

**FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)**

**Joint Meeting of the Nonprescription Drugs and  
the Pulmonary-Allergy Drugs Advisory Committees**  
*January 24, 2006*

*Continued need for designation of over-the-counter (OTC) epinephrine-metered dose inhalers  
for the treatment of asthma as an essential use of ozone-depleting substances (ODSs) under 21 CFR 2.125*

**AGENDA**

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|-------|--|--|
| 8:00  | Call to Order  | <b>Alastair Wood, M.D., Ph.D.</b><br>Chair, Nonprescription Drugs Advisory Committee,<br>NDAC              |
|       | Conflict of Interest Statement   | <b>LT Darrell Lyons, B.S.N.</b><br>Executive Secretary, NDAC   |
| 8:20  | Welcome and Introductory Comments  | <b>Charles Ganley, M.D.</b><br>Director, Office of Nonprescription Products                                |
| 8:30  | FDA Presentation   | <b>Robert J. Meyer, M.D.</b><br>Director, Office of Drug Evaluation II                                     |
| 8:45  | <b>Question and Answer Period</b>  |  |
| 9:15  | Amphastar Pharmaceuticals, Inc.  | <b>Stephen Campbell, Esq.</b><br>Sr. Vice President, Regulatory Affairs<br>Amphastar Pharmaceuticals, Inc. |
| 9:30  | <b>Question and Answer Period</b>  |  |
| 9:45  | <b>Break</b>   |  |
| 10:00 | Wyeth Consumer Healthcare Products   | <b>Roger Berlin, M.D.</b><br>President of Scientific Affairs<br>Wyeth Consumer Healthcare                  |
| 11:15 | <b>Question and Answer Period</b>  |  |
| 12:00 | <b>Lunch</b>   |  |
| 1:00  | Open Public Hearing  |  |
| 2:00  | <b>Committee Discussion / Questions</b><br>(Break, if needed, to be determined by Chair) |  |
| 5:00  | Adjourn  |  |

***MEETING ROSTER***  
***(January 24, 2006)***

Committee Members:

Erik R. Swenson, M.D.

Mark L. Brantly, M.D.

Steven Gay, M.D., M.S.

Carolyn M. Kercksmar, M.D.

Michael Schatz, M.D.

David A. Schoenfeld, Ph.D.

Alastair Wood, M.D.

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.

Wayne R. Snodgrass, M.D., Ph.D.

Mary E. Tinetti, M.D.

Temporary Voting Members:

Marie R. Griffin, M.D.

Sonia Patten, Ph.D.

Karen Schell, RRT

Nancy J. Sander

Non-Voting Committee Members

Theodore Reiss, M.D.

George S. Goldstein, M.D.

FDA Participants (Non-Voting):

Robert Meyer, M.D.

Charles Ganley, M.D.

Andrea Leonard-Segal, M.D.

Badrul Chowdhury, M.D.