AGENDA

The committees will discuss a completed postmarketing-requirement randomized, placebo controlled trial of the neuropsychiatric effects of CHANTIX (varenicline), ZYBAN (bupropion), and nicotine replacement therapy, along with relevant published observational studies to determine whether the findings support changes to product labeling.

8:00 a.m. Call to Order and Introduction of Committee

8:05 a.m. Conflict of Interest Statement

8:10 a.m. FDA Introductory Remarks / Regulatory History

8:25 a.m. APPLICANT PRESENTATIONS

Introduction

Evidence from Observational Studies

EAGLES Study Design, Investigator’s Perspective on Study Conduct and on Treating Patients for Smoking Cessation

EAGLES Study Execution

Call to Order and Introduction of Committee

Ruth Parker, MD
Acting Chairperson, PDAC

Kalyani Bhatt, BS, MS
Designated Federal Officer, PDAC

Judith A. Racoosin, MD, MPH
Deputy Director for Safety
Division of Anesthesia, Analgesia, and Addiction Products (DAAAP)
Office of Drug Evaluation II (ODE II)
Office of New Drugs (OND), CDER, FDA

Pfizer, Inc.

James Rusnak, MD, PhD
Chief Development Officer, Cardiovascular and Metabolic Diseases
Pfizer

Judith Prochaska, PhD, MPH
Associate Professor, Department of Medicine
Stanford University

Robert M. Anthenelli, MD
Professor and Executive Vice Chair, Department of Psychiatry
University of California, San Diego, School of Medicine

James Rusnak, MD, PhD
Chief Development Officer, Cardiovascular and Metabolic Diseases
Pfizer
APPLICANT PRESENTATIONS (CONT.)

EAGLES Study Results I  
Cristina Russ, MD, PhD  
Director, Medical Affairs  
Pfizer

Clinical Perspective on EAGLES Study Results  
A. Eden Evins, MD, MPH  
Director, Center for Addiction Medicine  
Massachusetts General Hospital and Cox Family  
Associate Professor of Psychiatry  
Harvard Medical School

Conclusions and Labeling Proposal  
James Rusnak, MD, PhD  
Chief Development Officer, Cardiovascular and Metabolic Diseases  
Pfizer

9:55 a.m.  Clarifying Questions to Applicant

10:15 a.m.  BREAK

10:30 a.m.  FDA PRESENTATIONS

Clinical Review of the PMR Safety Outcome Trial  
Celia Winchell, MD  
Clinical Team Leader, Addiction Products  
Division of Anesthesia, Analgesia, and Addiction Products (DAAAP)  
Office of Drug Evaluation II (ODE II)  
Office of New Drugs (OND), CDER, FDA

Statistical Review of the PMR Safety Outcome Trial  
Eugenio Andrae-Carrera, PhD  
Reviewer, Division of Biometrics VII  
Office of Translational Sciences (OTS)  
CDER, FDA

Review of Observational Studies of Neuropsychiatric Events Associated With Smoking Cessation Products  
Chih-Ying (Natasha) Pratt, PhD  
Reviewer, Division of Epidemiology  
Office of Surveillance and Epidemiology (OSE)  
CDER, FDA

12:00 p.m.  Clarifying Questions to FDA

12:20 p.m.  LUNCH
AGENDA (cont.)

1:20 p.m.  **OPEN PUBLIC HEARING**

2:20 p.m.  Charge to the Committee  
**Judith A. Racoosin, MD, MPH**

2:30 p.m.  Questions to the Committee/Committee Discussion

3:30 p.m.  **BREAK**

3:45 p.m.  Questions to the Committee/Committee Discussion (cont.)

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