Seleda M. Perryman,

Office of the Secretary, Paperwork Reduction Act Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–New; 60–day Notice]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above email address within 60-days.

Proposed Project: Wellness Program Study: Assessing the Impact of Workplace Health and Wellness Programs—OMB No. 0990–NEW—Assistant Secretary for Planning Evaluation (ASPE)

Abstract: The Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the Employee Benefits Security Administration (EBSA) is requesting Office of Management and Budget (OMB) approval on a new collection to conduct a survey on employers to learn about their experiences and attitudes regarding workplace wellness programs. ASPE will use the employers' experience to assess the effectiveness and impact of workplace wellness programs, as well as identify best practices and lessons learned in program implementation with a particular focus on the use of incentives. As part of the study, a one-time, self-administered survey will be administered to 3,000 employers selected from the Dun & Bradstreet database, a comprehensive listing of private companies and government agencies in the U.S. The survey will assess prevalence and type of wellness programs as well as the use of employee incentives. The survey design and content is informed by a review of the literature on the characteristics, prevalence and impact of workplace wellness programs. Data collection will also include employee focus groups and key informant semi-structured interviews at each of 4 employer sites that will inform in-depth case studies of those employers. The focus groups will consist of 12 employees and will be conducted to get the end-user perspective on the impact and effectiveness of the wellness program. The key informant interviews will be carried out with 5 wellness leaders at each employer, and will gather information on employer background, health insurance and wellness programs offered, and anticipated changes due to the Affordable Care Act. Data collection activities will be completed within 18 months of OMB Clearance.

EXHIBIT 1—ESTIMATE OF ANNUALIZED TIME BURDEN TO RESPONDENTS

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Survey	Human Resource Manager	3,000	1	30/60	1,500
Focus Group Protocol	Employees in All Occupations	48	1	1.5	72
Key Informant Interview Script.	Human Resource Manager	20	1	45/60	15
Total					1,587

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Planning, Research and Evaluation Advisory Committee on Head Start Research and Evaluation

AGENCY: Administration for Children and Families, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Administration for Children and Families (ACF). The meeting will be open to the public.

Name of Committee: Advisory Committee for Head Start Research and Evaluation.

General Function of Committee: The Advisory Committee for Head Start Research and Evaluation will provide feedback on the published final report for the Head Start Impact Study, offering interpretations of the findings, discussing implications for practice and policy, and providing recommendations on follow-up research, including additional analysis of the Head Start Impact Study data. The Committee will

also be asked to provide recommendations to the Secretary regarding how to improve Head Start and other early childhood programs by enhancing the use of research-informed practices in early childhood. Finally, the Committee will be asked to provide recommendations on the overall Head Start research agenda, including—but not limited to—how the Head Start Impact Study fits within this agenda. The Committee will provide advice regarding future research efforts to inform HHS about how to guide the development and implementation of best practices in Head Start and other early childhood programs around the country.

DATES: The meeting will be held on April 12th and April 13th, 2011, from 8:30 a.m. to 5 p.m.

ADDRESSES: Hyatt Arlington, 1325 Wilson Boulevard, Arlington, VA 22209, Phone: 703–525–1234.

FOR FURTHER INFORMATION CONTACT: Jennifer Brooks, Office of Planning, Research, and Evaluation, *e-mail jennifer.brooks@acf.hhs.gov* or call (202) 205–8212.

Agenda: The committee will review information on the federal Head Start program and the children and families it serves, hear information about the early Head Start program, and learn about the latest research in the area of quality teaching and learning.

Procedure: Interested persons may present data, information or views, in writing, on issues pending before the Committee. Written submissions may be made to the contact person on or before April 1, 2011. All written materials provided to the contact person will be shared with the Committee members.

ACF welcomes the attendance of the public at this advisory committee meeting and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jennifer Brooks at least seven days in advance of the meeting. Information about the committee and this meeting can be found at the committee Web site, *http://www.acf.hhs.gov/programs/opre/hs/advisory_com/.*

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Robert Sargis,

Reports Clearance Officer, Administration for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0016]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recordkeeping and Records Access Requirements for Food Facilities

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 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 0910–0560. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

Recordkeeping and Records Access Requirements for Food Facilities—21 CFR 1.337, 1.345, and 1.352 (OMB Control Number 0910–0560)—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added section 414 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350c), which requires that persons who manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food. Sections 1.326 through 1.363 of FDA's regulations (21 CFR 1.326 through 1.363) set forth the requirements for recordkeeping and records access. The requirement to establish and maintain records improves FDA's ability to respond to, and further contain, threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

Description of Respondents: Persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States are required to establish and maintain records, including persons that engage in both interstate and intrastate commerce.

FDA's regulations require that records for non-transporters include the name and full contact information of sources, recipients, and transporters, an adequate description of the food including the quantity and packaging, and the receipt and shipping dates (§§ 1.337 and 1.345). Required records for transporters include the names of consignor and consignee, points of origin and destination, date of shipment, number of packages, description of freight, route of movement and name of each carrier participating in the transportation, and transfer points through which shipment moved (§ 1.352). Existing records may be used if they contain all of the required information and are retained for the required time period.

In the **Federal Register** of January 13, 2011 (76 FR 2396), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one letter containing multiple comments in response to the notice.

(Comment 1) One comment was generally supportive of the necessity of the information collection and its practical utility.

(Response) FDA agrees. As discussed previously in this document, the requirement to establish and maintain records improves FDA's ability to respond to, and further contain, threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

(Comment 2) Another comment stated that accurate recordkeeping is integral to the effective and timely tracing of food products through the supply chain and, to support effective product tracing, suggested that industry should determine the Critical Tracking Events (CTEs) and the Key Data Elements (KDEs) necessary for product tracing; FDA should encourage the adoption of standard ways to express this