

**DATES:** Submit either electronic or written comments on the collection of information by April 21, 2014.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in

the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Focus Groups as Used by the Food and Drug Administration (All FDA-Regulated Products)—(OMB Control Number 0910-0497)—Extension**

FDA conducts focus group interviews on a variety of topics involving FDA-

regulated products including, drugs, biologics, devices, food, tobacco, and veterinary medicine.

Focus groups provide an important role in gathering information because they allow for a more in-depth understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies. Focus groups serve the narrowly defined need for direct and informal opinion on a specific topic and as a qualitative research tool have three major purposes:

- To obtain consumer information that is useful for developing variables and measures for quantitative studies,
- To better understand consumers' attitudes and emotions in response to topics and concepts, and,
- To further explore findings obtained from quantitative studies.

FDA will use focus group findings to test and refine their ideas, but will generally conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

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

Activity	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Focus Group Interviews .....	1440	1	1440	1.75	2520

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

Annually, FDA projects about 20 focus group studies using 160 focus groups with an average of 9 persons per group, and lasting an average of 1.75 hours each. FDA is requesting this burden for unplanned focus groups so as not to restrict the agency's ability to gather information on public sentiment of its proposals in its regulatory and communications programs.

Dated: February 10, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-03351 Filed 2-14-14; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0764]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Animal Feed Regulatory Program Standards**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Animal Feed Regulatory Program Standards" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On December 6, 2013; the Agency submitted a proposed collection of information entitled "Animal Feed Regulatory Program Standards" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0760. The approval expires on January 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: February 12, 2014.  
**Leslie Kux,**  
*Assistant Commissioner for Policy.*  
 [FR Doc. 2014-03460 Filed 2-14-14; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2014-N-0079]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Generic Drug User Fee Act Cover Sheet**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the paperwork burden of animal drug sponsors to fill out the Animal Generic Drug User Fee Act (AGDUFA) cover sheet.

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**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Form FDA 3728, Animal Generic Drug User Fee Act Cover Sheet—21 U.S.C. 379j-21 (OMB Control Number 0910-0632)—Revision**

Section 741 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j-21) establishes three different kinds of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic

new animal drugs (21 U.S.C. 379j-21(a)). Because concurrent submission of user fees with applications is required, the review of an application cannot begin until the fee is submitted. Form FDA 3728 is the AGDUFA cover sheet, which 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 Animal Generic Drug User Fee Amendments of 2013, signed by the President on June 13, 2013 (AGDUFA II) (Title II of Pub. L. 113-14), amended the FD&C Act authorizing FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. To implement changes under the reauthorization by their effective date of October 1, 2013, FDA sought and received OMB approval to update its Form FDA 3728 as described here:

On page 1 of the electronic questions under “Select an Application Type” users must select “Original” and then choose either, “Abbreviated New Animal Drug Application (ANADA)—under provisions of 512(b)(2) of the FD&C Act (21 U.S.C. 360b(b)(2))”; or “Abbreviated New Animal Drug Application—for certain combination pioneer products approved under provisions of 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)).” If they select the first ANADA type, they will be charged 100 percent of the application fee. If they select the second ANADA type, then they will be charged at rate of 50 percent of the original application fee. To facilitate the application process in this regard, on Form FDA 3728 we have added a line in Section 3 that allows applicants to select the option, “3.2 Original Abbreviated New Animal Drug Application—for certain combination pioneer products approved under provisions of 512(d)(4) of the FD&C Act.”

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3728	20	2	40	.08	3.2

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