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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 Revision; 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 1999 Revision." This revised plan updates FDA's anticipated prescription drug user fee revenues and planned expenditures of the fee revenues over the 5-year period from 1998 to 2002. The revised plan to achieve 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, takes into account changes in revenue projections and work load based on actual revenue and application receipts in fiscal year (FY) 1998. The amended and extended PDUFA is referred to as PDUFA II.

DATES: Written comments on the revised plan may be submitted at any time and will be considered as the agency makes annual adjustments to the revised plan in the second quarter of each FY.

ADDRESSES: Copies of this revised plan are available on the Internet at "www.fda.gov/oc/pdufa2/5yrplan.html". For those without Internet access, single copies of this revised plan may be obtained from the Office of Management and Systems (HFA-20), Attention: Frank P. Claunts, 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 revised 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, Office of Management Systems (HFA-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4427.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of an internal planning document entitled "PDUFA II Five-Year Plan: FY 1999 Revision." 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 revised 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 revised plan is based and how those assumptions have changed since the original plan was issued last year. Included is the assumption that this revised plan is dynamic, and it will be reassessed each FY through 2002. This is the first revision of the plan since it was initially published last year. The individual plans of agency components with major PDUFA responsibilities are summarized, followed by a summary of associated expenditures and an agency summary. Attachments include: Estimates of PDUFA fees and revenues, the **Federal Register** notice of December 22, 1998, establishing prescription drug user fee rates for FY 1999, and the revised "PDUFA II Information Management Five-Year Plan."

In FDA's continuing efforts to maximize the availability and clarity of information about the agency's review processes and plans, FDA is sharing this revised plan with all who have an interest, and the agency is making it available on the Internet. The agency welcomes comments, and it will consider them in the future as annual adjustments are made to the plan.

Interested persons may submit written comments on the revised plan 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 revised plan and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 8/20/99
August 20, 1999



Margaret M. Dotzel
Acting Associate Commissioner for Policy

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