

Dated: May 1, 2009.

Marilyn S. Radke,

Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Head Start Facilities Construction, Purchase and Major Renovation—45 CFR 1309.

OMB No.: 0970-0193.

Description: The Office of Head Start is proposing to renew, without changes, 45 CFR part 1309. This rule contains the

administrative requirements for Head Start and Early Head Start grantees who apply for funding to purchase, renovate, or construct Head Start program facilities. The rule ensures that grantees use standard business practices when acquiring real property and that Federal interest is preserved in properties acquired with public funds. The rule further ensures compliance with all other Federal statutes applicable to the expenditure of Federal funds when acquiring real property.

Respondents: Head Start and Early Head Start grantees and delegate agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Regulation	200	1	41	8,200

Estimated Total Annual Burden Hours: 8,200.

Additional Information: Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. *E-mail address:* infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork

Reduction Project, *Fax:* 202-395-7245, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: May 4, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9-10621 Filed 5-6-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Head Start Program Administrative Practice and Procedure; Appeal Procedures, 45 CFR 1303.

OMB No.: 0980-0242.

Description: Section 646 of the Head Start Act requires the Secretary of Health and Human Services to prescribe a timeline for conducting administrative hearings when adverse actions are taken or proposed against Head Start and Early Head Start grantees and delegate agencies. The Office of Head Start is proposing to renew, without changes, this rule, which implements these requirements and which prescribes when a grantee must submit certain information and what that information shall include.

Respondents: Head Start and Early Head Start grantees and Delegate Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Rule	20	1	26	520

Estimated Total Annual Burden Hours: 520.

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. 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: May 4, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9-10622 Filed 5-6-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0192]

Availability of Information Related to the Sentinel Initiative

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a docket to receive and to make available to the public reports and other relevant information received by FDA related to the Sentinel Initiative. The goal of the Sentinel Initiative is to develop a system that will ultimately enable FDA to actively monitor the safety of marketed regulated products. The information that will be made available is being developed primarily, but not exclusively, as a result of a series of contracts awarded by FDA to inform the development of the system. The information will be made available in the docket under the docket number at the top of this notice, as well as on FDA's Sentinel Initiative Web page (Sentinel Web page) at <http://www.fda.gov/oc/initiatives/advance/sentinel/>. FDA welcomes interested parties, including individuals, to submit to this docket their views and perspectives on the information included in the docket or on any other aspect of the Sentinel Initiative.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written comments on the information in this docket to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the information.

FOR FURTHER INFORMATION CONTACT: Melissa Robb, Office of Critical Path Programs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1512.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of FDA's mission is to protect public health by monitoring the safety of marketed regulated products. FDA currently has a number of reporting systems in place for learning about and tracking reports of adverse events and product problems associated with the use of FDA-regulated products. However, most of these systems are passive; someone (e.g., a healthcare professional, consumer, pharmaceutical company) must first report such an event or problem to FDA. To augment this mostly passive approach to monitoring postmarket safety, FDA announced in May 2008 the development of a system that would enable FDA to capitalize on the capabilities of multiple existing electronic health care data systems (e.g. electronic health record systems, administrative claims databases, registries) to actively monitor regulated product safety.

As currently envisioned, the system would enable FDA to query large participating data sources quickly and securely for relevant product safety information. FDA would send questions to participating data holders, who in turn would, in accordance with existing privacy and security safeguards, evaluate their data and send summary results to FDA for agency review. This system, which will be developed and implemented in stages, is expected to facilitate the development of active surveillance methodologies related to signal detection, signal strengthening, and signal validation.

To be successful, the system will require the participation of many stakeholders. Since announcing the Sentinel Initiative, FDA has fostered a broad public forum to explore the complexities of creating such a system. Numerous meetings have been held with a variety of stakeholders. Eight contracts have been awarded to explore a variety of topics that will inform the development of the system, and a

number of pilot projects are under way that will contribute to answering some of the many technical and policy challenges that need to be addressed. To ensure the broadest possible availability of information related to FDA's Sentinel Initiative and to encourage public participation in the initiative, FDA is announcing the opening of a docket to receive and make available to the public reports and other information received by FDA related to the Sentinel Initiative. FDA is making this information available in the docket listed at the top of this notice, as well as on FDA's Sentinel Web page at <http://www.fda.gov/oc/initiatives/advance/sentinel/>.

FDA is interested in receiving input from interested parties, including individuals, and encourages those parties to submit to this docket relevant views and perspectives on the information included in the docket or on any other aspect of the Sentinel Initiative.

As reports and other relevant information are submitted to the agency, FDA will make them available to the public by placing them in the docket and posting them on the Sentinel Web page. Those persons wishing to provide their views and perspectives are encouraged to send their input to the docket for broad public consideration.

II. Documents Being Submitted With This Notice

FDA is making available with this notice the first of a series of documents containing reports and other information related to the Sentinel Initiative. This document contains a report from the Group Health Cooperative Center for Health Studies as a result of the contract awarded on Evaluation of Existing Methods for Safety Signal Identification for the Sentinel Initiative.

III. Submission of Input on the Contents of This Docket

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic views and perspectives regarding this information. Submit a single copy of electronic submissions or two paper copies of any mailed submissions, except that individuals may submit one paper copy. Submissions are to be identified with the docket number found in brackets in the heading of this document. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.