

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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Health Equity Technical Assistance Monitoring and Tracking; *Use:* The Centers for Medicare & Medicaid Services (CMS) Office of Minority Health (OMH) developed the CMS Equity Plan for Improving Quality in Medicare (CMS Equity Plan for Medicare). The Plan outlines CMS’ path to help advance health equity by improving the quality of care provided to minority and other underserved Medicare beneficiaries, particularly those with disparities in chronic diseases. CMS identified six high-impact priority areas based on a review of the evidence base and stakeholder input. These priorities encompass both system- and community-level approaches to achieve equity in Medicare. Priority 2: Evaluate Disparities Impacts and Integrate Equity Solutions Across CMS Programs, focuses on increasing understanding of the impact CMS programs have on health disparities and on identifying, developing and integrating proven solutions to improve their impact on vulnerable populations.

CMS created a Health Equity Technical Assistance (TA) email ([HealthEquityTA@cms.hhs.gov](mailto:HealthEquityTA@cms.hhs.gov)) to support CMS programs as they integrate health equity into their programs. This TA offers guidance from health equity subject matter experts on a variety of topics including reviewing data to identify health disparities, identifying root causes of health disparities, gaining an organizational champion, building organizational capacity to address health disparities, implementing interventions, tracking success of intervention, and serves as a portal to

access health equity resources. *Form Number:* CMS–10669 (OMB control number: 0938—New); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other For-profits); *Number of Respondents:* 274; *Total Annual Responses:* 274; *Total Annual Hours:* 23. (For policy questions regarding this collection contact Alexandra Bryden at 410–786–2076).

Dated: July 11, 2018.

**William N. Parham, III,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity; Comment Request

##### Proposed Projects

*Title:* U.S. Repatriation Program Forms.

*OMB No.:* 0970—NEW (two of the forms have prior OMB No: [SSA–3955 & SSA–2061])

*Description:* The United States (U.S.) Repatriation Program was established by Title XI, Section 1113 of the Social Security Act (Assistance for U.S. Citizens Returned from Foreign Countries) to provide temporary assistance to U.S. citizens and their dependents who have been identified by the Department of State (DOS) as having returned, or been brought from a foreign country to the U.S. because of destitution, illness, war, threat of war, or a similar crisis, and are without available resources immediately accessible to meet their needs. The Secretary of the Department of Health and Human Services (HHS) was provided with the authority to administer this Program. On or about 1994, this authority was delegated by the HHS Secretary to the Administration for Children and Families (ACF) and later re-delegated by ACF to the Office of Refugee Resettlement. The Repatriation Program works with States, Federal agencies, and non-governmental organizations to provide eligible individuals with temporary assistance for up to 90-days. This assistance is in the form of a loan and must be repaid to the Federal Government.

The Program was later expanded in response to legislation enacted by Congress to address the particular needs of persons with mental illness (24

U.S.C. Sections 321 through 329). Further refinements occurred in response to Executive Order (E.O.) 11490 (as amended) where HHS was given the responsibility to “develop plans and procedures for assistance at ports of entry to U.S. personnel evacuated from overseas areas, their onward movement to final destination, and follow-up assistance after arrival at final destination.” In addition, under E.O. 12656 (53 CFR 47491), “Assignment of emergency preparedness responsibilities,” HHS was given the lead responsibility to develop plans and procedures in order to provide assistance to U.S. citizens and others evacuated from overseas areas.

Overall, the Program manages two major activities, Emergency and Non-emergency Repatriation Activities. The ongoing routine arrivals of individual repatriates and the repatriation of individuals with mental illness constitute the Program Non-emergency activities. Emergency activities are comprised of group repatriations (evacuations of 50–500 individuals) and emergency repatriations (evacuations of 500 or more individuals). Operationally, these activities involve different kinds of preparation, resources, and implementation. However, the core Program policies and administrative procedures are essentially the same. The Program provides services through agreements with local repatriation service providers (e.g. States, federal agencies, non-governmental agencies, etc.). For the purpose of this Program, local repatriation service provider (local provider) has the same definition of “agency” as defined under 45 CFR 212.1 (i).

