FDA estimates the burden for this collection of information as follows:

TABLE 1—ESTIMATE OF ONE-TIME REPORTING BURDEN[1]

Activity	Number of respondents	Annual frequency per response	Total average annual responses	Hours per response	Total hours
Providing negative response to request for dissolvable tobacco product documents	110	1	110	0.50	55
Submission of dissolvable tobacco products	10	1	10	230	2,300
Total	120		120		2,355

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

These burden estimates were derived by taking into consideration FDA's experience with document production, experience with submissions pertaining to other tobacco product-related information collections, and comments received in response to other tobacco product-related information collections. FDA is limiting the burden on respondents by only requesting documents on specific topics that will have utility for FDA. FDA is requesting the final version of documents or the most recent draft in the absence of a final document. Also, publically available published abstracts, editorials, letters, and manuscripts are not being requested, although FDA would appreciate a list of such publications. Information responsive to this section 904(b) information request that has been previously provided to FDA under the FD&C Act or other letter requests does not have to be resubmitted as long as the document is fully referenced. FDA believes that the number of documents being requested in this information collection will be limited due to the estimated small number of respondents and the relatively shorter amount of time these tobacco products have been in existence compared to other tobacco products.

FDA estimates that there are approximately 120 tobacco product manufacturers who may be affected by this collection of information. Of the total number of manufacturers, FDA estimates that most manufacturers (110) will not have documents which will be responsive to this section 904(b) request and that they will only need to send a letter notifying the FDA's Center for Tobacco Products that they have no documents to report. FDA anticipates it should take no longer than 30 minutes to draft such a response and send to FDA. The total one-time hourly burden to submit this letter to FDA is estimated to be 55 hours (30 minutes × 110 manufacturers).

FDA estimates that there are approximately 10 tobacco product manufacturers who may have documents meeting the criteria of this information collection request. Because the volume of responsive documents each of these respondents may have will likely vary, the corresponding time burden for each respondent to satisfy this information collection request will also vary. Therefore, FDA estimates that these 10 respondents will average approximately 230 hours each to satisfy the requirements of this section 904(b) request. The total one-time hourly burden to locate and send documents meeting the requirements of this request is estimated to be 2,300 hours (230 hours × 10 manufacturers). The total one-time hourly burden for this collection of information is 2,355 hours (55 hours + 2,300 hours).

Dated: October 19, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–26830 Filed 10–22–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0411]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guide To Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables

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 November 24, 2010.

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 0910–0609. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

Guide To Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables—(OMB Control Number 0910–0609)—Extension

Fresh-cut fruits and vegetables are fruits and vegetables that have been processed by peeling, slicing, chopping, shredding, coring, trimming, or mashing, with or without washing or other treatment, prior to being packaged for consumption. The methods by which produce is grown, harvested, and processed may contribute to its contamination with pathogens and, consequently, the role of the produce in transmitting foodborne illness. Factors such as the high degree of handling and mixing of the product, the release of cellular fluids during cutting or mashing, the high moisture content of the product, the absence of a step lethal

to pathogens, and the potential for temperature abuse in the processing, storage, transport, and retail display all enhance the potential for pathogens to survive and grow in fresh-cut produce.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) prohibits the distribution of adulterated food in interstate commerce (21 U.S.C. 331 and 342). In response to the increased consumption of fresh-cut fruits and vegetables and the potential for foodborne illness associated with these products, FDA recognizes the need for guidance specific to the processing of fresh-cut fruits and vegetables. The guidance document entitled "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables," which is available at: *http://www.fda.gov/FoodGuidances,* provides FDA's recommendations to fresh-cut produce processors about how to avoid contamination of their product with pathogens. The guidance is in addition to the current good manufacturing practices (cGMPs) provided in part 110 of FDA's regulations (21 CFR part 110). The guidance is intended to assist fresh-cut produce processors in minimizing microbial food safety hazards common to the processing of most fresh-cut fruits and vegetables sold to consumers and retail establishments in a ready-to-eat form. Accordingly, FDA encourages fresh-cut produce processors to adopt the general recommendations in the guidance and to tailor practices to their individual operations.

The guidance provides information and recommended procedures designed to help fresh-cut produce processors minimize microbial food safety hazards. The recommended procedures contained in the guidance are voluntary. Both FDA and fresh-cut produce processors will use and benefit from the information collected.

