awareness on resource availability. List the measurable variables and data elements that you believe need to be defined and captured in order to effectively support regional delivery of care. Also include any suggestions as to which common data elements, at a minimum, should be included within a standardized data language to facilitate, encourage, and improve the support and integration of the various state resource tracking mechanisms.

D. Opportunities and challenges in regionalized care delivery. Please share your opinions on the potential benefits, obstacles, drawbacks, and consequences (both intended and unintended) of regionalized healthcare models, providing specific evidence where feasible. If possible, elaborate on the effects regionalization may produce on providers' financial viability, patient access to care, healthcare service utilization rates, disaster preparedness efforts, and response capabilities.

E. Evaluation of regionalized care delivery systems. Please provide comments on how regionalized care systems can be objectively assessed and evaluated, including suggestions on appropriate measures of programmatic success or failure and opinions on which data sources could be used to establish compliance with regional performance benchmarks. Where possible, also list measurable ways to assess regionalization's impact with regard to health outcomes, including factors such as morbidity and mortality, time-to-care, condition-specific treatment, quality of care, patient safety, etc.

F. Adaptation of regionalization to emergency medical care. Given the legal requirement to screen and stabilize ED patients, the need for time-sensitive, high-quality care in emergency settings, and the diversity of patient populations and geographic locations, please provide insights or commentary on how the concept of regionalization could be adapted and/or customized to fit the unique aspects of emergency medical care.

G. Additional information. Please provide any additional opinions, suggestions, or comments as to how the ECCC and the Emergency Care Enterprise can shape demonstration projects of regionalized, coordinated, and accountable systems of emergency care to effectively utilize limited resources, facilitate information management and flow, increase the efficiency and effectiveness of the emergency healthcare delivery system, and enhance the overall quality of care provided.

Please indicate which type of institution or organization you are primarily affiliated with (using the following categories):

- Academia;
- Small Business;
- Healthcare Facility;
- Trauma or EMSS region;
- Federal Government;
- State Government;
- Healthcare Professional;
- Patient Advocacy Group;
- Other (briefly define).

This request for information is for planning purposes only and shall not be interpreted as a solicitation for applications or as an obligation on the part of the government. The government will not pay for the preparation of any information submitted or for the government's use of that information.

Dated: August 14, 2009.

Nicole Lurie,

Assistant Secretary for Preparedness and Response, Rear Admiral, U.S. Public Health Service.

[FR Doc. E9–20162 Filed 8–21–09; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0360]

Agency Information Collection Activities; Proposed Collection; Comment Request; FDA Public Health Notification Readership Survey (formerly known as ''Safety Alert/ Public Health Advisory Readership Survey'')

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA Public Health Notification Readership Survey.

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: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

FDA Public Health Notification Readership Survey (formerly known as Safety Alert/Public Health Advisory Readership Survey) (PHS Act, Section 1701 (a)(4)); OMB Control Number 0910–0341–Extension

Section 705(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21

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[1]

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

[1] 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.

[FR Doc. E9–20247 Filed 8–21–09; 8:45 am]

BILLING CODE 4160–01–S

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