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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–4143 Filed 2–22–12; 8:45 am]

BILLING CODE 4184–01–P

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.

Description: The U.S. Department of Health and Human Services, Administration for Children and Families (ACF) is proposing a data collection activity as part of an experimental evaluation of the Assets for Independence (AFI) Program. The purpose of this study is to assess the impact of participation in AFI-funded individual development account (IDA) projects on the savings, asset purchases, and economic well-being of low-income individuals and families. The two primary research questions are:

- What is the impact of AFI project participation on short-term outcomes such as savings, asset purchases, and material hardship?
- How do specific API project design features affect short-term participant outcomes?

While some evaluations suggest that IDAs help low-income families save, rigorous experimental research is limited. Few studies have focused on API-funded IDAs, and few have tested alternative design features.

This evaluation—the first experimental evaluation of IDA projects operating under the Assets for Independence Act—will contribute importantly to understanding the effects of IDA project participation on project participants, particularly effects that occur within the first 12 months of participation, and how these short-term effects differ under alternative project designs. The evaluation will be conducted in two sites, with the random assignment of API-eligible cases to program and control groups. The evaluation consists of both an impact study and an implementation study. Data collection activities will span a three-year period.

Respondents: Respondent groups will include: (1) API-eligible participants and (2) API project administrators and staff members of the participating API grantees and their partnering organizations.

ANNUAL RESPONSE BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Estimated burden hours
Baseline survey: AFI-eligible participants	567	1	.50	284
Follow-up survey: AFI-eligible participants	482	1	.50	241
Implementation interview: Administrators and staff	10	1	1.00	10

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.

Dated: February 14, 2012.

Steven M. Hanmer,

Office of Planning Research and Evaluation; ACF, Reports Clearance Officer.

[FR Doc. 2012–3946 Filed 2–22–12; 8:45 am]

BILLING CODE 4184–24–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0129]

Agency Information Collection Activities; Proposed Collection; Comment Request; General Licensing Provisions; Section 351(k) Biosimilar Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The 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,

Silver Spring, MD 20993–0002, 301–796–9148.

SUPPLEMENTARY INFORMATION: In FR Doc. 2012–3548, appearing on page 8880, in the **Federal Register** of Wednesday, February 15, 2012, the following correction is made:

On page 8880, in the second column, in the Docket No. heading, ''[Docket No. FDA–2012–N–1029]'' is corrected to read ''[Docket No. FDA–2012–N–0129]''.

Dated: February 16, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4168 Filed 2–22–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0674]

Draft Guidance for Industry: Food and Drug Administration Records Access Authority Under the Federal Food, Drug, and Cosmetic Act; Availability

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.'' This draft guidance provides updated information pertaining to FDA's authority to access and copy records relating to food. It is a revision of FDA's November 2005 guidance entitled ''Guidance for Industry and FDA Staff: Guidance for Records Access Authority Provided in Title III, Subtitle A, of 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 to *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.

FOR FURTHER INFORMATION CONTACT: William A. Correll, Jr., Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1611.

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. 350c(a) and 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 (Pub. L. 107–188). FSMA, signed into law on January 4, 2011, expanded FDA's access to records under section 414. Prior to the passage of FSMA, section 414(a) of the FD&C Act provided the Secretary (by delegation FDA) with authority to access records relating to food that was reasonably believed to be adulterated and to present a threat of serious adverse health consequences or death to humans or animals. Now under section 414(a)(1), as amended by FSMA, FDA's records access extends beyond records relating to the specific suspect article of food to records relating to any other article of food that FDA reasonably believes is likely to be affected in a similar manner. In addition, under section 414(a)(2), FDA can access records if it believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals. Furthermore, FSMA revised section 704(a)(1)(B), which pertains to factory inspections, to refer to the amended version of section 414(a).

This updated draft guidance is intended to provide individuals in the human and animal food industries with an overview of FDA's authority to access and copy records. It provides practical information by answering common questions that cover a range of topics, including when FDA has the authority to access and copy records, the circumstances under which FDA is likely to request records, the types of records FDA may request and copy, and the consequences of refusing to provide records access. The Agency has adopted good guidance practices (GGPs) that set forth the Agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115). This draft guidance is being issued as level 1 guidance consistent with GGPs.

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.