

for the entire information collection, we are also seeking approval for the provisions that were set out in the proposed rule. *Form Number:* CMS–R–267 (OMB control number: 0938–0753); *Frequency:* Yearly; *Affected Public:* Individuals or households and Business or other for-profits; *Number of Respondents:* 13,958,526; *Total Annual Responses:* 35,596,762; *Total Annual Hours:* 8,529,541. (For policy questions regarding this collection contact Russell Hendel at 410–786–0329.)

Dated: February 22, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–03972 Filed 2–26–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10536]

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

AGENCY: Centers for Medicare & Medicaid Services, HHS.

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 the necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and 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 *March 29, 2018*.

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' website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.
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: William Parham at (410) 786–4669.

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:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Eligibility and Enrollment (EE) Implementation Advanced Planning Document (IAPD) Template; *Use:* To assess the appropriateness of states' requests for enhanced federal financial participation for expenditures related to Medicaid eligibility determination systems, we will review the submitted information and documentation to make an approval determination for the advanced planning document. *Form Number:* CMS–10536 (OMB control number: 0938–1268); *Frequency:* Yearly, once, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 168; *Total Annual Hours:* 2,688. (For policy questions regarding this collection contact Martin Rice at 410–786–2417.)

Dated: February 22, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–03966 Filed 2–26–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Generic Clearance for Financial Reports used in the Administration of Mandatory Grants.

OMB No.: 0970–New.

Description: OMB has granted permission for ACF to submit a request for a generic clearance to be used for the financial reports used in the administration of mandatory grants. This clearance supports the Departments initiative of *Generating Efficiencies through Streamlined Processes* by employing an abbreviated process.

If approved program offices will be at liberty to tailor a financial report to their specific needs rather than adhering to a standard form.

Respondents: States and Territories.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Mandatory Grant Financial Report	900	4	5	18,000

Estimated Total Annual Burden Hours:

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, 330 C Street SW, Washington, DC 20201. Attention 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, Email: OIRA_SUBMISSION@OMB.EOP.GOV. Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018-03976 Filed 2-26-18; 8:45 am]

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abbreviated new drug applications from multiple applicants, withdrawn as of July 21, 2017. The document indicated that FDA was withdrawing approval of NDA 204508, Clinolipid 20% (olive oil and soybean oil) USP, 16%/4%, after receiving a request from the NDA holder, Baxter Healthcare Corp. (Baxter), 32650 N Wilson Rd., Round Lake, IL 60073. Before the approval of NDA 204508 was withdrawn, Baxter informed FDA that it did not want the approval of this NDA withdrawn. Because Baxter timely requested that approval of this NDA not be withdrawn, the approval of NDA 204508 is still in effect.

FOR FURTHER INFORMATION CONTACT:

Florine Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6366, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Wednesday, June 21, 2017, appearing on page 28322 in FR Doc. 2017-12908, the following correction is made:

On page 28329, in table 1, the entry for NDA 204508 is removed.

Dated: February 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-03925 Filed 2-26-18; 8:45 am]

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Considerations for Orphan Drug Designation.” The purpose of the public workshop is to discuss factors FDA should consider when evaluating drugs for orphan designation that treat a tissue agnostic disease or condition in oncology, and additional factors related to orphan exclusivity FDA should consider when approving a product with a tissue agnostic indication.

DATES: The public workshop will be held on May 9, 2018, from 9 a.m. to 5 p.m. The public workshop may be extended or may end early depending on the level of public participation. Submit either electronic or written comments on this public workshop by June 8, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 8, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of June 8, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-3203]

Wyeth Pharmaceuticals Inc. et al.; Withdrawal of Approval of 121 New Drug Applications and 161 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 21, 2017 (82 FR 28322). The document announced the withdrawal of approval of 121 new drug applications (NDAs) and 161

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0663]

Tissue Agnostic Therapies in Oncology: Regulatory Considerations for Orphan Drug Designation; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the following public workshop entitled “Tissue Agnostic Therapies in Oncology: Regulatory