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: October 6, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–25885 Filed 10–10–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Evaluation of the Early Head Start Fatherhood Demonstration.

OMB No.: 0970–0239.

Description: The Administration on Children, Youth and Families (ACYF), in partnership with the Office of Child Support Enforcement (OCSE), funded 21 Early Head Start grantees in 2001 to develop and implement creative practices to increase the involvement of fathers in their Early Head Start program and in the lives of their children. ACYF subsequently commissioned a study to identify promising practices emerging through the first two years of the demonstration. The study involved site visits to participating programs, a survey of demonstration staff, and collection of father participation data from the demonstration programs. ACYF recently commissioned a follow-up study to investigate programs' efforts to sustain meaningful fatherhood initiatives after the demonstration grant funding ends. This submission requests approval to conduct site visits to a subset of approximately 9 programs as well as a second survey of staff and collection of father participation data from all 21 demonstration programs.

Respondents: To reduce the burden on demonstration staff, the survey will be configured in four versions. The Director Version will be completed by the Early Head Start program directors. The Father coordinator Version will be completed by the staff member responsible for father activities. The Family Specialist Version will be completed by the staff member who works most closely with the Early Head Start families in the home. The Teacher Version will be completed by the staff member working with families of children participating in the Early Head Start child care programs. Program staff will also be asked to submit data on participating fathers. For each child enrolled in the Early Head Start program, the site will be asked to complete a short ''Father/Father Figure Information Form.'' To avoid duplication of individual-level data, the programs are requested to provide extracts of information on the children and fathers in the program from their current management information systems whenever possible. The staff survey and father data instruments will be the same as those used in the Phase I study under the current OMB clearance no. 0970–0239. Site visit protocols used in the Phase I evaluation will also modified and shortened to address only those issues that are relevant to the research questions proposed in Phase II, focusing primarily on changes in program practices and new strategies for sustaining fatherhood initiatives.

Respondents: Early Head Start directors, fatherhood program coordinators, family specialists, teachers, and fathers and mothers of Early Head Start children.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Site Visit Interviews and Focus Groups	243	1	1.0	243.0
Director Version of Survey	19	1	.5	9.5
Father Coordinator Version of Survey	19	1	.5	9.5
Family Specialist Version of Survey	19	1	.4	7.6
Teacher Version of Survey	17	1	.4	6.8
Father/Father Figure Information Forms	21	[1] 81	.16	272.1
Estimated Total Annual Burden Hours	.....	.....	.....	548.5

[1] Average number per site.

SUPPLEMENTARY 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, ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *rsargis@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, Attn: Desk Officer for ACF, E-mail addresses: *lauren-wittenberg@omb.eop.gov.*

Dated: October 6, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–25886 Filed 10–10–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0229]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 9, 2003 (68 FR 53174) , the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0518. The approval expires on March 31, 2004. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: October 6, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–25845 Filed 10–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0314]

Agency Information Collection Activities; Submission for the Office of Management and Budget Review; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements

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 November 13, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Food Labeling; Notification Procedures for Statements on Dietary Supplements—21 CFR Part 101.93 (OMB Control Number 0910–0331)—Extension

Section 403(r)(6) of the Federal Food, Drugs, and Cosmetics Act (the act) (21 U.S.C. 343(r)(6)) requires that the agency be notified by manufacturers, packers, and distributors of dietary supplements that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the act. Section 403(r)(6) of the act requires that the agency be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes the following: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) the signature of a responsible individual who can certify the accuracy of the information presented, who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

The agency established § 101.93 (21 CFR 101.93) as the procedural regulation for this program. Section 101.93 provides details of the procedures associated with the submission and identifies the information that must be included in order to meet the requirements of section 403 of the act.

Description of Respondents: Businesses or other forprofit organizations.

In the **Federal Register** of July 23, 2003 (68 FR 43533), FDA published a 60-day notice requesting public comment on the information collection provisions. One firm submitted a comment stating that it believed that the burden of making the required submission could be slightly reduced by enabling the electronic submission of the required information, perhaps submitted through the Agency's Web