NOTIFICATION PROCEDURE:

For purpose of notification, the subject individual should write to the system manager who will require the system name, and the retrieval selection criteria (*e.g.,* Provider number, SSN, etc.).

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2)).

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORD SOURCE CATEGORIES:

Information in the National Level Repository will be populated from other CMS systems of records, including the Provider Enrollment, Chain, and Ownership System (PECOS) and the National Plan & Provider Enumeration System (NPPES).

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 2010–29952 Filed 11–26–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Evaluation of Pregnancy Prevention Approaches and Teen Pregnancy Prevention Evaluation.

OMB No.: 0970–0360.

Description: The Administration for Children and Families (ACF), the Office of the Assistant Secretary for Planning and Evaluation (ASPE), and the Office of the Assistant Secretary for Health (ASH), 13.5. Department of Health and Human Services (HHS), are proposing a data collection activity to be undettaken by two related studies—the Evaluation of Pregnancy Prevention Approaches study and the Teen Pregnancy Prevention Evaluation. Both studies are sponsored by ASH and will use the same data collection instruments; ACF is facilitating the Evaluation of Pregnancy Prevention Approaches, while ASPE is facilitating the Teen Pregnancy Prevention Evaluation.

These two studies will assess the effectiveness of a range of programs designed to prevent or reduce sexual risk behavior and pregnancy among older adolescents. Knowing what types of programs are effective will enhance programmatic decisions by policymakers and practitioners.

The proposed activity involves the collection of information from observations of program activities and interviews with a range of experts and persons involved with programs about various aspects of existing prevention programs and topics the experts view as important to address through evaluation. These data will be used to help enhance decisions about the types of programs to be evaluated in the studies.

Respondents: Researchers and policy experts, program directors, program staff, or school administrators.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Estimated annual burden hours
Discussion Guide for Use with Researchers and Policy Experts	30	1	1	30
Discussion Guide for Use with Program Directors	30	2	2	120
Discussion Guide for Use with Program Staff	60	1	2	120
Focus Group Discussion Guide for Use with Program Participants	300	1	1.5	450
Discussion Guide for Use with School Administrators	200	1	1	200

Estimated Total Annual Burden Hours: 920.

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. E-mail address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 22, 2010.

Steven Hanmer,

OPRE Reports Clearance Officer.

[FR Doc. 2010–29917 Filed 11–26–10; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0601]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Medicated Feeds

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 recordkeeping requirements for manufacturers of medicated animal feeds.

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

Current Good Manufacturing Practice Regulations for Medicated Feeds—21 CFR Part 225 (OMB Control Number 0910–0152)—Extension

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351), FDA has the statutory authority to issue current good manufacturing practice (cGMP) regulations for drugs, including medicated feeds. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease, or growth promotion and feed efficiency. Statutory requirements for cGMPs have been codified under part 225 (21 CFR part 225). Medicated feeds that are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the FD&C Act. Under part 225, a manufacturer is required to establish, maintain, and retain records for a medicated feed, including records to document procedures required during the manufacturing process to assure that proper quality control is maintained. Such records would, for example, contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (*i.e.,* batch and stability testing), labels, and product distribution.

This information is needed so that FDA can monitor drug usage and possible misformulation of medicated feeds to investigate violative drug residues in products from treated animals and to investigate product defects when a drug is recalled. In addition, FDA will use the cGMP criteria in part 225 to determine whether or not the systems and procedures used by manufacturers of medicated feeds are adequate to assure that their feeds meet the requirements of the FD&C Act as to safety and also that they meet their claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the FD&C Act.

A license is required when the manufacture of a medicated feed involves the use of a drug or drugs that FDA has determined requires more control because of the need for a withdrawal period before slaughter or because of carcinogenic concerns. Conversely, a license is not required and the recordkeeping requirements are less demanding for those medicated feeds for which FDA has determined that the drugs used in their manufacture need less control. Respondents to this collection of information are commercial feed mills and mixer-feeders.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN (REGISTERED LICENSED COMMERCIAL FEED MILLS) [1]

21 CFR Section	No. of record-keepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
225.42(b)(5) through (b)(8)	1,004	260	261,040	1	261,040
225.58(c) and (d)	1,004	45	45,180	.5	22,590
225.80(b)(2)	1,004	1,600	1,606,400	.12	192,768
225.102(b)(1)	1,004	7,800	7,831,200	.08	626,496
225.110(b)(1) and (b)(2)	1,004	7,800	7,831,200	.015	117,468
225.115(b)(1) and (b)(2)	1,004	5	5,020	.12	602
Total					1,220,964

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN (REGISTERED LICENSED MIXER-FEEDERS) [1]

21 CFR Section	No. of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
225.42(b)(5) through (b)(8)	100	260	26,000	.15	3,900
225.58(c) and (d)	100	36	3,600	.5	1,800
225.80(b)(2)	100	48	4,800	.12	576
225.102(b)(1)	100	260	26,000	.4	10,400
Total					16,676

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

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN (NONREGISTERED UNLICENSED COMMERCIAL FEED MILLS) [1]

21 CFR Section	No. of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
225.142	8,000	4	32,000	1	32,000
225.158	8,000	1	8,000	4	32,000
225.180	8,000	96	768,000	.12	92,160
225.202	8,000	260	2,080,000	.65	1,352,000
Total					1,508,160

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

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN (NONREGISTERED UNLICENSED MIXER-FEEDERS) [1]

21 CFR Section	No. of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
225.142	45,000	4	180,000	1	180,000
225.158	45,000	1	45,000	4	180,000
225.180	45,000	32	1,440,000	.12	172,800
225.202	45,000	260	11,700,000	.33	3,861,000
Total					4,393,800

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

The estimate of the times required for record preparation and maintenance is based on Agency communications with industry. Other information needed to finally calculate the total burden hours (*i.e.,* number of recordkeepers, number of medicated feeds being manufactured, etc.) is derived from Agency records and experience.

Dated: November 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–29928 Filed 11–26–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0600]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Drug User Fee Cover Sheet, Form 3546

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 burden hours necessary to complete FDA Form 3546, Animal Drug User Fee Act (ADUFA) Cover Sheet.

DATES: Submit either electronic or written comments on the collection of information by January 28, 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