

FDA/Small Business Administrations Drug Educational Forum; Public Workshop
April 25, 2007

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 *Programs of the United States Small Business Administration (SBA)* by Jane Boorman, Manager of the Score Program and Director of international Visitors at SBA
- 9:30 -- 10:30 AM *Planning for Successful, Efficient, Pharmaceutical Product Approval* by Kim Colangelo, Associate Director for Regulatory Affairs, Office of New Drugs, CDER
- 10:30 -- 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
- 1:30 -- 2:15 PM *Mastering Regulatory Compliance* by Patricia Alcock, Deputy Director, Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs
- 2:15 -- 3:00 PM *Utilizing the Program of the National Institute of Standards and Technology(NIST) for Small Businesses* ,Paul Vinikoor, Manager of the Potomac Region of the Maryland Technology Extension (NIST)
- 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*