

FDA Small Pharmaceutical Business Educational Forum; Public Workshop
April 29, 2008

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 Olious D. Evans, Deputy Regional Food and Drug Director, Southwest Region, FDA
- 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 Walter Ellenberg, Ph.D. Senior Project Manager, Division of Nonprescription Regulation Development, 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 Tom Arista, Office of Regulatory Affairs
- 2:15 -- 3:00 PM Mark Langford, Associate Director, North Texas Small Business Development Center Network
- 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 David Arvelo, Office of Regulatory Affairs, Southwest Region Small Business Representative, FDA
- 4:30--5:00 PM *Question & Answer Session*