Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–01122 Filed 1–22–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number 93.645]

Correction to the Notice of Allotment Percentages to States for Child Welfare Services State Grants

AGENCY: Administration on Children, Youth and Families, Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: The Administration on Children, Youth and Families, Administration on Children and Families published a document in the **Federal Register** of November 28, 2014, concerning the biennial publication of allotment percentages for States under Title IV–B subpart 1, Child Welfare Services State Grants Program. The document contained an incorrect allotment percentage for the District of Columbia.

FOR FURTHER INFORMATION CONTACT: Deborah Bell, Grants Fiscal Management Specialist, Office of Grants Management, Office of Administration, Administration for Children and Families, telephone (202) 401–4611.

Correction: In the **Federal Register** of November 28, 2014, in FR. Doc. 2014–28135, on page 70873, in the second column, correct the ''Allotment Percentage'' for the District of Columbia from ''14.17'' to ''30.00.''

Melody Wayland,

Senior Grants Policy Specialist, Office of Administration.

[FR Doc. 2015–01106 Filed 1–22–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0312]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Extralabel Drug Use 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 February 23, 2015.

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 0910–0325. 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 Road; 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.

Extralabel Drug Use in Animals—21 CFR 530 (OMB Control Number—0910–0325)—(Extension)

The Animal Medicinal Drug Use Clarification Act of 1994 allows a veterinarian to prescribe the extralabel use of approved new animal drugs. Also, it permits FDA, if it finds that there is a reasonable probability that the extralabel use of an animal drug may present a risk to the public health, to establish a safe level for a residue from the extralabel use of the drug, and to require the development of an analytical method for the detection of residues above that established safe level. Although to date we have not established a safe level for a residue from the extralabel use of any new animal drug and, therefore, have not required the development of analytical methodology, we believe that there may be instances when analytical methodology will be required. We are, therefore, estimating the reporting burden based on two methods being required annually. The requirement to establish an analytical method may be fulfilled by any interested person. We believe that the sponsor of the drug will be willing to develop the method in most cases. Alternatively, FDA, the sponsor, and perhaps a third party may cooperatively arrange for method development. The respondents may be sponsors of new animal drugs, State, or Federal and/or State Agencies, academia, or individuals.

In the **Federal Register** of November 4, 2014 (79 FR 65408), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
530.22(b)	2	1	2	4,160	8,320

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

Dated: January 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–01113 Filed 1–22–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0915]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved 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 an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the FDA guidance for industry on ''Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application.'' This guidance document provides recommendations on postmarketing serious adverse event reporting for nonprescription (over-the-counter) human drugs marketed without an approved application. It provides recommendations on the minimum data elements that should be included in a serious adverse event report, the label that should be included with the report, reporting formats for paper and electronic submissions, and how and where to submit the reports.

DATES: Submit either electronic or written comments on the collection of information by March 24, 2015.

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: 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: 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.

Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application (OMB Control Number 0910–0636)—Extension

Respondents to this collection of information are manufacturers, packers, and distributors whose name (under section 502(b)(1) (21 U.S.C. 352(b)(1)) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act)) appears on the label of a nonprescription drug marketed in the United States. FDA is requesting public comment on estimates of annual submissions from these respondents, as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109–462) and described in the guidance. The guidance document discusses what should be included in a serious adverse drug event report submitted under section 760(b)(1) (21 U.S.C. 379aa(b)(1)) of the FD&C Act, including follow-up reports under 760(c)(2) (21 U.S.C. 379aa(c)(2)) of the FD&C Act, and how to submit these reports. The estimates for the annual reporting and recordkeeping burdens are based on FDA data on the number of adverse drug experience reports submitted for nonprescription drug products marketed without an approved application, including FDA's knowledge about the time needed to prepare the reports and to maintain records.

Based on FDA data, we estimate between 10,000 and 15,000 (*i.e.,* approximately 12,500) total annual responses from approximately 50 respondents for nonprescription drugs marketed without an approved application, and we also estimate that each submission will take approximately 2 hours to prepare and submit.

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
Reports of serious adverse drug events (21 U.S.C. 379aa((b) and (c))	50	250	12,500	2	25,000

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