drug application became effective was on August 19, 1987.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: April 15, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Flowmax™ (NDA 20–579) was initially submitted on April 15, 1996.

3. *The date the application was approved:* April 15, 1997. FDA has verified the applicant's claim that NDA 20–579 was approved on April 15, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,669 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 8, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 6, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 23, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–18407 Filed 7–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antimicrobial Drugs and Resistance; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss the development of drug products for the treatment of resistant bacteria, including selective spectrum agents. The purpose of the meeting is to provide information on the agency's plans for future public scientific discussions of issues unique to the development of these drug products and to invite members of the public to provide comments on the agency's plans.

DATES: The public meeting will be held on Tuesday, July 28, 1998, from 2 p.m. to 6 p.m.

ADDRESSES: The public meeting will be held in conference rooms G and H, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas H. Hassall, Center for Drug Evaluation and Research (HFD–104), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2489.

SUPPLEMENTARY INFORMATION: FDA will hold a public meeting on July 28, 1998, to discuss its plans for a presentation at a fall 1998 advisory committee meeting and possible future meetings on the development of drug products to treat resistant bacteria, including selective spectrum agents. At the fall 1998 advisory committee meeting, FDA plans to discuss issues unique to the development of such products, including clinical trial design and labeling issues. At the meeting, FDA will present its thoughts on the issues that should be presented to the advisory committee and will solicit public input on the structure of the discussion and additional issues that should be presented.

There is no registration for this meeting, however, space is limited. Persons interested in attending the meeting should contact the person listed above.

An agenda for the public meeting will be available 2 weeks before the meeting, via the Internet using the World Wide Web (WWW). To connect to the CDER home page, type ''http://www.fda.gov/cder'' and go to the ''What's Happening'' section.

Dated: July 3, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–18397 Filed 7–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

1998 FDA Science Forum—Biotechnology: Advances, Applications, and Regulatory Challenges

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration's (FDA's) Office of Science is announcing the following meeting: ''1998 FDA Science Forum—Biotechnology: Advances, Applications, and Regulatory Challenges.'' The Forum will bring FDA research and review scientists together with representatives of industry, academia, Government agencies, consumer groups, and the public to discuss the impact of the enormous advances in biotechnology on product development and regulation.

Date and Time: The meeting will be held on Tuesday and Wednesday, December 8 and 9, 1998; registration from 7:00 a.m. to 8:30 a.m.; meeting from 8:30 a.m. to 6:00 p.m. on December 8, and 8:30 a.m. to 5:00 p.m. on December 9.

Location: The meeting will be held at the Washington Convention Center, rms. 29–32 (lower level) and Hall C (upper level) 900 Ninth Street, NW., Washington, DC 20001.

Contact: American Association of Pharmaceutical Scientists at <meetings@aaps.org>, 703–518–8429, or Susan A. Homire, Food and Drug Administration, Office of Science (HF–32), 5600 Fishers Lane, Rockville, MD, 20857, 301–827–3366, e-mail <shomire@bangate.fda.gov>.

Registration: Registration information will be available in mid-July. Attendance will be limited; therefore, interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact the American Association of Pharmaceutical Scientists at least 3 weeks in advance.

Agenda: The program will encompass bioengineered products, novel therapeutic and preventive approaches, diagnostics and detection methodologies, and safety and efficacy

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