

**FOOD AND DRUG ADMINISTRATION**  
**Public Meeting -Voting and Nonvoting Consumer Representative Members**  
**on FDA Advisory Committees and Panels**

Center for Drug Evaluation and Research Advisory Committee Conference Room,  
rm. 1066, 5630 Fishers Lane, Rockville, Maryland

*April 30, 2010*  
*Draft AGENDA*

8:15 a.m. Registration

8:30 a.m. Welcome Jill Hartzler Warner, J.D.  
Associate Commissioner for Special  
Medical Programs (Acting), FDA

Opening Remarks Joshua Sharfstein, M.D.  
Principle Deputy Commissioner, FDA

8:45-10:30

**I. FDA Advisory Committees and the Consumer Representative**

**Moderator** Margaret Miller, Ph.D.  
National Center for Toxicological  
Research, FDA

Overview of FDA Advisory Committee Michael Ortwerth Ph.D.  
Director, Advisory Committee Oversight  
and Management Staff (ACOMS), FDA

Consumer Representative Nomination Process CDR Dornette Spell-LeSane, MSN, NP-C  
Deputy Director, ACOMS

Consumer Representative Nominating Group Lisa McGiffert  
Characteristics of a Consumer Representative Lee Richardson, Ph.D.

Q&A

10:30-10:45 Break

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10:45-11:45

**II. Consumer Representatives and Patient Representatives on FDA Advisory Committees**

**Moderator**

**Carolyn Jeletic**

Center for Food Safety and Applied  
Nutrition, Office of Regulations, Policy and  
Social Sciences, FDA

Importance of Consumer Representatives  
on FDA Advisory Committee and Panels

Peter Lurie, M.D., MPH  
Senior Advisor in the Office of Policy, Planning  
and Budget in the Office of the Commissioner,  
FDA

Role of the Patient Representative

David Banks, R.Ph., Ph.D.  
FDA Office of Special Health Issues

11:45-12noon  
Q&A

12:00-1:00 p.m. Lunch  
(on your own, local restaurants see handout)

1:00-2:30

**Panel Presentation - Consumer Representatives**

**Moderator**

Michael Ortwerth, Ph.D., FDA

Consumer Representatives:

Center for Drugs Evaluation and Research: Diane D. Aronson and Merrill Gozner

Center for Devices and Radiologic Health: Karen Rue

Center for Biologics: Vicky DeBold

2:30 Networking Opportunities for attendees to meet with Designated Federal Officers from the different FDA centers, to discuss vacancies on FDA advisory committees and panels

3:00 Meeting Adjourn