DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2005-N-0101]

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: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

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 (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 (BLAs). Under this authority, pharmaceutical companies pay a fee for certain new human drug applications (NDAs) and BLAs submitted to the Agency for review. Because the submission of prescription drug user fees concurrently with applications 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 and BLAs.

Respondents to this collection of information are drug and biologics manufacturers that submit NDAs and BLAs. Based on FDA's database system for fiscal year (FY) 2017, there are an estimated 155 manufacturers of products subject to the Prescription Drug User Fee Act (Pub. L. 105-115), as amended by the FDA Reauthorization Act of 2017 (Pub. L. 115-52.)

The total number of annual responses is based on the number of application submissions received by FDA in FY 2017. CDER received 250 annual responses that included the following

submissions: 218 NDAs and 32 BLAs. CBER received 12 BLAs. The estimated hours per response are based on past FDA experience with the various submissions.

In the *Federal Register* of August 24, 2018 (83 FR 42900), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

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

FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
3397	155	1.6903	262	0.5 (30 minutes)	131

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

Our estimated burden for the information collection reflects an overall decrease of 1,724 hours and a corresponding decrease of 3,448 responses. We attribute this program change to the restructuring of the Prescription Drug Use Fee Program fees. The FD&C Act, as amended by the Prescription Drug User Fee Amendments of 2017 , authorizes FDA to collect application fees for certain applications for the review of human drug and biological products and discontinued the supplement fee. This resulted in the removal of supplements from the Prescription Drug User Fee Cover Sheet, therefore reducing the burden for this collection of information.

Dated: February 1, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019-01249 Filed: 2/5/2019 8:45 am; Publication Date: 2/6/2019]