wells 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.

Robert Sargis, Reports Clearance Officer.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Administration for Children and Families
Proposed Information Collection Activity; Comment Request

Title: Assets for Independence (AFI) Program Evaluation.

OMB No.: New Collection.

ANNUAL RESPONSE BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Estimated burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline survey: AFI-eligible participants</td>
<td>567</td>
<td>1</td>
<td>.50</td>
<td>284</td>
</tr>
<tr>
<td>Follow-up survey: AFI-eligible participants</td>
<td>482</td>
<td>1</td>
<td>.50</td>
<td>241</td>
</tr>
<tr>
<td>Implementation interview: Administrators and staff</td>
<td>10</td>
<td>1</td>
<td>1.00</td>
<td>10</td>
</tr>
</tbody>
</table>

Estimated Annual Response Burden Hours: 535.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families (ACF), Department of Health and Human Services, 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 in 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. Email address: OPREinfocollection@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.


Steven M. Hanmer, Office of Planning, Research, and Evaluation, ACF, Reports Clearance Officer.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of February 15, 2012 (77 FR 8880). The document announced an opportunity for public comment on the proposed collection of certain information by the Agency. The document was published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT:

Joyce Strong, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3208,
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0674]


AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act.” The draft guidance is intended for persons who manufacture, process, pack, hold, or import human or animal foods intended for distribution to consumers, institutions, or food processors. This draft guidance provides updated information pertaining to FDA’s authority to access and copy records relating to food under sections 414(a) and 704(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 374(a)(1)(B), respectively), as amended by section 101 of the FDA Food Safety and Modernization Act (FSMA) (Pub. L. 111–353) of January 4, 2011. Section 414 was originally added to the FD&C Act by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Final Guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 23, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Outreach and Information Center (HFS–009), Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance http://www.regulations.gov. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.


SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act.” The draft guidance is intended for persons who manufacture, process, pack, hold, or import human or animal foods intended for distribution to consumers, institutions, or food processors. This draft guidance provides updated information pertaining to FDA’s authority to access and copy records relating to food under sections 414(a) and 704(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 374(a)(1)(B), respectively), as amended by section 101 of the FDA Food Safety and Modernization Act (FSMA) (Pub. L. 111–353) of January 4, 2011. Section 414 was originally added to the FD&C Act by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

The draft guidance, when finalized, will represent the Agency’s current thinking on its authority to access and copy records. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to information collection provisions found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). We conclude that these information collection provisions are exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or Agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an Agency against specific individuals or entities. The regulations in 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records.