

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.

8:00 a.m. Call to Order and Opening Remarks **Mary E. Tinetti, M.D.**
Chair, Nonprescription Drugs Advisory Committee

Introduction of Committee

Conflict of Interest Statement

Diem-Kieu H. Ngo, Pharm.D.
Designated Federal Official

8:15 a.m. FDA Introductory Remarks

Susan Johnson, Pharm.D., Ph.D.
Associate Director,
Office of Nonprescription Products, CDER, FDA

FDA PRESENTATION

8:25 a.m. History of the OTC Drug Review as it
Relates to Phenylephrine

Mary S. Robinson, M.S.
Regulatory Review Chemist,
Division of Nonprescription Regulation
Development
Office of Nonprescription Products, CDER, FDA

8:35 a.m. Effectiveness and Safety of Phenylephrine
as an OTC Oral Nasal Decongestant

Michael L. Koenig, Ph.D.
Interdisciplinary Scientist,
Division of Nonprescription Regulation
Development
Office of Nonprescription Products, CDER, FDA

9:05 a.m. Statistical Evaluation of Effectiveness
Submissions

Stan Lin, Ph.D.
Mathematical Statistician,
Division of Biometrics 4
Office of Biostatistics, OTS, CDER, FDA

9:25 a.m. Clinical Endpoints for Nasal Decongestants

Xu Wang, M.D., Ph.D.
Medical Officer
Division of Pulmonary and Allergy Products
Office of New Drugs, CDER, FDA

9:40 a.m. Questions/Clarifications

10:00 a.m. **BREAK**

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AGENDA
-CONTINUED-

PETITIONER PRESENTATION

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| 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

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| 11:05 a.m. Introduction | Linda A. Suydam, D.P.A.
President, Consumer Healthcare Products Association |
| 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 Data | Edwin K. Kuffner, M.D.
Senior Director, Medical Affairs
McNeil Consumer Healthcare |
| 11:50 a.m. PE Pharmacology/Pharmacokinetics | Cathy K. Gelotte, Ph.D.
Senior Director, Clinical Pharmacology
McNeil Consumer Healthcare |

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12:00 p.m. Efficacy of Phenylephrine 10 mg

Kenneth Dretchen, Ph.D.

Professor and Chairman, Department of Pharmacology
Georgetown University Medical Center

12:20 p.m. Closing Remarks

Linda A. Suydam, D.P.A.

President, Consumer Healthcare Products Association

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

1:25 p.m. Open Public Hearing

2:25 p.m. Questions/Clarifications

3:00 p.m. **BREAK**

3:15 p.m. Panel Discussion/Questions

5:00 p.m. **ADJOURNMENT**