addition, OHS will share actions taken and in progress to address the issues and concerns raised in 2014 OHS Tribal Consultations.

The Consultation Session will be conducted with elected or appointed leaders of Tribal Governments and their designated representatives [42 U.S.C. 9835, Section 640(l)(4)(A)]. Designees must have a letter from the Tribal Government authorizing them to represent the tribe prior to the Consultation Session. Other representatives of tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of the Consultation Session will be prepared and made available within 45 days of the Consultation Session to all Tribal Governments receiving funds for Head Start and Early Head Start programs. Tribes wishing to submit written testimony for the report should send testimony to Robert Bialas at *Robert.Bialas@acf.hhs.gov* either prior to the Consultation Session or within 30 days after the meeting.

Oral testimony and comments from the Consultation Session will be summarized in each report without attribution, along with topics of concern and recommendations. OHS has sent hotel and logistical information for the New Mexico Consultation Session to tribal leaders via email and posted information on the Early Childhood Learning and Knowledge Center Web site at *http://eclkc.ohs.acf.hhs.gov/hslc/hs/calendar/tc2015*.

Dated: February 6, 2015.

Linda K. Smith,

Deputy Assistant Secretary, Early Childhood Development.

[FR Doc. 2015–02859 Filed 2–10–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1031]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 March 13, 2015.

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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0249. 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, *PRAStaff@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.

FDA Recall Regulation—21 CFR Part 7 (OMB Control Number 0910–0249)—Extension

Section 701 of the Federal Food, Drug, and Cosmetic Act charges the Secretary of Health and Human Services, through 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 (21 CFR 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.

In the **Federal Register** of August 4, 2014 (79 FR 45197), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the total annual industry burden to collect and provide the previous information to be 721,886 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:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Recall	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Firm Initiated Recall (21 CFR 7.46) and Recall Communications (21 CFR 7.49)	3,801	1	3,801	25	95,025
Recall Status Reports (21 CFR 7.53)	3,801	13	49,413	10	494,130
Termination of a Recall (21 CFR 7.55(b))	3,801	1	3,801	10	38,010
Total					627,165

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

I. Total Annual Reporting

A. Firm Initiated Recall and Recall Communications

Request firms voluntarily remove or correct foods and drugs (human or animal), cosmetics, medical devices, biologics, and tobacco to immediately notify the appropriate FDA District Office of such actions. The firm is to provide complete details of the recall reason, risk evaluation, quantity produced, distribution information, firms' recall strategy and a contact official as well as requires firms to notify their direct accounts of the recall and to provide recipients with a ready means of reporting to the recalling firm. Under these portions of the collection of information, the Agency estimates it will receive 3,801 responses annually based on the average number of recalls over the last 3 fiscal years. The number of responses multiplied by the number of respondents equal 3,801. The average burden hours of 25 multiplied by the total number of annual responses equal 95,025. The average burden hour person response was 30 and has decreased by 5.

B. Recall Status Reports

Request that recalling firms provide periodic status reports so FDA can ascertain the progress of the recall. This request only applies to firms with active recalls, and is estimated to be reported every 2 to 4 weeks. This collection of information will generate approximately 3,801 responses annually, based on the average number of recalls over the last 3 fiscal years (11,403). The number of respondents multiplied by the number of responses per respondents (13) equal a total number of annual responses of 49,413. The total number of responses 49,413 with an average burden hours of 10 per response equal a total of 494,130 total hours.

C. Termination of a Recall

Provide the firms an opportunity to request in writing that FDA end the recall. The Agency estimates it will receive 3,801 responses annually based on the average number of terminations over the past 3 fiscal years. The total annual responses of 3,801 multiplied by the average burden hours of 10 per response equal a total number of hours of 38,010.

II. Total Annual Third-Party Disclosure Burden

Recall Communications. Request firms to notify their consignees of the recall and to provide recipients with a ready means of reporting to the recalling firm. Under this portion of the collection of information, the Agency estimates firms will provide 1,691,445 notifications annually based on the number of respondents/consignees (3,807) multiplied by the number of disclosures per respondent (445). The total number of hours is 94,721 (based on 1,691,445 multiplied by 0.056 hours).

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

21 CFR Part	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Recall Communications (21 CFR 7.49)	3,801	445	1,691,445	0.056 (3 minutes)	94,721

FDA regulates many different types of products including, but not limited to, medical products, food and feed, cosmetics, and tobacco products. FDA notes that not all third-party disclosures provided by firms to their consignees are similar in nature and may entail different methods and mediums of communication. FDA estimates the burden for third-party disclosure per recall event to be an average of 25 hours. This burden estimate factored out to the average number of consignees per recall (445) results in a burden per disclosure estimate of approximate hours (25 hours per recall/445 disclosures/recall = 0.056 hours).

Dated: February 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02788 Filed 2–10–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0403]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.