

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Screening Form	Non-Participating Household (Screened).	22,845	1	2/60	761
Interview Form	Eligible Household (Completes Survey).	2,570	1	14/60	600
Total	1361

Seleda Perryman,
Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0937-0166; 30-day notice]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.
 In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality,

utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to Sherrite.funncoleman@hhs.gov, or call the Reports Clearance Office on (202) 690-5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202-395-5806.

Proposed Project: HHS 42 CFR part 50, subpart B; Sterilization of Persons in Federally Assisted Family Planning Projects—OMB No. 0937-0166-Revision-Office of Population Affairs—Office of Family Planning.

Abstract: This is a request for revision of a currently approved collection for the disclosure and record-keeping requirements codified at 42 CFR part 50, subpart B ("Sterilization of Persons in Federally Assisted Family Planning Projects"). The consent form solicits

information to assure voluntary and informed consent to persons undergoing sterilization in programs of health services which are supported by Federal financial assistance administered by the Public Health Service (PHS). The form provides additional procedural protections to individuals undergoing sterilization. In order to obtain informed consent, the regulation requires that programs use either the form that is appended to the PHS regulation or another consent form approved by the Secretary.

In 2003, the sterilization consent form was revised to conform to OMB government-wide standards for the collection of race/ethnicity data and to incorporate the PRA burden statement as part of the consent form. The current form has been updated to conform to the changed name of a federal entitlement program. The program, Aid to Families with Dependent Children (AFDC), utilized by low-income families with dependent children who need federal assistance, has been replaced by a different program with similar aims, Temporary Assistance for Needy Families (TANF). Consequently, the reference to AFDC in the first paragraph has been replaced with a reference to TANF.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response	Total hours
Citizens Seeking Sterilization	Information Disclosure for Sterilization Consent Form.	100,000	1	1	100,000
Citizens Seeking Sterilization	Record-keeping for Sterilization Consent Form.	100,000	1	15/60	25,000
Total	125,000

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0511]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medicated Feed Mill License Application

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 a collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the medicated feed mill licensing applications.

DATES: Submit written or electronic comments on the collection of information by December 28, 2009.

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:

Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

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.

Medicated Feed Mill License Application—21 CFR Part 515 (OMB Control Number 0910-0337)—Extension

The Animal Drug Availability Act (ADAA) of October 9, 1996, amended section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) to replace the system for the approval of specific medicated feed with a general licensing system for feed mills. Before passage of the ADAA, medicated feed manufacturers were required to obtain approval of Medicated Feed Applications (MFAs), in order to manufacture certain types of medicated feeds. An individual approved MFA was required for each and every applicable medicated feed. The ADAA streamlined the paperwork process for gaining approval to manufacture medicated feeds by replacing the MFA system with a facility license for each medicated feed manufacturing facility.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
515.10(b)	20	1	20	0.25	5
515.11(b)	75	1	75	0.25	18.75
515.23	40	1	40	0.25	10
515.30(c)	0.15	1	0.15	24	3.6
Total Burden Hours					37.35

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
510.305	1,070	1	1,070	0.03	32.10

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