FDA Small Pharmaceutical Business Assistance Educational Forum
Public Workshop April 23, 2009

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 23, 2009 from 8:00 a.m. to 5:00 p.m in Jamaica, NY. There is no registration fee.

The event will be at the Food and Drug Administration, Atrium Conference Room, 158-15 Liberty Ave. Jamaica, NY 11433.

- Registration is open now. To register or for more information, call Ms. Odinga Charles (718) 662-5622 or the Small Business Representative, Marilyn Rodriguez-Bohorquez (718) 662-5618. marilyn.bohorquez@fda.hhs.gov. We appreciate advance notice of cancellations or replacements.

- 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