assessment. Regulatory issues related to standards and product quality and the impact of the Food and Drug Administration Modernization Act (FDAMA) will also be addressed. The Forum will feature plenary lectures and focused discussion groups that include FDA, industry, and university leaders in the field, on the following topics: (1) ''Biofarming and biopharming'' (bioengineered plants and animals as sources of foods and drugs); (2) diagnostics and detection methods; (3) microbial pathogens, antibiotics, and resistance; (4) therapeutic and preventive agents: Novel therapies, gene therapy, cell and tissue engineering, and vaccines; (5) new models/methods for safety and efficacy assessment; and (6) regulatory challenges: Standards, product quality, FDAMA and impact on biotechnology regulation, and public acceptance of novel products.

The meeting is co-sponsored by FDA, the American Association of Pharmaceutical Scientists, and the FDA Chapter of Sigma Xi, the Scientific Research Society.

Dated: June 30, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–18399 Filed 7–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0495]

Prescription Drug User Fee Act, ''PDUFA II Five-Year Plan;'' 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.'' This plan is intended to show FDA's anticipated prescription drug user fee revenues and planned expenditures of the fee revenues over the 5-year period from 1998 through 2002. The plan is designed to assist in achieving the new goals for the drug review process under the Prescription Drug User Fee Act of 1992 (PDUFA), which was amended and extended through the year 2002 by the Food and Drug Administration Modernization Act of 1997 (FDAMA). The amended and extended PDUFA is referred to as PDUFA II.

DATES: Written comments my be provided at any time and will be considered as the agency makes annual adjustments to the plan in the second quarter of each fiscal year.

ADDRESSES: Copies of this document are available on the Internet at ''www.fda.gov/oc/pdufa2/5yrplan.html''. For those without Internet access, single copies of this plan may be obtained from the Division of Management Systems and Policy (HFA–300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please send a self-addressed adhesive label to assist that office in processing your request. 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.

FOR FURTHER INFORMATION CONTACT: Frank P. Claunts, Division of Management Systems and Policy (HFA–300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5501.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of an internal planning document entitled ''PDUFA II Five-Year Plan.'' PDUFA was amended and extended through the year 2002 by FDAMA. 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 in the last 5 years and to achieve the even more stringent new goals.

The plan begins with a statement of purpose, provides background information on PDUFA and a summary of the new goals, and discusses the 10 major assumptions on which the plan is based. Included is the assumption that this plan is dynamic and will be reassessed each fiscal year through 2002. The individual plans of agency components with major PDUFA responsibilities are summarized, followed by a summary of associated expenditures and an agency summary.

In our continuing efforts to maximize the availability and clarity of information about our review processes and plans, we are sharing this plan with all who have an interest and making it available on the Internet. We welcome comments and will consider them in the future as annual adjustments are made to the plan.

Interested persons, may at any time, submit written comments 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 document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 3, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–18401 Filed 7–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0512]

Draft ''Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the FDA Form 356h, Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the FDA Form 356h, Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use.'' The draft guidance document is intended to assist applicants in the preparation of the content and format of the chemistry, manufacturing, and controls (CMC) section and the establishment description section of a biologics license application (BLA), revised Form FDA 356h, for human blood and blood components intended for transfusion or for further manufacture. In addition, the draft guidance document provides assistance for the completion of the BLA. This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives and the Food and Drug Administration

Modernization Act of 1997 (Modernization Act), to reduce unnecessary burdens for industry without diminishing public health protection.

DATES: Written comments may be submitted at any time, however, comments should be submitted by September 8, 1998, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the FDA Form 356h, Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the FDA Form 356h, Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use.'' The draft document, when finalized, is intended to provide instructions on the completion of the revised Form FDA 356h, including CMC and establishment description sections for human blood and blood components intended for transfusion or for further manufacture. In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of a new harmonized Form FDA 356h entitled ''Application to Market a New Drug, Biologic, or an Antibiotic for Human Use.'' The new harmonized form is intended to be used by applicants for all drug and biological products, to include blood and blood components. The new harmonized form when fully implemented will allow biological product manufacturers to submit a single application, the BLA, instead of two separate license application submissions, a product license application (PLA) and an establishment license application (ELA).

The draft guidance document represents the agency's current thinking on content and format of the CMC and establishment description information sections of a license application for human blood and blood components intended for transfusion or for further manufacture. 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. As with other guidance documents, FDA does not intend this document to be all inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Requests for Comments

The draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by September 8, 1998, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments and requests should be identified with the docket number found in the brackets in the heading of this document. A copy of the draft 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.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: June 30, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–18404 Filed 7–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0483]

Draft ''Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Virus Type 1;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: In the Manufacture and Clinical Evaluation of *In Vitro* Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Virus Type 1.'' The draft guidance document addresses general and specific concerns for gene based detection techniques, and it is intended to provide guidance on manufacturing and clinical trial design issues pertaining to the validation of tests based on nucleic acid detection either in the presence or absence of an amplification step.

DATES: Written comments may be submitted at any time, however, comments should be submitted by October 8, 1998, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: In the Manufacture and Clinical Evaluation of *In Vitro* Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Virus Type 1'' to the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist