DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: TANF Quarterly Financial Report, ACF–196.

OMB No.: 0970–0247.

Description: This information collection is authorized under Section 411(a)(3) of the Social Security Act. This request is for renewal of approval to use the Administration for Children and Families' (ACF) 196 form for periodic financial reporting under the Temporary Assistance for Needy Families (TANF) program. States participating in the TANF program are required by statute to report financial data on a quarterly basis. This form meets the legal standard and provides essential data on the use of Federal funds. Failure to collect the data would seriously compromise ACF's ability to monitor program expenditures, estimate funding needs, and to prepare budget submissions required by Congress. Financial reporting under the TANF program is governed by 45 CFR part 265.

Respondents: TANF Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–196	51	4	10	2,040

Estimated Total Annual Burden Hours: 2,040.

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, 370 L'Enfant Promenade SW., Washington, DC 20447, 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 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0643]

Guidance for Industry: What You Need To Know About Administrative Detention of Foods; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''What You Need to Know About Administrative Detention of Foods; Small Entity Compliance Guide'' (SECG) which updates an earlier guidance of similar title. Previously, this guidance restated the legal requirements of FDA's administrative detention regulation. This document also at one time served as FDA's guidance for administrative detention. In October 2011, FDA revised an earlier version of this guidance document to be consistent with the changes made by an interim final rule (IFR) issued in the **Federal Register** of May 5, 2011, and to serve as guidance for industry on administrative detention. FDA has since issued a final rule adopting the IFR as final without changes which was published in the **Federal Register** of February 5, 2013. Accordingly, FDA is further revising the existing guidance document to provide guidance intended to help any entity comply with the requirements in FDA's administrative detention regulation, including the amendments to these requirements made by the final rule. This notice also clarifies that this document continues to serve as FDA's guidance for administrative detention.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Outreach and Information Center (HFS–009), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: William A. Correll, Jr., Office of Compliance (HFS–607), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1611.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) was signed into law on January 4, 2011. Section 207 of FSMA amended the criteria for ordering administrative detention in section 304(h)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 334(h)(1)(A)) to provide FDA the authority to order administrative detention if there is reason to believe that an article of food is adulterated or misbranded. On May 5, 2011, in accordance with FSMA, FDA

published an IFR in the **Federal Register** amending its regulations in 21 CFR part 1, subpart K (76 FR 25538), that pertain to the criteria for ordering administrative detention. This IFR became effective on July 3, 2011. On February 5, 2013, FDA issued a final rule which adopted the IFR as final without changes. FDA is announcing the availability of an update to an existing guidance document that will also serve as FDA's SECG.

In October 2011, FDA updated an existing guidance which had restated the legal requirements of FDA's administrative detention regulation at 21 CFR part 1, subpart K, implementing section 304(h) of the FD&C Act, as added by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This document had also served as FDA's guidance for 21 CFR part 1, subpart K in accordance with the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). The title of the October 2011 guidance was ''What You Need to Know About Administrative Detention of Foods,'' (76 FR 66073, October 25, 2011). The guidance was intended to provide individuals in the human and animal food industries with an understanding of FDA's authority to order the administrative detention of human or animal food under section 304(h) of the FD&C Act, as amended by section 207 of FSMA. It provided practical information, including who can approve an administrative detention order, what food may be subject to administrative detention, who receives a copy of an administrative detention order, and the process for appealing an administrative detention order. Additionally, the guidance identified references that contain more information regarding FDA's authority to order administrative detention.

FDA received one general comment about FDA decisionmaking to the docket associated with the October 2011 version (Docket Number FDA–2011–D–0643). The comment stated that it would like to ensure that FDA makes sound decisions based on testing from qualified laboratories. As such, the comment continued, FDA and private laboratories must be accredited and must follow good laboratory practices in their testing programs. In addition, the comment stated that testing should be conducted using validated testing methods that have been accredited and approved. Sound science is the cornerstone of FDA regulatory programs and actions and, to that extent, FDA agrees with the comment; however, in the context of administrative detention, FDA is not limited, as implied by the comment, to relying on analytical test results to determine whether FDA has a reason to believe a food is adulterated or misbranded. All evidence available to the Agency may be considered when making such a determination.

Since then, in the **Federal Register** of February 5, 2013 (78 FR 7994), FDA issued a final rule adopting the IFR as final without changes. The final rule adopts without change the interim final rule's amendments to certain regulations in 21 CFR part 1, subpart K to be consistent with amendments to the criteria for ordering administrative detention of human or animal food made by FSMA. The final rule, which adopts the interim final rule as final, is effective upon publication in the **Federal Register**.

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires Agencies to determine whether a final rule will have a significant impact on small entities when an Agency issues a final rule ''after being required * * * to publish a general notice of proposed rulemaking.'' Although FDA is not required to perform a regulatory flexibility analysis because, in accordance with 5 U.S.C. 553(b)(3)(B) and 21 CFR 10.40(e)(1), the Agency found for good cause that use of prior notice and comment procedures were contrary to the public interest; FDA has nonetheless examined the economic implications of the final rule in accordance with the Regulatory Flexibility Act and determined that the final rule will not have a significant economic impact on a substantial number of small entities (78 FR 7994). Similarly because FDA is not required to perform a final regulatory flexibility analysis under 5 U.S.C. 605(b) for the final rule, FDA is not required to issue a guidance to comply with section 212 of SBREFA (Pub. L.104–121); nevertheless, FDA has updated this guidance to state in plain language the requirements of 21 CFR part 1, subpart K.

FDA is issuing this guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). This guidance represents the Agency's current thinking on administrative detention of foods. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). We conclude that the collections of information in §§ 1.381(d) and 1.402 are exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or Agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an Agency against specific individuals or entities. The regulations in 5 CFR 1320(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit, or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the decision to detain an article of food.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/RegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.* Always access an FDA guidance document by using FDA's Web site listed previously to find the most current version of the guidance.

Dated: March 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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