during the comment period have been carefully reviewed and incorporated in this revised guidance where appropriate. In addition, a workshop entitled ''Bioanalytical Method Validation—A Revisit with a Decade of Progress'' was held January 12 to 14, 2000. This guidance also incorporates the recommendations from the January 2000 workshop.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking on the validation of methods for the assay of drugs and/or metabolites in human biological matrices. 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 statutes and regulations.

II. Comments

Interested persons may, at any time, submit written comments on the 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 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm.

Dated: May 11, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–12908 Filed 5–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1497]

The Mammography Quality Standards Act Final Regulations Document #4; Final Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''The Mammography Quality Standards Act Final Regulations Document #4; Final Guidance for Industry and FDA.'' The final regulations implementing the Mammography Quality Standards Act of 1992 (the MQSA) became effective April 28, 1999. The final guidance document is intended to assist facilities and their personnel to meet the MQSA final regulations.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''The Mammography Quality Standards Act Final Regulations Document #4; Final Guidance for Industry and FDA'' 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 two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance 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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Charles A. Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. Background

The draft guidance document was issued for public comment in the **Federal Register** of September 13, 2000 (65 FR 55265). The comment period ended on December 13, 2000. The draft guidance was discussed with the National Mammography Quality Assurance Advisory Committee at the September 28, 2000, meeting. The final guidance document has been modified from the original draft guidance to address the seven public comments received. There were several clarifying changes made to the document, particularly dealing with the issues of what constitutes a ''major repair'' and when the physicist must perform onsite evaluations. Several decision tree flow diagrams were added to the document to help clarify these issues. Overall, there were no major substantive changes made to the document.

II. Significance of the Guidance

This guidance document represents the agency's current thinking on the MQSA final regulations guidance. 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 statutes and regulations.

The agency has adopted the good guidance practices (GGPs) regulation, which sets forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document is issued as a level 1 guidance consistent with GGPs.

III. Electronic Access

In order to receive ''The Mammography Quality Standards Act Final Regulations Document #4; Final Guidance for Industry and FDA'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1159) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, 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. ''The Mammography Quality Standards Act Final Regulations Document#4; Final Guidance for Industry and FDA'' will also be available on CDRH's mammography Web site at http://www.fda.gov/cdrh/mammography. Guidance documents are also available on the Dockets Management Branch Web site at http://www.fda.gov.ohrms/dockets/default.htm.

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]

BILLING CODE 4160–01–S

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]

BILLING CODE 4160–15–P