

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents   | Form name                                  | Number of respondents | Number of responses per respondent | Average burden per response (in hr) |
|---|--|-----------------------|------------------------------------|-------------------------------------|
| Private sector health care providers .....  | PPOD Guide and Toolkit Follow-up Survey .. | 80                    | 1                                  | 10/60                               |
| State and Local government health care providers and health education facilitators. | New Beginnings Assessment Survey .....     | 700                   | 1                                  | 15/60                               |
|   | PPOD Guide and Toolkit Follow-up Survey .. | 80                    | 1                                  | 10/60                               |
| Federal Government health care providers ....                                       | New Beginnings Assessment Survey .....     | 100                   | 1                                  | 15/60                               |
|   | PPOD Guide and Toolkit Follow-up Survey .. | 40                    | 1                                  | 10/60                               |

**Leroy A. Richardson,**

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014-25095 Filed 10-21-14; 8:45 am]

BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Notice of Intent To Award Ebola Response Outbreak Funding to Eligible Ministries of Health and Their Bona Fide Agents**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** This notice provides public announcement of CDC’s intent to award Ebola appropriations to select Ministries of Health and their bona fide agents for response to the Ebola outbreak funding. This award was proposed in Fiscal Year (FY) 2015 under funding opportunity announcement GH14-1418, “Protecting and Strengthening Public Health Impact, Systems, Capacity, and Security.”

Catalogue of Federal Domestic Assistance Number (CFDA): 93.318

**Authority:** Public Health Service 301(a) and 307 as amended [42 U.S.C. 241 and 242]

Multiple awards may be awarded to grantees totaling \$2,000,000 for Ebola response outbreak.

Funding is appropriated under the Continuing Appropriations Resolution, 2015, Public Law 113-164, 128 Stat. 1867 (2014).

**DATES:** Anticipated award date 10/30/2014 through 09/29/2015.

Application Due Date: 10/23/2014  
Project Number is CDC-RFA-GH14-1418.

**ADDRESSES:** CDC has waived the Grants.gov electronic submission process for this requirement. Recipients are hereby authorized to submit a paper copy application for (CDC-RFA-GH14-1418) via Express Mail (i.e. FedEx, UPS, or DHL) and send the application via email. Mailed applications must be address to Arthur C. Lusby, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341, telephone (770) 488-2865, or email him at [ALusby@cdc.gov](mailto:ALusby@cdc.gov). The application must include a detailed line-item budget and justification to support the Ebola activities from October 31, 2014 to September 29, 2015.

Please download the following to complete the application package:  
[http://apply07.grants.gov/apply/forms/sample/SF424\\_2\\_1-V2.1.pdf](http://apply07.grants.gov/apply/forms/sample/SF424_2_1-V2.1.pdf)—Application Package  
<http://www.cdc.gov/od/pgo/funding/docs/CertificationsForm.pdf>—Certifications  
[http://www.cdc.gov/od/pgo/funding/grants/Budget\\_Preparation\\_Guidelines\\_8-2-12.docx](http://www.cdc.gov/od/pgo/funding/grants/Budget_Preparation_Guidelines_8-2-12.docx)—CDC-PGO Budget Guidelines  
<http://apply07.grants.gov/apply/forms/sample/SF424A-V1.0.pdf>—SF-424A Budget Information

All applications must be submitted to and received by the Grants Management Officer (GMO) no later than 11:59 p.m. EST on *October 23, 2014* and please provide the GMO a PDF version of the application by email to the following email address: [pgoebolaresponse@cdc.gov](mailto:pgoebolaresponse@cdc.gov) subject line: CDC-RFA-GH14-1418.

Applicants will be provided with the Funding Opportunity Announcement (FOA) and additional application submission guidance via email notification. Applicants may contact the POCs listed with questions regarding the application process.

**FOR FURTHER INFORMATION CONTACT:**

**For Programmatic or Technical Assistance**

Kawi Mailutha, Project Officer, Department of Health and Human

Services, Centers for Disease Control and Prevention, 1600 Clifton Rd MS E-29, Atlanta, GA 30333, Telephone: 404-639-8093, E-Mail: [KMailutha@cdc.gov](mailto:KMailutha@cdc.gov).

