

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.

[FR Doc. 2014-30026 Filed 12-23-14; 8:45 am]

BILLING CODE 4120-01-P

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](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](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 [oir_
submission@omb.eop.gov](mailto:oir_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](mailto: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