UNITED STATES FOOD AND DRUG ADMINISTRATION

Hazard Analysis and Critical Control Point (HACCP) Procedures
for the Safe and Sanitary Processing and Importing of Juice

OMB Control No. 0910-0466

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency, us or we) regulations in part 120 (21 CFR part 120) which mandate the application of hazard analysis and critical control point (HACCP) principles to the processing of fruit and vegetable juices. HACCP is a preventive 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 that Act.

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 - not test for contamination after it may have taken place. Under HACCP, processors of fruit and vegetable juices establish and follow a pre-planned 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 (21 U.S.C. 342). 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.

We therefore request extension of OMB approval of the provisions found in 21 CFR part 120 as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

HACCP records are normally reviewed by appropriately trained employees at the end of a production lot or at the end of a day or week of production to verify that control limits have been maintained, or that appropriate corrective actions were taken if the critical limits were not maintained. Such verification activities are essential to ensure that the HACCP system is working as planned. A review of these records during the conduct of periodic plant inspections04

also permits FDA to determine whether the products have been consistently processed in conformance with appropriate HACCP food safety controls.

This information collection supports section 120.14, which requires that importers of juice take affirmative steps and maintain records that verify that the juice they offer for import into the United States were processed in accordance with the HACCP and sanitation provisions set forth in part 120. These records are also available for review by FDA.

Description of Respondents: Respondents to this information collection are processors of fruit and vegetable juices. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

Many of the observations required to document HACCP control point parameters (times, temperatures, acidity, etc.) are amenable to modern data acquisition and processing technology. The agency encourages the application of this technology for monitoring and recordkeeping operations to minimize the paperwork burden and labor costs, and also to enhance the organization of records and to facilitate their retrieval. We estimate that 95 percent (95%) of the responses would be collected electronically.

Companies are free to use whatever forms of information technology may best assist them in recordkeeping. We have made this clear in the records provisions of this regulation (§ 120.12 (g)), which states that records maintained as computer files are acceptable when controls are implemented to ensure the integrity of the electronic data and signatures.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Juice processors that currently use HACCP methods, voluntarily or in accord with State or other federal regulations, are likely to already meet specific hazard avoidance and record keeping requirements, because maintaining records of control point observations is a necessary component of the HACCP method, and not unique to these regulations. Moreover, juice processors that currently process low-acid products under the provisions of 21 CFR part 113, or acidified products under the provisions of 21 CFR part 114 are using HACCP based procedures and recordkeeping to avoid the hazard of *Clostridium botulinum* toxin that can result from the improper thermal processing of low-acid and acidified canned foods. These processors are exempted (§§ 120.7(e) and 120.24(a)(1)) from the HACCP requirements of these regulations that are addressed by the requirements of 21 CFR parts 113 or 114. In addition, juice processors using a single thermal processing step sufficient to achieve shelf-stability of the juice or a thermal concentration process that includes thermal treatment of all ingredients are also exempted (§ 120.24(a)(2)) from the requirements of these regulations that address hazards controlled by such thermal processes provided that these processors include a copy of the thermal process used to achieve shelf stability or concentration in their written hazard analysis required by § 120.7. Finally, processors do not need to include in their HACCP plans food hazards that are adequately controlled by a previous processor

5. Impact on Small Businesses or Other Small Entities

We estimate that a substantial proportion (75%) of juice processors affected by the regulation are small businesses, however we do not believe the information collection poses undue burden on these entities. At the same time, we aid small businesses in complying with the juice HACCP requirements through our Regional Small Business Representatives and through administrative and scientific staffs within the agency. We also provide a Small Business Guide on our website at https://www.fda.gov/industry/small-business-assistance, as well as a Juice HACCP Small Entity Compliance Guide at https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/juice-haccp.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs daily. Under a HACCP scheme, the frequency of data collection by each processor would occur periodically during daily food processing operations, but that frequency of observation and recording would vary considerably for different processors, depending on the nature and number of the hazards controlled under a HACCP plan. Recordkeeping must be continuous once a HACCP plan has been implemented. HACCP has little value if used on a part-time basis, particularly in the context of a regulatory program. In that sense, the "frequency of reporting," that is, the periodic recording and maintaining records of control point observations and related HACCP activities cannot be elective; it must continue from day to day.

