4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1618]

# Draft Prescription Drug User Fee Act V 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 "PDUFA V Information Technology Plan." This plan is intended to provide FDA's approach for enhancing business processes, data quality and consistency, supporting technologies, and IT operations as described in the Prescription Drug User Fee Act (PDUFA) Reauthorization Performance Goals and Procedures for Fiscal Years 2013 through 2017. FDA is publishing a draft version of the IT plan for comment to allow industry and other interested stakeholders to provide feedback as FDA moves towards a fully automated standards-based environment that enhances the regulatory review process for human pharmaceuticals.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER

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DATE OF PUBLICATION IN THE FEDERAL REGISTER]

ADDRESSES: Submit written requests for single copies of the draft "PDUFA V Information Technology Plan" to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,

Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft plan.

Submit electronic comments on the draft plan to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Cheryl Ford, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-6737, UserFeesProgram-Informatics@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

## I. Background

The draft PDUFA V IT plan considers assumptions, available resources, and statutory requirements that conform to the Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law on July 9, 2012. Section 1136 of FDASIA, Electronic Submission of Applications, gives FDA the authority to require a standardized electronic format for the submission of information and data in standardized formats. Section 1136 addresses investigational new drug applications, biologics license applications, and new drug applications under the PDUFA program as well as abbreviated new drug applications under the Generic Drug User Fee Act program and describes new standards and processes affecting drug and biologics approvals, drug supply chain, and other topics related to human pharmaceuticals. The draft PDUFA V IT plan describes key activities for enabling progress toward achieving PDUFA IT goals.

## II. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at http://www.regulations.gov.

## III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/ForIndustry/UserFees/default.htm or http://www.regulations.gov.

Dated: December 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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