
Page 8 – Michael J. Wagner, Esq., Quest Diagnostics Nichols Institute (“Quest Diagnostics”)

AA. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratories;
- This product has been authorized only for the detection of nucleic acid from monkeypox virus or other non-variola orthopoxviruses, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/s/

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

Enclosure

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21829 Filed 10–6–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1427]

Agency Information Collection Activities; Proposed Collection; 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, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our regulations mandating the application of hazard

analysis and critical control point (HACCP) principles to the processing and importing of fruit and vegetable juices.

DATES: Either electronic or written comments on the collection of information must be submitted by December 6, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 6, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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-2013-N-1427 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice." Received comments, those filed in a timely manner (see **ADDRESSES**), 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, 240-402-7500.

- **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.govinfo.gov/content/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, 240-402-7500.

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: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 regulations in part 120 (21 CFR part 120) which mandate the application of HACCP procedures 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)). Under section 402(a)(4) of the FD&C Act, a food is adulterated if it is prepared, packed, or held under

insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. The Agency also has authority under section 361 of the Public Health Service Act (42 U.S.C. 264) to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State, territory, or possession to another, or from outside the United States into this country. Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act.

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.

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. Included in this information are guidance documents entitled “Juice

HACCP and the FDA Food Safety and Modernization Act” (December 2021) (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-juice-haccp-and-fda-food-safety-modernization-act>) and “Juice HACCP Hazards and Controls Guidance—First Edition” (March 2004) (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-juice-hazard-analysis-critical-control-point-hazards-and-controls-guidance-first>). All Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record-keeping	Total hours
120.6(c) and 120.12(a)(1) and (b); require 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); require a record-keeping 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); require that all corrective actions taken in response to a deviation from a critical limit be documented.	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); require records showing that process monitoring instruments are properly calibrated and that end-product or in-process testing is performed in accordance with written procedures.	1,840	52	95,680	0.1 (6 minutes).	9,568
120.11(b) and (c); and 120.12(a)(5) and (b); require that every processor record the 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); require documentation of 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); require that 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); require written HACCP plan.	1,560	1.1	1,716	60	102,960
Total	461,426

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

Table 1 provides our estimate for the next 3 years for the total annual recordkeeping burden of our regulations in part 120. Based on our experience with the information collection over the past 3 years, our burden estimate

remains unchanged since our last review of the information collection.

Dated: October 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-21862 Filed 10-6-22; 8:45 am]

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