

Proposed Agenda: Tuesday, July 20, 1999
Joint Meeting: Nonprescription Drugs and Arthritis Advisory Committees

Food and Drug Administration
Holiday Inn, Gaithersberg, Maryland

8:30 Call to Order, Introductions

Eric P. Brass, M. D., Ph.D., Chair, NDAC, Acting Committee Chair

Conflict of Interest Statement

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

Welcome

John Hyde, M.D., Ph.D., Acting Deputy Director of Anti-Inflammatory, Analgesics and Ophthalmic Drug Products (DAAO)

Issue: Consideration of NDA 21-070, Flexeril 5mg (cyclobenzaprine HCL) Merck

8:45 FDA Presentations

Background and Efficacy

James Witter, M.D., Ph.D., Medical Officer, DAAO

Neurologic Impact

Paul Andreason, M.D., Medical Officer, Neuropharm

Abuse Potential

Michael Klein, Ph.D., Senior Interdisciplinary Scientist, Controlled Substance

Safety

Rosemarie Neuner, M.D., Medical Officer, Over-the-Counter (OTC)

Label Comprehension

Kathryn Aikin, Ph.D. Regulatory Review Officer for OTC, DDMAC

10:00 Break

10:15 Merck Presentations

Introduction

Edwin Hemwall, PhD, Regulatory Affairs, Merck

Review of Flexeril OTC Development Program

Scott Korn, M.D. Clinical Research, Merck

11:30 Questions from Advisory Committees

12:00 Lunch

1:00 Open Public Hearing

2:00 Charge to the Committee

Linda Katz, M.D., M.P.H., Deputy Director of OTC, ODE V

