Dated: November 18, 2005.

Betsey Dunaway,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Breast and Cervical Cancer Early Detection and Control Advisory Committee

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 following committee meeting:

Name: Breast and Cervical Cancer Early Detection and Control Advisory Committee (BCCEDCAC).

Times and Dates: 8:30 a.m.–5 p.m., December 6, 2005. 8:30 a.m.–1 p.m., December 7, 2005.

Place: Embassy Suites Hotel, Centennial Olympic Park, 267 Marietta Street, Atlanta, Georgia 30313.

Phone: 1–404–223–2300.

Status: Open to the public, limited only by the space available.

Purpose: The committee is charged with advising the Secretary, Department of Health and Human Services, and the Director, CDC, regarding the early detection and control of breast and cervical cancer. The committee makes recommendations regarding national program goals and objectives; implementation strategies; and program priorities including surveillance, epidemiologic investigations, education and training, information dissemination, professional interactions and collaborations, and policy.

Matters to be Discussed: The agenda will include discussion and review of the vision for National Cancer Prevention and Control Program; strategies for Performance-Based Funding; Case Management; update of expert panel meetings; HPV Testing and the Breast and Cervical Program; and HPV Vaccine update.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Debra Younginer, Executive Secretary, BCCEDCAC, Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway, Mailstop K–57, Chamblee, Georgia 30316, Telephone: 770–488–1074.

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.

Alvin Hall,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0374]

Nonprescription Drugs Advisory Committee and Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting and Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Nonprescription Drugs Advisory Committee and the Pulmonary-Allergy Drugs Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 24, 2006, from 8 a.m. to 5 p.m. Interested persons and organizations may submit written or electronic comments until January 6, 2006, to the Division of Dockets Management (see *Addresses*).

Addresses: Electronic comments should be submitted to *http://www.fda.gov/dockets/ecomments*. Select ''2005N–0374 Use of Ozone-Depleting Substance: Essential-Use Determination of Over-the-Counter (OTC) Epinephrine Metered Dose Inhalers'' and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Location: Holiday Inn Select Bethesda, The Ballrooms, 8120 Wisconsin Ave., Bethesda, MD. The hotel telephone number is 301–652–2000.

Contact Person: Darrell Lyons, Center for Drug Evaluation and Research (HFD 21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, (301–827–7001, FAX: 301–827–6776, e-mail: *lyonsd@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area) codes 3014512541 or 3014512545. Please call the Information Line for up to date information on this meeting.

Agenda: The committee will discuss the continued need for the designation of OTC epinephrine-metered dose inhalers for the treatment of asthma as an essential use of ozone-depleting substances (ODSs) under § 2.125 (21 CFR 2.125). ODSs are substances that deplete the stratospheric ozone, which include chlorofluorocarbons (CFCs). Once released, CFCs rise to the stratosphere. In the stratosphere, CFCs are gradually broken down by strong ultraviolet light, and they release chlorine atoms that then deplete stratospheric ozone. Depletion of stratospheric ozone by CFCs and other ODSs leads to higher ultraviolet B radiation levels, which in turn increase skin cancers and cataracts, as well as cause other significant environmental damage.

FDA is soliciting comments and data to support or refute an essential-use designation for OTC epinephrine metered-dose inhaler (MDI) drug products. These products include the only OTC drug available in an MDI dosage form for the treatment of asthma. The OTC epinephrine MDIs use CFCs as propellants. The OTC indication is ''for temporary relief of shortness of breath, tightness of chest, and wheezing due to bronchial asthma.'' In some instances, use of this product early during an asthma attack could avert a serious or life-threatening worsening of the attack. There are currently a limited number of marketed OTC drug products containing epinephrine in a MDI dosage form.

According to § 2.125(f)(1), the following are criteria for continued ODS essential-use designation:

(1) Substantial technical barriers exist to formulating the product without ODSs;

(2) The product will provide an otherwise unavailable important public health benefit; and

(3) Use of the product does not release cumulative significant amounts of ODSs into the atmosphere or the release is warranted in view of the high