May 11, 2005
Wednesday

All Day

FDA Drug Educational Workshop -- Kansas City Health Department Auditorium, 2400 Troost
This venue holds about 110 people. The seats are in stadium/classroom setting. The facility has state of the art presentation capabilities. You can bring your presentation in diskette, CD-ROM or USB drive.

Hotel Recommendations:

- Hyatt Hotels & Resorts, 2345 McGee St, Kansas City, MO 64108, (816) 421-1234
  This is the one recommended to all speakers.
- Westin Hotels & Resorts, 1 E Pershing Rd, Kansas City, MO 64108, (816) 474-4400

Lodging Rate: $98 per day max.

M&IE Rate: $47 per day

Airport: Kansas City International Airport (MCI)

8:00 AM - 8:30 AM **Registration**

8:30 AM - 9:00 AM **Introduction -- David Arvelo, Small Business Representative**

- Introductions
- Housekeeping
- Brief presentation about the ORA Small Business Representative Program

9:00 AM - 10:00 AM **Planning for Successful, Efficient, Pharmaceutical Product Approval -- Kim Colangelo, Associate Director for Regulatory Affairs, CDER Office of New Drugs**

- Bringing a Product to Market with Proper Protocol Design and the Pre-IND meeting with FDA
- Communication with the Agency throughout the Drug Development Process.
- Success in bringing a drug to market depends on factors that must be addressed long before initiating clinical trials
- Establishing Good Rapport between FDA and Industry to Achieve Results

10:00 AM - 10:15 AM **Break**

10:15 AM - 11:00 AM **Current Challenges and Concerns for Generic ANDA's -- Martin Shimer, Branch Chief, Regulatory Support Branch, Division of Labeling and Program Support, CDER Office of Generic Drugs**

11:00 AM - 12:15 PM **Lunch on your own -- Truman Medical Center Cafeteria**
This place is just across the street and withing walking distance. The cafeteria is willing to provide group discounts to those attending. Each person has to pay for their own meal. The facility will attempt to provide a separate room for the group, if possible, in their facility. This lunch period should be sufficient for getting there, eating, interacting and returning.

12:15 PM - 1:00 PM **Regulatory Aspects and Challenges in the Development of OTC Drugs -- David Hilfiker, Supervisory Project Manager, Division of Over-The-Counter Drug Products, CDER Office of Drug Evalualtion**

1:00 PM - 1:45 PM **The Basics of Chemistry, Manufacturing and Control -- Ramnarayan Randad, Chemist, Division of Chemistry, CDER Office of Generic Drugs**

1:45 PM - 2:00 PM **Break**

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2:00 PM - 2:45 PM **FDA 483 Issues -- John Thorsky, Director Investigations Branch, ORA Kansas City District**
Presentation on the top regulatory issues reported in 483's and Warning Letters. This should peak their interest in the next presentation.

2:45 PM - 3:45 PM **Mastering Regulatory Compliance -- Thomas Arista, National Expert, ORA Division of Field Investigations**

- An introduction and overview to the drug cGMP's.
- The presentation should convey key recommendations that will enable small businesses to effectively master regulatory compliance.
- It should include the "Risk-Based Approach to cGMP Initiatives"

3:45 PM - 4:00 PM **Incentives for Small Businesses -- Ron Wilson, Director, CDER Small Business Assistance**
Should include highlights of the Orphan Product Development Program and its incentives. This time slot can be extended if needed.