4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-0499]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice

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: 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 0910-0466. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Christopher Colburn, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8758, 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.

Hazard Analysis and Critical Control Point (HACCP) Procedures for the Safe and Sanitary Processing and Importing of Juice--21 CFR Part 120

OMB Control Number 0910-0466--Extension

This information collection supports FDA's regulations in part 120 (21 CFR part 120), which govern the application of HACCP principles to the processing of fruit and vegetable juices. HACCP is a preventative system of hazard control designed to help ensure the safety of foods. The regulations were issued under FDA's statutory authority to regulate food safety under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(a)(4)). Specifically, regulations in 21 CFR 120.12 provide for records documenting the establishment, implementation, and continued application of a HACCP system. The rationale in establishing a HACCP system of preventive controls is to design and check the process so that the final product is not contaminated. Under HACCP, processors of fruit and vegetable juices establish and follow a preplanned sequence of operations and observations (the HACCP plan) designed to avoid or eliminate one or more specific food hazards, and thereby ensure that their products are safe, wholesome, and not adulterated; in compliance with section 402 of the FD&C Act. Information development and recordkeeping are essential parts of any HACCP system. The information collection requirements are narrowly tailored to focus on the development of appropriate controls and document those aspects of processing that are critical to food safety.

HACCP records are retained by respondents and presented to FDA upon inspection. We use the information to determine compliance with applicable requirements. Products not in compliance with applicable statutory and regulatory requirements may be adulterated under the FD&C Act and subject to enforcement action.

In an effort to reduce burden and assist respondents, our website (https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/juice-haccp) offers guidance for industry, training and education, and background information to assist the food

industry in developing and implementing a Juice HACCP. All agency guidance documents are issued in accordance with our good guidance practice regulation in 21 CFR 10.115, which provides for public comment at any time.

Description of Respondents: Respondents to this information collection are processors of fruit and vegetable juices (plants identified in our official establishment inventory plus very small apple juice and very small orange juice manufacturers).

In the *Federal Register* of February 20, 2026 (91 FR 8251), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

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

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
120.6(c) and 120.12(a)(1) and (b); written monitoring and correction records for Sanitation Standard Operating Procedures	1,875	365	684,375	0.1 (6 minutes)	68,438
120.7; 120.10(a); and 120.12(a)(2), (b) and (c); require written hazard analysis of food hazards	2,300	1.1	2,530	20	50,600
120.8(b)(7) and 120.12(a)(4)(i) and (b); recordkeeping system that documents monitoring of the critical control points and other measurements as prescribed in the HACCP plan	1,450	14,600	21,170,000	0.01 (1 minute)	211,700
120.10(c) and 120.12(a)(4)(ii) and (b); document all corrective actions taken in response to a deviation from a critical limit	1,840	12	22,080	0.1 (6 minutes)	2,208
120.11(a)(1)(iv) and (a)(2) and 120.12(a)(5) and (b); records showing that process monitoring instruments are properly calibrated and that end-product or in-process testing is performed in	1,840	52	95,680	0.1 (6 minutes)	9,568

accordance with written procedures					
120.11(b) and (c); and 120.12(a)(5) and (b); record validation that the HACCP plan is adequate to control food hazards that are likely to occur	1,840	1	1,840	4	7,360
120.11(c) and 120.12(a)(5) and (b); document revalidation of the hazard analysis upon any changes that might affect the original hazard analysis (applies when a firm does not have a HACCP plan because the original hazard analysis did not reveal hazards likely to occur)	1,840	1	1,840	4	7,360
120.14(a)(2), (c), and (d) and 120.12(b); importers of fruit or vegetable juices, or their products used as ingredients in beverages, have written procedures to ensure that the food is processed in accordance with our regulations in part 120	308	1	308	4	1,232
120.8(a), 120.8(b), and 120.12(a)(3), (b), and (c); written HACCP plan	1,560	1.1	1,716	60	102,960
Total			21,980,369		461,426

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

Based on a review of the information collection since its last OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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