DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): The Incidence and Etiology of Influenza-Associated Pneumonia in Hospitalized Persons and Virologic Evaluation of the Modes of Influenza Virus Transmission Among Humans, Funding Opportunity Announcement (FOA) IP09–001 and IP09–003

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting.

Time and Date: 8 a.m.–5 p.m., April 6, 2009 (Closed).

Place: Sheraton Gateway Hotel Atlanta Airport, 1900 Sullivan Road, Atlanta, Georgia 30337.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of ''The Incidence and Etiology of Influenza-Associated Pneumonia in Hospitalized Persons and Virologic Evaluation of the Modes of Influenza Virus Transmission Among Humans, FOA IP09–001 and IP09–003.''

Contact Person for More Information: Gregory Anderson, M.S., M.P.H., Office of the Director, Coordinating Center for Infectious Diseases, CDC, 1600 Clifton Road, Mailstop E–60, Atlanta, GA 30333, *Telephone:* (404) 498–2275.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 13, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E9–6047 Filed 3–18–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Influenza and Other Emerging Infectious Diseases in Vietnam; and Research and Public Health Practice on Influenza and Other Respiratory Infectious Diseases in the Middle East, Southeast Asia, and South American Regions, Funding Opportunity Announcement (FOA) IP09–002 and IP09–004

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting.

Time and Date: 8 a.m.–5 p.m., April 7, 2009 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of ''Influenza and Other Emerging Infectious Diseases in Vietnam; and Research and Public Health Practice on Influenza and Other Respiratory Infectious Diseases in the Middle East, Southeast Asia, and South American Regions, FOA IP09–002 and IP09–004.''

Contact Person for More Information: Gregory Anderson, M.S., M.P.H., Office of the Director, Coordinating Center for Infectious Diseases, CDC, 1600 Clifton Road, Mailstop E–60, Atlanta, GA 30333, *Telephone:* (404) 498–2275.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 13, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10164, CMS–10062, CMS–10137, CMS–416, CMS–1557, CMS–2786, CMS–437A&B and CMS–10259]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Agency: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Electronic Data Interchange (EDI Enrollment Form and Medicare EDI Registration Form; *Form No.:* CMS–10164 (OMB # 0938–983); *Use:* Federal law requires that CMS take precautions to minimize the security risk to Federal information systems. Accordingly, CMS is requiring that trading partners who wish to conduct the Electronic Data Interchange (EDI) transactions provide certain assurances as a condition of receiving access to the Medicare system for the purpose of conducting EDI exchanges. Health care providers, clearinghouses, and health plans that wish to access the Medicare system are required to complete this form. The information will be used to assure that those entities that access the Medicare system are aware of applicable provisions and penalties; *Frequency:* Recordkeeping and Reporting—Other (one-time only); *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 240,000; *Total Annual*

Responses: 240,000; *Total Annual Hours:* 80,000. (For policy questions regarding this collection contact Michael Cabral at 410–786–6168. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Collection of Diagnostic Data from Medicare Advantage Organizations for Risk Adjusted Payments: *Use:* CMS requires hospital inpatient, hospital outpatient and physician diagnostic data from Medicare Advantage (MA) organizations to continue making payment under the risk adjustment methodology as required by the Social Security Act, as amended by the Balanced Budget Act; the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act; and the Medicare Prescription Drug Benefit, Improvement and Modernization Act. CMS will use the data to make risk adjusted payment under Parts C. MA and MA–PD plans will use the data to develop their Parts C bids. As required by law, CMS also annually publishes the risk adjustment factors for plans and other interested entities in the Advance Notice of Methodological Changes for MA Payment Rates (every February) and the Announcement of Medicare Advantage Payment Rates (every April). Lastly, CMS issues monthly reports to each individual plan that contains the CMS-Hierarchical Condition Category (HCC) and RxHCC models' output and the risk scores and reimbursements for each beneficiary that is enrolled in their plan. *Form Number:* CMS–10062 (OMB# 0938–0878); *Frequency:* Quarterly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 852; *Total Annual Responses:* 22,097,070; *Total Annual Hours:* 10,826.1. (For policy questions regarding this collection contact Henry Thomas at 410–786–0086. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Application for Prescription Drug Plans (PDP); Application for Medicare Advantage Prescription Drug (MA–PD); Application for Cost Plans to Offer Qualified Prescription Drug Coverage; Application for Employer Group Waiver Plans to Offer Prescription Drug Coverage; Service Area Expansion Application for Prescription Drug Coverage; *Use:* Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and under supporting regulations Subpart K of 42 CFR 423 entitled ''Application Procedures and Contracts with PDP Sponsors.'' Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA–PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application. The information will be collected under the solicitation of proposals from PDP, MA–PD, Cost Plan, PACE, and EGWP Plan applicants. The collected information will be used by CMS to: (1) Ensure that applicants meet CMS requirements, (2) support the determination of contract awards. *Form Number:* CMS–10137 (OMB#: 0938–0936); *Frequency:* Reporting—Once; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 455; *Total Annual Responses:* 455; *Total Annual Hours:* 11,890. (For policy questions regarding this collection contact Marla Rothouse at 410–786–8063. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Report; *Use:* States are required to submit an annual report on the provision of EPSDT services pursuant to section 1902(a)(43)(D) of the Social Security Act. These reports provide CMS with data necessary to assess the effectiveness of State EPSDT programs, to determine a State's results in achieving its participation goal and to respond to inquiries. This collection is being submitted as a revision based on minor changes made to the form and instructions. CMS has added three additional lines of data to the form (lines 12d, 12e and 12f). This information is currently being collected; however, CMS expanded the lines to obtain a better understanding for the utilization of dental services. CMS believes there will be no additional burden for the changes made to the form. The changes were necessary to accommodate a need for more specific dental data and to preliminary notify States of a change in CPT codes. A clarification was also made to line 14 of the instructions. *Form Number:* CMS–416 (OMB# 0938–0354); *Frequency:* Yearly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,568. (For policy questions regarding this collection contact Cindy Ruff at 410–786–5916. For all other issues call 410–786–1326.)

