Agenda October 19, 2000
Nonprescription Drugs Advisory Committee

Food and Drug Administration
Center for Drug Evaluation and Research
Holiday Inn, 2 Montgomery Avenue, Gaithersburg, MD

Safety Issues of Phenylpropanolamine (PPA) in Over-the-Counter Drug Products

8:00 Call to Order, Introductions
Eric Brass, M.D., Chair

Conflict of Interest Statement
Sandra Titus, Ph.D., Executive Secretary, NDAC

8:15 Open Public Hearing (5-10 minute statements)
Brian Strom, M.D., MPH, University of Pennsylvania representing Whitehall Corporation

David E. Schteingart, M.D., University of Michigan representing Chattem

Sidney Wolfe, M.D., Director, Public Citizen's Health Research Group

8:45 Regulatory History of OTC Phenylpropanolamine Hydrochloride
Robert L. Sherman, DOTCDP

9:00 Final Report of the Yale Hemorrhagic Stroke Project (45 minutes)
Walter Kernan, M.D., School of Medicine, Yale

9:45 Questions from the Committee to Yale Hemorrhagic Stroke Project

10:00 Break

10:30 Comments on the Yale Study by the Consumer Healthcare Products Association (45 min)

R. William Soller, Ph.D., Senior Vice President and Director of Science and Technology CHPA

Charles H. Hennekens, M.D., Dr. P.H., University of Miami School of Medicine

Noel S. Weiss, M.D., Dr. P.H., University of Washington

11:15 Questions from the Committee to the Consumer Healthcare Products Association

11:30 FDA Presentations (45 minutes)

Epidemiological Consult on the Yale Study and Recommendations to OTC Division
Lois La Grenade, M.D., M.P.H., Office of Postmarketing Drug Risk Assessment

Summary of Issues
Charles Ganley, M.D., Director, DOTCDP

12:15 Questions from the Committee to FDA

12:30 Lunch

1:30 Discussion by the Committee

4:30 Adjourn