Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Tribal TANF Data Report, TANF Annual Report, and Reasonable Cause/Corrective Action Documentation Process—Final.

OMB No.: 0970–0215.

Description: 42 U.S.C. 612 (Section 412 of the Social Security Act as amended by Public Law 104–193, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA)), mandates that federally recognized Indian Tribes with an approved Tribal TANF program collect and submit to the Secretary of the Department of Health and Human Services data on the recipients served by the Tribes' programs. This information includes both aggregated and disaggregated data on case characteristics and individual characteristics. In addition, Tribes that are subject to a penalty are allowed to provide reasonable cause justifications as to why a penalty should not be imposed or may develop and implement corrective compliance procedures to eliminate the source of the penalty. Finally, there is an annual report, which requires the Tribes to describe program characteristics. All of the above requirements are currently approved by OMB and the Administration for Children and Families is simply proposing to extend them without any changes.

Respondents: Indian Tribes.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Final Tribal TANF Data Report	74	4	451	133,496
Tribal TANF Annual Report	74	1	40	2,960
Tribal TANF Reasonable Cause/Corrective	74	1	60	4,440

Estimated Total Annual Burden Hours: 140,896.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018–24259 Filed 11–5–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0138]

Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry and FDA staff entitled ''Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff.'' The guidance provides information on the implementation of the mandatory food recall provisions of the FDA Food Safety Modernization Act (FSMA). The guidance is in the form of Questions and Answers and provides answers to common questions that might arise about the mandatory recall provisions and FDA's plans for their implementation.

DATES: The announcement of the guidance is published in the **Federal Register** on November 6, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–0138 for ''Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Building, Rm. 4141, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Seth Brown, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Building, Rm. 4141, Rockville, MD 20857, 240–402–4891.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff.'' We are issuing the guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

FDA's mandatory food recall authority went into effect when FSMA was enacted on January 4, 2011. Section 423 of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 350l), as added by section 206 of FSMA, gives FDA the authority to order a responsible party to recall an article of food where FDA determines that there is a reasonable probability that the article of food (other than infant formula) is adulterated under section 402 of the FD&C Act (21 U.S.C. 342) or misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)) and that the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals (SAHCODHA). The guidance provides answers to common questions that might arise about the mandatory recall provisions and FDA's plans for their implementation.

In the **Federal Register** of May 7, 2015 (80 FR 26269), we made available a draft guidance for industry entitled ''Questions and Answers Regarding Mandatory Food Recalls; Draft Guidance for Industry'' and gave interested parties an opportunity to submit comments by July 6, 2015, for us to consider before beginning work on the final version of the guidance. We received several comments on the draft guidance and have modified the final guidance where appropriate. Changes to the guidance include: Adding clarity regarding the process FDA will follow for a mandatory food recall; providing detail regarding the evidence or circumstances FDA may consider when deciding to move forward with a mandatory food recall; adding a question that lists examples of situations when FDA would deem a food product to represent a SAHCODHA risk; and making editorial changes to improve clarity.

We are removing two questions from the guidance. We are removing the question about when the mandatory recall provisions go into effect, as this provision has been in effect since 2011. We are also removing the question about user fees, as we have not yet issued guidance associated with these fees and we have previously stated that we do not intend to issue invoices for mandatory recall order fees until that guidance has been finalized.

The guidance announced in this notice finalizes the draft guidance dated May 2015.

II. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: November 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24247 Filed 11–5–18; 8:45 am]

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