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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0075]

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Certifier	J. [Signature]

Notice to Industry on the Development of a Web-Based System for Obtaining a User Fee Payment Identification Number and Prescription Drug User Fee Cover Sheet (FDA Form 3397); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a new Web-based system to electronically obtain a user fee payment identification number and to submit your Prescription Drug User Fee (PDUFA) cover sheet (FDA Form 3397) to the Office of Financial Management. The system will enable FDA to electronically track your company's application payments and will allow your organization to obtain the user fee payment identification number over the Web. By making the user fee payment identification number and the PDUFA cover sheet available on-line, we will be able to improve service, one of PDUFA's performance goals.

DATES: Submit written or electronic comments by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit electronic comments to <http://www.fda.gov/dockets.ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the new system.

FOR FURTHER INFORMATION CONTACT: Martha Louviere, Office of Financial Management (HFA-100), Food and Drug Administration, 5600 Fishers Lane, rm. 11-83, Rockville, MD 20857, 301-827-3912, e-mail: *userfees@fda.gov*.

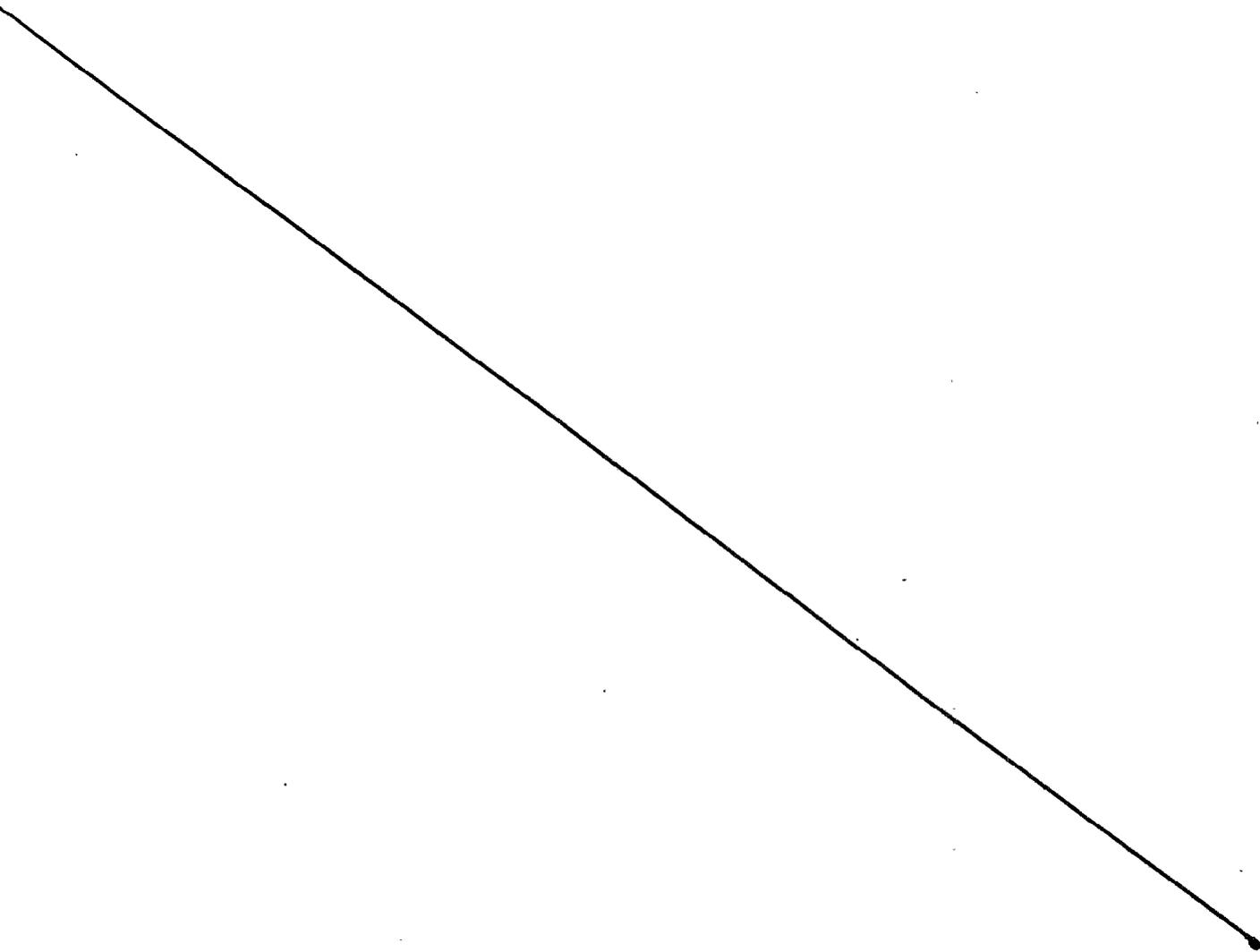
SUPPLEMENTARY INFORMATION: Under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h), FDA has the authority to assess and collect user fees for certain drug and biologics license applications and supplements. Under this authority, pharmaceutical companies pay fees for certain new human drug applications, biologics applications, and supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application by FDA cannot begin until the fee has been submitted. Form FDA 3397, the user fee cover sheet, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to help FDA track payments.

The form provides a cross-reference of the fee submitted for an application with the actual application by using a unique number tracking system to assign the user fee payment identification number. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new drug applications, biologics license applications, and supplemental applications.

FDA has created an on-line user fee cover sheet which will assist FDA and pharmaceutical companies by improving service and reducing the time for applicants and their affiliates to file and comply with PDUFA through more automated channels. The new system will allow customers to obtain a user fee payment identification number, create and complete a user fee cover sheet

on-line, and submit it electronically to FDA's Office of Financial Management. It will decrease the administrative burden on FDA, improve service by automating the cover sheet application process, and allow applicants to securely view their payments received by FDA on-line. This new system, which replaces the previous process, will be available on February 15, 2005.

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.



You can access this new system from the <http://www.fda.gov/oc/pdufa/coversheet.html> Web site. You may then select "PDUFA User Fee Cover Sheet" from Web site. Detailed instructions on how to use the user fee system are included at the Web site.

Dated: 31-05

March 1, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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