Estimated Total Annual Burden Hours: 13.75

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.

[FR Doc. 2011–19104 Filed 7–27–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Abuse Prevention Program.

OMB No.: 0970–0155.

Description: The Program Instruction, prepared in response to the enactment of the Community-Based Grants for the Prevention of Child Abuse and Neglect (administratively known as the Community Based Child Abuse Prevention Program, (CBCAP), as set forth in Title II of Public Law 111–320, Child Abuse Prevention and Treatment Act Amendments of 2010, provides direction to the States and Territories to accomplish the purposes of (1) supporting community-based efforts to develop, operate, expand, enhance and coordinate initiatives, programs, and activities to prevent child abuse and neglect; (2) supporting the coordination of resources and activities to better strengthen and support families to reduce the likelihood of child abuse and neglect, and; (3) fostering an understanding, appreciation, and knowledge of diverse populations in order to effectively prevent child abuse and neglect. This Program Instruction contains information collection requirements that are found in Pub. L. 111–320 at sections 201; 202; 203; 205; 206; and pursuant to receiving a grant award. The information submitted will be used by the agency to ensure compliance with the statute, complete the calculation of the grant award entitlement, and provide training and technical assistance to the grantee.

Respondents: State Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Application	52	1	40	2,080
Annual Report	52	1	24	1,248

Estimated Total Annual Burden Hours: 3,328.

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.

[FR Doc. 2011–19108 Filed 7–27–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0510]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Prohibited From Use in Animal Food or Feed

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 substances prohibited for use in animal food or feed.

DATES: Submit electronic or written comments on the collection of information by September 26, 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: Juanmanuel 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.

Substances Prohibited From Use in Animal Food or Feed—21 CFR Part 589 (OMB Control Number 0910–0627)—(Extension)

The final rule on bovine spongiform encephalopathy (BSE) (73 FR 22720, April 25, 2008) prohibits the use of certain cattle origin materials in the food or feed of all animals to help prevent the spread of BSE in U.S. cattle. BSE is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. These measures will further strengthen existing safeguards against BSE.

Description of Recordkeeping for Respondents: Rendering facilities, medicated feed manufacturers, livestock feeders.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours	Total operating and maintenance costs
589.2001 (c)(2)(vi) and (c)(3)(i)	175	1	175	20	3,500	$59,500
589.2001 (c)(2)(ii)	50	1	50	20	1,000	17,000
589.2001 (c)(3)(i)(A)	175	1	175	26	4,550	80,580
Total					9,050	157,080

[1] There are no capital costs associated with this collection of information.

The number of recordkeepers times the number of records per recordkeeper equals total annual records. Total annual records times average burden per recordkeeper equals total hours.

Description of Respondents for Reporting; The final rule on BSE (73 FR 22720) included a provision that exempts cattle materials prohibited in animal feed (CMPAF) from designated countries from the prohibition on its use in animal feed (21 CFR 589.2001(b)(1)(vi)). A foreign country seeking this designation will submit a written request to FDA that includes a variety of information about the countries' BSE status (21 CFR 589.2001(f)). FDA estimates that 10 countries could submit a request to FDA to be exempted from CMPAF restrictions.

FDA estimates the reporting burden for this information collection as follows:

TABLE 2—ESTIMATED ONE-TIME AND RECURRING REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
589.2001(b)(1) [2]	10	1	10	80	800
589.2001(f)	10	1	10	26	260

[1] There are no capital costs or operating costs associated with the collection of information.
[2] One-time burden.

Dated: July 20, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–19139 Filed 7–27–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0157]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Fast Track Drug Development Programs: Designation, Development, and Application Review

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 29, 2011.

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 e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0389. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@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.

Guidance for Industry: Fast Track Drug Development Programs: Designation, Development, and Application Review—(OMB Control Number 0910–0389)—[Extension]

Section 112(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 506 (21 U.S.C. 356). The section authorizes FDA to take appropriate action to facilitate the development and expedite the review of new drugs, including biological products, intended to treat a serious or life-threatening condition and that demonstrate a potential to address an unmet medical need. Under section 112(b) of FDAMA, FDA issued guidance to industry on fast track policies and procedures outlined in section 506 of the FD&C Act. The guidance discusses collections of information that are specified under section 506 of the FD&C Act, other sections of the Public Health Service Act (the PHS Act), or implementing regulations. The guidance describes three general areas involving collection of information: (1) Fast track designation requests, (2) premeeting packages, and (3) requests to submit portions of an application. Of these, fast track designation requests and premeeting packages, in support of receiving a fast track program benefit, provide for additional collections of information not covered elsewhere in statute or regulation. Information in support of fast track designation or fast track program benefits that has previously been submitted to the Agency, may, in some cases, be incorporated into the request by referring to the information rather than resubmitting it.

Under section 506(a)(1) of the FD&C Act, an applicant who seeks fast track designation is required to submit a request to the Agency showing that the product: (1) Is intended for a serious or life-threatening condition and (2) has the potential to address an unmet medical need. Mostly, the Agency expects that information to support a designation request will have been gathered under existing provisions of the FD&C Act, the PHS Act, or the implementing regulations. If such information has already been submitted to the Agency, the information may be summarized in the fast track designation request. The guidance recommends that a designation request include, where applicable, additional information not specified elsewhere by statute or regulation. For example, additional information may be needed to show that a product has the potential to address an unmet medical need where an approved therapy exists for the serious or life-threatening condition to be treated. Such information may include clinical data, published reports, summaries of data and reports, and a list of references. The amount of information and discussion in a designation request need not be voluminous, but it should be sufficient to permit a reviewer to assess whether the criteria for fast track designation have been met.

After the Agency makes a fast track designation, a sponsor or applicant may submit a premeeting package that may include additional information supporting a request to participate in certain fast track programs. The premeeting package serves as background information for the meeting and should support the intended objectives of the meeting. As with the request for fast track designation, the Agency expects that most sponsors or applicants will have gathered such information to meet existing requirements under the FD&C Act, the PHS Act, or implementing regulations. These may include descriptions of clinical safety and efficacy trials not conducted under an investigational new drug application (*i.e.,* foreign studies) and information to support a request for accelerated approval. If such information has already been submitted to FDA, the information may be summarized in the premeeting package. Consequently, FDA anticipates that the additional collection of information attributed solely to the guidance will be minimal.

Under section 506(c) of the FD&C Act, a sponsor must submit sufficient clinical data for the Agency to determine, after preliminary evaluation, that a fast track product may be effective. Section 506(c) also requires that an applicant provide a schedule for the submission of information necessary to make the application complete before FDA can commence its review. The guidance does not provide for any new collection of information regarding the submission of portions of an application that are not required under section 506(c) of the FD&C Act or any other provision of the FD&C Act. All forms referred to in the guidance have current OMB approval: FDA Forms 1571 (OMB control number 0910–0014), 356h (OMB control number 0910–0338), and 3397 (OMB control number 0910–0297).

Respondents to this information collection are sponsors and applicants who seek fast track designation under section 506 of the FD&C Act. The Agency estimates the total annual number of respondents submitting