

Agenda: May 10, 2002
Psychopharmacological Drugs Advisory Committee
Holiday Inn, Bethesda, Maryland

NDA 21-431: Acamprosate 333 mg tablets (Lipha Pharmaceuticals, Inc.)

8:00 Call to Order, Introductions

Dan Oren, M.D., Acting Chair, PDAC

Conflict of Interest Statement

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

Welcome and Introductory Comments

Cynthia McCormick, M.D., Director, Anesthetic, Critical Care and Addiction Drug Products

8:15 Lipha Presentations

Introduction

Anita M. Goodman, M.D., Executive Vice-President and COO, Lipha

European Development Program and Current Registration Status

Sylvie Chabac, M.D., International Project Manager, MERCK/Lipha s.a.

Acamprosate: Mechanism of Action, Preclinical Effects, & Pharmacokinetic Overview

George F. Koob, Ph.D., Professor, Director Neuropharmacology, Scripps Research Institute

Efficacy Results from 3 Pivotal Clinical Trials

Karl F. Mann, M.D., Department of Addiction Medicine, University of Heidelberg, Germany

Analysis of the US Study Results

Barbara J. Mason, Ph.D., Director, Division of Substance Abuse, U of Miami School of Medicine

Closing Remarks

Anita M. Goodman, M.D.

9:15 Questions from the Committee to Lipha

10:00 Break

10:30 FDA Presentations

Clinical Issues on Efficacy

Celia Winchell, M.D., Medical Team Leader, Anesthetic, Critical Care and Addiction Drug Products

Statistical Perspective of Acamprosate Experience

Sue Jane Wang, Ph.D., Statistics Leader in Alcoholism Treatment Clinical Trials, Office of Biostatistics

11:30 Questions from the Committee to FDA

12:15 Lunch

1:15 Open Public Hearing

Victor Hasselbok, Ph.D., Vice President Research Society on Alcohol

Jonathan Chick, M.D., Co-Director Alcohol Problems Service, Royal Edinburgh Hospital

Steven Mirin, M.D., Medical Director, American Psychiatric Association

Edward Eder, MD, Medical Director, Comprehensive Addiction Treatment Program, Fairfax, VA

J. Virgil Waggoner, Waggoner Center for Alcohol and Addiction Research, University of Texas, Austin

2:00 Charge to the Committee

Cynthia McCormick, M.D.

2:15 Continuation of Discussion

4:30 Time of Adjournment may vary

