

FDA and U.S. Small Business Administration Educational Forum for Small
Pharmaceutical Businesses
Washington, D.C. April 25, 2006

AGENDA

- 8:00 -- 8:30 AM Registration
- 8:30 -- 8:45 AM Introduction by John A Friel, J.D, Deputy Director, Office of Training and Communication, Center for Drug Evaluation and Research (CDER)
- 8:45 -- 9:30 AM U.S.Small Business Administration, Ellen M. Thrasher, Associate Administrator for Business and Community Initiatives
- 9:30 -- 10:00 AM *The Grant Program for Small Businesses at the National Institutes of Health*
by Kathleen Shino, Office of Extramural Programs, National Institutes of Health
- 10:00 -- 10:45 AM *Planning for Successful, Efficient, Pharmaceutical Product Approval*
by Kim Colangelo, Associate Director for Regulatory Affairs, Office of New Drugs, CDER
- 10:45 -- 11:00 AM Break
- 11:00 -- 11:45 AM *Utilizing the OTC Regulatory Process for Marketing of OTC Drugs* by Susan Johnson, Associate Director, Office of Nonprescription Products, CDER
- 11:45 -- 12:30 PM *Key Issues in the Marketing of Generic Drugs* by Ted Sherwood, Special Assistant to the Director, Office of Pharmaceutical Science, CDER
- 12:30 -- 1:30 PM Lunch (on your own)
- 1:30 -- 2:15 PM U.S. Small Business Administration, Jihoon Kim, Director, 504 Loan and Secondary Markets Programs
- 2:15 -- 3:00 PM *Mastering Regulatory Compliance* by Thomas Arista, National Expert, Office of Regulatory Affairs, Division of Field Investigations, Food and Drug Administration (FDA)
- 3:00 -- 3:30 PM Break
- 3:30 -- 4:00 PM *Financial Incentives for Small Businesses* by Ron Wilson, Director of Small Business Assistance, CDER
- 4:00 -- 4:30 PM *The ORA Small Business Representative Program* by Marie Falcone, Office of Regulatory Affairs, Central Region Small Business Representative, FDA
- 4:30--5:00 PM *Question & Answer Session*