Two general recommendations in the guidance are for operators to develop and implement both a written Standard Operating Procedures (SOPs) plan and a Sanitary Standard Operation Procedures (SSOPs) plan. SOPs and SSOPs are important components to properly implemented and monitored cGMPs that are required for processed food operations under part 110. Other recommended programs that require documentation and recordkeeping are recall and traceback programs. In the event of a food safety concern, processors who adopt these recommended programs will be prepared to recall products from the market place or be able to trace back fresh produce, which might be implicated in a foodborne illness outbreak, to its source. Fresh-cut produce processors are also asked to consider the application of Hazards Analysis and Critical Control Point (HACCP) principles or comparable preventive control programs to the processing of fruits and vegetables. FDA, other Federal and State food agencies, industry, and food establishments have found such preventive control programs, when properly designed and maintained by the establishment's personnel, to be valuable in managing the safety of food products.

FDA's fresh-cut guidance represents the agency's recommendations to industry based on the current state of science. Following the recommendations set forth in the fresh-cut guidance is the choice of each individual fresh-cut operation, plant, or processor. FDA estimates the burden of the guidance on industry by assuming that those in the fresh-cut industry who do not currently follow the recommendations put forth in the guidance will find it of value to do so. Therefore, the estimates of the burden associated with the issuance of the guidance represent the upper bound estimate of burden; the burden if every fresh-cut plant, processor, or operation that does not follow the recommendations of the guidance should choose to do so.

In the **Federal Register** of August 11, 2010 (75 FR 48692), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received .

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	No. of record-keepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
SOP and SSOP: Maintenance	122	3,315	404,430	0.067	27,097
Traceback development	10	1	10	20	200
Traceback maintenance	290	1	290	40	11,600
Preventive control program comparable to a HACCP system: System development	10	1	10	100	1,000
Preventive control program comparable to a HACCP system: System implementation	145	510	73,950	0.067	4,955
Preventive control program comparable to a HACCP system: Implementation review	145	4	580	4	2,320
Annual burden hours					47,172

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

Industry Profile

Estimates of the paperwork burden to the fresh-cut industry are based on information received from a fresh-cut processor who has developed and maintained these programs and information from a fresh-cut produce industry trade association. Because of the small number of fresh-cut processors, the agency is able to extrapolate data from industry programs to calculate the total estimated upper bound burdens (*see* table 1 of this document).

The burden to industry of developing and maintaining the activities recommended in FDA's fresh-cut guidance will vary considerably among fresh-cut processors, depending on the type and number of products involved, the sophistication of the equipment or instruments (e.g., those that automatically monitor and record food safety controls), and the type of controls monitored under any individual preventive control program, such as critical control points (CCPs) monitored under a HACCP program.

In 2007, FDA estimated that there were 250 fresh-cut plants in operation in the United States, and that approximately 10 new firms enter the fresh-cut industry each year (72 FR

11364, at 11366, March 13, 2007). Using these figures, we estimate that in 2010 there are 280 fresh-cut plants in operation and that approximately 10 new firms will enter the fresh-cut industry each year, over the next 3 years. Many of the existing firms in the fresh-cut industry already make use of cGMP-related, recall, HACCP, and other activities. FDA estimates that the burden of the fresh-cut guidance will fall on both existing and new firms entering the industry who may follow the recommendations in the guidance.

SOPs and SSOPs

Two general recommendations in the guidance are for operators to develop and implement both a written SOPs plan and a written SSOPs plan. SOPs describe in writing the performance of the day-to-day operations of a processing plant. Examples of activities that would fall under SOPs would be developing written specifications for agricultural inputs, ingredients, and packaging materials; production steps for the processing and packaging operations; instructions for packaging and storage activities; and procedures for equipment maintenance, calibration, and replacement and facility maintenance and upkeep; and maintaining SOP records on product processing and distribution activities.

SSOPs provide written instructions or procedures for sanitary practices developed for each specific sanitation activity in and around the facility. Sanitation activities include procedures for cleaning equipment, food-contact surfaces, and plant facilities; chemical use and storage; cleaning equipment maintenance, use, and storage; pest control; and maintaining SSOP records for the activities. From communication with the fresh-cut industry, we know that existing fresh-cut processors already have developed SOPs and SSOPs. We therefore consider the development of SOPs and SSOPs to be "usual and customary" for manufacturers and processors in the fresh-cut industry (*see* 5 CFR 1320.3(b)(2)). Thus, we do not calculate this burden for existing firms or new firms entering this industry.

