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