7. Currently, the vast majority of the agency's international resources are devoted to detecting and stopping product problems at the border, while developing the capability to allow safe products to go forward quickly. A smaller percentage of FDA's international resources are dedicated to working with other countries through our participation in international standard setting, developing mutual recognition agreements between the United States and other nations, and offering technical assistance to the public sector regulators and private sector producers of other countries. Do you think that the American consumer is adequately protected with this balance of activities?

II. Comments

Written comments should be identified with the docket number found in brackets in the heading of this document and should be submitted by September 21, 1998, to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments can be sent to the Dockets Management Branch at the following e-mail address ''FDADockets@bangate.fda.gov'' or via the FDA website ''http://www.fda.gov''.

The FDA website provides substantive background information. It is strongly recommended that those individuals or groups who wish to make a presentation or submit written comments consult the FDA website ''http://www.fda.gov'' for additional information. For pertinent information not on the website, consult with the designated contact person listed in this document.

Individuals who wish to present at this public meeting are encouraged to attend the entire day. Information will be presented throughout the meeting about cross-cutting issues and themes related to the FDA plan that will be derived from stakeholder input. This meeting will provide an opportunity for an open comment session in which attendees can express their views.

III. Additional Meetings

FDA held a series of public meetings to discuss the FDAMA objectives, within the context of its statutory obligations for foods, biologics, human drugs, medical devices, and veterinary medicine, as described in section I of this document. The public meeting for the Center for Food Safety and Applied Nutrition (CFSAN) was held on June 24 and 25, 1998. A summary of the views presented at the CFSAN meeting is available on the CFSAN website ''http://www.cfsan.fda.gov''. For more information on the CFSAN meeting, contact Tracy S. Summers, Center for Food Safety and Applied Nutrition (HFS–1), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4850, FAX 202–205–5025, e-mail ''tsummers@bangate.fda.gov''.

The other meetings were held in Washington, DC on August 14, 1998 (Biologics); August 17, 1998 (Human Drugs); August 18, 1998 (Medical Devices); and August 19, 1998 (Veterinary Medicine); and in Oakland, CA on August 28, 1998 (Biologics). For additional information about these meetings, please refer to the **Federal Register** of July 24, 1998 (63 FR 39877) or the FDA website ''http://www.fda.gov''.

IV. Transcripts

The transcript of this 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 be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA website ''http://www.fda.gov''.

Dated: August 11, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–22391 Filed 8–19–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0339]

Public Meeting on Section 406(b) of the FDA Modernization Act of 1997

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing a meeting with health professional organizations on section 406(b) of the FDA Modernization Act of 1997 (FDAMA) to discuss how FDA can best meet its statutory obligations under the Federal Food, Drug, and Cosmetic Act (the act). The agency intends to involve participants from health professional organizations in drafting FDA's developmental plan to meet the objectives of FDAMA.

Date and Time: The meeting will be held on Tuesday, September 8, 1998, 1 p.m. to 4 p.m.

Location: The meeting will be held at the Hyatt Regency Hotel, One Metro Center, Bethesda, MD.

Contact: Elizabeth B. Palsgrove, Office of Health Affairs (HFY–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6618, FAX 301–443–2446, or 1–800–433–3332, e-mail ''epalsgro@bangate.fda.gov''.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, e-mail, and fax number), and written material and requests to make oral presentations, to the designated contact person listed in this document. There is no registration fee, however, space is limited. Persons will be registered in the order in which registration is received.

If you need special accommodations due to a disability, please contact Elizabeth B. Palsgrove at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 406(b) of FDAMA, the agency is required to consult with its external stakeholders, specifically ''appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry.'' Following these consultations, FDA is to develop and publish a plan for achieving compliance with each of its obligations under the act.

Under section 406(b) of FDAMA, the plan, which must be published in the **Federal Register** by November 21, 1998, should address, but may not be confined to, the following six objectives: (1) Maximizing the availability and clarity of information about the agency application and submission review processes; (2) maximizing the availability and clarity of information for consumers and patients concerning new products; (3) implementing inspection and postmarket monitoring provisions of the act; (4) assuring access to the scientific and technical expertise needed to carry out FDA's obligations; (5) establishing mechanisms, by July 1, 1999, for meeting specified time periods for the review of applications and submissions; and (6) eliminating backlogs in the review of applications and submissions.

