SUPPORTING STATEMENT

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) PROCEDURES FOR THE SAFE AND SANITARY PROCESSING AND IMPORTING OF JUICE (21 CFR PART 120)

OMB No. 0910-0466

A. Justification

1. Necessity for Information Collection

FDA's mandate to ensure the safety of the nation's food supply is derived principally from the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*). Under the act, FDA has authority to ensure that all foods in interstate commerce, or that have been shipped in interstate commerce, are not contaminated or otherwise adulterated, are produced and held under sanitary conditions, and are not misbranded or deceptively packaged. Under 21 U.S.C. 371, the act authorizes the agency to promulgate regulations for its efficient enforcement. The agency also has authority under the Public Health Service Act (42 U.S.C. 264) to promulgate 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.

The "Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice" regulations establish Part 120 of Title 21 of The Code of Federal Regulations, which requires the use of (HACCP) methods by processors of fruit and vegetable juices. HACCP is a system of preventive controls, which was advocated by President Clinton in his remarks on Food Safety Regulations on October 2, 1997. 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 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 act (21 U.S.C. 342).

The foundation of a HACCP system is the use of current good manufacturing processes (CGMPs) and prerequisite program standard operating procedures (SOPs). The hazard analysis and HACCP plan builds on this foundation. By design, the HACCP method relies heavily on monitoring the critical control points established in the HACCP plan, and periodically recording the conditions at control points during the processing operations leading to the finished product. These recorded observations are necessary to verify adherence to the established control conditions during the critical processing operations, and thereby demonstrate that the finished food is safe. Information development and record keeping are essential parts of any HACCP system. The information collection requirements of these regulations are narrowly tailored to

focus on the development of appropriate controls and documenting those aspects of processing that are critical to food safety. Through these regulations, FDA is implementing its authority under 21 U.S.C. 342(a)(4). The information development and record keeping requirements of these regulations are likewise an implementation of 21 U.S.C. 342 (a)(4).

Under the authority of section 704 of the act (21 U.S.C. 374), FDA periodically inspects the facilities of, and collects samples from, domestic food processors to determine whether food is prepared, processed, and packaged in compliance with the adulteration (section 402), (21 U.S.C. 342 (a)(3) and (a)(4)), misbranding, and other provisions of the act. FDA also inspects and samples foods imported to the U.S. under the authority of section 801 of the act (21 U.S.C. 381). Compliance of foods with the act and its derivative regulations can often be established only by costly and statistically imperfect sampling and laboratory testing of finished products for physical, chemical, or microbial adulterants. HACCP procedures can largely eliminate the need for extensive testing of finished products. HACCP procedures yield products that are known, with a high degree of confidence, to be free of the hazards controlled by the plan.

We request OMB approval of the following information collection requirements.

21 CFR 120.6(c), 120.12(a)(1)&(b):
Sanitation standard operating procedures (SSOP's)

Requires written SSOPs for sanitation controls, sanitation monitoring and correction. The SSOPs are signed and dated by the individual performing the operation.

21 CFR 120.11(a)(1)(iv); 120.6(c); 120.12(a)(5)&(6):
Review of SSOP records

Requires that SSOP records be reviewed to determine whether control measures identified in the hazard analysis are being followed and signed and dated upon any modification or verification.

21 CFR 120.7; 120.10(a); 120.12(a)(2), (b) and (c):
Hazard analysis

Requires a documented written hazard analysis of food hazards that are reasonably likely to occur for each type of food processed by the processor.

21 CFR 120.8(a); 120.8(b)(7); 120.12(a)(3), (b) and (c):
Hazard Analysis Critical Control Point Plan

Sets forth requirements that every processor have a written HACCP plan when a hazard analysis reveals that a food hazard is reasonably likely to occur. Requires that plan be documented to signify its acceptance and implementation by the firm.

21 CFR 120.8(b)(7) and 120.12(a)(4)(i) & (b):
Monitoring Critical Control Points

Requires a recordkeeping system that documents monitoring of the critical

control points and other measurements as prescribed in the HACCP plan.

21 CFR 120.11(b) and 120.12(a)(5)&(b):
Validation of the HACCP Plan

Sets forth requirements that every processor record the validation that the HACCP plan is adequate to control food hazards that are likely to occur.

