



**AGENDA**  
**Center for Drug Evaluation and Research**  
**Stakeholders Meeting**

**August 17, 1998**  
**9:00 a.m. - 5:00 p.m.**  
**Hubert H. Humphrey Building**  
**Penthouse Conference Room (Room 800)**  
**200 Independence Avenue, S.W.**  
**Washington, DC 20201**

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9:00 Opening Remarks Linda Suydam  
Associate Commissioner for Strategic Management  
U. S. Food and Drug Administration

9:15 Center Director's Message Janet Woodcock, M.D.,  
Director  
Center for Drug Evaluation and Research

10:15 Break

10:30 Panel A John A. Gans, Pharm.D.,  
American Pharmaceutical Association (APhA)  
  
Cynthia T. Culmo, R.Ph.  
Association of Food and Drug Officials  
  
Bert Spilker, Ph.D., M.D.  
Pharmaceutical Research and Manufacturers of America (PhRMA)  
  
Hiroshi Mitsumoto, M.D.  
ALS Association

CDER/FDA Panel Moderator - Nancy Smith  
Janet Woodcock, CDER, Center Director  
Murray Lumpkin, CDER, Deputy Director for Review Management  
Roger Williams, CDER, Deputy Director for Pharmaceutical Science  
Stephanie Gray, CDER, Director, Office of Compliance  
Ralph Lillie, CDER, Acting Director, Division of Pharmacovigilance  
and Epidemiology

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12:00 Lunch

1:15 Panel B Cynthia Pearson  
National Women's Health Network

Mary Rouleau  
Consumer Federation of America

William Ray Bullman, M.A.M.  
National Council on Patient Information Education (NCPPIE)

Charles E. Myers  
American Society of Health-System Pharmacists (ASHP)

CDER/FDA Panel Moderator - Debbie Henderson  
Janet Woodcock, CDER, Center Director  
Robert Temple, CDER, Associate Director for Medical Policy  
Nancy Smith, CDER, Director, Office of Training and Communications  
Minnie Baylor-Henry, CDER, Director, Division of Drug Marketing  
and Advertising  
Steve Goldman, FDA, MedWatch

2:45 Break

3:00 Panel C Arthur A. Levin, M.P.H.  
Center for Medical Consumers

Scott Sanders  
Patients' Coalition

D. Craig Brater, M.D.  
American Society for Clinical Pharmacology and Therapeutics

CDER/FDA Panel Moderator - Roger Williams  
Janet Woodcock, CDER, Center Director  
Murray Lumpkin, CDER, Deputy Director for Review Management  
Stephanie Gray, CDER, Director, Office of Compliance  
Douglas Ellsworth, FDA, Office of Regulatory Affairs  
Bernard Schwetz, FDA, Office of Science

4:30 Open Questions/Wrap-up