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Survey Report Form for Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations in 42 CFR 493.1–493.2001; *Use:* This form is used by the State to determine a laboratory's compliance with CLIA. This information is needed for a laboratory's CLIA certification and recertification. *Form Number:* CMS–1557 (OMB# 0938–0544); *Frequency:* Biennially; *Affected Public:* Business or other for-profit, Not-for-profit institutions, State, Local or Tribal Governments and Federal Government; *Number of Respondents:* 21,000; *Total Annual Responses:* 10,500; *Total Annual Hours:* 5,248. (For policy questions regarding this collection contact Kathleen Todd at 410–786–3385. For all other issues call 410–786–1326.)

6. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Fire Safety Survey Reports; *Use:* The Life Safety Code (LSC) is a compilation of fire safety requirements for new and existing buildings and is updated and published every 3 years by the National Fire Protection Association (NFPA), a private, non-profit organization dedicated to reducing loss of life due to fire. The Medicare regulations have historically incorporated by reference these requirements along with Secretarial waiver authority.

The statutory basis for incorporating NFPA's LSC for our providers is under the Secretary's general rulemaking authority at Sections 1102 and 1871 of the Social Security Act. These forms are used by the State Agencies to record data collected to determine compliance with standards specified in 416.44(b) for ambulatory surgical centers (ASCs), and 494.60(e) for End-Stage Renal Disease (ESRD) facilities. The Medicare Health Insurance Program is authorized by Title XVIII of the Social Security Act. The CMS–2786U form is being revised to include ESRD information. *Form Number:* CMS–2786 (OMB# 0938–

0242); *Frequency:* Weekly; *Affected Public:* Individuals or households and State, Local or Tribal Government; *Number of Respondents:* 54; *Total Annual Responses:* 2442; *Total Annual Hours:* 4884. (For policy questions regarding this collection contact JoAnn Perry at 410–786–3336. For all other issues call 410–786–1326.)

7. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Rehabilitation Hospital Criteria Worksheet and Rehabilitation Hospital Criteria Worksheet; *Use:* The rehabilitation hospital and rehabilitation unit criteria worksheets are necessary to verify that these facilities/units comply and remain in compliance with the exclusion criteria for the Medicare prospective payment system. *Form Number:* CMS–437A and 437B (OMB# 0938–0986); *Frequency:* Annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 1227; *Total Annual Responses:* 1227; *Total Annual Hours:* 307. (For policy questions regarding this collection contact Georgia Johnson at 410–786–6859. For all other issues call 410–786–1326.)

8. *Type of Information Collection Request:* New collection; *Title of Information Collection:* State Plan Amendment Template for 1915(i) State Plan Home and Community-Based Services (HCBS) Benefit; *Use:* Section 6086 of the Deficit Reduction Act (DRA), expanded access to HCBS for the elderly and disabled and added a new section 1915(i) to the Social Security Act. Under 1915(i), States can amend their State plans to add these services. The template includes the information needed by CMS to determine whether the State's services will meet the requirements under 1915(i). *Form Number:* CMS–10259 (OMB# 0938-NEW); *Frequency:* Once; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 3; *Total Annual Hours:* 240. (For policy questions regarding this collection contact Kathy Poisal at 410–786–5940. 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 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 *April 20, 2009.*

OMB, Office of Information and Regulatory Affairs.

Attention: CMS Desk Officer.

Fax Number: (202) 395–6974.

E-mail: *OIRA_submission@omb.eop.gov*.

Dated: March 12, 2009.

Michelle Shortt,

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

[FR Doc. E9–6041 Filed 3–18–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2008–M–0535, FDA–2008–M–0547, FDA–2008–M–0536, FDA–2008–M–0563, FDA–2008–M–0593, FDA–2008–M–0601, FDA–2008–M–0562, FDA–2008–M–0596, FDA–2008–M–0579, FDA–2008–M–0594, FDA–2008–M–0608, FDA–2008–M–0645, FDA–2008–M–0646]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in Table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4010.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30 day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30 day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30 day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from October 1, 2008, through December 31, 2008. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.