21 CFR 120.11(a)(1)(iv); 120.11 (a)(2); and 120.12 (a)(5):
Verification

Sets forth requirements that records be reviewed for completeness and that the records show that process monitoring instruments are properly calibrated and that end-product or in-process testing is performed in accordance with written procedures. Records are to be documented by the reviewer.

21 CFR 120.10(c) and 120.12(a)(4)(ii)&(b):
Corrective Actions

Sets forth requirement that all actions taken in response to a deviation be documented.

21 CFR 120.11 and 120.12 (a)(5)&(b):
Verification and Validation

Sets forth requirements for validation of the hazard analysis. Requires documentation of verification of HACCP system and validation of HACCP plan or hazard analysis.

21 CFR 120.14(a)(2):
Application to Imported Products

Sets forth requirement 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 these regulations except when the product is obtained from countries that have an active memorandum of understanding with the Food and Drug Administration that the inspection system of the foreign country is equivalent to that of the U.S.

21 CFR 120.24(a)(2):
Process Control

Exempts producers of thermally treated shelf stable and concentrated products from the 5-log reduction requirement and associated recordkeeping requirements.

21 CFR 120.25:
Process Verification for Certain Processors

Sets forth requirements for the analysis of the finished product for the presence of pathogens for processors that choose surface treatment of fruit in t he production of citrus

juice products.

2. **How, by Whom, and for What Purpose Information is Used**.

These regulations establish a requirement that processors of fruit and vegetable juices apply HACCP principles to their processing operations. The HACCP records include documentation of the implementation of the SSOPs, the written hazard analysis, the HACCP plan, records documenting verification of the HACCP system and validation of the HACCP plan or hazard analysis, corrective actions, and contain data collected at selected monitoring points (critical control points) during the processing and packaging operations, as called for in a processor's HACCP plan. The primary purpose of HACCP records is to permit a processor to verify that products have been produced within carefully established processing parameters (critical limits) that ensure that hazards have been avoided. Monitoring 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.

The HACCP plan is validated periodically to demonstrate that it is adequate to control food hazards. The HACCP plan is modified if the validation reveals a need to do so. In the case that a processor has no HACCP plan because a hazard analysis has revealed no food hazards, the processor periodically reassesses the adequacy of that hazard analysis. Such validation activities are essential to ensure that the HACCP system is current.

HACCP places the burden of producing safe products and solving problems squarely on the processor. A specific frequency of data collection is not prescribed in the regulation. The schedule of critical control point observations and recording of data (the frequency of collection) is established by each processor according to factors such as the variability of the process and the proximity of nominal processing values to the control limits established in the HACCP plan. At a minimum, each production lot would have associated HACCP and sanitation records. To be effective, HACCP records must be available for all production lots. When a HACCP program is implemented, it becomes an integral part of the food production process.

Thus, a review of HACCP records, either by the processor or an FDA inspector conducting a periodic establishment inspection, would allow a determination of whether the HACCP system is up to date and whether any current or previous production lot has deviated from control conditions and may, as a result, present a public health hazard. These records would be highly beneficial to both the processor and the agency to expeditiously identify questionable production lots.

3. **Use of Improved Information Technology**

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. The agency estimates that about 25 percent of the responses would be collected electronically.

Companies are free to use whatever forms of information technology may best assist them in developing the proposed recordkeeping. FDA has 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. **Identification of Duplication and Similar Information Already Available**

The mandatory HACCP program represents a new regulatory approach. However, some juice processors are using or are in the process of implementing HACCP methods. In addition, processors of low-acid or acidified juices are using HACCP methods. Except for the manufacturers of low-acid canned foods, processors that do employ HACCP are not currently required to make their HACCP records available to FDA inspectors for examination.

There is no duplication of effort in this area. 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 are using HACCP procedures and record keeping to avoid the hazard of Clostridium botulinum toxin that can result from the improper thermal processing of low-acid canned food. These processors are exempted (§§ 120.8 (c) and 120.24(a)(1)) from the HACCP requirements of these regulations that are controlled by the requirements of 21 CFR Parts 113 or 114. 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 are 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 as 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 (120.8(e)).

5. **Small Businesses**

FDA recognizes that a substantial proportion of juice processors affected by this regulation is small businesses, and has kept their particular needs in mind throughout the development of these regulations. In order to aid small businesses in the implementation of HACCP systems, the proposed effective date for small businesses was extended for one year beyond the effective date of the regulations, and for very small businesses, two years beyond the proposed effective date of the regulations. Small businesses would be assisted in accordance with the provisions of the

Small Business Regulatory Enforcement Fairness Act of 1996 [Title II of Public Law 104-121 enacted March 29, 1996].

