

Dated: June 17, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10521]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the 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.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *July 21, 2014*.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by

the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 *OR* Email: *OIRA_submission@omb.eop.gov*.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. The term "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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Improving Quality of Care in Medicaid and CHIP through Increased Access to Preventive Services State Survey; *Use:* The survey will be used to gain a better understanding of state efforts to increase the utilization of preventive services and to develop resources (including

educational and outreach resources) to help states increase the utilization of these services. The results will provide a baseline regarding the coverage of preventive services and will help us identify ways to assist states with materials focusing on prevention and technical assistance.

Form Number: CMS-10521 (OMB control number: 0938-New); *Frequency:* Once; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 51; *Total Annual Hours:* 128. (For policy questions regarding this collection contact Mary Beth Hance at 410-786-4299).

Dated: June 17, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: OCSE-157 Child Support Enforcement Program Annual Data Report.

OMB No.: 0970-0177.

Description: The information obtained from this form will be used to: 1) Report Child Support Enforcement activities to the Congress as required by law; 2) calculate incentive measures performance and performance indicators utilized in the program; and 3) assist the Office of Child Support Enforcement(OCSE)in monitoring and evaluating State Child Support programs.

OCSE is proposing minor updates to the OCSE-157 report instructions to update submission procedures. Respondents will no longer have the option to submit hardcopy reports. The reports can only be submitted electronically by using the Online Data Collections (OLDC) system.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE-157	54	1	7	378

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Estimated Total Annual Burden Hours:	378

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0597]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

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 July 21, 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 0910-0620. 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.

Index of Legally Marketed Unapproved New Animal Drugs for Minor Species 21 CFR Part 516—(OMB Control Number 0910-0620)—(Extension)

Description: The Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize FDA to establish new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats), as well as uncommon diseases in major animal species.

The MUMS Act created three new sections to the FD&C Act (sections 571, 572, and 573), and this final rule implements section 572 of the FD&C Act (21 U.S.C. 360ccc-1), which provides for an index of legally marketed

unapproved new animal drugs for minor species. Participation in any part of the MUMS program is optional so the associated paperwork only applies to those who choose to participate. The final rule specifies, among other things, the criteria and procedures for requesting eligibility for indexing and for requesting addition to the index as well as the annual reporting requirements for index holders.

Under subpart C of part 516, § 516.119 provides requirements for naming a permanent-resident U.S. agent by foreign drug companies, and § 516.121 provides for informational meetings with FDA. Section 516.123 provides requirements for requesting informal conferences regarding Agency administrative actions and § 516.125 provides for investigational use of new animal drugs intended for indexing. Provisions for requesting a determination of eligibility for indexing can be found under § 516.129 and provisions for subsequent requests for addition to the index can be found under § 516.145. A description of the written report required in § 516.145 can be found under § 516.143. Under § 516.141 are provisions for drug companies to nominate a qualified expert panel as well as the panel's recordkeeping requirements. This section also calls for the submission of a written conflict of interest statement to FDA by each proposed panel member. Index holders are able to modify their index listing under § 516.161 or change drug ownership under § 516.163. Requirements for records and reports are under § 516.165.

Description of Respondents: Pharmaceutical companies that sponsor new animal drugs.

In the **Federal Register** of April 7, 2014 (79 FR 19094), 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: