

Family Assistance (OFA), Health Profession Opportunity Grants (HPOG) program announces the award of a single-source program expansion supplement to Pima County Community College District (PCC), a public/state controlled institution of higher education in Tucson, Arizona. Expansion supplement funds will support the acceleration of enrollment in Project Year Two, necessitated by a random assignment study entitled—Innovative Strategies for Increasing Self-Sufficiency (ISIS). This allows PCC to meet the sample size required by ISIS in the specific time period.

PCC was found to be an ideal fit as an ISIS evaluation site due to its unique program characteristics. The program has a clear articulated career pathway program, capacity to achieve a treatment sample of 500 or more over two project years, and a treatment sample that would be clearly distinct from the control sample because of the provision of intensive support and HPOG specific classes that are contextualized and compressed.

**DATES:** The project period for the award is September 30, 2011–September 29, 2012.

**FOR FURTHER INFORMATION CONTACT:** Stan Koutstaal, Program Manager, Office of Family Assistance, 370 L'Enfant Promenade SW., Washington, DC 20447. Telephone: 202-401-5457; Email: [stanley.koutstaal@acf.hhs.gov](mailto:stanley.koutstaal@acf.hhs.gov).

**Earl S. Johnson,**

*Director, Office of Family Assistance.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0430]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Submission of Food/Feed Facility Profile Information

**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 the information collection provisions of FDA's program of voluntary submission of food facility profile information and new Form FDA 3797, which may be submitted electronically via the FDA Industry Systems Web site.

**DATES:** Submit either electronic or written comments on the collection of information by July 10, 2012.

**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 docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, 301-796-5733, [domini.bean@fda.hhs.gov](mailto:domini.bean@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (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, FDA is publishing notice of the proposed collection of information set forth in this document.

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.

#### Voluntary Submission of Food/Feed Facility Profile Information (OMB Control Number 0910—New)

FDA has broad legal authority under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the Public Health Service Act to protect the public health and the safety of the nation's food supply. In addition, under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188) (the "Bioterrorism Act") FDA was further authorized to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. The Bioterrorism Act added section 415 of the FD&C Act (21 U.S.C. 350d), which requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA. FDA regulations at 21 CFR 1.230 through 1.235 set forth the procedures for registration of food (including animal food/feed) facilities. Information provided to FDA under these regulations helps us notify quickly the facilities that might be affected by a deliberate or accidental contamination of the food supply. Furthermore, the FDA Food Safety Modernization Act (Pub. L. 11-353) (FSMA) added section 421 of the FD&C Act (21 U.S.C. 350j), which directed FDA to allocate resources to inspect facilities according to the known safety risks of the facilities. We propose to collect additional food/feed facility profile information on a voluntary basis from firms that complete the FDA food facility registration process. Food facility profile information voluntarily provided to FDA will help us to determine whether a firm is high-risk or non-high-risk. We will use the profile information to assist us in determining the frequency at which we will inspect the firm. Facilities that voluntarily submit the food facility profile information would benefit from our advance preparation through interaction with better-informed investigators and potentially reduced inspection time. The need for this collection of information derives from our objective to obtain current, timely, and policy-relevant information to carry out our statutory functions. The FDA Commissioner is authorized to undertake this collection as specified in section 1003(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)).

Firms will be offered the opportunity to voluntarily complete a food/feed facility profile after they register with FDA using the electronic system known as the Food Facility Registration Module, which is available at <http://www.access.fda.gov>, the FDA Industry Systems Web site. The use of an electronic form would enhance our ability to store the information in a searchable form. Ideally, a searchable electronic system could allow FDA to assess information when a problem occurs with certain types of foods or controls, so that we could target inspections to facilities that manufacture, process, or pack foods that are at increased risk for a food safety problem. After completing their registration process, firms will see a popup screen by which they will be able to navigate to the food facility profile screens to provide the profile

information. Food and feed facility profile information will only be collected electronically in English.

Information we propose to request in the voluntary food and feed facility profile includes, among other things:

- The facility type (e.g., manufacturer/processor, repacker/packer, or warehouse/holding facility);
- The products, and hazards (e.g., biological, physical, chemical) and preventive control measures associated with those products where either there is a regulation in place requiring identification of hazards and preventive control measures, e.g., seafood and juice, or the firm as a matter of its own business practices voluntarily identifies hazards and implements preventive control measures; and
- Other facility information (e.g., food safety training, facility size, operational schedule, and number of employees).

Firms will be given the option of providing or updating their profile information whenever the firm accesses the Food Facility Registration Module (e.g., when completing their initial registration process or when updating their registration information). FDA will also provide a direct URL that a firm may use to submit the facility profile information at a time when they are not registering or updating their registration information.

*Description of Respondents:* The respondents to this information collection include owners, operators, or agents in charge of domestic or foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of New Domestic Food Facility Profile.	FDA 3797	6,780	1	6,780	0.25 (15 minutes)	1,695
Submission of New Foreign Food Facility Profile.	FDA 3797	11,685	1	11,685	0.75 (45 minutes)	8,764
Submission of Update to Existing Food Facility Profile.	FDA 3797	59,265	1	59,265	0.0833 (5 minutes)	4,937
Total .....	.....	.....	.....	.....	.....	15,396

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on our experience and the average number of new facility registrations and updates estimated in the notice published in the **Federal Register** of May 28, 2010 (75 FR 30033) (the May 2010 notice) during the most recent request for extension of OMB approval under the PRA for the FDA food facility registration process (approved under OMB control number 0910-0502). In the May 2010 notice, we estimated that the annual number of new domestic facility registrations will be 13,560. Assuming that approximately half of these firms will also choose to provide the food facility profile information, we estimate that 6,780 domestic firms will voluntarily submit Form FDA 3797 annually. We estimate that submitting the food facility profile information will require a burden of approximately 0.25 hour (15 minutes) per average domestic facility. Thus, the total annual burden for the submission of new domestic food facility profiles is estimated to be 1,695 hours (6,780 × 0.25 hour = 1,695 hours).