To help focus comments, FDA requests that oral and/or written views

regarding how the agency can best meet these six objectives of its modernization plan address seven questions. An information packet, available on the FDA webpage or from the designated contact person listed in this document, provides substantive background information; it is highly recommended that those individuals or groups who wish to make a presentation or submit written comments obtain this packet. Specific questions relate to each objective as follows:

1. What can FDA do to improve its explanation of the agency's submission review processes, and make explanations more available to product sponsors and other interested parties?

2. How can the agency maximize the availability and clarity of information concerning new products?

3. How can FDA work with its partners to ensure that products—both domestic and foreign—produced and marketed by the regulated industry are of high quality and provide necessary consumer protection; and how can FDA best establish and sustain an effective, timely, and science-based postmarketing surveillance system for reporting, monitoring, evaluating, and correcting problems associated with use/consumption of FDA-regulated products?

4. What approach should FDA use to assure an appropriate scientific infrastructure, with continued access to the scientific and technical expertise needed to meet its statutory obligations and strengthen its science-based decisionmaking process?

5. What do you believe FDA should do to adequately meet the demands that are beginning to burden the application review process, especially for non-user fee products, so that it can meet its statutory obligations to achieve timely product reviews?

6. What suggestions do you have for the agency to eliminate backlogs in the review process?

7. What other objectives related to the agency's statutory obligations or public expectations—beyond the six objectives—should be included in the FDA plan?

II. Comments

Written comments should be identified with the docket number found in brackets in the heading of this document and should be submitted by September 11, 1998, to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments can be sent to the Dockets Management Branch at the following e-mail address ''FDADockets@bangate.fda.gov'' or via the FDA website ''http://www.fda.gov''.

III. Additional Meetings

This meeting is related to a series of other public meetings held that were announced in the **Federal Register** of July 24, 1998. A separate FDAMA section on the FDA website is available for information about these public meetings.

An additional public meeting is being planned for September 14, 1998, to obtain stakeholder views on potential recurring themes and the best approach for consolidating these themes agencywide. A separate notice of this meeting will be published in the **Federal Register**.

IV. Transcripts

Transcripts of these meetings 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 be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA website ''http://www.fda.gov''.

Dated: August 13, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–8003 and HCFA–R–185]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Home and Community-Based Services Waiver Requests and Supporting Regulations in 42 CFR 440.180–.185, and 441.301–441.310; *Form No.:* HCFA–8003 (OMB# 0938–0449); *Use:* Under a Secretarial waiver, States may offer a wide array of home and community-based services to individuals who would otherwise require institutionalization. States requesting a waiver must provide certain assurances, documentation and cost & utilization estimates which are reviewed, approved and maintained for the purpose of identifying/verifying States' compliance with such statutory and regulatory requirements. The purpose of this request is to provide authority for the State to furnish such individuals with services in the home and community-based setting; *Frequency:* When a State requests a waiver or amendment to a waiver; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 50; *Total Annual Responses:* 140; *Total Annual Hours:* 8,220.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and of CLIA Exemption Under State Laboratory Programs and Supporting Regulations in 42 CFR 493.501, 493.506, 493.513, and 493.515; *Form No.:* HCFA–R–185 (OMB# 0938–0686); *Use:* The information required is necessary to determine whether a private accreditation organization/State licensure program standards and accreditation/licensure process is equal to or more stringent than those of CLIA. This information also provides a CLIA exemption of laboratories in a State that applies licensure requirements that are equal to or more stringent than those of CLIA; *Frequency:* Initial Application/as needed; *Affected Public:* Not-for-profit institutions, and State, Local, or Tribal Government; *Number of Respondents:* 22; *Total Annual Responses:* 11; *Total Annual Hours:* 2,112.

To obtain copies of the supporting statement and any related forms for the