2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Testing of Revised OASIS Instrument for Home Health Quality Measures & Data Analysis; *Use:* Medicare-certified home health agencies (HHAs) must meet the Conditions of Participation (COPs) as set forth at 42 CFR Part 484 and 488. Since 1999, the COPs have mandated that HHAs use the ''Outcome and Assessment Information Set'' (OASIS) data set when evaluating adult, non-maternity patients receiving skilled services. The OASIS is a patient-specific, comprehensive assessment that identifies each patient's need for home care and that meets the patient's medical, nursing, rehabilitative, social and discharge planning needs.

Since OASIS data collection was mandated in 1999, CMS has been systematically collecting input on ways to improve the OASIS instrument and reduce the burden of the collection effort. In 2002, CMS introduced the ''reduced-burden'' OASIS that was a product of the Secretary's Regulatory Reform Advisory Committee to help guide HHS' broader efforts to streamline unnecessarily burdensome or inefficient regulations that interfere with the quality of health care. Since the 2002 revision, CMS has continued to solicit input on potential refinements and enhancements of the OASIS instrument from HHAs, industry associations, consumer representatives, researchers and other stakeholders.

Abt Associates and their subcontractor UCHSC were awarded a contract by CMS in September 2006 to continue the process of refining the OASIS data set, as well as for the testing of the instrument and analysis of the impact of proposed changes. Under this contract, researchers from Abt Associates, University of Colorado Health Sciences Center (UCHSC), and Case Western Reserve University have assisted CMS in carrying out the revisions based on the input described in the previous section. Changes to the OASIS instrument include the following removal and revision of items:

- Elimination of 7 original OASIS items not required for payment, quality or risk adjustment;
- Replacement of 44 original OASIS items with items that are revised and/or simplified to respond to industry concerns by increasing clarity and user-friendliness, and/or reducing complexity and burden (e.g., removal of ''prior status'' assessment for all Activity of Daily Living (ADL) and Instrumental Activity of Daily Living (IADL) items).

The revised OASIS also includes the addition of the following process items to support evidence-based practices:

- A total of 7 process items to be collected only at Start of Care/Resumption of Care, 4 of which are to be asked seasonally (e.g.; flu vaccine);
- A total of 10 process items to be collected only at Follow-up, Transfer or Discharge, either seasonally or on a small subpopulation;
- A total of 13 process items to be collected at all OASIS time points, 6 of which are to be collected on a small subpopulation.

We estimate the elimination, simplification and revision of existing OASIS items will have a burden impact equivalent to the complete elimination of 19 items. Since many of the process items will be collected only on small subpopulations or during specific months of the year, we estimate the impact of the addition of these items on burden to be equivalent to the addition of 20 items. Therefore, total impact of proposed OASIS revisions, including the elimination, revision and addition of items, changes the estimated burden of the OASIS very little while incorporating process measures needed to support evidence-based practices across the post-acute care spectrum.

As a result of comments received during the 60-day comment period from the notice that published July 27, 2007 (72 FR 41328), we revised the information collection. The revisions include clarified language, corrected time point guidance, improved alignment with items in the CARE tool, improved skip patterns that allow clinicians to bypass questions not relevant to patients, and the addition of response options that allow clinicians to document patient improvement. It is the opinion of CMS that these revisions have resulted in an improved tool that addresses many of the concerns expressed by commenters, with no increase in burden. *Form Number:* CMS–10238 (OMB#: 0938–NEW); *Frequency:* Reporting: One-time; *Affected Public:* Private Sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 11; *Total Annual Responses:* 11; *Total Annual Hours:* 173.58. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *November 19, 2007.*

OMB Human Resources and Housing Branch, Attention: Katherine Astrich, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: October 11, 2007.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E7–20649 Filed 10–18–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee for People With Intellectual Disabilities; Notice of Meeting

AGENCY: President's Committee for People With Intellectual Disabilities (PCPID).

ACTION: Notice of quarterly meeting.

DATES: Thursday, November 15, 2007, from 2 p.m.–4 p.m. EST. The meeting will be conducted via conference call and will be open to the public using the dial-in information provided below.

ADDRESSES: The conference call may be accessed on the date and time indicated by dialing 888–989–6481, passcode: PCPID.

Agenda: PCPID will meet to formulate an action plan and timeline for completion of the 2008 Report to the President.

FOR FURTHER INFORMATION CONTACT: Sally D. Atwater, Executive Director, President's Committee for People With Intellectual Disabilities, The Aerospace Center, Second Floor, West, 370 L'Enfant Promenade, SW., Washington, DC 20447. Telephone: 202–619–0634, fax: 202–205–9591. E-mail: *satwater@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and supports for persons with intellectual disabilities. PCPID, by Executive Order, is responsible for evaluating the adequacy of current

practices in programs, services and supports for persons with intellectual disabilities, and for reviewing legislative proposals that impact the quality of life experienced by citizens with intellectual disabilities and their families.

Dated: October 3, 2007.

Sally D. Atwater,

Executive Director, President's Committee for People With Intellectual Disabilities.

[FR Doc. E7–20617 Filed 10–18–07; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0079]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guide to Minimize Food Safety Hazards for Fresh-Cut Fruits and Vegetables

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guide to Minimize Food Safety Hazards for Fresh-Cut Fruits and Vegetables'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 13, 2007 (72 FR 11364), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0609. The approval expires on October 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: October 15, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–20632 Filed 10–18–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0182]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Maintaining a Data Bank

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 19, 2007.

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: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0459. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Maintaining a Data Bank—(OMB Control Number 0910–0459)—Extension

In the **Federal Register** of March 18, 2002 (67 FR 12022), FDA issued a guidance to industry on recommendations for investigational new drug application (IND) sponsors on submitting information about clinical trials for serious or life-threatening diseases to a Clinical Trials Data Bank developed by the National Library of Medicine (NLM), National Institutes of Health (NIH). This information is especially important for patients and their families seeking opportunities to participate in clinical trials of new drug treatments for serious or life-threatening diseases. The guidance describes three collections of information: Mandatory submissions, voluntary submissions, and certifications.

Mandatory Submissions

Section 113 of the Food and Drug Administration Modernization Act (FDAMA) of 1997 (the Modernization Act) (Public Law 105–115) requires that sponsors shall submit information to the Clinical Trials Data Bank when the clinical trial: (1) Involves a treatment for a serious or life-threatening disease and (2) is intended to assess the effectiveness of the treatment. The guidance discusses how sponsors can fulfill the requirements of section 113 of the Modernization Act. Specifically, sponsors should provide: (1) Information about clinical trials, both federally and privately funded, of experimental treatments (drugs, including biological products) for patients with serious or life-threatening diseases; (2) a description of the purpose of the experimental drug; (3) patient eligibility criteria; (4) the location of clinical trial sites; and (5) a point of contact for patients wanting to enroll in the trial.

Senate 1789, ''Best Pharmaceuticals for Children Act'' (Public Law 107–109) (BPCA), established a new requirement for the Clinical Trials Data Bank mandated by section 113 of FDAMA. Information submitted to the data bank must now include ''a description of whether and through what procedure, the manufacturer or sponsor of the investigation of a new drug will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the new drug, particularly in children.'' The guidance was updated on January 27, 2004, to include a discussion of how sponsors can fulfill the BPCA requirements.

As part of the resubmission process for OMB approval, this information collection request (ICR) has been revised to include the burden associated with new requirements imposed by the Centers for Medicare and Medicaid Services (CMS). On September 19, 2000, the Health Care Financing Administration (now CMS)