



Food and Drug Administration

**Public Meeting on
The FDA Modernization Act of 1997 [FDAMA]
Section 406(b)**

**September 14, 1998
9:00 a.m. - 1:00 p.m.
Bethesda Holiday Inn
Bethesda, Maryland 20814**

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AGENDA

9:00 - 9:15 a.m. Introductions and Opening Remarks

Moderator: Linda Suydam, Associate Commissioner for Strategic Management, FDA

FDA Panel

- Robert J. Byrd, Deputy Commissioner for Management and Systems
- Sharon Smith Holston, Deputy Commissioner for External Affairs
- Daniel L. Michels, Director, Office of Enforcement, Office of Regulatory Affairs
- Bernard A. Schwetz, DVM, Ph.D., Interim Chief Scientist
- William B. Schultz, Deputy Commissioner for Policy

9:15 - 11:00 a.m. Panel I

- Carl F. Dixon, President and Executive Director, Kidney Cancer Association
- Joshua Javits, Trustee, Amyotrophic Lateral Sclerosis Association
- Robin A. Harrison, Director, Diabetes Consumer Cooperative
- Millicent Gorham, Executive Director, National Black Nurses Association and
Member of the FDA Consumer Consortium
- David Nelson, Senior Director for Special Initiatives, National Mental Health Association
- Diane Griffith, Congressional Liaison, Breast Implant National Support Organizations

*** A 15-minute break will be provided during this panel session*

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11:00 - 12:15

Panel II

- Bert Spilker, Ph.D., M.D., Senior Vice President, Scientific and Regulatory Affairs, PhRMA
- ✓ Stephen J. Northrup, Executive Director, Medical Device Manufacturers Association
- ✓ Susan K. Zagame, Vice President for Technology & Regulatory Affairs, HIMA
- ✓ Kay R. Gregory, MS, MT(ASCP), SBB, Director, Regulatory Affairs
American Association of Blood Banks
- ✓ Jacqueline Eng, Vice President for Policy and Strategic Planning, U.S. Pharmacopeia
- ✓ Andrew Lee, M.H.S., Program Director, The Angiogenesis Foundation

12:15 - 12:45 p.m.

Open Discussion Session

12:45 - 1:00 p.m.

Summation and Closing Remarks

Linda Suydam, Associate Commissioner for Strategic Management, FDA

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