

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)**

Nonprescription Drugs Advisory Committee
Hilton Washington DC North/Gaithersburg
Gaithersburg Maryland
September 25, 2006

The committee will consider issues related to the analysis and interpretation of consumer behavior studies conducted to support marketing of nonprescription drug products.

AGENDA

- 8:00 Call to Order
Introduction of Committee Members
- Eric Brass, MD, PhD**
Acting Chair, Nonprescription Drugs Advisory Committee, NDAC
- Conflict of Interest Statement
- LT Darrell Lyons, BSN**
Designated Federal Official, NDAC
- 8:30 Welcome and Opening Comments
- Andrea Leonard-Segal, MD, Director**
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products, FDA

FDA Presentations:

- 8:50 Health Literacy
- Ruth Parker, MD**
Associate Professor of Medicine
Department of Medicine, Emory University
School of Medicine
Atlanta, GA
- Terry Davis, PhD**
Professor,
Health Science Center-Shreveport
Louisiana State University
Shreveport, LA
- 9:20 Consumer Behavior Studies
- Saul Shiffman, PhD**
Professor,
Department of Psychology
University of Pittsburgh
Pittsburgh, PA
- 9:50 Break
- 10:05 Information Processing
- Ruth Day, PhD**
Director,
Medical Cognition Laboratory and Director,
J.D. /M.A. Program, Duke University

10:35 Statistical Considerations

Ralph D'Agostino, PhD
Professor,
Boston University
Boston, MA

11:05 Complexities of the Rx to OTC Switch

Alastair Wood, MD
Vanderbilt Medical School
Nashville, TN

11:35 Final Questions from the Committee to the Speakers

12:00 Lunch

1:00 Open Public Hearing

2:00 Break

2:15 Committee Questions/Discussion

5:00 Adjourn

MEETING ROSTER

Committee Members:

Ernest B. Clyburn, MD

Jack E. Fincham, PhD

Ruth M. Parker, MD

Robert E. Taylor, MD, PhD

Temporary Voting Members:

Neal Benowitz, MD

Eric P. Brass, MD, PhD

Ralph B. D'Agostino, PhD

Terry C. Davis, PhD

Ruth S. Day, PhD

Marie R. Griffin, MD

Musa J. Mayer, M.S. (Patient Representative)

Richard A. Neill, MD

Wayne R. Snodgrass, MD, PhD

FDA Participants (Non-Voting):

Charles Ganley, MD

Andrea-Leonard Segal, MD

Member (Non-Voting)

George S. Goldstein, MD (Industry Representative)

Consultant (Non-Voting)

Saul Shiffman, PhD (Guest Speaker)

Alastair Wood, MD (Guest Speaker)

Participants List

Consultants (voting)

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Consultants (non-voting)

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Alastair Wood, MD (Guest Speaker)

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Professor of Pharmacology
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