Additionally, the evaluation will capture information to describe the quality of the implementation of the various mentor-coaching approaches including consistency of the mentor-coach implementation with the planned approach, the frequency and content of interactions between the mentor-coaches and the teaching staff, and apparent changes in teaching staff behavior, including their own professional development. The evaluation will also capture information about the characteristics of those who provided coaching, the characteristics of teaching staff that were mentored, as well as the characteristics of the settings and the systems in which the mentor-coaching was embedded. Lastly, the evaluation will document the factors that appear to be most critical to successful implementation and implementation challenges.

The data collection will include a census survey of all grantees; a census survey of all mentor-coaches; telephone interviews with a sub-sample of administrators, mentor-coaches, and teaching staff; and a mentor-coach activity snapshot.

Respondents: Grantee and center administrative staff, mentor-coaches, teaching staff.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Grantee Census Survey	131	1	0.5	66
Mentor-Coach Census Survey	400	1	0.5	200
Administrator Telephone Interview	85	1	1.0	85
Mentor-Coach Telephone Interview	65	1	1.0	65
Teaching Staff Telephone Interview	130	1	1.0	130
Mentor-Coach Activity Snapshot	65	2	0.25	33

Estimated Total Annual Burden Hours: 579.

Additional Information: In compliance with the requirements of Section 3506(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 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.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: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: May 17, 2011.

Steven M. Hanmer,

OPRE Reports Clearance Officer.

[FR Doc. 2011–12787 Filed 5–25–11; 8:45 am]

BILLING CODE 4184–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0153]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry and Food and Drug Administration Staff: Food and Drug Administration and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act

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 (the PRA).

DATES: Fax written comments on the collection of information by June 27, 2011.

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: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title "Draft Guidance for Industry and FDA Staff: FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

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.

Draft Guidance for Industry and FDA Staff: FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act—(OMB Control Number 0910–NEW)

Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from 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 before submitting the collection to OMB for approval. To comply with this requirement, in the **Federal Register** of April 29, 2010 (75 FR 22599), FDA published a notice of availability of the draft guidance document providing a 60-day public comment period on the proposed collection of information provisions.

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.

Title: Draft Guidance for Industry and FDA Staff: FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act.

Description: Section 513(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(g)) provides a means for obtaining the Agency's views about the classification and regulatory requirements that may be applicable to your particular device. Section 513(g) provides that within 60 days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act, the Secretary of Health and Human Services shall provide such person a written statement of the classification (if any) of such device and the requirements of the FD&C Act applicable to the device.

Section 513(g) of the FD&C Act provides a means for obtaining FDA's views about the classification and the regulatory requirements that may be applicable to a particular device. The purpose of this draft guidance is to establish procedures for submitting, reviewing, and responding to requests for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act that are submitted in accordance with section 513(g) of the FD&C Act. FDA does not review data related to substantial equivalence or safety and effectiveness in a 513(g) request for information. FDA's responses to 513(g) requests for information are not device classification decisions and do not constitute FDA clearance or approval for marketing. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act. Additionally, the FD&C Act, as amended by the FDA Amendments Act of 2007 (Pub. L. 110–85), requires FDA to collect user fees for 513(g) requests for information.

In the **Federal Register** of April 29, 2010, FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Act 513(g)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Center for Devices and Radiological Health (CDRH)	110	1	110	12	1,320
Center for Biologics Evaluation and Research (CBER)	4	1	4	12	48
Total					1,368

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to this collection of information are mostly device manufacturers; however, anyone may submit a 513(g) request for information. The total number of annual responses is based on the average number of 513(g) requests received each year by the Agency. FDA based its estimates on the number of 513(g) requests for information received by both CDRH and CBER from 2007 to 2009.

Dated: May 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–13058 Filed 5–25–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0320]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study on Consumer Responses to Whole Grain Labeling Statements on Food Packages

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 a study entitled: "Experimental Study on Consumer Responses to Whole Grain Labeling Statements on Food Packages."

DATES: Submit either electronic or written comments on the collection of information by July 25, 2011.

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