

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research (CDER)
Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee (PCNS)

AGENDA

December 6, 2007

The committee will discuss new drug application (NDA) 21-894, tetrabenazine, Prestwick Pharmaceuticals Inc. for the proposed indication to treat chorea associated with Huntington's disease.

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| 8:00 | Call to Order Introduction of Committee | Larry B. Goldstein, M.D. Acting Chair, PCNS |
| | Conflict of Interest Statement | Darrell Lyons, B.S.N., R.N. Designated Federal Official |
| 8:15 | Welcome and Introductory Comments | Russell Katz, M.D., Director Division of Neurology Products, CDER, FDA |
| 8:30 | SPONSOR PRESENTATIONS | |
| | Introduction | Martin Stogniew, Ph.D. Executive Vice President Prestwick Pharmaceuticals, Inc. |
| | Overview of Huntington's disease | Joseph Jankovic, M.D. Professor of Neurology Baylor College of Medicine |
| | Clinical Efficacy | Fred Marshall, M.D. Associate Professor of Neurology, Chief, Geriatric Neurology Unit and the Huntington Study Group University of Rochester |
| | Non-Motor Endpoints | Peter Como, Ph.D. Associate Professor of Neurology, Clinical Psychiatry, and Brain and Cognitive Sciences, and the Huntington Study Group, University of Rochester |
| | Clinical Safety | David Stamler, M.D. Chief Scientific Officer Prestwick Pharmaceuticals, Inc. |
| | Safety and Efficacy of Tetrabenazine | Ira Shoulson, M.D. Professor of Neurology, Medicine, Pharmacology & Physiology Louis C Lasagna Professor of Experimental Therapeutics and Chair, Huntington Study Group, University of Rochester |
| 10:00 | Questions to Sponsor | |
| 10:15 | Break | |

10:30 **FDA PRESENTATIONS**

Efficacy Considerations

Carole Davis, D.O., Medical Officer
Division of Neurology Products, CDER, FDA

Dose-Response Analysis for Effectiveness
and Safety

Atul Bhattaram, Ph.D., Pharmacometrics Reviewer
Pharmacometrics, Office of Clinical Pharmacology, FDA

Safety Review

Lourdes Villalba, M.D., Medical Officer
Division of Neurology Products, CDER, FDA

12:00 *Questions to FDA*

12:15 ***Lunch***

1:15 ***Open Public Hearing***

2:15 ***Break***

2:30 *Committee Questions and Panel Discussion*

5:00 ***Adjourn***