for Neurological Embolization Devices,'' and (2) the reclassification of the totally implanted spinal cord stimulator. Single copies of the guidance and the draft guidances are available to the public by calling 1–800–899–0381 or 301–827–0111 and requesting CDRH Facts-on-Demand by assigned document number, or the documents may be obtained on the Internet at the CDRH website as follows: ''Guidance Document for Dura Substitute Devices,'' Facts-on-Demand document number 1152, or ''http://www.fda.gov/cdrh/ode/1152.pdf''; ''Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater,'' Facts-on-Demand document number 054, or ''http://www.fda.gov/cdrh/ode/054.pdf''; and ''Guidance Document for Neurological Embolization Devices,'' Facts-on-Demand document number 1151, or ''http://www.fda.gov/cdrh/ode/1151.pdf''.

Procedure: On September 16, 1999, from 11 a.m. to 6 p.m., and on September 17, 1999, from 8:30 a.m. to 3:30 p.m., the meeting is open to the public. 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 by September 8, 1999. Oral presentations from the public will be scheduled on September 16, 1999, between approximately 12 noon and 12:30 p.m. for the discussion of the draft guidance entitled ''Guidance Document for Dura Substitute Devices'' and between approximately 3:45 p.m. and 4:15 p.m. and 5 p.m. and 5:30 p.m. for the classification of processed human dura mater. On September 17, 1999, oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m. for the discussion of the draft guidance entitled ''Guidance Document for Neurological Embolization Devices'' and between approximately 12:15 p.m. and 12:45 p.m. and 2:30 p.m. and 3 p.m. for the reclassification of the totally implanted spinal cord stimulator. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 8, 1999, 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.

Closed Committee Deliberations: On September 17, 1999, from 8 a.m. to 8:30 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information regarding pending and future FDA issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)). Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 25, 1999.

Linda Suydam,

Senior Associate Commissioner.

[FR Doc. 99–22713 Filed 8–27–99; 10:49 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2445]

Draft Guidance for Industry on Clinical Considerations for Accelerated and Traditional Approval of Antiretroviral Drugs Using Plasma HIV RNA Measurements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Clinical Considerations for Accelerated and Traditional Approval of Antiretroviral Drugs Using Plasma HIV RNA Measurements.'' The draft guidance is intended to assist pharmaceutical sponsors in the development of antiretroviral drugs and to serve as a focus for continued discussion among the agency, the public, industry, and scientific communities regarding the use of plasma human immunodeficiency virus (HIV) ribonucleic acid (RNA) measurements in phase 3 clinical studies of antiretroviral drugs.

DATES: Written comments on the draft guidance may be submitted by November 30, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance entitled ''Clinical Considerations for Accelerated and Traditional Approval of Antiretroviral Drugs Using Plasma HIV RNA Measurements'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments concerning the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5600 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jeffrey S. Murray, Center for Drug Evaluation and Research (HFD–530), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2495.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Considerations for Accelerated and Traditional Approval of Antiretroviral Drugs Using Plasma HIV RNA Measurements.'' The draft guidance summarizes the scientific basis supporting the use of HIV RNA as a primary study endpoint in both accelerated and traditional approvals of antiretroviral drugs. This summary is based on scientific data presented at a July 14 and 15, 1997, meeting of the Antiviral Drugs Advisory Committee. At this meeting, there was expert consensus that the use of plasma HIV RNA endpoints in certain situations could reliably predict clinical benefit. The draft guidance suggests that accelerated approvals could be based on studies that show a drug's contribution toward shorter-term reductions in HIV RNA (e.g., 24 weeks) while traditional approvals could be based on trials that show a drug's contribution toward durability of HIV RNA suppression (e.g., at least 48 weeks) in lieu of a traditional clinical endpoint study. Changes in CD4 cell counts should be consistent with observed HIV RNA changes when considering approval of an antiretroviral drug.

The draft guidance describes the agency's current thinking on clinical trial designs using HIV RNA changes as an endpoint for accelerated and traditional approvals. Considerations regarding control arms, study procedures, endpoints, and statistical methods for analyzing HIV RNA endpoints are discussed. The draft guidance also includes recommendations for sponsors who plan to use a new or unapproved HIV RNA assay in a clinical study. When using such assays, sponsors are encouraged to provide supporting data on the assay's limits and performance characteristics as outlined in the last section of the draft guidance.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on certain aspects of antiretroviral drug product

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.