

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0481]

Draft Prescription Drug User Fee Act IV Information Technology Plan; Availability for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for public comment of the draft information technology (IT) plan entitled "Prescription Drug User Fee Act (PDUFA) IV Information Technology Plan." This plan is intended to provide regulated industry and other stakeholders with information on FDA's vision and plan for improving the automation of business processes and maintaining information systems that support the process for the review of human drug applications to achieve the objectives defined in the PDUFA Performance Goals.

DATES: Submit written or electronic comments on the draft IT plan by February 22, 2008.

ADDRESSES: Submit written requests for single copies of the draft plan to the Office of the Chief Information Officer (HFA-080), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft IT plan to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://*

/www.fda.gov/dockets/ecomments or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

FOR FURTHER INFORMATION CONTACT: Suzanne Mitri, Office of the Chief Information Officer, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-255-6700.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing for public comment the availability of the draft IT plan entitled “Prescription Drug User Fee Act (PDUFA) IV Information Technology Plan.” This plan is intended to provide regulated industry and other stakeholders with information on FDA’s vision and plan for improving the automation of business processes and maintaining information systems that support the process for the review of human drug applications to achieve the objectives defined in section XIV, Information Technology Goals, of the PDUFA Performance Goals (*http://www.fda.gov/oc/pdufa4/pdufa4goals.html*).

On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007, which includes the reauthorization and expansion of PDUFA. The reauthorization of PDUFA will significantly broaden and upgrade the agency’s drug safety program, increase resources for review of television drug advertising, and facilitate more efficient development of safe and effective new medications for the American public. The reauthorization also includes Information Technology Goals that are divided into four subsections: Objectives, Communications and Technical Interactions, Standards and IT Plan, and Metrics and Measures. In addition, there are information technology goals associated with the upgrade of the agency’s drug

safety program in section VIII, Enhancement and Modernization of the FDA Drug Safety System.

The objectives of the PDUFA IV IT Goals are to move FDA towards the long-term goal of an automated standards-based information technology environment for the exchange, review, and management of information supporting the process for the review of human drug applications throughout the product life cycle. As part of this process, FDA will develop and periodically update a 5-year IT plan and will solicit and consider comments from the public on the draft IT plan. At the end of the comment period, FDA will review the comments, update the IT plan, and publish the final version no later than May 30, 2008.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: December 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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