IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this guidance at any time. 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 guidance document 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: May 16, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 01–12909 Filed 5–22–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0495]

Prescription Drug User Fee Act (PDUFA) II Five-Year Plan—FY 2001 Update; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an internal planning document entitled ''PDUFA II Five-Year Plan—FY 2001 Update.'' The updated plan to achieve PDUFA II goals for the drug review process takes into account changes in revenue projections and workload based on actual revenue and application receipts in fiscal year (FY) 1998, FY 1999, and FY 2000 and updated projections for FY 2001 and FY 2002.

DATES: Submit written comments on the plan at any time. Comments will be considered as the agency makes annual adjustments to the plan in the second quarter of each FY.

ADDRESSES: Submit written requests for single copies of this plan to the Office of Management and Systems (HF–300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, Attn: Frank Claunts. Send a self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the plan to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the plan.

FOR FURTHER INFORMATION CONTACT: Frank Claunts, Office of Management Systems (HF–300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4427.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of an internal planning document entitled ''PDUFA II Five-Year Plan—FY 2001 Update.'' The Prescription Drug User Fee Act of 1992 (PDUFA) was amended and extended through the year 2002 by the Food and Drug Administration Modernization Act of 1997. The amended and extended PDUFA is referred to as PDUFA II. PDUFA II authorizes appropriations and fees that will provide FDA with resources to sustain the drug review staff developed through FY 1997 and to achieve the even more stringent new goals.

The updated FY 2001 plan begins with a statement of purpose, provides background information on PDUFA and a summary of the new goals, and updates the 10 major assumptions on which the plan is based. This is the third update of the plan since it was initially published in July 1998. The updated plan summarizes individual plans of agency components with major PDUFA responsibilities and also provides a consolidated agency summary. The updated plan to achieve PDUFA II goals for the drug review process takes into account changes in revenue projections and workload based on actual revenue and application receipts in FY 1998, FY 1999, and FY 2000 and updates projections for FY 2001 and FY 2002. Attachments include the **Federal Register** notice of December 18, 2000 (65 FR 79107), establishing prescription drug user fee rates for FY 2001, updated 5-year estimates of PDUFA fees and revenues, and the revised PDUFA II Information Management Five-Year Plan.

We are making this plan available to all that have an interest. We welcome comments and will consider them in the future as annual adjustments are made to the plan.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the plan at any time. 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 FY 2001 update and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/oc/pdufa2/5yrplan.html.

Dated: May 17, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–13069 Filed 5–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of June 2001.

Name: National Advisory Council on the National Health Service Corps.

Date and Time: June 21, 2001; 3 p.m.–6:30 p.m.; June 22, 2001, 8 a.m.–5 p.m.; June 23, 2001, 9 a.m. to 5:30 p.m.; June 24, 2001, 8 a.m.–10:15 a.m.

Place: Hyatt Regency Hotel, 575 Memorial Drive, Cambridge, MA 02139–4896, Phone: (617) 492–1234.

The meeting is open to the public.

Agenda: The Council will focus its agenda on strategic and operational plans for the current fiscal year. The Council will be attending three community meetings in Raymond, NH, Worcester, MA, and Providence, RI, on Friday, June 22, to discuss integrated primary medical care, the integration of primary care, mental and behavioral health, and oral health. Transportation will not be provided to the general public.

Agenda items and times are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT: Ms. Eve Morrow, Division of National Health Service Corps, at (301) 594–4144.

Dated: May 17, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–12910 Filed 5–22–01; 8:45 am]

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