1. *The HHS Repatriation Program Emergency and Group Processing Form:* Under 45 CFR 211 and 212, ORR is to make findings setting forth the pertinent facts and conclusions according to established standards to determine whether an individual is an eligible person. This form allows authorized staff to gather necessary information to determine eligibility and needed services. This form is to be utilized during emergencies and group repatriations. Individuals interested in receiving Repatriation assistance will complete appropriate portions of this form. State personnel will utilize this form as a guide to perform an initial eligibility and needs assessment. An authorized federal staff from the ACF will make final eligibility determinations through the approval of this form.

2. *The U.S. Repatriation Program Privacy and Repayment Agreement*

*Form:* Under 45 CFR 211 and 212, individuals who receive Program assistance are required to repay the federal government for the cost associated to the services received. This form authorizes ORR to release personal identifiable information to partners for the purpose of providing services to eligible repatriates. In addition, through this form, eligible repatriates agree to accept services under the terms and conditions of the Program. Specifically, eligible repatriates commit to repay the federal government for all services received while in the Program. This form is to be completed by eligible repatriates or authorized legal custodian. Exception applies to unaccompanied minors and individuals eligible under 45 CFR 211, if no legal custodian is identified.

**3. Relinquish Repatriation Services Form:** For individuals who are eligible to receive repatriation assistance but opt to relinquish services, this form is utilized to confirm and record repatriate's decision to refuse Program assistance. This form is to be completed by eligible repatriates or authorized legal custodian. Exception applies to unaccompanied minors and individuals eligible under 45 CFR 211, if no legal custodian is identified.

**4. The U.S. Repatriation Program Emergency Financial Form:** Under Section 1113 of the Social Security Act, ORR is authorized to provide temporary assistance directly or through utilization

of the services and facilities of appropriate public or private agencies and organizations, in accordance with agreements providing for payment, as may be determined by ORR. This form is to be utilized and completed by ORR local providers to request reimbursement of reasonable and allowable costs, both administrative and actual temporary services, after emergency activities.

**5. The U.S. Repatriation Program Non-emergency Reimbursement Form:** Under Section 1113 of the Social Security Act, ORR is authorized to provide temporary assistance directly or through arrangements, in accordance with agreements providing for payment, as may be determined by ORR. This form is to be utilized and completed by ORR local providers to request reimbursement of reasonable and allowable costs, both administrative and actual temporary services.

**6. The U.S. Repatriation Program Financial Waiver Request Form:** In accordance with 45 CFR 211 & 212 individuals who have received Repatriation assistance may be eligible to receive a waiver or deferral of their repatriation loan. This form is to be completed by eligible repatriates, authorized legal custodian, or the repatriation local provider. Exception applies to unaccompanied minors and individuals eligible under 45 CFR 211, if no legal custodian is identified.

**7. The U.S. Repatriation Program Temporary Assistance Extension**

*Request Form:* Under 45 CFR 211 & 212 temporary assistance may be furnished beyond the 90 days eligibility period. This form is to be completed by the eligible repatriates, authorized legal custodian, or the repatriation local provider. This form should be submitted to ORR or its authorized grantee 14 days prior to the expiration of the 90 days eligibility period.

**8. The U.S. Repatriation Program Individual Case Management Report and Financial Claim Form:** Under Section 1113 of the Social Security Act, ORR is authorized to provide temporary assistance directly or through agreements with public and private agencies. This form is to be utilized and completed by ORR local provider to request reimbursement of reasonable and allowable costs, both administrative and actual temporary services. This form should also be utilized by the local repatriation provider for submit case updates. This forms is to be completed by authorized local providers.

*Respondents:* Repatriation Program local repatriation service provider and individuals repatriated or evacuated by DOS from overseas. These respondents are authorized under Title XI, Section 1113 of the Social Security Act (42 U.S.C. 1313), Executive Order 12656 (amended by E.O. 13074, February 9, 1998; E.O. 13228, October 8, 2001; E.O. 13286, February 28, 2003), and 45 CFR 211 & 212.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
U.S. Repatriation Program Emergency and Group Processing Form ...	500 or more .....	1 .....	0.15	75 or more.
U.S. Repatriation Program Privacy and Repayment Agreement Form:	1000 or more ....	1 .....	0.05	50 or more.
U.S. Repatriation Program Relinquish Temporary Assistance Form .....	50 or more .....	1 .....	0.05	0.8 or more.
U.S. Repatriation Program Emergency and Group Financial Form .....	4 or more .....	1 .....	.20	4 or more.
U.S. Repatriation Program Non-emergency Monthly Financial Statement Form.	53 or more .....	1 .....	0.20	10.6 or more.
U.S. Repatriation Program Loan Waiver Request Form .....	100 or more .....	1 .....	1	100 or more.
U.S. Repatriation Program Temporary Assistance Extension Request Form.	500 or more .....	1 .....	0.20	100 or more.
U.S. Repatriation Program Individual Case Management Report .....	1000 or more ....	1 or more .....	0.20	200 or more.

