

Food and Drug Administration
Center for Drug Evaluation and Research
**Process Analytical Technologies Subcommittee of the
Advisory Committee for Pharmaceutical Science**

June 12, 13, 2002

Acting Chair

Thomas Layloff, Ph.D.
Principle Program Associate
Center for Pharmaceutical Management
Management Sciences for Health
5 Thomas Court
Granite City, IL 62040-0286

Executive Secretary, Acting

Kathleen Reedy, RDH, MS
Advisors and Consultants Staff
Center for Drug Evaluation and Research
Food and Drug Administration (HFD-21)
5600 Fishers Lane
Rockville, MD 20857
(301) 827-7001 Fax: (301) 827-6776

Members

Gloria L. Anderson, Ph.D. 10/31/02
Consumer Representative
Fuller E. Callaway Professor of
Chemistry
Morris Brown College
643 Martin Luther King Jr. Drive, NW
Atlanta, GA 30314-4140

Judy P. Boehlert, Ph.D. 10/31/02
President, Boehlert Associates, Inc.
102 Oak Avenue
Park Ridge, NJ 07656-1325

Arthur H. Kibbe, Ph.D. 10/31/04
Professor and Chairman
Dept of Pharmaceutical Sciences
Nesbitt School of Pharmacy
Wilkes University
170 S. Franklin St.
Wilkes-Barre, PA 18766

SGE Consultants

Melvin V. Koch, Ph.D., Director, CPAC
University of Washington
Room 141 CHL, Box 351700
Seattle, WA 98195-1700

Robert A. Lodder, Ph.D., Associate Professor
University of Kentucky College of Pharmacy
A-123, Astec, 907 Rose Street
Lexington, KY 40506-0286

G.K. Raju, Ph.D.
Executive Director, MIT/PHARMI
MIT Program on the Pharmaceutical Industry
Massachusetts Institute of Technology,
77 Massachusetts Avenue,
Cambridge, MA 02139

Guests/Speakers Participants

Eva M. Sevick-Muraca, Ph.D.
Professor
Dept. of Chemical Engineering
Texas A&M University
337 Zachry Engineering Center
College Station, TX 77843-3122

Leon Lachman, Ph.D., President
Lachman Consulting
1600 Stewart Avenue
Westbury, NY 11590

Emil Walter Ciurczak, Ph.D.
77 Park Road
Golden's Bridge, NY 10526

Kenneth R. Morris, Ph.D.
Associate Department Head
Department of Industrial and Physical
Pharmacy
Purdue University
1336 Robert E. Heine Pharmacy Bldg
West Lafayette, IN 47907-13306

Howard Mark, Ph.D
Mark Electronics
21 Terrace Street
Suffern, NY 10901

Industry Guests/Participants

Efraim Shek, Ph.D.
Divisional Vice President,
Pharmaceutical and Analytical Research
and Development
Abbott Laboratories
Dept. 04R-1, Building NCA4-4
1401 Sheridan Road
North Chicago, IL

Ronald W. Miller, Ph.D.
Associate Director of Pharmaceutical
Technology & Development
Bristol-Myers Squibb
One Squibb Drive
Building 107, Second floor
New Brunswick, NJ 08903-0191

David Richard Rudd, Ph.D.
Analytical Manager
GlaxoSmithKline Research and Development
Building 5, Park Road
Ware, Hertfordshire SG12 0DP
United Kingdom

Rick E. Cooley
Engineering Consultant
Eli Lilly and Company
Measurement Technology Group
Corporate Center
Indianapolis, IN 46285

Colin Walters
Senior Engineer
Pharmaceutical Process Development
Schering Plough Research Institute
2000 Galloping Hill Road, K-2-1, F31A
Pharmaceutical Development
Kenilworth, NJ 07033

Doug Dean, Ph.D.
Global Pharmaceutical Sector Team
PricewaterhouseCoopers Consulting
St. Jakobs-Strasse 25
Ch-4002 Basel
Switzerland

John G. Shabushnig, Ph.D.
Business Unit Director,
Center for Advanced Sterile Technology
Pharmacia Corporation
7171 Portage Road
Kalamazoo, MI 49001

Jerome Workman, Jr., M.A., Ph.D., FAIC,
CChem, FRSC
Senior Research Fellow
Analytical Science & Technology
Kimberly-Clark Corp.
2100 Winchester Road
Neenah, WI 54956

Jozef H. M. T. Timmermans, Ph.D.
Manager, Pharmaceutical Technical
Operations
Merck and Company, Inc.
Sumneytown Pike
Mailstop: WP762M-1
West Point, PA 19486

Robert S. Chisholm
International Technology Manager
AstraZeneca International
Alderley House
Alderley Park
Macclesfield
Cheshire SK10 4TF
United Kingdom

John C. James, Ph.D.
Executive Director
Analytical Research and Development
Teva Pharmaceuticals USA
1090 Horsham Road
PO Box 1090
North Wales, PA 19454-1090

FDA Participants

Helen N. Winkle
Acting Director
Office of Pharmaceutical Science, HFD-003

Ajaz S. Hussain, Ph.D.
Deputy Director,
Office of Pharmaceutical Science, HFD-003

Yuan-yuan Chiu, Ph.D.
Director
Office of New Drug Chemistry, HFD-800

Joseph Famulare
Director
Division of Manufacturing and Product
Quality
Office of Compliance, HFD-320

Douglas I. Ellsworth
District Director, NJ District
Office of Regulatory Affairs, Central Region,
HFR-CE300

Moheb M. Nasr, Ph.D.
Director
Division of Pharmaceutical Analysis
Office of Testing and Research, HFD-920

Michael C. Olson
Director
Division of Field Science
Office of Regional Operations
Office of Regulatory Affairs, HFC-140

Frank O. Holcombe Jr., Ph.D.
Associate Director for Chemistry
Office of Generic Drugs, HFD-600