

Agenda: July 19, 2000
Psychopharmacological Drugs Advisory Committee

Holiday Inn, 8120 Wisconsin Avenue, Bethesda, Maryland

NDA 20-825: Zeldox(ziprasidone hydrochloride capsules, Pfizer)

8:00 Call to Order, Introductions

Carol Tamminga, M.D., Chair, PDAC

Conflict of Interest Statement

Sandra Titus, Ph.D., Executive Secretary, PDAC

Welcome

Russell Katz, M.D., Director, Neuropharmacological Drug Products

8:15 Historical Review and Issues for Today's Discussion

Thomas Laughren, M.D., Team Leader, Psychiatric Drug Products Group

8:30 Pfizer Presentations

Safety and Efficacy of Zeldox

Edmund P. Harrigan, M.D., Pfizer Global Research and Development, Executive Director
CNS Therapeutics

Schizophrenia and Unmet Medical Needs

Daniel E. Casey, M.D., Professor of Psychiatry and Neurology, Oregon Health Sciences University, and
Chief of Psychiatry Research Veterans Administration Medical Center

10:00 Break

10:30 FDA Presentations

Introduction

Thomas Laughren, M.D., Team Leader, Psychiatric Drug Products Group

Introductions to QTC Prolongation

Arthur Moss, M.D., Professor of Cardiology, Rochester Medical Center

Antipsychotics

Gregory M. Dubitsky, M.D., Medical Officer, Psychiatric Drug Products Group

Antiarrhythmics and other CV Drugs

Doug Throckmorton, M.D., Medical Officer, Cardio-Renal Drug Products Group

Antihistamines

Badrul Chowdhury, M.D., Ph.D., Acting Medical Team Leader, Pulmonary and Allergy Drug Products

Quinolone Antibiotics

Joyce Korvick, M.D., DSIDP

Cisapride and Compliance with Labeling Advice

Evelyn Rodriguez, M.D., MPH, Director, Division of Drug Risk Evaluation II, Office of Postmarketing
Drug Risk Assessment

12:00 Lunch

1:00 Open Public Hearing

2:00 Committee Discussion

4:30 Adjourn

