

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb-3(b)(4).

Dated: June 28, 2012.

Kathleen Sebelius,
Secretary.

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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.

Description: 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 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 and later re-delegated 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. 321 through 329). Further refinements occurred in response to Executive Order (EO) 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 EO 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 or 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.

1. *The U.S. Repatriation Program Emergency and Group Processing Form:* Under 45 CFR parts 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 to identify the services that need to be provided. 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 assessment and to identify the type of services an eligible person might be able to receive. Furthermore, an authorized federal staff from the Administration for Children and Families (ACF) will make final eligibility determination by completing the appropriate section of this form.

2. *The U.S. Repatriation Program Privacy and Repayment Agreement Form:* Under 45 CFR parts 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 minors

and individuals eligible under 45 CFR part 211 when 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 minors and individuals eligible under 45 CFR part 211 when no legal custodian is identified.

4. *The U.S. Repatriation Program Emergency Reimbursement 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, in advance or by way of reimbursement, as may be determined by ORR. This form is to be utilized and completed by ORR partners to request reimbursement of reasonable and allowable costs, both administrative and actual temporary services, associated to services provided under the Program Emergency activities. For the purpose of this document, the word partner has the same meaning of “agency.” Definition is found under 45 CFR 212.1 (i).

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 utilization of the services and facilities of appropriate public or private agencies and organizations, in accordance with agreements providing for payment, in advance or by way of reimbursement, as may be determined by ORR. This form is to be utilized and completed by ORR partners to request reimbursement of reasonable and allowable costs, both administrative and actual temporary services, associated to services provided under the Program non-emergency activities.

6. *The U.S. Repatriation Program Financial Waiver Request Form:* Under 45 CFR parts 211 & 212 individuals who have received Repatriation assistance may be eligible to receive waivers and/or deferral if they fall within the repayment exceptions found with these regulations. This form is to be completed by eligible repatriates or authorized legal custodian or state repatriation coordinator whenever appropriate. Exception applies to minors and individuals eligible under 45 CFR part 211 when no legal custodian is identified.

7. *The U.S. Repatriation Program Temporary Assistance Extension Request Form*: Under 45 CFR parts 211 & 212 temporary assistance may be furnished beyond the 90 days eligibility period if the individual falls within the eligibility requirements for an extension. This form is to be completed by the eligible repatriates or authorized legal custodian or state repatriation coordinator whenever appropriate. This form must be submitted to ORR or its authorized grantee 14 days prior to the 90 days eligibility period ends, unless the circumstances surrounding the case merits submission after the 14th day.

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

services, and to provide individual case updates. This form is to be completed by the eligible individual case worker and/or service provider.

Respondents: Repatriation Program partners (e.g. States, federal agencies, non-governmental agencies, etc.) 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 parts 211 & 212.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|-----------------------|------------------------------------|-----------------------------------|--------------------|
| The U.S. Repatriation Program Emergency and Group Processing Form. | 50 or more | 1 | 0.15 | 7.5 or more. |
| The U.S. Repatriation Program Privacy and Repayment Agreement Form: | 700 or more | 1 | 0.10 | 70 or more. |
| Relinquish Repatriation Services Form | 10 or more | 1 | 0.05 | 0.5 or more. |
| The U.S. Repatriation Program Emergency Reimbursement Form: | 4 or more | 1 | 1 | 4 or more. |
| The U.S. Repatriation Program Non-emergency Reimbursement Form: | 53 or more | 1 | 0.30 | 17.9 or more. |
| The U.S. Repatriation Program Financial Waiver Request Form: | 100 or more | 1 | 1 | 100 or more. |
| The U.S. Repatriation Program Temporary Assistance Extension Request Form. | 20 or more | 1 | .30 | 6 or more. |
| The U.S. Repatriation Program Individual Case Management Report and Financial Claim Form: | 53 or more | 1 | 1 | 53 or more. |

Estimated Total Annual Burden Hours: 258.90

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. 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 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-2012-D-0529]

Draft Guidance for Industry on Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use—Labeling for Products That Contain Acetaminophen; 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 “Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use—Labeling for Products That Contain Acetaminophen.” The draft guidance is intended to inform manufacturers of certain over-the-counter (OTC) internal analgesic, antipyretic, and antirheumatic (IAAA) drug products that contain