Because of the consolidation of OMB control number 0910–0813, our estimate reflects an annual increase of 188,442 responses and 188,282 hours. These estimates are based on our experience with food labeling, related submissions of petitions, and informal communications with industry.

Dated: January 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–02253 Filed 2–4–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1427]

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: Fax written comments on the collection of information by March 6, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0466. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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

FDA's regulations in part 120 (21 CFR part 120) 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 (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 the **Federal Register** of September 26, 2019 (84 FR 50852), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received in response to the notice.

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

21 CFR Section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	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 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); 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

21 CFR Section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
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) and (b), and 120.12(a)(3), (b), and (c); require 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.

Table 1 provides our estimate of the total annual recordkeeping burden of our regulations in part 120. Our estimate remains unchanged since last review of the information collection. We base our estimate of the average burden per recordkeeping on our experience with the application of HACCP principles in food processing. We base our estimate of the number of recordkeepers on our estimate of the total number of juice manufacturing plants affected by the regulations (plants identified in our official establishment inventory plus very small apple juice and very small orange juice manufacturers). These estimates assume that every processor will prepare sanitary standard operating procedures and an HACCP plan and maintain the associated monitoring records, and that every importer will require product safety specifications. In fact, there are likely to be some small number of juice processors that, based upon their hazard analysis, determine that they are not required to have an HACCP plan under these regulations

Dated: January 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–02243 Filed 2–4–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0144]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Qualified Importer Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 FDA's Voluntary Qualified Importer Program (VQIP).

DATES: Submit either electronic or written comments on the collection of information by April 6, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 6, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 6, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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: