or a combination product, and which FDA medical product Agency Center (Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, or Center for Devices and Radiological Health) will regulate it, if it is a non-combination product, or will have the primary jurisdiction for the premarket review and regulation of the product, if it is a combination product.

There are two ways that a sponsor can receive such feedback from OCP. One option is to submit an RFD to receive a formal, binding determination for the sponsor's product with respect to classification and/or center assignment that may be changed under conditions specified in section 563 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–2) and 21 CFR 3.9 in the regulations. The RFD process is codified in 21 CFR part 3, and OCP has issued a guidance about this process (see ''How to Write a Request for Designation'' at *https://www.fda.gov/RegulatoryInformation/Guidances/ucm126053.htm*). A second more flexible option is for a sponsor to submit an inquiry to OCP to receive a preliminary jurisdictional assessment, which is not binding.

Many sponsors seek to utilize the flexibility of more approachable ways to interact with OCP and the medical product Agency Centers to obtain feedback from the Agency before submitting a marketing application to the Agency. Over time, these informal methods of obtaining feedback have become increasingly customary with sponsors, and for some, even preferable to the formal RFD process. Accordingly, FDA is enhancing the transparency and consistency of this process, which will now be called the ''Pre-Request for Designation (Pre-RFD) Program.''

This draft guidance describes this structured process with clear recommendations for sponsors wishing to submit Pre-RFDs. It also provides the process for review of Pre-RFDs by FDA staff, the general timeframes for sponsors to receive feedback from OCP, and the process for scheduling teleconferences and meetings in relation to a Pre-RFD.

This draft guidance describes how to prepare a Pre-RFD. The guidance provides recommendations regarding the information that should be submitted in a Pre-RFD request and procedures that should be followed for meetings or conference calls between OCP, the Centers, and industry representatives or sponsors.

The proposed collections of information are necessary to allow the Agency to receive Pre-RFD requests in order to implement this voluntary submission program.

In the **Federal Register** of January 13, 2017 (82 FR 4351), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, they were not responsive to the four collection of information topics solicited and therefore will not be discussed.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pre-RFD Submissions	136	1	136	12	1,632
Pre-RFD Meetings	136	1	136	1	136
Total					1,768

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

Dated: July 12, 2017.

Anna K. Abram,

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

[FR Doc. 2017–15005 Filed 7–17–17; 8:45 am]

BILLING CODE 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 August 17, 2017.

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 0910–0539. 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, *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.

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 BURDEN [1]

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.

[FR Doc. 2017–14997 Filed 7–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0037]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Drug User Fee Act Waivers and Reductions

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 August 17, 2017.

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 0910–0540. 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, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

Animal Drug User Fees and Fee Waivers and Reductions OMB Control Number 0910–0540—Extension

Enacted on November 18, 2003, the Animal Drug User Fee Act (Pub. L. 108–130) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 740 of the FD&C Act (21 U.S.C 379j–12), which requires that FDA assess and collect user fees with respect to new animal drug applications for certain applications, products, establishments, and sponsors. It also requires the Agency to grant a waiver from, or a reduction of, those fees in certain circumstances. Thus, to implement this statutory provision of ADUFA, FDA developed a guidance entitled ''Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions.'' This document provides guidance on the types of fees FDA is authorized to collect under ADUFA, and how to request waivers and reductions from FDA's animal drug user fees. Further, this guidance also describes the types of fees and fee waivers and reductions; what information FDA recommends be submitted in support of a request for a fee waiver or reduction; how to submit such a request; and FDA's process for reviewing requests. FDA uses the information submitted by respondents to determine whether to grant the requested fee waiver or reduction.

Respondents to this collection of information are new animal drug sponsors. Requests for waivers or reductions may be submitted by a person paying any of the animal drug user fees assessed, including application fees, product fees, establishment fees, or sponsor fees.

In the **Federal Register** of October 17, 2016 (81 FR 71506), 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: