

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)  
*Nonprescription Drugs Advisory Committee Meeting*

HILTON WASHINGTON, DC/SILVER SPRING  
8727 COLESVILLE ROAD, SILVER SPRING, MARYLAND  
DECEMBER 14, 2007

**AGENDA**

The committee will discuss the safety and effectiveness of phenylephrine hydrochloride and phenylephrine bitartrate as OTC oral nasal decongestants.

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|-------------------------|---|---|
| 8:00 a.m.               | Call to Order and Opening Remarks   | <b>Mary E. Tinetti, M.D.</b><br>Chair, Nonprescription Drugs Advisory Committee   |
|                         | Introduction of Committee   |   |
|                         | Conflict of Interest Statement  | <b>Diem-Kieu H. Ngo, Pharm.D.</b><br>Designated Federal Official  |
| 8:15 a.m.               | FDA Introductory Remarks  | <b>Susan Johnson, Pharm.D., Ph.D.</b><br>Associate Director,<br>Office of Nonprescription Products, CDER, FDA   |
| <b>FDA PRESENTATION</b> |   |   |
| 8:25 a.m.               | History of the OTC Drug Review as it Relates to Phenylephrine               | <b>Mary S. Robinson, M.S.</b><br>Regulatory Review Chemist,<br>Division of Nonprescription Regulation<br>Development<br>Office of Nonprescription Products, CDER, FDA     |
| 8:35 a.m.               | Effectiveness and Safety of Phenylephrine as an OTC Oral Nasal Decongestant | <b>Michael L. Koenig, Ph.D.</b><br>Interdisciplinary Scientist,<br>Division of Nonprescription Regulation<br>Development<br>Office of Nonprescription Products, CDER, FDA |
| 9:05 a.m.               | Statistical Evaluation of Effectiveness Submissions                         | <b>Stan Lin, Ph.D.</b><br>Mathematical Statistician,<br>Division of Biometrics 4<br>Office of Biostatistics, OTS, CDER, FDA   |
| 9:25 a.m.               | Clinical Endpoints for Nasal Decongestants                                  | <b>Xu Wang, M.D., Ph.D.</b><br>Medical Officer<br>Division of Pulmonary and Allergy Products<br>Office of New Drugs, CDER, FDA  |
| 9:40 a.m.               | Questions/Clarifications  |   |
| 10:00 a.m.              | <b>BREAK</b>  |   |

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**-CONTINUED-**

**PETITIONER PRESENTATION**

10:15 a.m. Background on Decongestants and  
Citizens Petition

**Leslie Hendeles, Pharm.D.**  
Professor, Pharmacy and Pediatrics  
University of Florida

10:35 a.m. Efficacy and Safety of Oral  
Phenylephrine: Systematic Review  
and Meta-Analysis

**Randy Hatton, Pharm.D.**  
Co-Director, Drug Information and Pharmacy  
Resource Center, Shands Hospital at the  
University of Florida; Clinical Professor,  
College of Pharmacy, University of Florida

10:45 a.m. Evaluation of the Statistical Methods  
Used in the CHPA Meta-Analysis

**Jonathan J. Shuster, Ph.D.**  
Research Professor, Division of Biostatistics,  
Department of Epidemiology and Health Policy;  
Research Biostatistician, General Clinical  
Research Center, College of Medicine,  
University of Florida

**INDUSTRY PRESENTATION**

11:05 a.m. Introduction

**Consumer Healthcare Products Association  
(CHPA)**

11:10 a.m. Clinical Overview of Two Allergy  
Chamber Studies with Phenylephrine

**Melvyn Danzig, Ph.D.**  
Project Director  
Clinical Research - Allergy/Respiratory  
Schering-Plough/Merck Pharmaceuticals

11:25 a.m. Understanding Phenylephrine Metabolism,  
Pharmacokinetics, Bioavailability, and  
Activity

**John O'Mullane, Ph.D.**  
Group Vice President, Research and Development  
Schering-Plough Corporation

11:40 a.m. Safety, Pharmacology & Efficacy, and  
Summary

**CHPA Task Force**

12:25 p.m. **LUNCH**

1:25 p.m. Open Public Hearing

2:25 p.m. Questions/Clarifications

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**-CONTINUED-**

- 3:00 p.m. **BREAK**
- 3:15 p.m. Panel Discussion/Questions
- 5:00 p.m. **ADJOURNMENT**

DRAFT