PUBLIC MEETING ON THE USE OF OZONE-DEPLETING SUBSTANCES; REMOVAL OF ESSENTIAL-USE DESIGNATIONS

Thursday, August 2, 2007
9:00 a.m. to 3:30 p.m.

Food and Drug Administration
Center for Drug Evaluation and Research
Advisory Committee Conference Room 1066
5630 Fishers Lane
Rockville, MD 20852

AGENDA AND SCHEDULE

9:00 a.m. – 9:30 a.m.	Welcoming Remarks FDA's NPRM on Removing the Essential-Use Designations of 7 Marketed "Moieties" **Robert Meyer, M.D.** Food and Drug Administration Center for Drug Evaluation and Research Director, Office of Drug Evaluation II
9:30 a.m. – 9:45 a.m.	Comments by Allergy and Asthma Network Mothers of Asthmatics **Nancy Sander** President **Sandra J. Fusco-Walker** Director, Government Affairs
9:45 a.m. – 9:55 a.m.	Comments by the International Pharmaceutical Aerosol Consortium on the Proposed Rule **Peter Blenkinsop** Secretary and Legal Counsel International Pharmaceutical Aerosol Consortium
9:55 a.m. – 10:10 a.m.	How FDA's Proposed Changes to the Essential-Use List Will Impact My Patients **Joseph A. Bellanti, M.D.** Professor of Pediatric and Microbiology-Immunology Director, Immunology Center Georgetown University Medical Center
10:10 a.m. – 10:20 a.m.	**Discussion**

10:20 a.m. – 10:35 a.m.	AARC Comments Regarding Patient Compliance, Safety and Access in Consideration of Essential Drug Designation **Miriam O'Day** Legislative Affairs, American Association for Respiratory Care
10:35 a.m. – 10:40 a.m.	Extending Essential-Use for Combivent **Vlady Rozenbaum, Ph.D.** Founder and Moderator of the Online Patient Support Network COPD Alert
10:40 a.m. – 10:45 a.m.	Use of Ozone-Depleting Substances; Removal of Essential-Use Designation **John W. Walsh** President and CEO, COPD Foundation Alpha-1 Foundation
10:45 a.m. – 10:55 a.m.	**BREAK**
10:55 a.m. – 11:10 a.m.	Maintenance of Essential-Use of CFC Metered Dose Ipratropium Bromide and Albuterol Sulfate in Combination: Ensuring Continued Patient Access to Combivent **Barbara Rogers** President and CEO, National Emphysema/COPD Association
11:10 a.m. – 11:15 a.m.	Patient Need, Compliance and Environmental Protection **Bruce P. Imbruce, Ph.D.** Director, National Emphysema Foundation
11:15 a.m. – 12:15 p.m.	**Boehringer Ingelheim Pharmaceuticals** Introduction **Dr. Thor Voigt** Senior Vice President Medicine/DRA Boehringer Ingelheim's Comments on the Proposed Rule **Dr. Steven Kesten** Corporate Medical Affairs – Respiratory
12:15 p.m. – 1:15 p.m.	**LUNCH**

1:15 p.m. – 1:25 p.m.	A Petition for the Continued Availability of CFC Combivent **Nicholas J. Gross, M.D., Ph.D.** Professor of Medical and Molecular Biochemistry Loyola University Medical Center
1:25 p.m. – 1:45 p.m.	**Discussion**
1:45 p.m. – 1:50 p.m.	Personal Experiences with Maxair Metered Dose Inhaler **Charles A. Martin, PA-C** Instructor in Surgical Services/Ophthalmology Wake Forest University Health Services
1:50 p.m. – 1:55 p.m.	Personal Experiences with Maxair Metered Dose Inhaler **Meg Griffiths** Patient
1:55 p.m. – 2:55 p.m.	**Graceway Pharmaceuticals** Essential-Use Designation: Breath-Actuated Pirbuterol Acetate Inhalation Aerosol **James Lee, M.D., Ph.D.** Chief Medical Officer **Sharon Levy, M.D.** Vice President, Clinical Development **Michael E. Weschsler, M.D., MMSc** Associate Director, Brigham and Women's Hospital **Clifford W. Bassett, M.D., FAAAI, FACAAI** Vice Chair, Public Education Committee, American Academy of Allergy, Asthma, and Immunology **James V. Heck, Ph.D.** Medicinal Chemistry Consultant Former Vice-President, Merck Research Laboratories
2:55 p.m. – 3:05 p.m.	**Discussion**

3:05 p.m. – 3:15 p.m.	Use of Ozone-Depleting Substances; Removal of Essential-Use Designations – Statement of Abbott Laboratories **Rita Jain, M.D.** Divisional Vice-President for Pain, Respiratory, and Metabolic Disease Drug Development
3:15 p.m. – 3:20 p.m.	**Discussion**
3:20 p.m. – 3:30 p.m.	Closing Remarks **Robert Meyer, M.D.** Food and Drug Administration Center for Drug Evaluation and Research Director, Office of Drug Evaluation II