development for accelerated and traditional approval. 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, regulations, or both.

Interested persons may, at any time, submit written comments on the draft guidance to the Dockets Management Branch (address above). 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 in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 20, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–22720 Filed 8–31–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0359]

Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments concerning the establishment of program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for the year 2000. As part of its annual planning, budgeting, and resource allocation process, CFSAN is conducting a comprehensive review of its programs to set priorities and establish work product expectations. This notice is being published to give the public an opportunity to provide input into the priority-setting process.

DATES: Written comments by September 30, 1999.

ADDRESSES: Submit written comments concerning this document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Donald J. Carrington, Center for Food Safety and Applied Nutrition (HFS–666), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–5290, email DCarring@bangate.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On January 25, 1999, CFSAN released a document entitled ''1999 CFSAN Program Priorities.'' The document, a copy of which is available on CFSAN's web page (www.cfsan.fda.gov), constitutes the Center's priority workplan for calendar year 1999. The workplan is based on input we received at a stakeholders meeting on June 24 and 25, 1998 (see 63 FR 30242, June 3, 1998), as well as input generated internally. Throughout the priority-setting process, we focused on one central question: ''Where do we do the most good for consumers?''

Approximately half of the 1999 workplan consists of activities implementing the President's Food Safety Initiative (FSI). This is consistent with the fact that currently, approximately half the Center's resources are devoted to FSI work (i.e., all activities related to pathogen reduction in food.) Outside of FSI, the workplan identifies five program areas and four cross-cutting areas that need emphasis. The five program areas are: (1) Premarket review of food ingredients; (2) nutrition, health claims, and labeling; (3) dietary supplements; (4) chemical and other contaminants; and (5) cosmetics.

The four cross cutting areas are: (1) Enhancing the science base; (2) Federal/State/local collaborations; (3) international; and (4) human resources.

Within most major program areas in the workplan, there are two lists of activities. The first list of priorities in each section, identified as the ''A'' list, are activities that CFSAN is committing to complete by the end of 1999. Activities on the ''B'' list are those the Center plans to make progress on during the year, but may not complete. CFSAN has responsibility for many important ongoing activities that are not identified in the workplan. The workplan addresses primarily those initiatives representing something new or different that needs to be addressed in that year. In addition, the workplan does not address the myriad of unanticipated issues which often require a substantial investment of CFSAN resources e.g., recent concerns about potential dioxin-contamination in certain European imports.

II. 2000 CFSAN Program Priorities

FDA is requesting comments concerning the establishment of program priorities in CFSAN for the year 2000. The input will be used to develop CFSAN's 2000 workplan. The workplan will set forth the Center's program priorities for a 9-month period, from January 1, 2000, through September 30, 2000, the end of the fiscal year. Henceforth, to be compatible with the Federal budgetary cycle, the priority-setting process and development of annual workplans will be done on a fiscal year basis. FDA intends to make this new workplan public in January 2000.

The 2000 workplan will be organized in the same format as the 1999 workplan. Accordingly, comments are requested on specific program activities for CFSAN to complete by September 30, 2000, in each of the categories described in the document entitled ''1999 CFSAN Program Priorities'' (i.e., ''A'' list activities.) Comments are also requested on those additional activities that should be worked on during the 9-month period, but not necessarily completed by the end of the fiscal year (i.e., the ''B'' list activities.)

To help focus comments, FDA requests that input regarding CFSAN program priorities address the following questions:

1. With respect to products under the jurisdiction of CFSAN, do you believe there are issues that directly affect consumer safety that are not being adequately addressed?

2. Within the 10 program areas identified previously, what specific activities do you believe should be top priorities for CFSAN and why?

3. FDA needs to ensure that its research programs provide the scientific information upon which regulatory decisions are made. In CFSAN, what do you believe should be the highest priority areas for conducting research?

4. Because so much of our nation's food supply is either imported or exported, what do you believe should be the highest priority international activities? Please identify specific activities in your answer.

Interested persons may, on or before September 30, 1999, submit to the Dockets Management Branch (address above) written comments regarding this notice. 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 in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 25, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–22678 Filed 8–31–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2873]

Medical Devices; Draft Guidance on Evidence Models for the Least Burdensome Means to Market; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Evidence Models for the Least Burdensome Means to Market.'' This draft guidance is intended to provide guidance to the medical device industry and FDA reviewers on implementing section 205 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). Section 205 requires FDA, in consultation with the product sponsor, to consider the ''least burdensome'' means that will allow appropriate premarket development and review of a product without unnecessary delays and expense to manufacturers. This draft guidance represents the agency's current thinking on implementing section 205 of FDAMA, and it is neither final nor is it in effect at this time.

DATES: Written comments concerning this draft guidance must be submitted by November 30, 1999.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Evidence Models for the Least Burdensome Means to Market'' to the Division of Small Manufacturers 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 301–443–8818. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Susan Alpert, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Evidence Models for the Least Burdensome Means to Market.'' Section 205 of FDAMA requires FDA, in consultation with the product sponsor, to consider the ''least burdensome'' means that will allow appropriate premarket development and review of a product without unnecessary delays and expense to manufacturers. This draft guidance is designed to help both the Center for Devices and Radiological Health (CDRH) reviewers and the medical device industry apply the new provisions of FDAMA. Through this draft guidance, CDRH intends to establish a general approach for applying the least burdensome provisions that will be applicable to any device application; this draft guidance does not attempt to establish specific clinical data requirements for any particular type of submission.

The focus of this draft guidance is the application of the least burdensome provisions to clinical data requirements because the input from stakeholders has indicated that the regulated industry is most concerned with FDA's interpretation of these provisions with respect to clinical data.

In addition, as this draft guidance was being developed, it became clear that it cannot easily be applied to in vitro diagnostic devices (IVD's) because of the unique clinical data needs associated with establishing IVD performance. The agency is soliciting comments on applying the least burdensome provisions to data requirements for IVD's.

To foster a collaborative approach to the implementation of section 205 of FDAMA, FDA's CDRH hosted a meeting with stakeholders on January 4, 1999, to solicit comments and suggestions regarding the least burdensome approach to medical device development and evaluation. CDRH heard formal presentations at that meeting and also received written comments.

This draft guidance has incorporated, in part, the written proposal dated March 11, 1999, from the ''Least Burdensome Industry Task Force'' convened by the Health Industry Manufacturers Association, comments from the January 4, 1999, stakeholders meeting, and other stakeholder communications.

This draft guidance represents the agency's current thinking on implementing the ''least burdensome'' provisions of section 205 of FDAMA. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance is issued as a level 1 guidance consistent with GGP's.

II. Electronic Access

In order to receive the draft guidance document entitled ''Evidence Models for the Least Burdensome Means to Market'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch tone telephone. At the first voice prompt press 1 to access DMSA Facts, at the second voice prompt press 2, and then enter the document number 1154 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes the draft guidance document entitled ''Evidence Models for the Least Burdensome Means to Market,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''.

III. Comments

Interested persons may, on or before November 30, 1999, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments