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

The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER), Small Business Assistance, is announcing a public workshop. The workshop is to provide information to small pharmaceutical businesses about FDA's premarket requirements; good manufacturing practices; OTC and generic drug issues.

- Date and Time: The public workshop will be held on April 29, 2008 from 8:00 a.m. to 5:00 p.m in Dallas Texas. There is no registration fee.

  The event will be at the Auditorium of the Risk Management Small Business Development Center, located inside the Bill Priest Campus of the El Centro College - Bill Priest Campus of the Dallas County Community College District. The address is 1402 Corinth in Dallas. Directions and maps are available at http://www.dcccd.edu/About+DCCCD/Our+Locations/El+Centro/directionsECCBPI.htm. While there are no hotels associated with this venue or our event, most hotels in Downtown Dallas should be able to transport their guests to the venue with their hotel shuttle or an inexpensive cab ride.

- Registration is open now. To register, call Saira Roberts at 214-860-5887. Space is limited to 150 participants. We appreciate advance notice of cancellations or replacements. Registration on the day of the event may be possible on a space availability basis. For more information, call Saira Roberts at 214-860-5887 or David Arvelo at 214-253-4952 or david.arvelo@fda.hhs.gov.

Additional Information: The purpose of the public workshop is to provide small pharmaceutical businesses with firsthand knowledge of FDA's requirements and compliance policies for marketing drug products. Information will also be provided on current issues with the-over-counter (OTC), generic and new drug programs.

Topics to be discussed at the workshop include the following:

- Planning for successful, efficient pharmaceutical product approval
- Current challenges and concerns for generic abbreviated new drugs applications (ANDAs)
- Regulatory aspects and challenges in the development of over- the-counter (OTC) drugs
- Mastering regulatory compliance

- Financial incentives and assistance provided by FDA and National Institutes of Health (NIH) for the development of new drug products
- FDA's Small Business Assistance Program