

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 24, 2014.

Richard Kronick,
AHRQ Director.

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**
Food and Drug Administration

[Docket No. FDA-2014-N-1072]

**Agency Information Collection
Activities; Proposed Collection;
Comment Request; Application for
Participation in the Food and Drug
Administration Commissioner's
Fellowship Program**

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 application for participation in the FDA Commissioner's Fellowship Program (CFP).

DATES: Submit either electronic or written comments on the collection of information by October 3, 2014.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@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.

**Application for Participation in the
FDA Commissioner's Fellowship
Program; (OMB Control Number 0910—
New)**

Sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of Title 5 of the United States Code authorize Federal Agencies to rate applicants for Federal jobs. Collecting applications for the CFP will allow FDA's Office of the Commissioner to easily and efficiently elicit and review information from students and health care professionals who are interested in becoming involved in FDA-wide activities. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of applications being misrouted within the Agency mail system. It will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their expertise with FDA.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity/5 U.S.C. Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1104,1302, 3301, 3304, 3320, 3361, 3393, and 3394	600	1	600	1.33	798
Total					798

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

FDA based these estimates on the number of inquiries that have been received concerning the program and the number of requests for application forms over the past 5 years.

Dated: July 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-18302 Filed 8-1-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1031]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Recall Regulations

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 including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA recalls for human drugs, biological products, devices, animal drugs, food, cosmetics, and tobacco.

DATES: Submit either electronic or written comments on the collection of information by October 3, 2014.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver

Spring, MD 20993-0002, PRASStaff@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, including each proposed extension of an existing 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. FDA Recall Regulation—21 CFR Part 7 (OMB Control Number 0910-0249)—Extension

Section 701 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) charges the Secretary of Health and Human Services (HHS), through the FDA, with the responsibility of assuring recalls (21 U.S.C. 371, Regulations and hearings, and 21 CFR Part 7, Enforcement Policy, Subpart C, Recalls (Including Product Corrections)—Guidance on Policy, Procedures, and Industry Responsibilities) which pertain to the recall regulations and provide guidance to manufacturers on recall responsibilities. The guidelines apply to all FDA-regulated products (i.e., food,

including animal feed; drugs, including animal drugs; medical devices, including in vitro diagnostic products; cosmetics; biological products intended for human use; and tobacco). These responsibilities include providing FDA with complete details of the recall including reason(s) for the removal or correction, risk evaluation, quantity produced, distribution information, the firm's recall strategy, a copy of any recall communication(s), and a contact official (§ 7.46); notifying direct accounts of the recall, providing guidance regarding further distribution, giving instructions as to what to do with the product, providing recipients with a ready means of reporting to the recalling firm (§ 7.49); and submitting periodic status reports so that FDA may assess the progress of the recall. Status report information may be determined by, among other things, evaluation return reply cards, effectiveness checks and product returns (§ 7.53); and providing the opportunity for a firm to request in writing that FDA terminate the recall (§ 7.55(b)).

A search of FDA's database was performed to determine the number of recalls that took place during fiscal years 2011 to 2013. The resulting number of total recalls (11,403) from this database search were then averaged over the 3 years, and the resulting per year average of recalls (3,801) are used in estimating the current annual reporting burden for this report. The resulting number of total terminations (11,403 from this database search were then averaged over the 3 years, and the resulting per year average of terminations (3,801) are used in estimating the current annual reporting burden for this report.

FDA estimates the total annual industry burden to collect and provide the previous information to be 627,165 burden hours.

The following is a summary of the estimated annual burden hours for recalling firms (manufacturers, processors, and distributors) to comply with the voluntary reporting requirements of FDA's recall regulations. Recognizing that there may be a vast difference in the information collection and reporting time involved in different recalls of FDA's regulated products.

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