ANNUAL BURDEN ESTIMATES—Continued

Instrument	Total number of respondents	Annual number of respondent	Number of responses per respondent	Average burden hours per response	Annual burden hours
Pre-survey information form	6,000	2,000	1	0.05	100

Estimated Total Annual Burden Hours: 3,300.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Sec. 413. [8 U.S.C. 1523].

Emily B. Jabbour,

ACF/OPRE Certifying Officer.

[FR Doc. 2018–22441 Filed 10–15–18; 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: Sponsorship Review Procedures for Approval for Unaccompanied Alien Children.

OMB No.: 0970–0278.

Description: The Administration for Children (ACF), Office of Refugee Resettlement (ORR) requests the continuation of an existing information collection under OMB control number 0970–0278, Reunification Procedures for Unaccompanied Alien Children, renamed to Sponsorship Review Procedures for Approval of Unaccompanied Alien Children. The information collection allows ACF to conduct suitability assessments to vet potential sponsors of unaccompanied alien children in accordance with a Memorandum of Agreement (MOA) between ORR and the Department of Homeland Security. Specifically, the information collection allows ORR to obtain biometric and biographical information from sponsors, adult members of their household, and adult care givers identified in a sponsor care plan, where applicable. ORR in turn shares the information collected with other federal departments to conduct background checks. The existing OMB approval for these instruments expires October 31, 2018.

Respondents: Sponsors, adult household members, parents or legal guardians of unaccompanied alien children.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Family Reunification Application	50,000	1	0.75	37,500
Authorization for Release of Information	90,000	1	0.5	45,000
Fingerprint Instructions	90,000	1	1.25	112,500
Letter of Designation	25,000	1	0.5	12,500

Estimated Total Annual Burden per Respondent: 207,500.

Additional Information: Copies of the existing 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.*

ACF first sought comments on this revised collection of information on May 11, 2018 (83 FR 22490) and again on August 24, 2018 (83 FR 42895). The more recent request for comment erroneously described the request as one for emergency processing and immediate approval. This notice corrects that error to clarify that ACF is seeking public comments on the proposed information collection, including aspects previously approved under emergency processing, prior to its renewal.

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 A. Sargis,

Reports Clearance Officer.

[FR Doc. 2018–22461 Filed 10–15–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6617]

Developing Targeted Therapies in Low-Frequency Molecular Subsets of a Disease; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Developing Targeted Therapies in Low-Frequency Molecular Subsets of a Disease.'' This final guidance incorporates public comments to the draft guidance published in the **Federal Register** of December 18, 2017.

The pharmacological effect of a targeted therapy is often related to a particular molecular alteration, and many diseases are caused by a range of different molecular alterations (some of which may be rare). Therefore, a targeted therapy may have differential effects among patients with the same disease who have different molecular alterations. The purpose of this guidance is to describe general approaches to evaluating the benefits and risks of targeted therapeutics within a clinically defined disease where some molecular alterations may occur at low frequencies.

DATES: The announcement of the guidance is published in the **Federal Register** on October 16, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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 solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–6617 for ''Developing Targeted Therapies in Low-Frequency Molecular Subsets of a Disease.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Michael Pacanowski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 301–796–3919; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Developing Targeted Therapies in