

defined by Section 510(b) of the Social Security Act (42 U.S.C. 710(b)) with a focus on those groups that are most likely to bear children out-of-wedlock, such as youth in or aging out of foster care.

States are encouraged to develop flexible, medically accurate and effective abstinence-based plans responsive to their specific needs. These plans must provide abstinence education, and at the option of the State, where appropriate, mentoring,

counseling, and adult supervision to promote abstinence from sexual activity, with a focus on those groups which are most likely to bear children out-of-wedlock. An expected outcome for all programs is to promote abstinence from sexual activity.

OMB approval is requested to solicit comments from the public on paperwork reduction as it relates to ACYF's receipt of the following documents from applicants and awardees:

Application for Mandatory Formula Grant

State Plan

Performance Progress Report

Respondents: 50 States and 9 Territories, to include, District of Columbia, Puerto Rico, Virgin Islands, Guam, American Samoa, Northern Mariana Islands, the Federated States of Micronesia, the Marshall Islands and Palau.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Application, to include program narrative	59	1	24	1,416
Post-Award State Plan	59	1	40	2,360
Performance Progress Reports	59	2	30	3,540

Estimated Total Annual Burden Hours: 7,316

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address:* infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-7285, *E-mail:* OIRA_SUBMISSION@OMB.EOP.GOV Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0182]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 18, 2010 (75 FR 34746), the Agency announced that the proposed information collection had been submitted 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 0910-0354. The approval expires on November 30, 2013. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: November 26, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-30277 Filed 12-1-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0603]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Drug User Fees and Fee Waivers and Reductions

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 reporting requirements for the

animal drug user fees and fee waivers and reductions.

DATES: Submit either electronic or written comments on the collection of information by January 31, 2011.

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: Johnny Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, Juanmanuel.Vilela@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.

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 (ADUFA)

(Pub. L. 108-130) amended the Federal Food, Drug, and Cosmetic Act and requires FDA to assess and collect user fees 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." It provides guidance on the types of fees FDA is authorized to collect under ADUFA, and on how to request waivers and reductions from FDA's animal drug user fees. The guidance also describes the types of fees and fee waivers and reductions, the information FDA recommends respondents submit in support of a request for a fee waiver or reduction, how respondents may submit such a request, and FDA's process for reviewing requests.

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—application fees, product fees, establishment fees, or sponsor fees.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR Section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
740(d)(1)(A) Significant barrier to innovation	22	1	22	2	44
740(d)(1)(B) Fees exceed cost	0	1	0	2	0
740(d)(1)(C) Free choice feeds	2	1	2	2	4
740(d)(1)(D) Minor use or minor species	52	1	52	2	104
740(d)(1)(E) Small business	0	1	0	0	0
Request for reconsideration of a decision	5	1	5	2	10
Request for review—(user fee appeal officer)	2	1	2	2	4
Total					166

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

Based on FDA's database system, there are an estimated 250 sponsors of products subject to ADUFA. However, not all sponsors will have any submissions in a given year and some may have multiple submissions. The total number of waiver requests is based on the number of submission types received by FDA in fiscal year 2008.

Dated: November 24, 2010.
Leslie Kux,
Acting Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA-2010-N-0001]

Gastrointestinal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee