



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0600]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal 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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0539. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@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.

Animal Drug User Fee Cover Sheet OMB Control Number 0910-0539--Extension

Under section 740 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j-12), FDA has the authority to assess and collect application fees from each person who submits certain new animal drug applications or certain supplemental animal drug applications. The Animal Drug User Fee cover sheet (Form FDA 3546) is designed to collect the minimum necessary information to determine whether a fee is required for the review of an application or supplement or whether an application fee waiver was granted, to determine the amount of the fee required, and to assure that each animal drug user fee payment is appropriately linked to the animal drug application for which payment is made. The form, when completed electronically, will result in the generation of a unique payment identification number used by FDA to track the payment. FDA's Center for Veterinary Medicine and FDA's Office of Management will use the information collected to initiate the administrative screening of new animal drug applications and supplements to determine whether the payment has been received.

Description of Respondents: Respondents to this collection of information are new animal drug applicants.

In the Federal Register of October 21, 2016 (81 FR 72810), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments. FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

FD&C Act Section/Description	FDA Form No.	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
740(a)(1); Animal Drug User Fee cover sheet	FDA 3546	21	1	21	1	21

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

The estimates in table 1 are based on our experience with new animal drug applications and supplemental animal drug applications and the average number of Animal Drug User Fee cover sheets submitted during fiscal years 2013-2015. We estimate 21 respondents will each submit a cover sheet (Form FDA 3546) for a total of 21 responses. We calculate a reporting burden of 1 hour per response, for a total of 21 hours. The burden hours are increased. The overall increase in burden hours (by 4 hours) is due to the normal variation in the number of Animal Drug User Fee cover sheets submitted to FDA.

Dated: July 12, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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