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.

[FR Doc. 2012–16285 Filed 7–3–12; 8:45 am]

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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

acetaminophen of the circumstances in which FDA intends to exercise enforcement discretion with regard to the liver warning required in the labeling.

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 September 4, 2012.

ADDRESSES: Submit written requests for single copies of the draft 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. 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: Tina Walther, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5108, Silver Spring, MD 20993–0002, 301–796–5086.

SUPPLEMENTARY INFORMATION:

I. Background

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.'' In the **Federal Register** of December 26, 2006 (71 FR 77314), FDA published a proposed rule on organ-specific warnings and related labeling for OTC IAAA drug products. In the **Federal Register** of April 29, 2009 (74 FR 19385), FDA published the final rule (2009 final rule). In the **Federal Register** of November 25, 2009 (74 FR 61512), FDA published a technical amendment to clarify several provisions in response to industry feedback. The 2009 final rule, as amended, changed some of the labeling requirements for OTC IAAA drug products to inform consumers about the risk of liver injury when using acetaminophen and the risk of stomach bleeding when using nonsteroidal anti-inflammatory drugs. It went into effect April 29, 2010.

The labeling for OTC IAAA products that contain acetaminophen and are labeled for adults only, must include the following liver warning:

> **Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take • more than [insert maximum number of daily dosage units] in 24 hours, which is the maximum daily amount [optional: ''For this product''] • with other drugs containing acetaminophen • 3 or more alcoholic drinks every day while using this product.

Although the currently proposed total daily dose of acetaminophen is 4,000 milligrams (mg), some OTC IAAA products that contain acetaminophen have directions for use that provide a maximum daily dose of acetaminophen for the product that is less than 4,000 mg. For example, for some OTC IAAA drug products that contain both acetaminophen and one or more other active ingredients, the maximum number of daily dosage units might be limited by an active ingredient other than acetaminophen, which could result in a maximum daily dose of acetaminophen that is less than 4,000 mg for that product. The optional statement, ''for this product,'' in the first bullet of the liver warning is intended to address these situations, by clarifying that the maximum number of daily dosage units for a product might not reflect the maximum daily dose of acetaminophen.

However, the Agency understands that in certain circumstances, despite this optional statement, the wording of the first bulleted warning might be interpreted as indicating that severe liver damage is associated with a total daily dose of acetaminophen that is less than 4,000 mg. This suggestion is not the intent of the requirement that the liver warning be included in the labeling. To address this potential confusion, the Agency intends to exercise enforcement discretion with respect to the liver warning required in the circumstances described in this draft guidance.

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 this topic. 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: June 21, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–16244 Filed 7–3–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c) (2) (A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance 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