

U.S.C. 375(b)) authorizes FDA to disseminate information concerning imminent danger to public health by any regulated product. The Center for Devices and Radiological Health (CDRH), communicates these risks to user communities through two publications: (1) The Public Health Notification (PHN) and (2) the Preliminary Public Health Notification (PPHN). The PHN is published when CDRH has information or a message to convey to health care practitioners that they would want to know in order to make informed clinical decisions about the use of a device or device type, and that information may not be readily available to the affected target audience in the health care community. CDRH can make recommendations that will help the health care practitioner mitigate or avoid the risk.

The PPHN is also published when CDRH has information to convey to health care practitioners that they would want to know in order to make informed clinical decisions about the use of a device or device type. However,

two additional conditions exist that make the use of this type of notification preferable: (1) CDRH's understanding of the problem, its cause(s), and the scope of the risk that is still evolving, so that in order to minimize the risk, the center believes that health care practitioners needs the information they can provide, however incomplete, as soon as possible and (2) the problem is actively being investigated by the center, private industry, another agency or some other reliable entity, so that the center expects to be able to update the PPHN when definitive new information becomes available. Notifications are sent to organizations affected by risks discussed in the notification, such as hospitals, nursing homes, hospices, home health care agencies, retail pharmacies, and other health care providers. Through a process for identifying and addressing postmarket safety issues related to regulated products, CDRH determines when to publish notifications.

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)), authorizes FDA to conduct

research relating to health information. FDA seeks to evaluate the clarity, timeliness and impact of safety alerts and public health advisories by surveying a sample of recipients. Subjects will receive a questionnaire to be completed and returned to FDA. The information to be collected will address how clearly notifications for reducing risks are explained, the timeliness of the information and whether the reader has taken any action to eliminate or reduce risk as a result of the information in the alert. Subjects will also be asked whether they wish to receive future notifications electronically, as well as how the PHN program might be improved.

The information collected will be used to shape FDA's editorial policy for the PHN and PPHN. Understanding how target audiences view these publications will aid in deciding what changes should be considered in their content and format, and method of dissemination.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

PHS Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 1701(a)(4)	308	3	924	.17	157

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on the history of the PHN program, it is estimated that an average of three collections will be conducted a year. The total burden of response time is estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey and through discussions with the contacts in trade organizations.

Dated: August 17, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity; Comment Request

#### Proposed Projects

*Title:* Refugee Unaccompanied Minor Placement Report & Minor Progress Reports; ORR-3 and ORR-4.

*OMB No.:* 0970-0034.

*Description:* The two reports collect information necessary to administer the Unaccompanied Refugee Minor (URM) program. The ORR-3 (Placement Report) is submitted to the Office of Refugee Resettlement (ORR) by the State agency at initial placement and whenever there is a change in the child's status, including termination from the program. The ORR-4 (Progress Report) is submitted annually and records the child's progress toward the goals listed in the child's case plan.

*Respondents:* State governments.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR-3 .....	15	63	0.25	236.25
ORR-4 .....	15	63	0.30	283.50

*Estimated Total Annual Burden Hours:* 519.75

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 Administration, Office of Information Services, 370

L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail 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.

Dated: August 18, 2009.

**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

#### **Proposed Project: HRSA/Bureau of Primary Health Care Capital Improvement Program Application Electronic Health Records (EHR) Readiness Checklist (OMB No. 0915-0325)—Extension**

The American Recovery and Reinvestment Act (ARRA) provides \$1.5 billion in grants to support

“construction, renovation and equipment”, and “the acquisition of health information technology systems, for health centers including health center controlled networks receiving operating grants under section 330” of the Public Health Service (PHS) Act, as amended (42 U.S.C. 254b). HRSA is requesting extension of the approval of the Electronic Health Records (EHR) Readiness Checklist portion of the application where applicants must provide information to demonstrate readiness for electronic health records if they propose to use funds for electronic health record (EHR) related purchases. Of the \$1.5 billion, HRSA will award approximately \$850 million, through limited competition grants, for one-time Capital Improvement Program (CIP) grant funding in fiscal year (FY) 2009 to support existing section 330 funded health centers. Funding under this opportunity will address pressing capital improvement needs in health centers, such as construction, repair, renovation, and equipment purchases, including health information technology systems. Applicants must provide information using the EHR Readiness Checklist that demonstrates comprehensive planning and readiness for implementing EHRs.

The estimated annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
EHR Readiness Checklist .....	568	1	568	.25	142
Total .....	568	.....	568	.....	142

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974. Please direct all correspondence to the “attention of the desk officer for HRSA.”

Dated: August 18, 2009.

**Alexandra Huttinger,**

*Director, Division of Policy Review and Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0345]

#### Agency Information Collection Activities: Proposed Collection; Comment Request; Internet Survey on Barriers to Food Label Use

**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, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Internet Survey on Barriers to Food Label Use.

**DATES:** Submit written or electronic comments on the collection of information by October 23, 2009.

**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:** Daniel Gittleston, Office of Information Management (HFA-710), Food and Drug