

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 | Acting Chair, PCNS |
| | Conflict of Interest Statement | Darrell Lyons, BSN, RN
Designated Federal Official |
| 8:15 | Welcome and Introductory Comments | Russell Katz, M.D., Director
Division of Neurology Products, CDER, FDA |
| 8:30 | SPONSOR PRESENTATIONS | |
| 10:00 | Questions to Sponsor | |
| 10:15 | Break | |
| 10:30 | FDA PRESENTATIONS | Carole Davis, D.O., Medical Officer
Division of Neurology Products, CDER, FDA |
| | | Atul Bhattaram, Ph.D., Pharmacometrics Reviewer
Pharmacometrics, Office of Clinical Pharmacology, FDA |
| | | 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 | <i>Committee Questions and Panel Discussion</i> | |
| 5:00 | Adjourn | |