FDA recommends that facilities not only develop but also maintain SOPs and SSOPs. Implementation and maintenance of SOPs and SSOPs include maintaining daily records for each of the firm's operational days for the following activities: Inspection of incoming ingredients, such as the fresh produce and packaging material; facility and production sanitation inspections; equipment maintenance, sanitation, and visual safety inspections; equipment calibration, e.g., checking pH meters; facility and premises pest control audits; temperature controls during processing and in storage areas; and audits of ingredients, food contact surfaces, and equipment for microbiological contamination. Of the 280 fresh-cut processors, we estimate that well over half have SOP and SSOP maintenance programs in place. Therefore, for purposes of estimating the annual recordkeeping burden for SOP and SSOP maintenance programs, the agency assumed that 40 percent of the existing processors, or 112 firms, and the 10 new firms do not have SOP and SSOP maintenance programs in place. FDA estimates the recordkeeping burden for SOP and SSOP maintenance programs by assuming that these 122 firms will choose to implement such a maintenance strategy as a result of the recommendations in the fresh-cut guidance document.

A typical fresh-cut processing plant operates about 255 days per year. For an 8-hour shift, assuming the ingredients are received twice during that time, under the recommendations in the guidance, there would be about 13 records kept (2 for inspecting incoming ingredients; 2 for inspecting the facility and production areas once every 4 hours; 3 records for equipment (maintenance, sanitation, and visual inspections for defects); 1 for calibrating equipment; 2 temperature recording audits (1 time for each of the 2 processing runs); and 3 microbiological audits (ingredients, food contact surfaces, and equipment)). Therefore, the annual frequency of recordkeeping for SOPs and SSOPs is calculated to be 3,315 times (255×13) per year per firm; 122 firms will be performing these activities to generate a total 404,430 records ($3{,}315 \times 122$) annually, assuming all firms choose to follow the recommendations on keeping records.

The total time to record observations for SOP and SSOP maintenance is estimated to take 4 minutes or 0.067 hours per record, and the number of records maintained is 404,430. Therefore, the total annual burden in hours for 122 processors to maintain their SOP and SSOP records is approximately 27,097 hours ($404{,}430 \times 0.067$). The maintenance burden for these 122 firms, along with the annual maintenance burden of audits or testing, is estimated in row 1 of table 1 of this document. Again, these figures assume that all firms choose to follow the recommendations on recording observations.

Recall and Traceback

We recommend that fresh-cut processors establish and maintain written traceback procedures to respond to food safety hazard problems when they arise and establish and maintain a written contingency plan for use in initiating and effecting a recall. In order to facilitate tracebacks and recalls, we recommend that processors establish a program that documents and tracks fresh-cut products back to the source of their raw ingredients, and keep records of product identity and specifications, the product in inventory, and where, when, to whom, and how much of the product is shipped.

Traceback programs are used for those times when a food safety problem has been identified or a product has been implicated in a foodborne illness outbreak. The burden to develop a traceback program is a one-time activity estimated to take approximately 20 hours. In 2007, we previously estimated that firms in the industry would choose to begin a traceback program after the guidance was made available and estimated that the 250 existing fresh-cut firms and the 10 new businesses expected to enter the industry annually from 2007 to 2010 would spend 5,200 hours (250×20) on this activity. Accordingly, we only need to estimate the burden of this one-time activity on the 10 new businesses expected to enter the industry annually in the next 3 years. We estimate that the 10 new firms will spend 20 hours each preparing a traceback program, for a total of 200 hours (10×20). The burden estimate of developing a traceback program is shown in row 2 of table 1 of this document.

Traceback program adjustments or revisions may, or may not, be needed annually. Firms may test their traceback programs yearly to see if adjustments are needed to maintain traceback capabilities. Evaluating and updating traceback programs is estimated to take 40 hours to complete. The annual burden of maintaining a traceback program is estimated for the 280 existing firms in the industry plus the 10 firms new to the industry that may decide to implement this type of program. Assuming that each firm completes this exercise once a year, the total maintenance burden of traceback programs is 11,600 hours yearly (290×40). This burden estimate is shown in row 3 of table 1 of this document.

The fresh-cut guidance refers to previously approved collections of information found in FDA regulations. The recommendations in this document regarding establishing and maintaining

a recall plan, as provided in 21 CFR 7.59, have been approved under OMB control number 0910–0249. Therefore, FDA is not calculating a new paperwork burden for recall plans.

Preventative Control Program

When properly designed and maintained by the establishment's personnel, a preventive control program is a valuable program for managing the safety of food products. A common preventive control program used by the fresh-cut industry is a HACCP system. A HACCP system allows managers to assess the inherent risks and identify hazards attributable to a product or a process, and then determine the necessary steps to control the hazards. Monitoring and verification steps, which include recordkeeping, are included in the HACCP system to ensure that potential risks are controlled. We use HACCP as an example of a preventive control program that a firm may choose based on the recommendations in the guidance to estimate the burden of developing, implementing, and reviewing a preventive control program.

