4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0471]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug User Fee Cover Sheet; Form FDA 3397

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0297. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug User Fee Cover Sheet; Form FDA 3397--(OMB Control Number 0910-0297)--Extension

Under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (sections 735 and 736 (21 U.S.C. 379g and 379h)), as amended, FDA has the authority to assess and collect user fees for certain drug and biologics license applications and supplements to those applications. Under this authority, pharmaceutical companies pay a fee for certain new drug applications (NDAs), biologics license applications (BLAs), or 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 is submitted. The Prescription Drug User Fee Cover Sheet, Form FDA 3397, 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 account for and track user fees. The form provides a cross-reference of the fee submitted for an application by using a unique number tracking system. 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 NDAs, BLAs, and/or supplemental applications to those applications.

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's database system for fiscal year (FY) 2011, there are an estimated 260 manufacturers of products subject to the Prescription Drug User Fee Act (Public Law 105-115). The total number of annual responses is based on the number of submissions received by FDA in FY 2011. CDER received 3,363 annual responses that include the following submissions: 114 NDAs; 4 BLAs; 1,900 manufacturing supplements; 1,209 labeling supplements; and 136 efficacy supplements. CBER received 768 annual responses that include the following submissions: 6 BLAs; 698 manufacturing supplements; 44 labeling supplements; and 20 efficacy supplements. The estimated hours per response are based on past FDA experience with the various submissions.

FDA is revising Form FDA 3397 in the following ways: (1) By updating the applicable Web sites; (2) by adding a Privacy Act Notice pursuant to the Privacy Act of 1974, 5 U.S.C. 552a(3)j; (3) by adding 351(k) applications to the CDER and CBER lists of applications and supplements for which Form FDA 3397 need not be submitted; (4) by adding "or proper name" to instruction number 3; and (5) by making minor editorial changes.

In the Federal Register of May 18, 2012 (77 FR 29663), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Form FDA 3397	260	15.89	4,131	0.5 (30 min.)	2,065.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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