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

national and State statistics on public and private residential services for individuals with intellectual and developmental disabilities, including disaggregation of data related to specific demographic groups. The project will conduct analyses that describe the movement of individuals with intellectual and developmental disabilities from institutional to community settings. 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.

Contact for Further Information: Ophelia McLain, Supervisory Program Specialist, Administration on Developmental Disabilities, 370 L'Enfant Promenade, SW., Mail Stop: HHH–405D, Washington, DC 20447. Telephone: 202–690–7025 E-mail: *ophelia.mclain@acf.hhs.gov*.

Dated: October 14, 2010.

Sharon Lewis,

Commissioner, Administration on Developmental Disabilities.

[FR Doc. 2010–26933 Filed 10–22–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; Interagency Pain Research Coordinating Committee; Call for Nominations

The Department of Health and Human Services has created the Interagency Pain Research Coordinating Committee and is seeking nominations for this committee. As specified in Public Law 111–148 ("Patient Protection and Affordable Care Act") the Committee will: (a) Develop a summary of advances in pain care research supported or conducted by the Federal agencies relevant to the diagnosis, prevention, and treatment of pain and diseases and disorders associated with pain; (b) identify critical gaps in basic and clinical research on the symptoms and causes of pain; (c) make recommendations to ensure that the activities of the National Institutes of Health and other Federal agencies are free of unnecessary duplication of effort; (d) make recommendations on how best to disseminate information on pain care; and (e) make recommendations on how to expand partnerships between public entities and private entities to expand collaborative, cross-cutting research.

Membership on the committee will include six (6) non-Federal members from among scientists, physicians, and other health professionals and six (6) non-Federal members of the general public who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions. Members will serve overlapping three year terms. It is anticipated that the committee will meet at least once a year.

The Department strives to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that the views of women, all ethnic and racial groups, and people with disabilities are represented on HHS Federal advisory committees and, therefore, the Department encourages nominations of qualified candidates from these groups. The Department also encourages geographic diversity in the composition of the Committee. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Nominations are due by COB November 26, 2010, and should be sent to Amy Adams, PhD, NIDCR/NIH, 31 Center Drive, Room 5B55, MSC–2190, Bethesda MD 20892–2190, *adamsamy@mail.nih.gov* by either USPS mail or e-mail. Nominations should include contact information and a current curriculum vitae or resume.

Dated: October 18, 2010.

Amy Adams,

National Institute of Dental and Craniofacial Research, National Institutes of Health.

[FR Doc. 2010–26937 Filed 10–22–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0529]

Draft Guidance for Industry on Qualification Process for Drug Development Tools; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Qualification Process for Drug Development Tools." This draft guidance describes the qualification process for drug development tools (DDTs) intended for potential use, over time, in multiple drug development programs. The draft guidance provides a framework for interactions between the Center for Drug Evaluation and Research (CDER) and DDT sponsors to support work towards qualification of an identified DDT and creates a mechanism for formal review of data by CDER to qualify the DDT and ensure that the evaluation is comprehensive and reliable.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 24, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Shaniece Gathers, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4555, Silver Spring, MD 20993–0002, 301–796–2600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Qualification Process for Drug Development Tools." In March 2006, FDA issued the "Critical Path Opportunities Report" and the "Critical Path Opportunities List." In these reports, FDA described six key areas along the critical path to improved therapies, and a list of specific opportunities for advancement within these topic areas. The opportunities report noted that a new product