In the May 2010 notice, we estimated that the annual number of new foreign

facility registrations will be 23,370. Assuming that approximately half of these firms will also choose to provide the food facility profile information, we estimate that 11,685 foreign firms will voluntarily submit Form FDA 3797 annually. We estimate that submitting the food facility profile information will require a burden of approximately 0.75 hour (45 minutes) per average foreign facility, taking into account that for some foreign facilities the respondent completing the registration may not be fluent in English. The information must be submitted electronically in the English language. Thus, the total annual burden for the submission of new foreign food facility profiles is estimated to be 8,764 hours (11,685 × 0.75 hour = 8,763.75 rounded to 8,764 hours).

In the May 2010 notice, we estimated that we will receive 118,530 registration updates annually. Assuming that approximately half of these firms will also choose to update their food facility profile information, we estimate that 59,265 firms will voluntarily submit Form FDA 3797 for that purpose annually. FDA estimates that updating

food facility profile information will require a burden of approximately 0.0833 hour (5 minutes) per average facility, taking into account fluency in English. Thus, we estimate the total annual burden for updating food facility profiles to be 4,937 hours (59,265 × 0.0833 hour = 4,936.77 rounded to 4,937 hours).

We recognize that the May 2010 notice was issued prior to the passage of FSMA, which was signed into law on January 4, 2011. Section 102(a) of FSMA amended section 415 of the FD&C Act to create section 415(a)(3) (21 U.S.C. 350d(a)(3)), which requires that during the period beginning on October 1 and ending on December 31 of each even-numbered year, a registrant that has previously registered shall submit a renewal registration. We anticipate that this provision will impact the number of firms that access the Food Facility Registration Module and that are therefore given the option of providing or updating their profile information. Estimates regarding the impact of section 415(a)(3) will be provided in our next request for extension of OMB

approval under the PRA for the FDA food facility registration process (approved under OMB control number 0910-0502).

Dated: May 8, 2012.

**David Dorsey,**

*Acting Associate Commissioner for Policy and Planning.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Comment Request**

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Officer at (301) 443-1984.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance 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.

**Proposed Project: Maternal, Infant, and Early Childhood Home Visiting Program FY 2012 Non-Competing Continuation Progress Report (OMB No. 0915-xxxx)—[New] Activity Code: X02**

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (ACA). Section 2951 of the Act amended Title V of the Social Security Act by adding a new section, 511, which authorized the creation of the Maternal, Infant, and Early Childhood Home Visiting Program, ([http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111\\_cong\\_bills&docid=f:h3590enr.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf), pages 216-225). The Act responds to the diverse needs of children and families in communities at risk and provides an unprecedented opportunity for collaboration and partnership at the Federal, State, and community levels to improve health and development outcomes for at-risk children through evidence-based home visiting programs.

Under this program, \$125,000,000 was made available to States on a formula basis in both FY 2010 and 2011. This funding was awarded to support States in implementing their Updated State Plans. Additionally, a competitive funding opportunity announcement (FOA) was issued in June 2011 to allow interested States to apply for one of two possible grants: Development Grants and Expansion Grants. Development Grants are intended to support States and jurisdictions with modest evidence-based home visiting programs to expand the depth and scope of these efforts, with the intent to develop the infrastructure and capacity needed to seek an Expansion Grant in the future. Expansion Grants are intended to recognize States and jurisdictions that had already made significant progress towards a high-quality home visiting program or embedding their home visiting program into a comprehensive, high-quality early childhood system. Thirteen States were awarded Development Grants, and nine States were awarded Expansion Grants. State grantees of both competitive programs will need to complete non-competitive continuation (NCC) progress reports in order to secure the release of FY 2012 and out-year grant funds.

The MIECHV Program intends to make approximately \$125,000,000 in formula-based funds available to States and jurisdictions in FY 2012 subsequent to the completion of FY11 Progress Reports. The project period is 2 years.

The annual estimate of burden is as follows:

Instrument: A summary of the progress on the following activities	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Accomplishments and Barriers .....	54	1	2	108
Program Goals and Objectives .....	54	1	8	432
Update on Evaluation Plan .....	54	1	4	216
Implementation in Targeted At-Risk Communities .....	54	1	24	1296
Progress on Benchmark Reporting .....	54	1	6	324
CQI efforts .....	54	1	4	216
Program Administration .....	54	1	4	216
<b>Total .....</b>	<b>54</b>	<b>.....</b>	<b>.....</b>	<b>2808</b>

Email comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Reports Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 3, 2012.

**Reva Harris,**

*Acting Director, Division of Policy and Information Coordination.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Non-Competitive One-Year Extension With Funds for State Early Childhood Comprehensive Systems Grantees**

**AGENCY:** Health Resources and Services Administration, HHS.