For financial, awards management, or budget assistance: Arthur C. Lusby, Grants Management Officer, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341, Telephone (770) 488-2865, Email: [ALusby@cdc.gov](mailto:ALusby@cdc.gov).

**SUPPLEMENTARY INFORMATION:** The purpose of this notice is to solicit applications from eligible Ministries of Health and their bona fide agents to quickly arrest the spread of the Ebola virus in West Africa and contain the disease as quickly as possible. The funding will support the impacted countries and the surrounding countries to combat this health crisis. This funding will target the following countries: Liberia, Sierra Leone, Guinea, Mauritania, Mali, Senegal, Guinea Bissau, Ghana, Gambia, Cote d’Ivoire, Togo, Benin, and Nigeria to support the responses of the CDC to the outbreak of Ebola virus in West Africa. This funding will enable the U.S. to provide unified mobilization to address a crisis of this magnitude. CDC will continue to build partnerships and strengthen existing projects to respond to Ebola. CDC and its partners will help to address the need for surveillance, detection, coordination, response, and increase eligible governments’ capacity to respond to the Ebola outbreak.

**Award Information:**

Type of Award: Amended FOA.

Approximate Total Current Fiscal Year ACA Funding: \$2,000,000.

Anticipated Number of Awards: multiple.

Fiscal Year Funds: 2015.

Anticipated Award Date: October 30, 2014.

Application Selection Process: Funding will be awarded to applicant based on results from the technical review recommendation.

Dated: October 17, 2014.

**Ron A. Otten,**

*Acting Deputy Associate Director for Science, Centers for Disease Control and Prevention.*

[FR Doc. 2014-25133 Filed 10-17-14; 4:15 pm]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2014-N-1027]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Infant Formula Recall Regulations**

**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 November 21, 2014.

**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 emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0188. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**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.

**Infant Formula Recall Regulations—21 CFR 107.230, 107.240, 107.250, 107.260, and 107.280 (OMB Control Number 0910-0188)—(Extension)**

Section 412(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350a(e)) provides that if the manufacturer of an infant formula has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer has left its control and may not provide the nutrients required in section 412(i) of the FD&C Act or is otherwise adulterated or misbranded, the manufacturer must promptly notify the Secretary of Health and Human Services (the Secretary). If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary. Section 412(f)(2) of the FD&C Act states that “the Secretary shall by regulation prescribe the scope and extent of recalls of infant formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall.” Our infant formula recall regulations in part 107 (21 CFR part 107) implement these statutory provisions.

Section 107.230 requires each recalling firm to conduct an infant formula recall with the following elements: (1) Evaluate the hazard to human health, (2) devise a written recall strategy, (3) promptly notify each affected direct account (customer) about the recall, and (4) furnish the appropriate FDA district office with copies of these documents. If the recalled formula presents a risk to

human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide us with a copy of the notice. Section 107.240 requires the recalling firm to conduct an infant formula recall with the following elements: (1) Notify the appropriate FDA district office of the recall by telephone within 24 hours, (2) submit a written report to that office within 14 days, and (3) submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for our written concurrence (§ 107.250). Where the recall strategy or implementation is determined to be deficient, we may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (§ 107.260). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§ 107.280).

The reporting and recordkeeping requirements described previously are designed to enable us to monitor the effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination or nutritional inadequacy or otherwise adulterated or misbranded. We use the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market.

In the **Federal Register** of August 7, 2014 (79 FR 46270), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the annual burden of this collection of information as follows:

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

| 21 CFR section; activity                                   | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours   |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|---------------|
| 107.230; elements of infant formula recall .....           | 2                     | 1                                  | 2                      | 4,450                       | 8,900         |
| 107.240; notification requirements .....                   | 2                     | 1                                  | 2                      | 1,482                       | 2,964         |
| 107.250; termination of infant formula recall ...          | 2                     | 1                                  | 2                      | 120                         | 240           |
| 107.260; revision of an infant formula recall <sup>2</sup> | 1                     | 1                                  | 1                      | 625                         | 625           |
| <b>Total .....</b>   |                       |                                    |                        |                             | <b>12,729</b> |

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

<sup>2</sup> No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.