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Certifier:	<i>[Signature]</i>

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 2000 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 2000 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 and FY 1999 and updated projections for FY 2000 through 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: 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 Office of Management and Systems (HF-20), Attention: Frank P. Claunts (HF-20), 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, Office of Management Systems (HF-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4427.

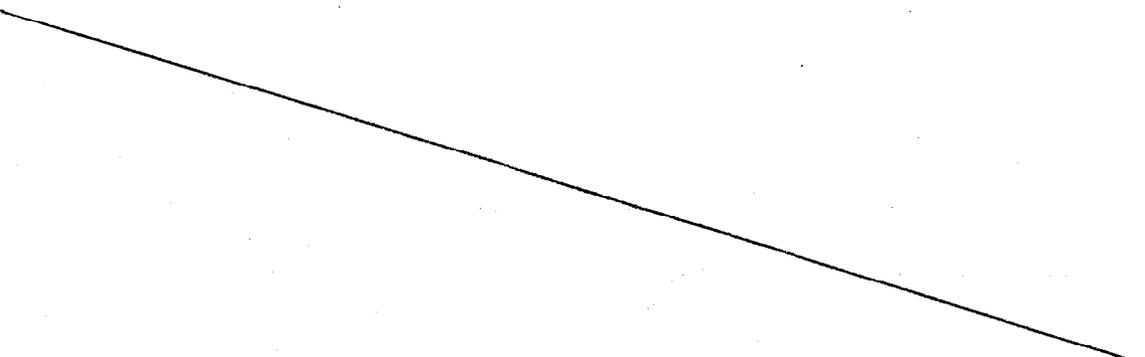
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SUPPLEMENTARY INFORMATION: FDA is announcing the availability of an internal planning document entitled "PDUFA II Five-Year Plan—FY 2000 Update." PDUFA was amended and extended through the year 2002 by the Food and Drug Administration Modernization 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 FY 2000 updated 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 second 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 it 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 and FY 1999 and updated projections for FY 2000 through FY 2002. Attachments include: The **Federal Register** notice of December 28, 1999 (64 FR 72669) establishing prescription drug user fee rates for FY 2000, 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 who have an interest. We welcome comments and will consider them in the future as annual adjustments are made to the plan.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the plan. 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: 7/21/00
July 21, 2000.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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