to date. The input provided by stakeholders at that meeting was useful in providing insight into stakeholder needs and in helping to improve the Childhood Agricultural Injury Prevention Initiative.

In 2001, a Childhood Agricultural Injury Prevention Summit was organized and convened by the National Children's Center for Rural and Agricultural Health and Safety (NCCRAHS), an extramurally funded component, five years after the implementation of the NIOSH Childhood Agricultural Injury Prevention Initiative. The goal of the summit was to conduct a five-year review of the 1996 National Action Plan and to use a consensus development process to generate strategies for the future. Specifically, participants were asked to consider: (a) Successes to date, (b) gaps and barriers in achieving objectives, (c) current and potential effective interventions not addressed in the National Action Plan, and (d) strategies for the future. To date, NIOSH has undertaken a number of activities, both intramurally and extramurally, to address the recommendations in the 1996 National Action Plan and the 2001 Childhood Agricultural Injury Prevention Summit.

Status: The Document, *NIOSH Childhood Agricultural Injury Prevention Initiative: Progress and Proposed Future Activities*, will be available for comment by stakeholders and other interested members of the public. Written comments should be submitted to the NIOSH Docket Office as outlined in the next section.

Docket: Written comments on the usefulness of the Childhood Agricultural Injury Prevention Initiative for improving childhood agricultural safety and suggestions for enhancing or improving the impact of the Initiative should be mailed to the NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone (513) 533–8303, facsimile (513) 533–8285. Comments may also be submitted by e-mail to *niocindocket@cdc.gov*. E-mail attachments should be formatted in Microsoft Word. All materials submitted to the Agency should reference NIOSH docket number 145 and must be submitted by May 15, 2009 to be considered by the Agency. All electronic comments should be formatted as Microsoft Word. All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, Room 111, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After the comment period has closed, comments may be accessed electronically at *http://www.cdc.gov/niosh* under the link to the NIOSH docket. As appropriate, NIOSH will post comments with the commenters' names, affiliations, and other information, on the Internet.

Contact Person for Technical Information: David Hard, Health Scientist, Analysis and Field Investigations Branch, Division of Safety Research, telephone (304) 285–6068, E-mail *DHard@cdc.gov*, facsimile (304) 285–6235.

Dated: March 9, 2009.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–5583 Filed 3–13–09; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Proposed Project

Title: Head Start Family and Child Experiences Survey (FACES 2009).

OMB No.: 0970–0151.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is planning to collect data on a new cohort for the Head Start Family and Child Experiences Survey (FACES). FACES is a longitudinal study of a nationally representative sample of Head Start programs and children that will collect information for Head Start performance measures. Data for FACES will be collected annually through interviews with Head Start parents, teachers, program directors and other Head Start staff, as well as direct child assessments and observations of Head Start classrooms.

Data will be collected on a sample of approximately 3,400 children and families from 60 Head Start programs. Data collection will include assessments of Head Start children, interviews with their parents, and ratings by their Head Start teachers. Site visitors will interview Head Start teachers in approximately 405 classrooms and make observations of the types and quality of classroom activities. Interviews will also be conducted with Head Start program directors and other staff. A follow-up for children in Kindergarten will include child assessments, parent interviews, and teacher questionnaires and child ratings.

The purpose of this data collection is to fulfill the requirements of the Government Performance and Results Act (GPRA) of 1993 (Pub. L. 103–62), and by the 1994 reauthorization of the Head Start program (Head Start Act, as amended, May 18, 1994, Section 649 (d)), which call for periodic assessments of Head Start's quality and effectiveness.

Respondents: Parents of Head Start Children, Head Start Children, Head Start Teachers, Head Start Program Directors and Staff, and Kindergarten Teachers of former Head Start enrollees.

ANNUAL BURDEN ESTIMATES

	Annual number of respondents	Number of responses per respondent	Average burden hour per response	Estimated annual burden hours
Parent Interview	3,185	1.0	.81	2,564
Child Assessment	3,245	1.0	0.75	2,434
Head Start Teacher Interview	405	1.0	0.50	203
Head Start Teacher Child Rating	405	9.0	0.17	620
Program Director Interview	20	1.0	0.50	10
Center Director Interview	40	1.0	0.50	20
Education Coordinator Interview	20	1.0	0.50	10
Kindergarten Teacher Questionnaire	1,128	1.3	0.50	733
Kindergarten Teacher Child Rating	1,128	1.3	0.17	249
Total Annual Burden Hours:				6,843

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *OPREinfocollection@acf.hhs.qov*.

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 0MB 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: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: March 9, 2009.

Brendan C. Kelly,

OPRE Reports Clearance Officer.

[FR Doc. E9–5511 Filed 3–13–09; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0556]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 15, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0429. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Formal Meetings With Sponsors and Applicants for PDUFA Products (OMB Control Number 0910–0429)—Extension

This information collection approval request is for an FDA guidance on the procedures for formal meetings between FDA and sponsors or applicants regarding the development and review of Prescription Drug User Fee Act (PDUFA) products. The guidance describes procedures for requesting, scheduling, conducting, and documenting such formal meetings. The guidance provides information on how the agency will interpret and apply section 119(a) of the Food and Drug Administration Modernization Act (the Modernization Act), specific PDUFA goals for the management of meetings associated with the review of human drug applications for PDUFA products, and provisions of existing regulations describing certain meetings (§§ 312.47 and 312.82 (21 CFR 312.47 and 312.82)).

The guidance describes two collections of information: The submission of a meeting request containing certain information and the submission of an information package in advance of the formal meeting. Agency regulations at § 312.47(b)(1)(ii), (b)(1)(iv), and (b)(2) describe information that should be submitted in support of a request for an End-of-Phase 2 meeting and a Pre-New Drug Application meeting. The information collection provisions under § 312.47 have been approved by OMB (OMB control no. 0910–0014). However, the guidance provides additional recommendations for submitting information to FDA in support of a meeting request. As a result, FDA is submitting additional estimates for OMB approval.

I. Request for a Meeting

Under the guidance, a sponsor or applicant interested in meeting with the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) should submit a meeting request to the appropriate FDA component as an amendment to the underlying application. FDA regulations (§§ 312.23, 314.50, and 601.2 (21 CFR 312.23, 314.50, and 601.2)) state that information provided to the agency as part of an investigational new drug application (IND), new drug application (NDA), or biological license application (BLA) must be submitted with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs and Form FDA 356h must accompany submissions under NDAs and BLAs. Both forms have valid OMB control numbers as follows: FDA Form 1571 (OMB control no. 0910–0014) and FDA Form 356h (OMB control no. 0910–0338).

In the guidance document, CDER and CBER ask that a request for a formal meeting be submitted as an amendment to the application for the underlying product under the requirements of §§ 312.23, 314.50, and 601.2; therefore, requests should be submitted to the agency with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The agency recommends that a request be submitted in this manner for two reasons: (1) To ensure that each request is kept in the administrative file with the entire underlying application and (2) to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the agency's tracking databases enables the agency to monitor progress on the activities attendant to scheduling and holding a formal meeting and to ensure that appropriate steps will be taken in a timely manner.

Under the guidance, the agency requests that sponsors and applicants include in meeting requests certain information about the proposed meeting as follows:

- Information identifying and describing the product;
- The type of meeting being requested;
- A brief statement of the purpose of the meeting;
- A list of objectives and expected outcomes from the meeting;
- A preliminary proposed agenda;
- A draft list of questions to be raised at the meeting;
- A list of individuals who will represent the sponsor or applicant at the meeting;