

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0257]

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Display Date 5-2-08  
Publication Date 5-5-08  
Certifier Shee

Draft Prescription Drug User Fee Act IV Drug Safety Five-Year Plan;

Availability for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

73 FR 24599  
5/5/08

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability for public comment of the draft drug safety 5-year plan entitled "Prescription Drug User Fee Act (PDUFA) IV Drug Safety Five-Year Plan." This plan is intended to communicate FDA's strategy for meeting the commitments for enhancing and modernizing the drug safety system within the context of the PDUFA IV program.

**DATES:** Submit written or electronic comments on the draft drug safety 5-year plan by *[insert date 45 days after date of publication in the Federal Register]*.

6/19/08

**ADDRESSES:** Submit written requests for single copies of the draft plan to the Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6100, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft drug safety 5-year 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 <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

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**FOR FURTHER INFORMATION CONTACT:** Jayne C. Ware, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Executive Programs, 10903 New Hampshire Ave., Bldg. 51, rm. 6100, Silver Spring, MD 20993-0002, 301-796-3200.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

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 modernize the agency's drug safety program and facilitate more efficient development of safe and effective new medications for the American public. During the user fee negotiation process leading up to the renewal of PDUFA, FDA and the relevant regulated industries mutually agreed to certain commitments that the FDA will carry out during fiscal years 2008 through 2012. Congress signaled its agreement with the commitments by authorizing PDUFA funds for them. Among those commitments is the responsibility of the FDA to develop and periodically update a 5-year plan describing activities that will lead to enhancing and modernizing FDA's drug safety system.

FDA is announcing for public comment the availability of the draft drug safety 5-year plan entitled "Prescription Drug User Fee Act (PDUFA) IV Drug Safety Five-Year Plan." This plan is intended to communicate FDA's strategy for meeting the commitments for enhancing and modernizing the drug safety system within the context of the PDUFA IV program. The plan describes the agency's strategy for achieving the commitments defined in section VIII, Enhancement and Modernization of the FDA Drug Safety System, and section IX, Review of Proprietary Names to Reduce Medication Errors, of the PDUFA

IV Performance Goals (<http://www.fda.gov/oc/pdufa4/pdufa4goals.html>). At the end of the comment period, FDA will review the comments, update the “PDUFA IV Drug Safety Five-Year Plan,” and publish the final version.

## 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 on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at [http://www.fda.gov/cder/pdufa/PDUFA\\_IV\\_5yr\\_plan\\_draft.pdf](http://www.fda.gov/cder/pdufa/PDUFA_IV_5yr_plan_draft.pdf).

Dated: 4/25/08  
April 25, 2008.

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Jeffrey Shuren,  
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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