6. **Program Consequences if Less Frequent or No Collection**

The consequences of processors not collecting any or all HACCP information (i.e., juice processors not maintaining HACCP records) would prevent the adoption of a meaningful industry-wide HACCP program that has been recommended by the National Advisory Committee on Microbiological Criteria for Foods and sought by industry and consumer advocates. The adoption of HACCP techniques and the associated record keeping requirements are the most effective and efficient way for government and industry to ensure food safety.

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. Records "collection" 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 can not be elective; it must continue from day to day.

The agency 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 act.

7. **Special Circumstances**

The collection of HACCP information does not involve submission of information to the agency, written responses to the agency, retention of records for more than three years, the use of statistical methods, pledges of confidentiality by FDA, or require the disclosure of trade secrets or other confidential information.

8. **Outside Consultation**

In accordance with 5 CFR 1320.8(d), in the FEDERAL REGISTER of May 14, 2007 (72 FR 27138), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received no comments that were responsive to the comment request.

9. **Gifts**

This information collection does not provide for payment or gifts to respondents.

10. **Confidentiality**

Company records describing manufacturing procedures, which may be consulted during FDA plant inspections, and HACCP records that the agency may copy or take possession of would be treated as records that are exempt from release under the provisions of the Freedom of Information Act (FOIA) to the maximum extent permitted by that statute and FDA regulations. Confidentiality of the information submitted is protected from disclosure under FOIA under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's 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.

11. **Sensitive Questions**

There are no questions of a personally sensitive nature associated with the data collected. All records bear upon conditions under which a food was processed and corrective actions taken upon the detection of deviations from critical control point conditions.

12. **Respondent Hour Burden and Annualized Burden Hour Cost Estimates**

Table 1 sets forth an estimate of the annual hourly burden for compliance with each section in part 120 that is associated with collecting or recording information.

The time and costs of these activities will vary considerably among processors depending on the type and number of products involved, process details, and nature of the related equipment or instruments required to monitor critical control points. Therefore the burdens have been estimated using the typical small juice-processing firm as a model because these firms represent a significant proportion of the industry. However, the burden hours in Table 1, include only that portion of the compliance burden that may be regarded as a new information collection or recordkeeping requirement under the regulations.

Thus, where an activity is required under existing regulations, its cost is not considered as a new burden arising from these regulations. For example, the Current Good Manufacturing Practices provisions in 21 CFR part 110, already require that all food processors ensure good sanitary practices and conditions, monitor the quality of incoming materials, monitor and control food

temperatures to prevent bacterial growth, and perform certain corrective actions and verification procedures. Consequently, the burden hours that are reflected in Table 1 account only for the new information collection and recording requirements under part 120.

There are an estimated 850 domestic producers of fruit and vegetable juices. The model upon which these estimates are based is a producer with 5 production lines that operate for 16 hours per day, 365 days per year. The estimated number of critical control points per line per 8 hour shift is 5 and the frequency of monitoring and recording of results is every 2 hours for each control point or 40 entries per 16 hour production day. The time involved for the entry of data is 0.01 hours or 0.6 minutes per entry. The paperwork burden for monitoring the critical control points is 850 producers x 40 entries per production day x 365 days per year x 0.01 hours per entry = 124,100 hours per year.

Additionally, the agency recognizes that the regulations will place a paperwork burden on juice importers. In calendar year 1996, FDA records show that 386 firms imported fruit or vegetable single strength juices, juice blends, juice concentrates and/or purees that could be used in juice production. It is estimated that 80 percent of the importers or 308 importers do business in juice products intended for inclusion in juice beverages and that the remaining 20 percent are involved in other food industries, such as bakeries, condiment and jams and jellies manufacturers. FDA has estimated a burden for importers that includes the time necessary for importers to develop a written verification plan, verify compliance of imports, and to keep records of their verification activities.

Juice processors include both large corporations producing a variety of juices and very small businesses producing a single type of juice only on a seasonal basis. Therefore, HACCP record keeping burdens will differ widely among processors, depending on the size of the facility and complexity of the HACCP control scheme (i.e., the number of products, the number of process lines, the number of hazards controlled, and number of production days); the frequency that control points are monitored and values recorded; and also on the extent that data recording time and cost are minimized by the use of automated data entry technology.

