ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Grant Application	53	1	10	530
Tribal Grant Application	150	1	5	750
State Domestic Violence Coalition Application	56	1	10	560
State FVPSA Grant Performance Progress Report	53	1	10	530
Tribal FVPSA Grant Performance Progress Report	150	1	10	1,500
State Domestic Violence Coalition Performance Progress Report	56	1	10	560

Estimated Total Annual Burden Hours: 4,430.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 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. Email 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, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–26101 Filed 11–3–14; 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: Annual Statistical Report on Children in Foster Homes and Children in Families Receiving Payment in Excess of the Poverty Income Level from a State Program Funded Under Part A of Title IV of the Social Security Act.

OMB No.: 0970–0004.

Description: The Department of Health and Human Services is required to collect these data under section 1124 of Title I of the Elementary and Secondary Education Act, as amended by Public Law 103–382. The data are used by the U.S. Department of Education for allocation of funds for programs to aid disadvantaged elementary and secondary students. Respondents include various components of State Human Service agencies.

Respondents: The 52 respondents include the 50 States, the District of Columbia, and Puerto Rico.

ANNUAL BURDEN ESTIMATES

Instrument title	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Annual Statistical Report on Children in Foster Homes and Children Receiving Payments in Excess of the Poverty Level From a State Program Funded Under Part A of Title IV of the Social Security Act	52	1	264.35	13,746.20

Estimated Total Annual Burden Hours: 13,746.20.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 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. Email 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, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–26138 Filed 11–3–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0341]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices

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 December 4, 2014.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0638. Also include the FDA 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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 on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices—(OMB Control Number 0910–0638)—Extension

The Food and Drug Administration Amendments Act of 2007 (FDAAA) includes a requirement that FDA identify and periodically update susceptibility test interpretive criteria for antibacterial drug products and make those findings publicly available. As a result of this provision, the guidance explains the importance of making available to health care providers the most current information regarding susceptibility test interpretive criteria for antibacterial drug products. To address concerns about antibacterial drug product labeling with out-of-date information on susceptibility test interpretive criteria, quality control parameters, and susceptibility test methods, the guidance describes procedures for FDA, applications holders, and antimicrobial susceptibility testing device manufacturers to ensure that updated susceptibility test information is available to health care providers. Where appropriate, FDA will identify susceptibility test interpretive criteria, quality control parameters, and susceptibility test methods by recognizing annually, in a **Federal Register** notice, standards developed by one or more nationally or internationally recognized standard development organizations. FDA recognized standards will be available to application holders of approved antibacterial drug products for updating their product labeling.

Application holders can use one of the following approaches to meet their responsibilities to update their product labeling under the guidance and FDA regulations: Submit a labeling supplement that relies upon a standard recognized by FDA in a **Federal Register** notice or submit a labeling supplement that includes data supporting a proposed change to the microbiology information in the labeling. In addition, application holders should include in their annual report an assessment of whether the information in the ''Microbiology'' subsection of their product labeling is current or whether changes are needed. This information collection is already approved by OMB under control numbers 0910–0572 (the requirement in 21 CFR 201.56(a)(2) to update labeling when new information becomes available that causes the labeling to become inaccurate, false, or misleading) and 0910–0001 (the requirement in 21 CFR 314.70(b)(2)(v) to submit labeling supplements for certain changes in the product's labeling and the requirement in 21 CFR 314.81(b)(2)(i) to include in the annual report a brief summary of significant new information from the previous year that might affect the labeling of the drug product).

In addition, under the guidance, if the information in the applicant's product labeling differs from the standards recognized by FDA in the **Federal Register** notice, and the applicant believes that changes to the labeling are not needed, the applicant should provide written justification to FDA why the recognized standard does not apply to its drug product and why changes are not needed to the ''Microbiology'' subsection of the product's labeling. This justification should be submitted as general correspondence to the product's application, and a statement indicating that no change is currently needed and the supporting justification should be included in the annual report. Based on our knowledge of the need to update information on susceptibility test interpretive criteria, susceptibility test methods, and quality control parameters in the labeling for systemic antibacterial drug products for human use, and our experience with the FDAAA requirement and the guidance recommendations during the past 16 months, we estimate that, annually, approximately two applicants will submit the written justification described previously and in the guidance, and that each justification will take approximately 16 hours to prepare and submit to FDA as general correspondence and as part of the annual report.

