observations that are communicated to a firm through issuance of a form FDA 483, list of inspectional observations.

DATES: The program will begin on September 15, 2009.

FOR FURTHER INFORMATION CONTACT: Karen Stutsman, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6860.

SUPPLEMENTARY INFORMATION:

I. Background

FDA issues a form FDA 483, Inspectional Observations, upon completion of an inspection, to notify an inspected establishment's top management of objectionable conditions relating to products and/or processes, or other violations of the Federal Food, Drug, and Cosmetic Act and related acts, that were observed during the inspection.

The FDA 483 form includes this preprinted instruction: ''This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations; and do not represent a final agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address [on the form].''

When FDA determines, based on the inspection, that the establishment is in violation of the Federal Food, Drug, and Cosmetic Act or another statute that we enforce, we may issue a warning letter. Warning letters are issued only for significant violations that may lead to enforcement action if they are not promptly and adequately corrected. The decision to issue a warning letter is made by senior officials within FDA, often including the product center, after a thorough review of all of the relevant facts.

It is not uncommon for an inspected establishment to respond in writing to observations made on an FDA 483 to describe completed or ongoing corrective actions or to promise future corrections. In fact, some inspected establishments submit multiple responses to FDA, sometimes over many months. Delayed and multiple responses to an FDA 483 have resulted in delays in the issuance of warning letters while these responses are reviewed and addressed. FDA's timely issuance of a warning letter should help to achieve prompt voluntary compliance and is therefore in the public interest.

While FDA considers corrective actions, and other factors, in determining whether to issue a warning letter, ongoing or promised corrective actions generally do not preclude the issuance of a warning letter. A warning letter is an important means of notifying regulated industry of violations and achieving prompt voluntary correction. Warning letters serve to ensure that the seriousness and scope of the violations are understood by top management of the inspected establishment, and that the appropriate resources are allocated to fully correct the violations and to prevent their recurrence. FDA is initiating a program to establish a timeframe for the submission of such post-inspection responses to FDA 483 inspectional observations for FDA's consideration in deciding whether to issue a warning letter. Under the program (described in more detail later in this document), the agency will not ordinarily delay the issuance of a warning letter in order to review a response to an FDA 483 that is received more than 15 business days after the FDA 483 was issued.

The purpose of this program is to optimize resource utilization, facilitate the timely issuance of warning letters, and promote prompt correction of violations. FDA will use the information from the program to determine whether to make the program permanent. FDA will conduct an assessment of the program after approximately 18 months.

II. Program Description

Under the program, before issuing a warning letter, FDA will generally allow firms 15 business days to provide a response to FDA 483 observations. If we receive a response to FDA 483 observations within 15 business days after the FDA 483 was issued, we plan to conduct a detailed review of the response before determining whether to issue a warning letter. If we issue a warning letter after reviewing a firm's timely response, the warning letter will recognize receipt of the response and reply as to the apparent adequacy of the firm's corrective actions set forth in the response. Additional correspondence from FDA may be issued with regard to the response, if needed.

If we receive a response to FDA 483 observations more than 15 business days after the FDA 483 was issued, we do not plan to routinely include a response on the apparent adequacy of the firm's corrective actions in the warning letter. Rather, we plan to evaluate the response along with any other written material provided as the direct response to the warning letter (a firm's response to a warning letter may reference any of the firm's earlier responses).

Note that FDA, at its discretion, may issue Warning Letters at any time, independent of receiving a response; and that firms are expected to implement needed corrections to conform to the requirements of the Federal Food, Drug, and Cosmetic Act and associated regulations regardless of whether they respond in writing to FDA or whether such a response is reviewed by FDA.

After the 18-month time period, FDA will evaluate this program and decide whether to continue it with or without adjustments.

Dated: August 4, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–19107 Filed 8–10–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2009–0001]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice; 60-day notice and request for comments; revision of a currently approved information collection; OMB No. 1660–0099; FEMA Form 646–0, Citizen Corps Individual Registration.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed revision of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this Notice seeks comments concerning the online registration process for Citizen Corps Individual Registration.

DATES: Comments must be submitted on or before October 13, 2009.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at www.regulations.gov under docket ID FEMA–2009–0001. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Office of Chief Counsel, Regulation and Policy Team, DHS/FEMA, 500 C Street, SW., Room 835, Wash, DC 20472–3100.

(3) *Facsimile.* Submit comments to (703) 483–2999.

(4) *E-mail.* Submit comments to FEMA–POLICY@dhs.gov. Include docket ID FEMA–2009–0001 in the subject line.

All submissions received must include the agency name and docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available on the Privacy and Use Notice link on the Administration Navigation Bar of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Kerry Hoerth, Community Preparedness Division Program Specialist, FEMA, 202–786–9775 for additional information. You may contact the Records Management Branch for copies of the proposed collection of information at facsimile number (202) 646–3347 or e-mail address: *FEMA–Information-Collections@dhs.gov.*

SUPPLEMENTARY INFORMATION: Citizen Corps was launched as a Presidential Initiative, Executive Order 13254, in 2002 with a mission to harness the power of every individual through education, training, and volunteer service to make communities safer, stronger, and better prepared for the threats of terrorism, crime, public health issues, and disasters of all kinds. In order to fulfill its mission, the Federal Emergency Management Agency (FEMA) Community Preparedness Division (CPD) requires individuals to submit profiles electronically through its information collection online process and forms.

Collection of Information

Title: Citizen Corps Individual Registration.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: OMB No. 1660–0099.

Form Titles and Numbers: FEMA Form 646–0, Citizen Corps Individual Registration.

Abstract: FEMA's Community Preparedness Division (CPD) would like to revise a currently approved collection for its individual registration to allow members of the public to provide contact information to receive national programmatic updates and announcements such as upcoming preparedness demonstrations and training opportunities and the opportunity to get involved in local organizations and events.

Affected Public: Individuals or households.

Estimated Total Annual Burden Hours: 1,600 burden hours.

ANNUAL HOUR BURDEN

TABLE A.12—ESTIMATED ANNUALIZED BURDEN HOURS AND COSTS

Type of respondent	Form name/ form No.	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)	Total annual burden (in hours)	Avg. hourly wage rate*	Total annual respondent cost
Individuals or households	FEMA Form	20,000	1	5 minutes (.08 hours)	1,600	27.38	43,808.00
Total		20,000			1,600		43,808.00

*Note: The ''Avg. Hourly Wage Rate'' for each respondent includes a 1.4 multiplier to reflect a fully-loaded wage rate.

Estimated Cost: None.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Larry Gray,

Director, Records Management Division, Office of Management, Federal Emergency Management Agency, Department of Homeland Security.

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2009–0001]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice; 60-day notice and request for comments; revision of a currently approved information collection; OMB No. 1660–0098; FEMA Form 646, Citizen Corps Council Registration.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed revision of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this Notice seeks comments concerning the online database of Citizen Corps Councils and Community Emergency Response Team (CERT) so that they can submit profiles via the national Web site. Approved registration of a Council or CERT program allows them to be recognized as official entities