FDA estimates the burden of this information collection as follows:

TABLE 1 - Estimated Annual Recordkeeping Burden[1]

21 CFR	Number of Recordkeepers	Annual Frequency of Records	Total Annual Records	Hours per Record	Total Hours
120.6(c) & 120.12(a)(1) & (b)	1,875	365	684,375	0.1	68,437.5
120.7; 120.10 (a); & 120.12(a)(2), (b) & (c)	2,300	1.1	2,530	20	50,600
120.8(b)(7) & 120.12(a)(4)(i), & (b)	1,450	14,600	21,170,000	0.01	211,700
120.10(c) & 120.12(a)(4)(ii), & (b)	1,840	12	22,080	0.1	2,208
120.11(a)(1)(iv); 120.11(a)(2); 120.12(a)(5)	1,840	52	95,680	0.1	9,568
120.11(b) & 120.12(a)(5), & (b)	1,840	1	1,840	4	7,360
120.11 (c) & 120.12(a)(5) & (b)	1,840	1	1,840	4	7,360
120.14(a)(2); & 120.14 (c) & (d)	308	1	308	4	1,232
TOTAL					358,466

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

The burden estimates identified in Table 1 above are based on an estimation of the total number of plants (i.e., 2300) affected by the regulations. Included in this total are 810 juice manufacturing plants currently identified in FDA's Official Establishment Inventory (OEI) plus 1220 very small apple juice manufacturers and 230 very small orange juice manufacturers. Burden estimates are derived by estimating the number of plants affected by each portion of the regulations (not a constant of 2300 but a variable of each category) and multiplying the corresponding number by the number of records required and the hours required to complete the record. These numbers were obtained from the agency's Final Regulatory Impact Analysis performed for these regulations.

Moreover, these estimates assume that every processor will prepare SSOPs and a HACCP plan and maintain the associated monitoring records and that every importer will require product safety specifications.

Table 1 provides a breakdown of the total estimated recordkeeping burden for each year following the first year of the regulations. The entries in this table have been reviewed by the

agency's HACCP experts, who have practical experience in observing various processing operations and related record keeping activities, and have been found to be reasonable estimates. The total burden costs for each year following the first year of the regulations approximate $24 million. Table 2 identifies these costs.

Cost to the Respondent

The agency has identified a total of 850 U.S. processors that produce fruit and vegetable juices and estimates they will spend an average of 97,000 hours per year to keep HACCP and sanitation records after the first year.

The annual hourly recordkeeping burden was calculated for all processors and the sum of these hours was divided by the total number of firms to yield an average annual hourly burden for each processor (97,000 hours/850 U.S. processors = 114 hours/U.S. processor). Hourly rates for workers involved in recordkeeping were estimated at approximately $15.00 per hour.

FDA records show that in 1996, 386 firms imported fruit and vegetable juices from other countries. The agency estimates 308 of these importers are supplying products to the juice industry and that this level of import activity will continue and that each importer will average 12 hours per year for a total recordkeeping time of 3,696 hours.

For processors:
Total annual cost/respondent = $15.00/hr x 114 hr = $1,710

For importers:
Total annual cost/importer = $15.00/hr x 12 hr = $180

13. **Annual Cost Burden to Respondents**

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

14. **Annualized Cost to the Federal Government.**

FDA estimates that the annualized cost to the Federal Government will be minimal. It estimates that the cost for the review and evaluation of the records generated under this proposed rule will not differ significantly from the annual expenditures for juice processor inspections.

15. **Changes of Adjustments in Burden**

Both the increase in the annual number of responses and the decrease in annual hour burden is due to the correction of mathematical errors. The annual hour burden estimated in 2004 was erroneously high by 2,464 hours because it reflected an error in the last line of the burden table in the 2004 submission (308 x 4 = 1,232; not 3,696). The error has been corrected in this

submission. Similarly, the total annual number of responses reported in 2004 was erroneously low by 15,035 responses, due to an addition error, which was unnoticed in the 2004 submission. The correct total of 21,978,653 is reported in this submission.

16. **Statistical Analysis, Publication Plans and Schedule**

The agency has no plans for publication of information from this information collection.

17. **Approval Not to Display Expiration Date**

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

18. **Exception to the Certification Statement Identified in Item 19**.

No exceptions to the certification statement identified in Item 19 of the instructions for completing OMB Form 83-I have been identified.