metastases in beneficiaries in whom bone metastases are strongly suspected based on clinical symptoms or the results of other diagnostic studies. Qualifying clinical studies must ensure that specific hypotheses are addressed; appropriate data elements are collected; hospitals and providers are qualified to provide the PET scan and interpret the results; participating hospitals and providers accurately report data on all Medicare enrolled patients; and all patient confidentiality, privacy, and other Federal laws must be followed. Consistent with section 1142 of the Social Security Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that the CMS determines meet specified standards and address the specified research questions. To qualify for payment, providers must prescribe certain NaF–18 PET scans for beneficiaries with a set of clinical criteria specific to each solid tumor. The statuary authority for this policy is section 1862 (a)(1)(E) of the Social Security Act. The need to prospectively collect information at the time of the scan is to assist the provider in decision making for patient management. *Form Number:* CMS–10152 (OCN: 0938–0968); *Frequency:* Annual; *Affected Public:* Private Sector—Business or other for-profits; *Number of Respondents:* 25,000; *Total Annual Responses:* 25,000; *Total Annual Hours:* 2,084. (For policy questions regarding this collection contact Stuart Caplan at 410–786–8564. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Reinstatement of a currently approved collection; *Title:* Medicare Program: Procedures for Making National Coverage Decisions; *Use:* The Centers for Medicare & Medicaid Services (CMS) revised the April 27, 1999 (64 FR 22619) notice and published a new notice on September 26, 2003 (68 FR 55634) that described the process we use to make Medicare coverage decisions including decisions regarding whether new technology and services can be covered. We have made changes to our internal procedures in response to the comments we received following publication of the 1999 notice and experience under our new process. Over the past several years, we received numerous suggestions to further revise our process to continue to make it more open, responsive, and understandable to the public. We share the goal of increasing public participation in the development of Medicare coverage issues. This will assist us in obtaining the information we require to make a national coverage determination in a timely manner and ensuring that the Medicare program continues to meet the needs of its beneficiaries. *Form Number:* CMS–R–290 (OCN: 0938–0776); *Frequency:* Annual; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 200; *Total Annual Responses:* 200; *Total Annual Hours:* 8,000. (For policy questions regarding this collection contact Katherine Tillman at 410–786–9252. For all other issues call 410–786–1326.)

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 Email 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.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *October 9, 2012:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 7, 2012.

Martique Jones,

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

[FR Doc. 2012–19694 Filed 8–9–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0781]

Request for Notification From Industry Organizations Interested in Participating in Selection Process for Nonvoting Industry Representative on the Pediatric Advisory Committee and Request for Nominations for Nonvoting Industry Representatives on the Pediatric Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Pediatric Advisory Committee for the Office of the Commissioner (OC) notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the Pediatric Advisory Committee. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by September 10, 2012, for the vacancy listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by September 10, 2012.

ADDRESSES: All letters of interest and nominations should be submitted in writing to Walter Ellenberg (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 301–796–0885, FAX: 301–847–8640, *walter.ellenberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative(s) to the following advisory committee:

I. OC Advisory Committee

Pediatric Advisory Committee

The Committee reviews and evaluates and makes recommendations to the Commissioner of Food and Drugs

regarding: (1) Pediatric research conducted under sections 351, 409I, and 499 of the Public Health Service Act and sections 501, 502, 505, 505A, and 505B, 510K, 515, and 520m of the Federal Food, Drug, and Cosmetic Act; (2) identification of research priorities related to pediatric therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments of specific pediatric diseases or conditions, (3) the ethics, design, and analysis of clinical trials related to pediatric therapeutics (including drugs and biological products) and medical devices, (4) pediatric labeling disputes as specified in Public Law 107–109 and Public Law 110–85, (5) pediatric labeling changes as specified in Public Law 107–109 and Public Law 110–85, (6) adverse event reports for drugs studied under Public Law 107–109 and 110–85 and labeled, (7) any safety issues that may occur as specified Public Law 107–109 and Public Law 110–85, (8) any other pediatric issue or pediatric labeling dispute involving FDA-regulated products, (9) pediatric ethical issues including research involving children as subjects as specified in 21 CFR 50.54; and (10) any other matter involving pediatrics for which FDA has regulatory responsibility.

The Committee also advises and makes recommendations to the Secretary directly or to the Secretary through the Commissioner on research involving children as subjects that is conducted or supported by the Department of Health and Human Services as specified in 45 CFR 46.407.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA contact person (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the pediatric pharmaceutical research and biotechnology manufacturing industry.

Authority: This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: August 7, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–19639 Filed 8–9–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Proposed Information Collection Activity: Comment Request

The Health Resources and Services Administration (HRSA) periodically publishes abstracts of information collection submitted for review to the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office at (301) 443–1984.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Maternal, Infant, and Early Childhood Home Visiting Program Information System: Data Collection Forms (OMB No. 0915–xxxx)—[New]

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), legislation designed to make quality, affordable, health care available to all Americans, reduce costs, improve health care quality, enhance disease prevention, and strengthen the health care workforce. Through a provision authorizing the creation of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program, the Act responds to the diverse needs of children and families in communities at risk and provides an unprecedented opportunity for collaboration and partnership at the Federal, State, Tribal, and community levels to improve health and development outcomes for at-risk children through evidence-based home visiting programs. The MIECHV Program is designed: (1) To strengthen and improve the programs and activities carried out under Title V; (2) to improve coordination of services for at-risk communities; and (3) to identify and provide comprehensive services to improve outcomes for families who reside in at-risk communities. Formula-based and competitive grants have been awarded to States, other eligible jurisdictions, and, under a legislative provision setting aside dedicated funds for a Tribal MIECHV program, to eligible Indian Tribes and consortia of Tribes, Tribal Organizations, and Urban Indian Organizations. Competitive grants to non-profit organizations to provide home visiting in certain States are anticipated.

The Social Security Act, Title V, Section 511 (42 U.S.C. 711), as amended by the Patient Protection and Affordable Care Act of 2010, requires that MIECHV grantees collect both socio-demographic data and data to measure improvements for eligible families in six specified areas (referred to as ''benchmark areas'') that encompass the major goals for the program. The Supplemental Information Request for the Submission of the Updated State Plan for a State Home Visiting Program (SIR), published on February 8, 2011, further listed a variety of constructs under each benchmark area for which grantees were to select and submit relevant performance measures. Per Section 511(d)(1)(B)(i) of the legislation, no later than 30 days after the end of the third year of the program, grantees are required to