PUBLIC MEETING ON USE OF OZONE-DEPLETING SUBSTANCES
REMOVAL OF ESSENTIAL-USE DESIGNATION (EPINEPHRINE)
Food and Drug Administration
Center for Drug Evaluation and Research
Advisory Committee Conference Room 10666
5630 Fishers Lane
Rockville, MD 20852
Wednesday, December 5, 2007
9:00 a.m. to 11:30 a.m.

AGENDA AND SCHEDULE

9:00 a.m. – 9:15 a.m.	Welcoming Remarks FDA's NPRM on Removal of Essential-Use Designation of Epinephrine **Charles Ganley, M.D.** Food and Drug Administration Center for Drug Evaluation and Research Director, Office of Nonprescription Drug Products
9:15 a.m. – 9:30 a.m.	**Robert M. Sussman** Counsel for Amphastar Pharmaceuticals, Inc. & Armstrong Pharmaceuticals, Inc. Latham Watkins, LLP
9:30 a.m. – 9:45 a.m.	**Discussion**
9:45 a.m. – 10:00 a.m.	**Nancy Sander**, President **Sandra J. Fusco-Walker,** Director, Government Affairs Allergy and Asthma Network Mothers of Asthmatics
10:00 a.m. – 10:15 a.m.	**Discussion**
10:15 a.m. – 10:45 a.m.	**Open Comment & Discussion Period**
10:45 a.m. – 11:00 a.m.	Closing Remarks **Charles Ganley, M.D.** Food and Drug Administration Center for Drug Evaluation and Research Director, Office of Nonprescription Drug Products

Panel Members:
Kirsten Cappel, Environmental Protection Specialist, Office of Atmospheric Programs, Stratospheric Protection Division, EPA
Badrul Chowdhury, Director, Division of Pulmonary & Allergy Drug Products, CDER, FDA
Charles Ganley, Director, Office of Nonprescription Drug Product, CDER, FDA
Wayne Mitchell, Regulatory Counsel, Office of Regulatory Policy, CDER, FDA
Clark Nardinelli, Supervisory Industry Economist, Office of Policy & Legislation, FDA
Martha Nguyen, Regulatory Counsel, Office of Regulatory Policy, CDER, FDA