

probability of an unavailable important public health benefit.

Under section 610 of the Clean Air Act (42 U.S.C. 7671(i)), MDIs that are not the subject of an essential-use designation cannot be legally distributed in interstate commerce.

We particularly encourage comments on the second criterion in § 2.125(f)(i) regarding the public health benefit derived from the availability of these products in the OTC setting. Information that may aid in the Committee's discussion of essential use includes:

- Who currently uses OTC epinephrine MDIs?
- How many of these MDIs are used annually?
- What are the alternatives if these products are no longer available?
- From literature sources, what is the value of use of the product to the users, and why do they use it?
- What established treatment guidelines recommend the use of OTC epinephrine?
- How many people with asthma do not have ready access to prescription medication through healthcare professionals?

The background material will become available no later than the day before the meeting and will be posted under the Nonprescription Drugs Advisory Committee (NDAC) and the Pulmonary Drugs Advisory Committee (PADAC) on FDA's website at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2006 and scroll down to NDAC or PADAC).

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written comments should be submitted by close of business January 6, 2006, to the Division of Dockets Management (see *Addresses*). Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by close of business January 6, 2006, and submit a brief statement of the general nature of the information they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee

meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Darrell Lyons (see *Contact Person*) at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 17, 2005.

**Jason Brodsky,**

*Acting Associate Commissioner for External Relations.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

**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 Committee:* Vaccines and Related Biological Products Advisory Committee.

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

*Date and Time:* The meeting will be held on December 14, 2005, from 9 a.m. to 4:30 p.m. and on December 15, 2005, from 9 a.m. to 4:30 p.m.

*Location:* Holiday Inn Select, 8120 Wisconsin Ave., Bethesda, MD.

*Contact Person:* Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On December 14, 2005, the committee will hear presentations and make recommendations on the safety and efficacy of a rotavirus vaccine manufactured by Merck. On December 15, 2005, the committee will hear presentations and make

recommendations on the safety and efficacy of ZOSTAVAX (zoster vaccine live (Oka/Merck)) manufactured by Merck.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 7, 2005. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 1:45 p.m. on December 14, 2005, and from approximately 1:30 p.m. and 2 p.m. on December 15, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 7, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

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Dated: November 17, 2005.

**Jason Brodsky,**

*Acting Associate Commissioner for External Relations.*

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## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Federal Emergency Management Agency, Department of Homeland Security.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Federal Emergency Management Agency, as part of its