FDA would not collect HACCP records or plans as a routine matter. HACCP records would remain on file at each processing facility and would be examined there periodically by the agency to determine, for example, whether a processor is practicing preventive control measures that are consistent with the hazards presented by fruit and vegetables juices. HACCP plans and records would document that the appropriate HACCP control measures are applied and have been used for all production lots. Finally, the records would establish that the firm is continuously producing safe juices that are in compliance with the provisions of the FD&C Act.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the *Federal Register* of September 26, 2019 (84 FR 50852). We received no comments.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

Company records describing manufacturing procedures, which may be reviewed during FDA plant inspections, and HACCP records that the agency may copy often contain trade secret and commercial confidential information. Confidential commercial information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), by Section 301(j) of the Act, and by part 20 of our regulations (21 CFR part 20). The agency would attempt to maintain an equitable position consistent with its disclosure regulations and the public interest. Thus, § 120.12(f)(1) states that HACCP plans and records required by part 120 are not available for public disclosure unless they have been previously disclosed, and that HACCP records may be subject to the discretionary disclosure provisions of §20.81 to the extent that they contain materials that are otherwise publicly available or could not reasonably be expected to cause a competitive hardship if revealed.

This information collection request (ICR) requires the respondent to collect personally identifiable information (PII) or other data of a personal nature to be used for events such as an inspection by FDA staff. The respondent will collect information to provide records of evaluation. PII which is collected is the signature or initials of the person performing the operation or creating the record required under 21 CFR 120 (see 21 CFR 120.12(b)(3)). The signature of the most responsible individual onsite at the processing facility or by a higher-level official of the processor for written hazard analysis and written HACCP plan is also collected by the respondent (see 21 CFR 120.12(c)). The PII maintained by the respondent is collected in the context of the individual's professional capacity. Regulations in section 120 mandate the application of hazard analysis and critical control point (HACCP) principles to the processing of fruit and vegetable juices. HACCP is a preventive system of hazard control designed to help ensure the safety of foods. All information collected by the respondent is stored at the facility and viewed during inspection, and if there is an issue, the information will be sent to the FDA for further review.

We determined that although PII is collected, this collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, we do not use name or any other personal identifier to routinely retrieve records from the information collected.

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate handling of information collected.

11. Justification for Sensitive Questions

The information collection does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Recordkeeping Burden

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Record	Total Hours
120.6(c) and 120.12(a)(1) and (b); Require written monitoring and correction records for Sanitation Standard Operating Procedures (SSOP's).	1,875	365	684,375	0.1 (6 min.)	68,438
120.7; 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 min.)	211,700
120.10(a), 120.10(c) and 120.12(a)(4)(ii) and (b); Set forth requirements for written corrective action plans when such plans are included in a HACCP plan and 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 min.)	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 min.)	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

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Record	Total Hours
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

Table 1 provides our estimate of the total annual recordkeeping burden of our regulations in part 120. 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 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 a HACCP plan under these regulations.

12b. Annualized Cost Burden Estimate

We estimate that the average hourly wage for respondents' workers involved in recordkeeping is equivalent to a GS-5/Step 1 rate in the locality pay area of Washington-Baltimore in 2019, approximately $18.19/hour. Doubling this wage to account for overhead costs, we assume the average hourly cost to respondents to be $36.38/hour. The overall estimated cost incurred by the respondents is $16,786,677.88 (461,426 burden hours x $36.38/hr. = $16,786,677.88).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Hourly Wage Worker	461,426	$36.38	$16,786,677.88

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

Our review of the retained records would generally occur as part of its routine or for cause establishment inspection activities. We estimate that our review of the retained records would take five hours per inspection. We estimate the hourly cost for review and evaluation to be $47.52 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2019. To account for overhead, this cost is increased by 100 percent, making the total cost $95.04 per hour. Thus, we estimate the cost to the Federal Government for the review of records to be $475.20 per review ($95.04/hour x 5 hours). We estimate that we review records for an average of 100 inspections per year. Thus, we estimate that the total annual cost to the Federal Government would be $47,520 ($475.20 x 100 inspections).

15. Explanation for Program Changes or Adjustments

The burden for this collection of information has remained unchanged since the last review of this information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.