In the **Federal Register** of April 7, 2014 (79 FR 19099), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment. The comment expressed support for FDA's efforts to review updated breakpoints published by appropriate nationally or internationally recognized standard setting bodies, and then determine whether to recognize these recommendations in an annual **Federal Register** notice based upon the best available scientific and clinical evidence. The comment also urged FDA and outside organizations to prioritize the harmonization of breakpoints, taking into account possible differences in doses and dosing schedules used in different parts of the world. The comment also expressed support for the provisions in the Antibiotic Development to Advance Patient Treatment (ADAPT) Act, H.R. 3742. The comment said that the ADAPT Act would direct FDA to publish quarterly on its Web site new or updated breakpoints set by an appropriate standard setting organization and recognized by the Agency. The comment said it would also support additional statutory changes to remove breakpoint information from the paper labeling of antibacterial drugs and establish a scheme whereby FDA may clear antimicrobial susceptibility testing devices that incorporate breakpoints that have been set by an outside standard setting body and recognized by the FDA.

FDA appreciates the comment and we will continue our efforts on updating information on susceptibility test interpretive criteria, susceptibility test methods, and quality control parameters in the labeling for systemic antibacterial drug products for human use.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Justification Submitted as General Correspondence and in the Annual Report	2	1	2	16	32

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

Dated: October 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26140 Filed 11–3–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0420]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Testing Communications on Food and Drug Administration-Regulated Products Used in Animals

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 December 4, 2014.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0689. Also include the FDA 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, 8455 Colesville Rd.; COLE–14526, Silver Spring, MD 20993–0002 *PRAStaff@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.

Testing Communications on FDA/Center for Veterinary Medicine (CVM)-Regulated Products Used in Animals (21 U.S.C. 393 (d)(2)(D))—OMB Control Number 0910–0689—Reinstatement

FDA is authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)) to conduct educational and public information programs relating to the safety of CVM-regulated products. FDA must conduct needed research to ensure that such programs have the highest likelihood of being effective. FDA expects that improving communications about the safety of regulated animal drugs, feed, food additives, and devices will involve many research methods, including individual indepth interviews, mall-intercept interviews, focus groups, self-administered surveys, gatekeeper reviews, and omnibus telephone surveys.

The information collected will serve three major purposes. First, as formative research it will provide critical knowledge needed about target audiences to develop messages and campaigns about the use of FDA-regulated products for use in animals. Knowledge of consumer and veterinary professional decision-making processes will provide the better understanding of target audiences that FDA needs to design effective communication strategies, messages, labels, and labeling. These communications will aim to improve public understanding of the risks and benefits of using regulated animal drugs, feed, food additives, and devices by providing users with a better context in which to place risk information more completely.

Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while still in the developmental stage. Respondents will be asked to give their reaction to the messages in either individual or group settings.

Third, as evaluative research, it will allow FDA to ascertain the effectiveness of the messages and the distribution method of these messages in achieving the objectives of the message campaign. Evaluation of campaigns is a vital link in continuous improvement of communications at FDA.

In the **Federal Register** of June 16, 2014 (79 FR 34312) FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was submitted; however, it was not responsive to the four collection of information topics solicited and therefore is not discussed in this document.

FDA estimates the burden of this collection of information based on recent prior experience with the various types of data collection methods described in this document:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 U.S.C. 393(d)(2)(D)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Individual Indepth Interviews	360	1	360	0.75	270
General Public Focus Group Interviews	288	1	288	1.5	432
Intercept Interviews: Central Location	600	1	600	0.25	150
Intercept Interviews: Telephone	[2] 10,000	1	10,000	0.08	800
Self-Administered Surveys	2,400	1	2,400	0.25	600