FDA estimated the paperwork burden of developing and implementing a HACCP plan based on a plan with two CCPs. The number of CCPs may vary depending on how the processor chooses to identify the CCPs for a particular operation. Developing a HACCP plan is a one-time activity that is estimated to take 100 hours based on a trained HACCP team working on the plan full time. The HACCP team identifies the CCPs and measures needed to control them, and then identifies the approach needed to verify the effectiveness of the controls. During this plan development period, the firm chooses the records to be kept and information and observations to be recorded. This is a one-time process during the first year.

In 2007, we previously estimated that, of the estimated 250 fresh-cut processors, approximately 50 percent of the firms already have HACCP plans in place. We therefore assumed that the remaining fresh-cut processors (125 existing firms plus the 10 new firms), would voluntarily develop a HACCP plan, and estimated that 135 processors would spend 13,500 hours (135×100) to develop their individual HACCP plans. Accordingly, we only need to estimate the burden of this one-time activity on the 10 new businesses expected to enter the industry annually in the next 3 years. We estimate that the 10 new firms will spend 100 hours each to develop their individual HACCP plans, for a total of 1,000 hours (10×100). This burden estimate is shown in row 4 of table 1 of this document.

After the HACCP plan is developed, the frequency for recordkeeping for implementing or maintaining daily records is estimated to be 510 records per year. (This is based on a firm choosing to maintain daily records for 2 CCPs for one 8-hour shift per day for each of the estimated 255 operational days per year.) The total time to record observations for the CCPs was estimated to take 4 minutes or 0.067 hours per record. Therefore, the total annual records kept by 145 firms (the 135 firms plus the 10 new businesses expected to enter the industry) is 73,950 (510×145), and the total hours required are 4,955 (73,950 records $\times$ 0.067 hours per record = 4,954.65, rounded to 4,955). This annual burden is shown in row 5 of table 1 of this document.

After the HACCP plan has been developed and implemented, we recommend that the plan is reviewed regularly to ensure that it is working properly. Fresh-cut processors are estimated to review their HACCP plans four times per year (once per quarter). Assuming that it takes each of the 145 firms 4 hours per review each quarter, the total burden of this activity, for firms that choose to review their plans annually, is 2,320 ($145 \times 4 \times 4$) hours per year. This annual burden is shown in row 6 of table 1 of this document.

Dated: October 18, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–26829 Filed 10–22–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Award of Three Single-Source Expansion Supplements to The University of Colorado Health Sciences Center in Aurora, CO, The University of Massachusetts (Institute for Community Inclusion) in Boston, MA, and The University of Minnesota (The Research and Training Center) in Minneapolis, MN

AGENCY: Administration on Developmental Disabilities, ACF, HHS.

ACTION: Notice.

CFDA Number: 93.631.

Statutory Authority: This award will be made pursuant to Section 161 of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15081–15083).

Amount of Award: $200,000 per award.

Project Period: 9/30/2010–9/29/2012.

SUMMARY: This notice announces that the Administration for Children and Families (ACF), Administration on Developmental Disabilities (ADD) has awarded three single-source expansion supplements for data collection, analyses, and reporting.

The following projects will be funded:

The University of Colorado Health Sciences Center, Aurora, CO. This cooperative agreement will allow for data collection, analysis and reporting on spending and services for individuals with intellectual and developmental disabilities, including disaggregation of data related to specific demographic groups. The project will analyze and report on trends in utilization of and spending for institutional services and home and community-based services. Project staff will also participate in collaborative efforts with ADD and other data collection projects to review and report on unmet needs in data collection, analyses, and reporting activities that would promote the self-determination, independence, productivity, and integration and inclusion of people with intellectual and developmental disabilities in all facets of community life.

The University of Massachusetts (Institute for Community Inclusion), Boston, MA. This cooperative agreement will provide for data collection and analyses related to the effectiveness of State agencies in promoting community integrated employment for individuals with intellectual and developmental disabilities. The project will collect data, analyze, and report on the employment and economic status of individuals with intellectual and developmental disabilities including disaggregation of data related to specific demographic groups. The project will also make recommendations related to the standardization of data and reporting of employment outcomes. Project staff will also participate in collaborative efforts with ADD and other data collection projects to review and report on unmet needs in data collection, analyses, and reporting activities that would promote the self-determination, independence, productivity, and integration and inclusion of people with intellectual and developmental disabilities in all facets of community life.

The University of Minnesota (The Research and Training Center), Minneapolis, MN. This cooperative agreement will provide for data collection, analyses, and reporting of