Dated: May 23, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–12953 Filed 5–30–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Unaccompanied Refugee Minor Placement and Outcomes Reports; ORR–3 and ORR–4.

OMB No.: 0970–0034.

Description: The two reports collect information necessary to administer the Unaccompanied Refugee Minor (URM) program. The ORR–3 (Placement Report) is submitted to the Office of Refugee Resettlement (ORR) by the State agency at initial placement within 30 days of the placement, and whenever there is a change in the child's status, including termination from the program, within 60 days of the change or closure of the case. The ORR–4 (Outcomes Report) is submitted within approximately 12 months of the initial placement and each subsequent 12 months to record outcomes of the child's progress toward the goals listed in the child's case plan and particularly for youth 17 years of age and above related to independent living and/or educational plans. ORR–4 is also submitted as a baseline report along with the initial ORR–3 report for 17 years old and above youth, and as a follow-up annual report for cases that have terminated and are 17 to 21 years old. ORR regulations at 45 CFR 400.120 describes specific URM program reporting requirements.

Respondents: State governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–3	15	Estimate responses 75	0.25 (15 Minutes)	Estimated 281.25
ORR–4	15	Estimate responses 119	1.5 (1 Hour and 30 Minutes)	Estimated 2,677.5

Estimated Total Annual Burden Hours: 2,958.75.

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, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF 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, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–12875 Filed 5–30–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Job Search Assistance (JSA) Strategies Evaluation.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF) is proposing an information collection activity as part of the Job Search Assistance (JSA) Strategies Evaluation. The proposed information collection consists of semi-structured interviews with key respondents involved with job search assistance programs in states and localities. Through this information collection and other study activities, ACF seeks to identify the types of job search assistance strategies that should be tested within the context of current TANF policies and requirements.

Respondents: State and local TANF administrators, program staff, and stakeholders such as researchers and policy experts.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Discussion Guide for Use with Researchers and Policy Experts	15	1	1	15	7.5
Discussion Guide for use with State and Local TANF Administrators	35	1	2.5	87.5	43.75
Discussion Guide for Use with Program Staff	50	1	2	100	50

Estimated Total Annual Burden Hours: 101.25.

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. 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, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

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.

Steven M. Hanmer,

Reports Clearance Officer.

[FR Doc. 2013–12904 Filed 5–30–13; 8:45 am]

BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0571]

Draft Guidance for Industry on Rheumatoid Arthritis: Developing Drug Products for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Rheumatoid Arthritis: Developing Drug Products for Treatment.'' This guidance outlines FDA's current thinking on the principles of clinical development relevant to dose-selection and assessment of efficacy and safety to support the approval of drug products for the treatment of patients with rheumatoid arthritis (RA). It also addresses additional considerations for drug products developed as drug-device combination products. This guidance revises the guidance for industry entitled ''Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA),'' published in February 1999.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 30, 2013.

ADDRESSES: 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, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448; or the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in 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: Nikolay Nikolov, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3335, Silver Spring, MD 20993–0002, 301–796–5281; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210; or Markham Luke Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1680, Silver Spring, MD 20993–0002, 301–796–5556.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Rheumatoid Arthritis: Developing Drug Products for Treatment.'' This draft guidance reflects current FDA thinking on RA drug product development. FDA's current thinking has been influenced by clinical development programs conducted for RA since the 1999 guidance published, and by changes in the standard of care for RA because of availability of many effective treatments. RA drug product development has evolved to reflect the current status of the RA therapeutic armamentarium, good clinical practice, and treatment goals.

The draft guidance addresses:

- Dose(s) and dosing regimen(s) selection throughout the clinical development program.
- Expectations for establishing efficacy in RA based on signs and symptoms and physical function domains.
- Use of efficacy endpoints such as clinical remission and prevention of structural damage progression.
- Limiting the use of placebo.
- Use of active comparator for safety and efficacy trials.
- Principles of safety assessment.
- Development of drug-device combination products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on developing drug products for the treatment of RA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. 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