

the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* We require that Medicare Advantage organizations and Prescription Drug Plans complete the Bid Pricing Tool (BPT) as part of the annual bidding process. During this process, organizations prepare their proposed actuarial bid pricing for the upcoming contract year and submit them to us for review and approval. The purpose of the BPT is to collect the actuarial pricing information for each plan. The BPT calculates the plan's bid, enrollee premiums, and payment rates. We publish beneficiary premium information using a variety of formats (www.medicare.gov, the Medicare & You handbook, Summary of Benefits marketing information) for the purpose of beneficiary education and enrollment. *Form Number:* CMS-10142 (OMB control number 0938-0944); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 555; *Total Annual Responses:* 4,995; *Total Annual Hours:* 149,850. (For policy questions regarding this collection contact Rachel Shevland at 410-786-3026).

Dated: December 18, 2014.

Martique Jones,

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 Identifiers CMS-1557]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by February 23, 2015.

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

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:

Contents

This notice sets out a summary of the use and burden associated with the

following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-1557 Survey Report Form for Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations

Under the Paperwork Reduction Act (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 requires federal agencies to publish a 60-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.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection. *Title of Information Collection:* Survey Report Form for Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations. *Use:* The form is used to report surveyor findings during a CLIA survey. For each type of survey conducted (*i.e.*, initial certification, recertification, validation, complaint, addition/deletion of specialty/subspecialty, transfusion fatality investigation, or revisit inspections) the Survey Report Form incorporates the requirements specified in the CLIA regulations. *Form Number:* CMS-1557 (OMB control number: 0938-0544). *Frequency:* Biennially. *Affected Public:* Business or other for-profit, not-for-profit institutions, State, Local or Tribal Governments and Federal Government. *Number of Respondents:* 19,051. *Total Annual Responses:* 9,526. *Total Annual Hours:* 4,763. (For policy questions regarding this collection contact Kathleen Todd at 410-786-3385).

Dated: December 18, 2014.

Martique Jones,

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

[FR Doc. 2014-30027 Filed 12-23-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1461]

Rare Pediatric Disease Priority Review Vouchers; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice of availability (NOA) that appeared in the **Federal Register** of November 17, 2014. In the NOA, FDA requested comments on the Agency's implementation of the Rare Pediatric Disease Priority Review Vouchers Program. This action will allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the NOA published November 17, 2014 (79 FR 68451). Submit either electronic or written comments by February 16, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communications, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002; or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002; or Office of Orphan Products Development, Office of Special Medical Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5295, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office that will be processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets

Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Henry Startzman III, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5295, Silver Spring, MD 20993-0002, 301-796-8660.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 17, 2014, FDA published a NOA with a 60-day comment period to request comments on FDA's implementation of the Rare Pediatric Disease Priority Review Vouchers Draft Guidance. Comments on the draft guidance will inform FDA's drafting of its final guidance for this program.

The Agency has recognized a discrepancy between the 90-day comment period included in the draft guidance and the 60-day comment period written in the November 17, 2014, NOA. Thus, it is publishing this NOA to extend the comment period cited in the previous NOA by 30 days.

The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying drafting of the final guidance on these important issues.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: December 18, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014-30154 Filed 12-23-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0155]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Veterinary Feed Directive

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 January 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 aira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0363. 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.

Veterinary Feed Directive—21 CFR 558 (OMB Control Number 0910-0363)—(Extension)

With the passage of the Animal Drug Availability Act of 1996 (Public Law 104-250), Congress enacted legislation establishing a new class of restricted feed use drugs, VFD drugs, which may be distributed without involving State pharmacy laws. Although controls on the distribution and use of VFD drugs are similar to those for prescription drugs regulated under section 503(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(f)), the implementing VFD regulation (21 CFR 558.6) was tailored to the unique circumstances