

January 24, 2006

Joint Meeting of the Nonprescription Drugs and the Pulmonary-Allergy Drugs Advisory Committee

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This is the final report of the Nonprescription Drugs Advisory Committee Meeting held on January 24, 2006. A verbatim transcript will be available in about 2 weeks, sent to the Division and posted on the FDA website at <http://www.fda.gov/ohrms/dockets/ac/cder05.html#NonprescriptionDrugs>

All external requests should be submitted to the Freedom of Information office.

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The Nonprescription Drugs and the Pulmonary-Allergy Drugs Advisory Committee of the Food and Drug Administration, Center for Drug Evaluation and Research, met on January 24, 2006, at the Holiday Inn Select Bethesda, the Ballrooms, 8120 Wisconsin Avenue, Bethesda, Maryland. Alastair Wood, M.D. chaired the meeting. There were approximately 150 in attendance.

**Nonprescription Drugs Advisory Committee (voting):**

Alastair Wood, M.D. (Chair), Neal Benowitz, M.D., Terrence F. Blaschke, M.D., Ernest B. Clyburn, M.D., Ruth M. Parker, M.D., Robert E. Taylor, M.D., Ph.D., F.A.C.P. Wayne R. Snodgrass, M.D., Ph.D., Mary E. Tinetti, M.D.

**Nonprescription Drugs Advisory Committee (absent)**

Jack E. Fincham, Ph.D.,

**Pulmonary-Allergy Drugs Advisory Committee (voting):**

Mark L. Brantly, M.D., Steven Gay, M.D., Carolyn M. Kerckmar, M.D., Michael X. Schatz, M.D., David A. Schoenfeld, PhD., (Participated via Audio Conference) Erik R. Swenson, M.D.

**Pulmonary-Allergy Drugs Advisory Committee (absent):**

Marc I. Moss, M.D., Calman P. Prussin, M.D., Fernando D. Martinez, M.D., Peter E. Morris, M.D., William J. Calhoun, M.D., Lee S. Newman, M.D.

**Consultants (voting):**

Marie R. Griffin, M.D., Sonia Patten, Ph.D. [CR], Nancy Sander [PR], Karen Schell, RRT

**Industry Representative (non-voting):**

George S. Goldstein, M.D., Theodore Reiss, M.D.

**FDA Speakers:**

Robert Meyer, M.D., Charles Ganley, M.D.

**FDA Participants:**

Robert Meyer, M.D., Charles Ganley, M.D., Andrea Leonard Segal, M.D., Badrul Chowdhury, M.D.

**Open Public Hearing Speakers:**

Manuel Mirabel, National Puerto Rican Coalition, Inc.  
Sandra Fusco-Walker, Allergy & Asthma Network, Mothers of Asthmatics  
Bryan Martin, Allergy & Asthma Care  
Alex Perez, Self-Interest

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On January 24, 2006, the committee discussed 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 21 CFR 2.125. ODSs are substances that deplete stratospheric ozone, which include chlorofluorocarbons (CFCs).

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Alastair Wood, M.D. (Committee Chair), called the meeting to order at 8:00 a.m. The Committee members, consultants, and FDA participants introduced themselves. The conflict of interest statement was read into the record by Darrell Lyons B.S.N. The agenda proceeded as follows:

Call to Order	Alastair Wood, M.D., Ph.D. Chair, Nonprescription Drugs Advisory Committee, NDAC
Conflict of Interest Statement	LT Darrell Lyons, B.S.N. Executive Secretary, NDAC
Welcome and Introductory Comments	Charles Ganley, M.D. Director, Office of Nonprescription Products
FDA Presentation	Robert J. Meyer, M.D. Director, Office of Drug Evaluation II
Wyeth Consumer Healthcare Products	Roger Berlin, M.D. President of Scientific Affairs Wyeth Consumer Healthcare
Open Public Hearing Presentations	

**Question to the Committee:**

1. Given the current practice of medicine and overall treatment goals and therapeutic strategies for asthma, does the use of CFCs in epinephrine MDIs available without a prescription, remain an essential use at the current time?

Yes: 7

No: 11

Abstain: 0

The meeting was adjourned at approximately 12:30 p.m. on January 24, 2006.

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These summary minutes for the January 24, 2006 Meeting of the Nonprescription Drugs and the Pulmonary-Allergy Drugs Advisory Committee of the Food and Drug Administration were approved on January 27, 2006.

I certify that I attended the January 24, 2006, Meeting of the Nonprescription Drugs and the Pulmonary-Allergy Drugs Advisory Committee of the Food and Drug Administration meeting and that these minutes accurately reflect what transpired.

\_\_\_\_\_/S//\_\_\_\_\_  
Darrell Lyons, B.S.N.  
Executive Secretary

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Alastair Wood, M.D.  
Chair