ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Instrument 4: Subrecipient Data Collection and Reporting Form					
SPREP subrecipients	259	6	14	21,756	7,252
TPREP subrecipients	27	6	14	2,268	756
CPREP subrecipients	54	6	12	3,888	1,296
PREIS subrecipients	20	6	12	1,440	480

Estimated Total Annual Burden Hours: 41,052.

Comments: 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. 50503, Pub. L. 115–123.

John M. Sweet, Jr.,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–05992 Filed 3–22–23; 8:45 am]

BILLING CODE 4184–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Operation Allies Welcome Afghan Supplement Survey (New Collection)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services is proposing to collect data for a new Operation Allies Welcome (OAW) Afghan Supplement Survey.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Under the Afghanistan Supplemental Appropriations Act, 2022, and Additional Afghanistan Supplemental Appropriations Act, 2022, Congress authorized ORR to provide resettlement assistance and other benefits available to refugees to specific Afghan populations in response to their emergency evacuation and resettlement. The OAW Afghan Supplement Survey is a sample survey of Afghan households entering the United States under OAW, collecting both household- and individual-level information. It will generate nationally representative data on OAW Afghans' well-being, integration outcomes, and progress towards self-sufficiency. Data collected will help ORR and service providers better understand the impact of services and on-going service needs of OAW Afghan populations.

Respondents: OAW Afghan populations.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total/annual burden hours *
OAW Afghan Supplement Survey Contact Update Requests	1,100	1	0.05	55
OAW Afghan Supplement Survey	1,100	1	0.92	1,012

* Survey is one-time and will be completed within the 1st year.

Estimated Total Annual Burden Hours: 1,067.

Comments: 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: Division C, Title III, Public Law 117–43, 135 Stat. 374; Division B,

Title III, Public Law 117–70, 1102 Stat. 4.

John M. Sweet, Jr.,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–05980 Filed 3–22–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0573]

Changes to Third-Party Vendors for Risk Evaluation and Mitigation Strategies; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the establishment of a docket to solicit comments on factors that generally should be considered by the Secretary of Health and Human Services (Secretary) when reviewing modification requests from sponsors of drugs subject to risk evaluation and mitigation strategies (REMS) related to changes in third-party vendors engaged by sponsors to aid in implementation and management of the strategies.

DATES: Submit either electronic or written comments by July 21, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 21, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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 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–2023–N–0573 for ''Proposed Changes to Third-Party Vendors Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Marcus Cato, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4475, 301–796–2380, *OSE.PMKTREGS@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 505–1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355–1), authorizes FDA to require a REMS if FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks. A REMS is a required risk management strategy that employs tools beyond prescribing information to ensure that the benefits of a drug outweigh its risks. A REMS may require a Medication Guide (or patient package insert) to provide risk information to patients, a communication plan to disseminate risk information to healthcare providers, and certain packaging and safe disposal systems for drugs that pose a serious risk of abuse or overdose. FDA may also require certain elements to assure safe use (ETASU) when such elements are necessary to mitigate a specific serious risk listed in the labeling of the drug. ETASU may include, for example, requirements that healthcare providers who prescribe the drug have particular training or experience, that patients using the drug be monitored, or that the drug be dispensed to patients with evidence or other documentation of safe-use conditions. Certain REMS with ETASU may also include an implementation system through which the applicant is able to monitor and evaluate implementation of the ETASU