MD 20857, approximately 15 working days after the forum, at a cost of 10 cents per page.

Dated: August 11, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–22392 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 the following meeting: Public Meeting on Section 406(b) of the FDA Modernization Act of 1997 (FDAMA). The topic to be discussed is how FDA can best meet its statutory obligations under the Federal Food, Drug, and Cosmetic Act (the act). The meeting is intended to involve participants from consumer and patient advocacy groups, health professionals, scientific and academic experts, and the regulated industry in drafting FDA's developmental plan to meet the objectives of FDAMA.

Date and Time: The meeting will be held on Monday, September 14, 1998, 9 a.m. to 5 p.m.

Location: The meeting will be held at Bethesda Holiday Inn, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact: Patricia M. Kuntze, Office of External Affairs (HF–60), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3363, FAX 301–594–0113, or e-mail ''PKuntze@bangate.fda.gov''.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person by Monday, August 31, 1998.

If you need special accommodations due to a disability, please contact Patricia M. Kuntze 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 statutory obligations.

Section 406(b) of FDAMA further requires that 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.

The agency held a series of public meetings to obtain public views on how FDA can best meet its statutory obligations related to foods, biologics, human drugs, medical devices, and veterinary medicine. FDA also solicited specific suggestions on how the agency can most effectively achieve the six FDAMA objectives outlined above. The views received by the agency on these topics were used as a source for identifying crosscutting issues, themes, and priorities that should be addressed in the FDA plan.

This meeting will focus on these crosscutting issues, themes, and priorities. Of particular interest to the agency are its stakeholder views on FDA's consumer health protection obligations and the approaches that should be used to fulfill them. These obligations include: (1) Conducting the research, or taking other steps, necessary to assess risks associated with product consumption/use; (2) establishing standards, based on risk assessment, for products and the processes necessary to produce them; (3) reviewing new product applications and determining the product's acceptability for entry onto the market; (4) assisting new product sponsors in designing and implementing research and testing protocols that will facilitate the progress of their applications through the FDA review process; (5) determining ''experience'' with products once they are on the market; (6) conducting inspections to determine the state of industry compliance with FDA standards; (7) carrying out a variety of strategies to ensure compliance, including education, technical assistance, and more directed enforcement activities such as warning letters, product seizures, and prosecutions; and (8) educating consumers and health professionals on risks and risk-avoidance behavior.

The agency is open to all views and ideas about what methods should be used to carry out these basic consumer protection functions, the level of consumer protection that will be provided by different methods and whether this level of protection is acceptable, and what will be needed to reach the desired level of consumer protection by using the proposed method. To help clarify stakeholder views on FDA's role and approaches for fulfilling its consumer protection obligations, the agency requests that oral and/or written views address the following seven questions:

1. Should the above-listed consumer protection functions be modified in any way? If so, what functions would you change, add, or delete?

2. For which of the above-listed functions do you believe that it would be acceptable for FDA to charge fees?

3. For which of the above-listed functions could, and should, FDA rely more on the efforts of third parties, such as testing laboratories, health professional organizations, standard setting organizations, States, or regulated industry?

4. For which of the above-listed functions do you see the best potential for FDA to collaborate with its external stakeholders, such as States, industry, other regulatory agencies, international organizations, etc. to the greater benefit of all parties?

5. Which of the above-listed functions do you believe offers the greatest opportunities for FDA to place more emphasis on non-regulatory approaches—such as education, technical assistance, and collaborative problem solving—to protect and promote the public health?

6. FDA's product and process standards have long been considered as the ''benchmark'' by which to judge the safety, quality, and efficacy of foods, drugs, biologicals, and medical devices. Would it be appropriate for the agency to sanction the use of an FDA seal or mark on products that meet the 'gold' standard, as a way of encouraging more widely behavior that meets the standard? Should FDA charge user fees to third parties and others who use the seal, as a way of financing agency operations?

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]

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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