ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Youth Outcome Survey	20,667	1	0.50	10,334
Data File	52	2	1,849	192,296

Estimated Total Annual Burden Hours: 202,630.

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. 2015–21728 Filed 9–1–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Refugee Data Submission System for Formula Funds Allocations

OMB No.: 0970–0043.

Description: The information collection of Refugee Data Submission System for Formula Funds Allocations replaces the ORR–11 Refugee State of Origin Report and is designed to satisfy the statutory requirements of the Immigration and Nationality Act (INA). Section 412(a)(3)of the Act requires the Director of the Office of Refugee Resettlement (ORR) to make a periodic assessment, based on refugee population and other relevant factors, of the relative needs of refugees for assistance and services and the resources available to meet those needs. This includes compiling and maintaining data on the secondary migration of refugees within the United States after arrival. Further, INA 412(c)(1)(B)states that formula funds shall be allocated based on the total number of refugees, taking into account secondary migration.

In order to meet the statutory requirements, ORR requires each state to submit disaggregated individual records containing certain data elements for eligible refugee populations. This revised collection differs from the ORR–11 Refugee State-of-Origin Report process, whereby states submitted the ORR–11 form containing aggregate data on the number of refugees and entrants served whose ''area numbers'' (the first three digits of the social security number) fell into each of several designated numerical ranges. ORR used the information on the ORR–11 to measure secondary migration for the purposes of formula funds allocation to states. The revision is proposed due to the realization that:

(1) The Social Security Administration states that the first three digits of social security numbers (area number) should not be used for any other purpose than as an individual identifier for book-keeping purposes.

(2) It is possible for individuals to apply for social security numbers from any social security office, not just offices in the state in which they were born or first resided. This is particularly likely in metropolitan statistical areas where individuals may live in one of several states (*e.g.,* the Washington Metropolitan Area). In these cases, the area number of the social security number may be unreliable as a measure of refugees' state of initial resettlement.

(3) In recent years, the Social Security Administration has begun to issue social security numbers whose area number is not connected to any specific state.

The submission of individual records via the Refugee Data Submission System for Formula Funds Allocations Web site is a more reliable and secure process for collecting data for the purposes of tracking secondary migration and allocating formula funds. Data submitted by the States via the secure Web site are compiled and analyzed by the ORR statistician for the purpose of refugee secondary services formula funds allocation. The statistician also prepares a summary report, which is included in ORR's Annual Report to Congress.

Respondents: States and the District of Columbia.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Refugee Data Submission for Formula Funds Allocations	50	1	20	1,000

Estimated Total Annual Burden Hours: 1,000.

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. 2015–21727 Filed 9–1–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0164]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the requirement to make safety related labeling changes based upon new safety information that becomes available after the drug or biological product is approved under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) or the Public Health Service Act (PHS Act.)

DATES: Submit either electronic or written comments on the collection of information by November 2, 2015.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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.*

SUPPLEMENTARY INFORMATION: 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. ''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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (OMB Control Number 0910–0734)—Extension

Section 505(o)(4) of the FD&C Act (21 U.S.C. 355(o)(4)) authorizes FDA to require, and if necessary, order labeling changes if FDA becomes aware of new safety information that FDA believes should be included in the labeling of certain prescription drug and biological products approved under section 505 of the FD&C Act or section 351 of the PHS Act (42 U.S.C. 262). Section 505(o)(4) of the FD&C Act applies to prescription drug products with an approved new drug application (NDA) under section 505(b) of the FD&C Act, biological products with an approved biologics license application under section 351 of the PHS Act, or prescription drug products with an approved abbreviated new drug application under section 505(j) of the FD&C Act if the reference listed drug with an approved NDA is not currently marketed. Section 505(o)(4) imposes timeframes for application holders to submit and FDA staff to review such changes, and gives FDA new enforcement tools to bring about timely and appropriate labeling changes. The guidance provides information on the implementation of the new provisions, including a description of the types of safety labeling changes that ordinarily might be required under the new legislation, how FDA plans to determine what constitutes new safety information, the procedures involved in requiring safety labeling changes, and enforcement of the requirements for safety labeling changes.

FDA requires safety labeling changes by sending a notification letter to the application holder. Under section 505(o)(4)(B), the application holder must respond to FDA's notification by submitting a labeling supplement or notifying FDA that the applicant does not believe the labeling change is warranted and submitting a statement detailing the reasons why the application holder does not believe a change is warranted (a rebuttal statement).

Based on FDA's experience to date with safety labeling changes requirements under section 505(o)(4), we estimate that approximately 42 application holders will elect to submit approximately one rebuttal statement each year and that each rebuttal statement will take approximately 6 hours to prepare.

In addition, in the guidance, FDA states that new labeling prepared in