4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3404]

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

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 0910-0727. 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.

Generic Drug User Fee Coversheet

OMB Control Number 0910-0727--Extension

On July 9, 2012, the President signed the Generic Drug User Fee Amendments (GDUFA) (Pub. L. 112-144, Title III) into law. GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to the industry. Section 744B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f, et seq.), as added by GDUFA, authorized FDA to assess and collect the fees related to generic drugs, beginning fiscal year (FY) 2013 and expiring at the close of FY 2017 on September 30, 2017. GDUFA was reauthorized on August 18, 2017 (GDUFA II), and is effective beginning October 1, 2017, through September 30, 2022. GDUFA II enables FDA to assess industry user fees to bring greater predictability and timeliness to the review of generic drug applications.

Form FDA 3794, the Generic Drug User Fee Cover Sheet available at https://www.ipqpubs.com/wp-content/uploads/2012/09/GDUFA-cover-sheet.pdf, requests the minimum necessary information from applicants to account for and track user fees and to determine the amount of the fee required. Applicants complete the cover sheets to accompany payments. While applicants may submit payment through multiple means, all cover sheets are prepared using FDA's web-based electronic User Fee System. Upon submitting the completed cover sheet, the User Fee System generates a user fee identification number, which is provided to applicants at the bottom of the cover sheet. It also notes the correct FY user fee assessment that is due for the submission/program. FDA requests that applicants submit a copy of this

completed cover sheet along with the abbreviated new drug application, and other GDUFA fees, so FDA can verify that the applicant has paid the correct user fee.

Respondents to the collection of information are potential or actual generic drug application holders or related Active Pharmaceutical Ingredient and Finished Dosage Form manufacturers. Companies with multiple user fee obligations will submit a cover sheet for each user fee obligation.

In the *Federal Register* of September 25, 2018 (83 FR 48430), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received asking whether the information was "essential for FDA to conduct its duties," and whether "there is a way to reduce burden" on respondents. We appreciate this feedback. As discussed in both the 60-day notice and this notice, the information collection implements statutory provisions FDA must fulfill under GDUFA II. The information requested from respondents on Form FDA 3794 represents what we consider to be the minimum necessary for us to efficiently and electronically assess, collect, and track user fees associated with generic drug applications.

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

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

Form FDA 3794	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Generic Drug User Fee Cover Sheet	500	7.616	3,808	0.5 (30 minutes)	1,904

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

The estimated burden for the information collection reflects an increase since last OMB approval. This adjustment corresponds with an increase in submissions received by the Agency.

Dated: February 4, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.
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