Regulatory Education for Industry (REdI): GENERIC DRUGS FORUM

Sheraton | Silver Spring, MD | April 22-23, 2015

April 23, 2015

Today's program will begin at:
8:20 AM (Eastern – UTC-4h)

Regulatory Education for Industry (REdI): GENERIC DRUGS FORUM

Sheraton | Silver Spring, MD | April 22-23, 2015

Welcome

Renu Lal, Pharm.D.
Consumer Safety Officer
Division of Drug Information (DDI)
Office of Communications (OCOMM)
Center for Drug Evaluation and Research

Regulatory Education for Industry (REdI):
GENERIC DRUGS FORUM

Sheraton | Silver Spring, MD | April 22-23, 2015

Stability Recommendations for Filing Acceptance

Johnny Young, M.A.
OGD/ORO/Division of Filing Review, Acting Director

Dates

- **Pre-June 20, 2014**
- **Post-June 20, 2014**
- **Date of Original ANDA Submission is key!**

API Lots

2 API Lots should be used to manufacture exhibit batches

Exhibit Batches

- 3 exhibit batches for each strength
- May bracket or matrix
- Common granulation or justification

Stability Data

- From batch(es) used for BE studies
- 6 months' worth of data
- 3 time points (0, 3, 6)
- Intermediate data (if needed)

Orientation

For certain dosage forms, use the worst-case orientation, at minimum.

Manufacturing Threshold

100K across all three batches, per strength

References (Guidances)

- ***ANDA Submissions—Refuse-to-Receive Standards***
- ***Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products***
- ***ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers***

Questions?

Evaluation: surveymonkey.com/s/GDF-D2S2