

Agenda Day 1

FDA - OTC Part 15 Hearing June 28, 2000

Holiday Inn, Gaithersburg, MD

8:30am Opening Remarks
Robert DeLap M.D., Office of Drug Evaluation V Director, CDER

SESSION 1A: PROCESS ISSUES

8:45am Consumer Healthcare Products Association
Michael D. Maves, M.D., M.B.A., President
Eve E. Bachrach, Esq. Senior Vice President, General Counsel and Secretary
R. William Soller, Ph.D. Senior Vice President & Director of Science & Technology

9:10 The Cosmetic, Toiletry, and Fragrance Association
Thomas J. Donegan, Jr., Vice President – Legal and General Counsel, CTFA
James Leyden, M.D., University of Pennsylvania School of Medicine

9:30am Francesco International
Steve Francesco, President and Founder

9:50am National Consumers League
Linda Golodner, President
Brett Kay, Program Associate, Health Policy

10:10am – 10:25am Break

10:25am RxHealth Value
Mark Cloutier, MPP, MPH, Project Director

10:40am Buchanan Ingersoll, Attorneys at Law
Robert G. Pinco and Mary Johnson

10:55am Steinberg and Associates, Inc
David C. Steinberg

11:10am American Pharmaceutical Association
John A. Gans, PharmD, Executive Vice President

11:25am National Community Pharmacists Association
Doug Hoey, Vice President Professional and Practice Affairs

11:40am Becton, Dickinson and Company
BD Consumer Healthcare
Anna M. Longwell, Esq., Director, Corporate Regulatory Affairs

1:55 – 1:25pm Lunch

SESSION 1B: PROCESS ISSUES

- 1:30pm** **Public Citizen’s Health Research Group**
Larry D. Sasich, Pharm.D., MPH, FASHP
- 1:40pm** **MedImpact**
Schumarry Chao, M.D., MBA
- 1:50pm** **PEGUS Research**
David C. Bradford, Ph.D., MPH, Dept. of Family and Preventive Medicine
University of Utah School of Medicine
- 2:00pm** **National Women’s Health Network**
Amy Alhna, Program and Policy Director
- 2:10pm** **Whitehall Robins**
Roger Berlin, M.D.
- 2:20pm** **Bristol Myers Squibb**
Alan R. Bennett, Bennett, Turner and Coleman, LLP
- 2:30pm** **Pharmaceutical Research and Manufacturers of America**
Matthew Van Hook, Deputy General Counsel, PHRMA
- 2:40pm** **Peter Barton Hutt**
- 2:50pm – 3:05pm** **Break (15 minutes)**
- 3:05pm** **Smith Kline Beecham**
John Dent, Ph.D., Vice President of Research and Development
- 3:15pm** **Ammsys Research, Inc.**
Gerald F. Dunnaway, Ph.D., President

SESSION 2: MISCELLANEOUS

- 3:20pm** **Infectious Disease Society of America (IDSA)**
Frederick P. Sparling, M.D., Chairman, IDSA
- 3:30pm** **Cholestech Corporation**
Warren E. Pinchert II, President and Chief Executive Officer
- 3:40pm** **American Academy of Allergy Asthma and Immunology**
Fellow and Board Member AAAAI
- 3:50pm** **Chris Kahlenborn, M.D.**
- 4:00pm** **Saint Louis University**
Jerome D. Cohen, FACC
- 4:10pm** **Kaiser Permanente**
Anthony Barrueta, Counsel, Government Relations

Agenda Day 2

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SESSION 3: ORAL CONTRACEPTIVES

- 8:30am American Life League, Inc.
Judie Brown, President
- 8:35am Why Life?
Cathy Brown, Director
- 8:40am American Bioethics Advisory Commission
Father Joseph C. Howard, Jr., M.Div.
- 8:45am Rosalie M. Gross

SESSION 4: EMERGENCY CONTRACEPTIVES

- 8:50am Reproductive Health Technologies Project
Kirsten Moore, Project Director
- 8:55am Gynetics Inc.
Jack E. Stover, Chief Operating and Financial Officer
- 9:00am American Society for Emergency Contraception
Tara Shochet, MPH, Deputy Director
- 9:05am Population Council
Beverly Winikoff, M.D., M.P.H.
- 9:10am NARAL
Elizabeth A. Carendish, Legal Director
- 9:15am American College of Obstetricians and Gynecologists
Michael Greene, M.D.
- 9:20am Family Health International
Elizabeth Raymond

SESSION 5: CARDIOLOGY – VASCULAR DRUG CLASS ISSUES

- 9:30am Lipid Nurse Task Force
Kathy Berra, MSN, ANP, Clinical Trial Director
Stanford Center for Research in Disease Prevention
- 9:40am National Council of Negro Women
Patricia Brantley, Chief Development Officer
- 9:50am Merck Research Laboratories
Jeffrey L. Anderson, M.D., Chief, Division of Cardiology
Professor of Internal Medicine, University of Utah School of Medicine
- 10:00am – 10:15am Break

- 10:20am Bristol Myers Squibb
Lorie G. Rice, MPH, UCSF School of Pharmacy
- 10:30am Association of Black Cardiologists, Inc.
B. Wayne Kong, Ph.D., JD, Chief Executive Officer
- 10:40am Heeger and Barnett, LLP
Bruce Philip Barnett, M.D. and Mr. Calabio
- 10:50am American College of Cardiology
Alan N. Yaunt, J.D. . Assistant Director, Regulatory and Legal Affairs

SESSION 6: ANTI-MICROBIALS AND ANTIBIOTIC ISSUES

- 11:00am Alliance for the Prudent Use of Antibiotics
Kathleen T. Young, Executive Director APUA
- 11:10am Alliance for Microbicide Development
Gretchen F. Kidder, Alliance Research Associate
- 11:20am ReProtect, LLC
Thomas R. Moench, M.D., Medical Director
- 11:30am EPIcyte Pharmaceutical, Inc.
Kevin J. Whaley, Ph.D., Director
- 11:40am – 1:05pm Lunch

SESSION 7: ALLERGY AND ASTHMA DRUG ISSUES

- 1:10pm Allergy and Asthma Network
Mothers of Asthmatics, Inc.
Nancy Sander, President and Founder
- 1:20pm Linda Borschuk
Patient Advocate
- 1:30pm Blue Cross of California/ Well Point Health Networks
Robert C. Seidman, PharmD, MPH, Vice President, Pharmacy

SESSION 8: LABEL COMPREHENSION ISSUES

- 1:40pm Q2 Marketing Research, Inc.
Stephen J. Hellebusch, Ph.D.
- 1:50pm Hill Top Research
Susan Shellabarger, Senior Director, Business Development, OTC Products

SESSION 9 PROCESS ISSUES

- 2:00pm Blue Cross Blue Shield Association
Allan Korn, M.D., Senior Vice President Clinical Affairs and Chief Medical Officer
- 2:10pm CHPA
Randy P. Juhl, Ph.D. University of Pittsburgh, Dean and Professor, School of Pharmacy & Associate Vice Chancellor for Research Conduct

2:20pm - 2:35pm

Break

SESSION 10: OPEN PUBLIC

2:35pm – 4:00pm

Please register at the front desk if you are interested in speaking at this session.