

*Description:* The Performance Progress Report (SF-PPR) is a set of uniform reporting formats used for standard reporting on performance under grants and cooperative agreements.

In addition to allowing for uniformity of information collection, these formats will support systematic electronic collection and submission of information. These formats will provide interim and final performance progress information as required by OMB Circulars A-102 and 2 CFR part 215.

The SF-PPR consists of a cover page and six optional formats. The cover page contains identifying data elements and a section for a performance narrative. Use of the cover page is required, and programs may require their respondents to submit only this page and/or attach a performance narrative. Alternatively, programs may opt to require the cover page and one or more of the six optional formats: Performance Measures, Program Indicators, Benchmark Evaluations, Table of Activity Results, Activity-Based Expenditures, and Program/Project Management

The SF-PPR has been successfully piloted at the Administration for Children and Families (ACF). All discretionary programs (starting with FY09 awards) are to submit the SF-PPR to the ACF Office of Grants Management. Program offices with expiring data collections are required to migrate to the SF-PPR format. Additionally, a number of program offices have voluntarily migrated their collections to the SF-PPR format in anticipation of government-wide standardization. ACF, with its Online Data Collection tool (OLDC), has provided program offices with the capability to collect SF-PPR data electronically.

ACF and the Grants Center of Excellence (CoE) is sponsoring this collection on behalf of the Grants Policy Committee, other Federal grant-making agencies, and the CoE partners.

CoE Partners are defined as: Corporation for National and Community Service, Denali Commission, Department of State, DHHS/Administration on Aging,

DHHS/Centers for Medicare Services, DHHS/Health Research and Services Administration, DHHS/Indian Health Services, DHHS/Office of Public Health Services, DOT/Federal Air Administration, DOT/Federal Highway Administration, DOT/Federal Motor Carrier Safety Administration, DOT/Federal Railroad Administration, DOT/Federal Transport Administration, DOT/Pipeline and Hazardous Materials Safety Administration, Environmental Protection Agency, Institute of Museum and Library Services, Social Security Administration, Department of Treasury, USDA/Food Safety and Inspection Service, Veterans Administration.

The revised burden estimates are based on grant projects and awards for ACF and its CoE partners for FY2008 as reported by internal ACF reporting systems and *USASpending.gov*.

*Respondents:* Federal government grantees

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Performance Progress Report (SF-PPR) .....	131,281	1	0.42	55,138.02
Cover Page Continuation (SF-PPR-2) .....	86	1	0.33	28.38
Performance Measures (SF-PPR-A) .....	430	1	0.75	322.50
Program Indicators (SF-PPR-B) .....	8,961	1	3	26,883
Benchmark Evaluations (SF-PPR-C) .....	248	1	1.50	372
Table of Activity Results (SF-PPR-D) .....	4,238	1	0.75	3,178.50
Activity Based Expenditures (SF-PPR-E) .....	2,616	1	0.33	863.28
Program/Project Management (SF-PPR-F) .....	45	1	0.50	22.50

*Estimated Total Annual Burden Hours:* 86,808.18

*Additional Information:*

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address:* [infocollection@acf.hhs.gov](mailto:infocollection@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:* 202-395-7245, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: June 8, 2009.

**Janean Chambers,**

*Reports Clearance Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2009-D-0260]

**Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007; Availability; Announcement of Further Delay in Implementation of the Food and Drug Administration Amendments Act of 2007**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Guidance for Industry: Questions and

Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007." The draft guidance, when finalized, will assist the industry in complying with the Reportable Food Registry requirements prescribed by the Food and Drug Administration Amendments Act of 2007 (FDAAA). FDA is also announcing a further delay in the implementation of the Reportable Food Registry (the Registry) of FDAAA until September 8, 2009, to consider any comments received on the draft guidance and through the agency's planned outreach initiatives, and to allow for further testing of the electronic portal for reportable foods.

**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 the draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by July 27, 2009.

**ADDRESSES:** Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written requests for single copies of the draft guidance to the Office of Food Defense, Communication and Emergency Response, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:** Faye Feldstein, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2428.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance entitled "Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007." The draft guidance is intended to assist those parties responsible for complying with the Reportable Food Registry requirements prescribed by FDAAA.

FDA is issuing this draft guidance as a level 1 draft guidance consistent with

FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. 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. Notice of Further Delay in Implementation**

On September 27, 2007, the President signed FDAAA into law (Public Law 110-85). Section 1005 of FDAAA amends the Federal Food, Drug, and Cosmetic Act (the act) by creating a new section 417 (21 U.S.C. 350f), among other things. Section 417 of the act requires the Secretary of Health and Human Services to establish within FDA a Reportable Food Registry (the Registry); the Registry is to be established not later than 1 year after the date of enactment (i.e., by September 27, 2008).

To further the development of the Registry, section 417 of the act requires FDA to establish, also within 1 year after the date of enactment (i.e., by September 27, 2008), an electronic portal (the Reportable Food electronic portal) by which instances of reportable food must be submitted to FDA by responsible parties and may be submitted by public health officials.

FDA made the decision that the most efficient and cost effective means to implement the requirements of section 417 of the act relating to the Registry was to utilize the business enterprise system currently under development within the agency: the MedWatch<sup>Plus</sup> Portal. This would permit the agency to establish an electronic portal through which instances of reportable food may be submitted to the agency. However, FDA recognized that the MedWatch<sup>Plus</sup> Portal would not be implemented in time to meet the September 27, 2008, deadline for establishing the Reportable Food electronic portal and therefore announced that it was delaying its implementation until spring 2009 (73 FR 30405; May 27, 2008).

The agency now expects the system to be operational on September 8, 2009, and is therefore announcing that the implementation of the requirements of section 417 of the act will be further delayed until September 8, 2009.

In the interim, FDA strongly encourages persons to continue to report instances of adulterated food through existing mechanisms, such as notifying the relevant FDA District office, until such time as the Registry and its

associated electronic portal are fully implemented.

##### **III. Paperwork Reduction Act of 1995**

This draft guidance document contains a collection of information that requires clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. FDA intends to submit the collection of information to OMB in the near future for emergency processing. At that time, the agency will publish a notice in the **Federal Register** soliciting comments on the collection of information.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in question 28 of the guidance have been approved under OMB control no. 0910-0249.

##### **IV. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

##### **V. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/default.htm> or <http://www.regulations.gov>.

Dated: June 5, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Centers for Disease Control and Prevention**

##### **Draft Guideline for Prevention of Catheter-Associated Urinary Tract Infections 2008 [Correction]**

The notice "Draft Guideline for Prevention of Catheter-Associated Urinary Tract Infections 2008," was published in the **Federal Register** on June 3rd, 2009, (Vol. 74 FR No. 105).