mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms include, Internet Web site that includes information on part D plan description. MA organizations (formerly M+C organizations) and Prescription Drug Plan Sponsors use the information to comply with the eligibility requirements and the MA and part D contract requirements. CMS will use this information to ensure that correct information is disclosed to Medicare beneficiaries, both potential enrollees and enrollees. *Form Number:* CMS–10260 (OMB#: 0938–1051); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 740; *Total Annual Responses:* 740; *Total Annual Hours:* 8,880. (For policy questions regarding this collection contact Camille Brown at 410–786–0274. For all other issues call 410–786–1326.)

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid and Children's Health Insurance (CHIP) Managed Care; *Use:* The Payment Error Rate Measurement (PERM) program measures improper payments for Medicaid and the State Children's Health Insurance Program (SCHIP). The program was designed to comply with the Improper Payments Information Act (IPIA) of 2002 and the Office of Management and Budget (OMB) guidance. Although OMB guidance requires error rate measurement for SCHIP, 2009 SCHIP legislation temporarily suspended PERM measurement for this program and changed to Children's Health Insurance Program (CHIP) effective April 01, 2009. See Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) Public Law 111–3 for more details.

There are two phases of the PERM program, the measurement phase and the corrective action phase. PERM measures improper payments in Medicaid and CHIP and produces State and national-level error rates for each program. The error rates are based on reviews of Medicaid and CHIP fee-for-service (FFS) and managed care payments made in the Federal fiscal year under review. States conduct eligibility reviews and report eligibility related payment error rates also used in the national error rate calculation. CMS created a 17 State rotation cycle so that each State will participate in PERM once every three years.

The information collected from the selected States will be used by Federal contractors to conduct Medicaid and CHIP managed care data processing reviews on which State-specific error rates will be calculated. The quarterly capitation payments will provide the contractor with the actual claims to be sampled. The managed care contracts, rate schedules, and updates to both, will be used by the federal contractor when conducting the managed care claims reviews. *Form Number:* CMS–10178 (OMB#: 0938–0994); *Frequency:* Reporting—Occasionally; *Affected Public:* State, Local, or Tribal governments; *Number of Respondents:* 34; *Total Annual Responses:* 2,040; *Total Annual Hours:* 28,050. (For policy questions regarding this collection contact Nicole Perry at 410–786–8786. 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 October 26, 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: September 18, 2009.

Michelle Shortt,

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

[FR Doc. E9–23124 Filed 9–24–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection: Comment Request; 0MB No. 0925–0601/exp. 2/28/2010, ''Request for Human Embryonic Stem Cell Line To Be Approved for Use in NIH Funded Research''

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of Extramural Research, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (0MB) for review and approval.

Proposed Collection: Title: Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research. *Type of Information Collection Request:* Extension, 0MB 0925–0601, Expiration Date 2/28/2010. *Form Number:* 2890. The form is used by applicants to request that human embryonic stem cell lines be approved for use in NIH funded research. Applicants may submit applications at any time; this request is a one-time submission. Affected Public: Business or other for-profit; Not-for-profit institutions; Federal Government; and State, Local or Tribal Government. Type of Respondents: Adult scientific professionals. The annual reporting burden is as follows:

Estimated Number of Respondents: 100; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 3; and *Estimated Total Annual Burden Hours Requested:* 300. The estimated annualized cost to respondents is $10,500.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Mikia Currie, Division of Grants Policy, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 3505, 6705 Rockledge Drive, Bethesda, MD 20892–7974, or call non-toll-free number 301–435–0941, or E-mail your request, including your address to: [*curriem@od.nih.gov*].

Comments Due Date: Comments regarding this information collection are

best assured of having their full effect if received within 60-days of the date of this publication.

Dated: September 17, 2009.

Joe Ellis,

Director, OPERA, OER, National Institutes of Health.

[FR Doc. E9–23078 Filed 9–24–09; 8:45 am]

BILLING CODE 4140–10–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0449]

Enforcement of General Tobacco Standard Special Rule for Cigarettes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Family Smoking Prevention and Tobacco Control Act (FSPTCA), establishes a tobacco standard special rule for cigarettes. This special rule for cigarettes prohibits a cigarette or any of its component parts (including the tobacco, filter, or paper) from containing, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. The Food and Drug Administration (FDA) is providing this notice to remind regulated industry that as of the effective date identified in the FSPTCA, cigarettes that contain certain characterizing flavors are considered adulterated under the act. FDA is also providing in this notice contact information to which individuals who observe violative products after the effective date of the tobacco standard special rule may report their observations to FDA.

DATES: Effective September 22, 2009.

ADDRESSES: To report tobacco products that fail to comply with section 907(a)(1)(A) of the act after September 22, 2009, please contact the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 877–287–1373 or *http://www.fda.gov/flavoredtobacco*.

FOR FURTHER INFORMATION CONTACT: Michele Mital, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 877–287–1373, *Michele.Mital@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Smoking is the leading preventable cause of death in the United States. An important way to reduce the death and disease caused by smoking is to prevent children and adolescents from starting to smoke. Congress has stated that flavors make cigarettes more appealing to youth and often result in exposure to additional carcinogens and other toxic constituents. The removal from the market of cigarettes that contain certain characterizing flavors is an important step in FDA's efforts to reduce the burden of illness and death caused by tobacco products.

The FSPTCA provides FDA with regulatory authority over the manufacture, marketing, and distribution of tobacco products. Specifically, section 907(a)(1)(A) of the act, as amended by the FSPTCA, establishes a tobacco product standard special rule for cigarettes that states in part: ''* * * a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.''

This standard applies to all tobacco products that meet the definition of a ''cigarette'' in section 900(3) of the act, as amended, even if they are not labeled as ''cigarettes'' or are labeled as cigars or as some other product.

As of the September 22, 2009, effective date, cigarettes and their component parts that fail to comply with the special rule established under section 907 of the act, as amended, are deemed adulterated under section 902 of the act, as amended. Under the act, adulterated products sold or held for sale in the United States may be subject to seizure under section 304 of the act (21 U.S.C. 334). In addition, manufacturers, distributors, and retailers may be subject to injunction actions, civil money penalties, and/or criminal prosecution for violating the requirements of the act (sections 301, 302, and 303 of the act (21 U.S.C. 331, 332, and 333, respectively)). FDA intends to use the full range of enforcement tools within the agency's authority to ensure compliance with the new requirement.

FDA encourages individuals who observe violative products after September 22, 2009, to report their observations to FDA. This collection of information was approved under OMB control number 0910–0647 and expires on March 31, 2010. Individuals may report products in violation of this standard to FDA through the contact information provided in the **ADDRESSES** section of this document.

Dated: September 21, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–23144 Filed 9–22–09; 11:15 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2487–FN]

Medicare and Medicaid Programs; Application by the American Osteopathic Association for Continued Deeming Authority for Ambulatory Surgical Centers

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the American Osteopathic Association (AOA) for continued recognition as a national accreditation program for ambulatory surgical centers (ASCs) seeking to participate in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice is effective on October 23, 2009 through October 23, 2013.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786–0310. Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in an ambulatory surgical center (ASC) provided certain requirements are met. Sections 1832(a)(2)(F)(i) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as an ASC. Under this authority, the minimum requirements that an ASC must meet to participate in Medicare are set forth in regulations at 42 CFR part 416, which determine the basis and scope of ASC covered services, and the conditions for Medicare payment for facility services. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities