4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0341]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Safety; Federal-State Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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: Submit written comments (including recommendations) on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].**

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0760. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, 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.

Food Safety; Federal-State Food Regulatory Program Standards

OMB Control Number 0910-0760--Revision

This information collection supports implementation of FDA's Federal-State Regulatory Program Standards, part of our National Integrated Food Safety System (IFSS) Programs and Initiatives. For more information we invite you to visit our website at: https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/national-integrated-food-safety-system-ifss-programs-and-initiatives. In the United States, Federal and State governments work cooperatively to ensure the safety of food intended for both human and animal consumption. Part of this effort includes developing and maintaining uniform review criteria by which to assess food safety. FDA has established and maintains a number of program standards aimed at improving the safety evaluation for certain food products including manufactured foods and animal feed. Similarly, we are establishing regulatory program standards for eggs and have developed the "Eggs Regulatory Program Standards" (ERPS). The ERPS is intended for use by State and local regulatory officials and identifies 10 elements we believe are essential to the effective regulatory assessment of egg safety. States are encouraged to build systems that are sustainable and implement plans corresponding to the IFSS.

In the course of their normal duties, State, local, Territorial, and Tribal governments collect information pertaining to compliance with the respective State, local, Territorial, and Tribal food safety requirements within their jurisdictions. Although content and format of the information collected may vary, these activities are a usual and customary part of routine regulatory oversight. Respondents to the information collection are State, local, Territorial, and Tribal regulatory agencies.

The ERPS offers forms, worksheets, and templates to help respondents assess and meet the program elements identified and discussed. Respondents are not required to use the sample collection instruments included in the ERPS, however all data elements should be submitted to FDA and supporting documentation retained. The ERPS is not intended to address any

performance appraisal processes that any State, local, Territorial, or Tribal agency may use to evaluate its employees' performance. Funding opportunities are available to respondents who choose to implement the ERPS; however, these opportunities are limited and contingent upon the availability of funds, and are available to those respondents who currently have an egg inspection contract with FDA and thus are subject to auditing. A copy of the ERPS has been posted to FDA-2021-N-0341 and is available at https://www.regulations.gov.

In the *Federal Register* of May 14, 2021 (86 FR 26528), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1.--Estimated Annual Recordkeeping Burden[1]

Type of Respondents; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
State, local, Territorial, and/or Tribal Governments; submission of data elements to FDA consistent with ERPS	10	10	100	50	5,000

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

Based on our experience with similar information collection, we estimate an initial 10 respondents will participate in the ERPS, and assume an average of 50 burden hours per response is necessary for the attendant recordkeeping and submission of data elements to FDA. We expect participation in the ERPS to increase. Finally, upon submission of the Information Collection Request, we are correcting an inadvertent calculation error in the total burden hours as displayed on page 26530, in Table 1, in our 60-day notice in the *Federal Register* of May 14, 2021 (86 FR 26528).

Dated: September 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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