings

The teleconference will be held in several locations throughout the country. The scheduled times and locations are listed as follows:

TABLE 1.—TELECONFERENCE SCHEDULES

Address/Food and Drug Administration (FDA) District	Scheduled Time of Teleconference
Denver District: Sixth & Kipling Sts., Denver Federal Center, Bldg. 20, rm. B1409, Denver, CO 80225–0087	11 a.m. to 2 p.m. Mountain Time.
San Francisco District: 1431 Harbor Bay Pkwy., Alameda, CA 94502	10 a.m. to 1 p.m. Pacific Time.
Los Angeles District: 19900 MacArthur Blvd., suite 300, Irvine, CA 92715–2445	10 a.m. to 1 p.m. Pacific Time.
Minneapolis District: 240 Hennepin Ave., Minneapolis, MN 55401	12 noon to 3 p.m. Central Time.
New England District: One Montvale Ave., Fourth Floor, Stoneham, MA 02180	1 p.m. to 4 p.m. Eastern Time.

IV. Registration

Send registration information (including name, title, firm name, address, telephone, and fax number) for the public meeting or teleconference, by mail, fax or e-mail to the contact person by Monday, November 8, 1999. Registration at the site will be done on a space available basis on the day of the meeting. There is no registration fee for the meeting. Space is limited, therefore, interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact Melanie N. Whelan (address above) at least 7 days in advance.

V. Transcripts

Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript of the meeting will also be available on the CBER web site at ''http://www.fda.gov/cber/minutes/workshop-min.htm''.

Dated: September 10, 1999

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–24236 Filed 9–16–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–3089]

Draft Affirmative Agenda for International Activities—Center for Food Safety and Applied Nutrition; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the document entitled ''Draft Affirmative Agenda for International Activities'' (Draft International Affirmative Agenda) for FDA's Center for Food Safety and Applied Nutrition (CFSAN). The Draft International Affirmative Agenda presents, consistent with the center's mission and resources, CFSAN's international priorities for the next 3 years (2000–2002).

DATES: Written comments by November 1, 1999.

ADDRESSES: The Draft International Affirmative Agenda is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.1061, Rockville, MD 20852. To view the document electronically or to print copies: World Wide Web at ''http://vm.cfsan.fda.gov/''.

FOR FURTHER INFORMATION CONTACT: To obtain a single copy of the Draft International Affirmative Agenda: John W. Jones, Office of Constituent Operations, Center for Food Safety and Applied Nutrition (HFS–550), 200 C St. SW., Washington, DC 20204, 202–205–4311.

SUPPLEMENTARY INFORMATION:

I. Background

CFSAN participates in numerous international activities pertaining to the safety, quality, and labeling of foods and cosmetics. These activities are intended, first and foremost, to enhance FDA's ability to ensure that foods and cosmetics available to American consumers are safe and appropriately labeled, whether the products are produced in or imported into the United States.

The international environment in which CFSAN operates has changed dramatically in the last 20 years. International trade in foods and cosmetics has grown markedly and international trade agreements have introduced new requirements that affect FDA's traditional approaches for regulating such products. Furthermore, resources available for CFSAN to accomplish its international activities are finite and limited.

Thus, CFSAN must establish priorities that are consistent with FDA's mission and resources. CFSAN's Draft International Affirmative Agenda is intended to present achievable, international priorities for the next 3 years for those areas where it is critical for the safety and regulation of foods and/or cosmetics that the center maintain a strong presence.

CFSAN is actively seeking comments on this Draft International Affirmative Agenda and will, if interest is sufficient, consider holding a public meeting to enable further dialogue on its contents. The center would appreciate hearing in the next two weeks from persons regarding the need for a public meeting on the draft document. Comments on the document, itself, may be submitted within the next 45 days.

II. Comments

Interested persons may, on or before November 1, 1999, submit to the Dockets Management Branch (address above) written comments on the draft document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets at the head of this notice. Received comments may be seen in the office above between 9 a.m. and 4 p.m. Monday through Friday.