*Estimated Total Annual Burden Hours:* 540.4.

In compliance with the requirements of Section 506(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: ACF Reports Clearance Officer. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@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.

**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-0341]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drugs for Investigational Use

**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 August 15, 2018.

**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](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0117. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.

#### New Animal Drugs for Investigational Use

*OMB Control Number 0910-0117—Extension*

FDA has the authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to approve new animal drugs. A new animal drug application (NADA) cannot be approved until, among other things, the new animal drug has been demonstrated to be safe and effective for its intended use(s). In order to properly test a new animal drug for an intended use, appropriate scientific investigations must be conducted. Under specific circumstances, section 512(j) of the FD&C Act (21 U.S.C. 360b(j)) permits the use of an investigational new animal drug to generate data to support an NADA approval. Section 512(j) of the FD&C Act authorizes us to issue regulations relating to the investigational use of new animal drugs.

Our regulations in 21 CFR part 511 set forth the conditions for investigational use of new animal drugs and require reporting and recordkeeping. The information collected is necessary to protect the public health. We use the information to determine that investigational animal drugs are distributed only to qualified investigators, adequate drug accountability records are maintained, and edible food products from treated food-producing animals are safe for human consumption. We also use the information collected to monitor the validity of the studies submitted to us to support new animal drug approval.

**Reporting:** Our regulations require that certain information be submitted to us in a “Notice of Claimed Investigational Exemption for a New Animal Drug” (NCIE) to qualify for the exemption and to control shipment of the new animal drug and prevent potential abuse. The NCIE must contain, among other things, the following specific information: (1) Identity of the new animal drug, (2) labeling, (3) statement of compliance of any nonclinical laboratory studies with good laboratory practices, (4) name and address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6) information regarding the use of edible tissues from investigational animals (§ 511.1(b)(4) (21 CFR 511.1(b)(4)). If the new animal drug is to be used in food-producing animals, e.g., cattle, swine, chickens, fish, etc., certain data must be submitted to us to obtain authorization for the use of edible food products from treated food-producing animals

(§ 511.1(b)(5)). We require sponsors upon request to submit information with respect to the investigation to determine whether there are grounds for terminating the exemption (§ 511.1(b)(6)). We require sponsors to report findings that may suggest significant hazards pertinent to the safety of the new animal drug (§ 511.1(b)(8)(ii)). We also require reporting by importers of investigational new animal drugs for clinical investigational use in animals (§ 511.1(b)(9)). The information provided by the sponsor in the NCIE is needed to ensure that the proposed investigational use of the new animal drug is safe and that any edible food will not be distributed without proper authorization from FDA. Information contained in an NCIE submission is monitored under our Bio-Research Monitoring Program. This program permits us to monitor the validity of the studies and to ensure the proper use of the drugs is maintained by the investigators.

**Recordkeeping:** If the new animal drug is only for tests in vitro or in laboratory research animals, the person distributing the new animal drug must maintain records showing the name and post office address of the expert or expert organization to whom it is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery (§ 511.1(a)(3) and (b)(3)). We require complete records of the investigation, including records of the receipt and disposition of each shipment or delivery of the investigational new animal drug (§ 511.1(b)(7)). We also require records of all reports received by a sponsor from investigators to be retained for 2 years after the termination of an investigational exemption or approval of a new animal drug application (§ 511.1(b)(8)(i)).

**Description of Respondents:** Respondents to this collection of information are persons who use new animal drugs for investigational purposes. Investigational new animal drugs are used primarily by drug industry firms, academic institutions, and the government. Investigators may include individuals from these entities, as well as research firms and members of the medical professions.

In the **Federal Register** of February 22, 2018 (83 FR 7735), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows: