

DATES: Comments must be received by February 18, 2020.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. 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’ website address at 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 N. Parham at (410) 786-4669.

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-10302 Collection Requirements for Compendia for Determination of Medically-Accepted Indications for Off-label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen

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. 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:* Collection Requirements for Compendia for Determination of Medically-accepted Indications for Off-label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen; *Use:* Section 182(b) of the Medicare Improvement of Patients and Providers Act (MIPPA) amended section 1861(t)(2)(B) of the Social Security Act (42 U.S.C. 1395x(t)(2)(B)) by adding at the end the following new sentence: ‘On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest.’ We believe that the implementation of this statutory provision that compendia have a “publicly transparent process for evaluating therapies and for identifying potential conflicts of interests” is best accomplished by amending 42 CFR 414.930 to include the MIPPA requirements and by defining the key components of publicly transparent processes for evaluating therapies and for identifying potential conflicts of interests.

All currently listed compendia will be required to comply with these provisions, as of January 1, 2010, to remain on the list of recognized compendia. In addition, any compendium that is the subject of a future request for inclusion on the list of recognized compendia will be required to comply with these provisions. No compendium can be on the list if it does not fully meet the standard described in section 1861(t)(2)(B) of the Act, as revised by section 182(b) of the MIPPA. *Form Number:* CMS-10302 (OMB control number: 0938-1078); *Frequency:* Annually; *Affected Public:* Business and other for-profits and Not-for-profit institutions; *Number of Respondents:*

845; *Total Annual Responses:* 900; *Total Annual Hours:* 5,135. (For policy questions regarding this collection contact Sarah Fulton at 410-786-2749.)

Dated: December 16, 2019.

William N. Parham, III,

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

[FR Doc. 2019-27385 Filed 12-18-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; OCSE-75 Tribal Child Support Enforcement Program Annual Data Report (OMB #0970-0320)

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting a three-year extension of the form OCSE-75—Tribal Child Support Enforcement Annual Data Report (OMB # 0970-0320, expiration 03/31/2020). There are no changes requested to the form.

DATES: *Comments due within 30 days of publication.* 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.

ADDRESSES: 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.

Copies of the proposed collection may be obtained by emailing infocollection@acf.hhs.gov. Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The data collected by form OCSE-75 are used to prepare the OCSE preliminary and annual data reports. In addition, Tribes administering CSE programs under Title

IV-D of the Social Security Act are required to report program status and accomplishments in an annual narrative report and submit the OCSE-75 report annually.

Respondents: Tribal Child Support Enforcement Organizations or the Department/Agency/Bureau responsible for Child Support Enforcement in each tribe.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
OCSE-75	60	1	60	3,600

Estimated Total Annual Burden Hours: 3,600.

Authority: Title IV-D of the Social Security ACT as required by CFR 45 Section 309.170(b).

Mary B. Jones,
ACF/OPRE Certifying Officer.

[FR Doc. 2019-27423 Filed 12-18-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0403]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Protection of Human Subjects; Informed Consent; and Institutional Review Boards

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 21, 2020.

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 0910-0130. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, 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.

Protection of Human Subjects; Informed Consent; and Institutional Review Boards—21 CFR Parts 50 and 56

OMB Control Numbers 0910-0755 and 0910-0130—Revision

This information collection supports Agency regulations pertaining to the protection of human subjects, informed consent, and responsibilities of Institutional Review Boards (IRBs) as set forth in parts 50 and 56 (21 CFR parts 50 and 56). Parts 50 and 56 apply to all clinical investigations regulated by FDA under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i) and 360j(g), respectively), as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA. The regulations in parts 50 and 56 are intended to protect the rights and safety of subjects involved in such investigations. The regulations also contain the standards for composition, operation, and responsibilities of IRBs that review clinical investigations regulated by FDA.

21 CFR Part 50—Protection of Human Subjects

Provisions in 21 CFR part 50 provide for the protection of human subjects involved in FDA-regulated clinical investigations. With few exceptions, no investigator may involve a human being as a subject in FDA-regulated research unless the investigator has obtained the legally effective informed consent of the

subject or the subject's legally authorized representative.

Basic elements of informed consent are set forth in § 50.25 and include, among other things, a statement of the purpose and duration of a subject's participation in the research; a description of the procedures to be followed; identification of any experimental procedures; a description of risks, benefits, and appropriate alternative procedures or treatments; a description of extent to which confidentiality of records identifying the subject will be maintained; certain contact information; and a statement that participation is voluntary and may be discontinued at any time. Additional elements set forth in § 50.25 are required in the informed consent as appropriate. Exceptions to these requirements are governed by § 50.23, which requires both investigator and physician to certify in writing that necessary elements for exception from general requirements have been satisfied; and § 50.24, which covers exception from informed consent requirements for emergency research. In accordance with § 50.27, informed consent must be documented, except as provided in § 56.109(c), which provides for an IRB to waive documentation of informed consent in certain circumstances. Informed consent must be documented using a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. For each clinical investigation reviewed by an IRB, we believe there will typically be one associated written consent form developed by an investigator. In some cases, investigators will seek IRB approval of changes in the research and/or consent form after initial IRB approval. For some multi-institutional clinical investigations, the IRB of each institution involved may separately conduct initial and continuing review of the research, including review of the written consent form to determine