CHICAGOLAND PHARMACEUTICAL DISCUSSION GROUP

Affiliated with the American Association of Pharmaceutical Scientists

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PROGRAM: BIOEQUIVALENCE STUDIES UPON SUPAC CHANGES FOR GENERIC DRUGS

DATE: THURSDAY, OCTOBER 19, 2017

SPEAKER: DR. BING LI – FDA

Bioequivalence (BE) studies focus on demonstration of absence of difference in rate and extent between two products in the body. It serves as a major component in evaluating therapeutic equivalence (TE). TE products are expected to have the same safety and efficacy profiles, when administered under the conditions listed in the product labeling. For generic drugs, BE studies confirm the clinical equivalence between the generic and reference products. For new drugs, BE studies verify the clinical equivalence between different formulations and sometimes between different strengths. This presentation focuses on the scientific and regulatory considerations for establishing BE of generic drug products. The approaches to determine BE, and BE recommendations upon various Scale-Up and Post-approval Changes (SUPAC) will be discussed. Case studies will also be elaborated.

Dr. Bing Li serves as the Director in the Division of Bioequivalence I, Office of Generic Drugs, Center of Drug Evaluation and Research, FDA. Her responsibility is to direct and oversee the work of professionals in reviewing drug product bioequivalence studies submitted in Abbreviated New Drug Applications (ANDAs), develop guidelines, plan and manage the regulatory review operations. Prior to joining FDA in 2004, she was a Research Investigator at Bristol-Myer-Squibb where her responsibilities included formulation identification, development and optimization for oral solid dosage form formulations. Dr. Li is an expert pharmacologist at FDA in the area of bioequivalence of aerosolized drug products and editor for book “FDA Bioequivalence Standard”. She has published over 50 papers, meeting abstracts, book chapters, and patents, and has been invited to present at various national and international conferences. Dr. Li is the winner of numerous awards including Thomas Edison Invention Award, AAPS Outstanding Contributed Paper for Regulatory Sciences Awards, National Institute of Health Biotechnology Award, Bristol-Myers Squibb Triumph Award, FDA Center Director’s Special Citation Award and FDA Regulatory Science Excellence Award. She received her Ph.D. in Pharmaceutical Sciences from University of Wisconsin at Madison in 2001, and a bachelor degree in Medical Chemistry in 1990 in Beijing University, China.

TIME: 5:30 PM – SOCIAL HOUR
6:00 PM – DINNER
7:00 PM – MEETING
PLACE: CROWN PLAZA NORTHBROOK
2875 N. MILWAUKEE AVE.
COST: $40.00

REGISTER AT CPDGmeeting@yahoo.com

THE DINNER MEAL CHOICES ARE THE FOLLOWING:

1. ATLANTIC SALMON WITH BÉARNAISE SAUCE PREPARED DAIRY-FREE AND GLUTEN-FREE
2. CHICKEN MARSALA
3. CHEESE RAVIOLI IN PESTO SAUCE (VEGETARIAN)

WHEN REGISTERING, PLEASE INDICATE YOUR SELECTED DINNER MEAL:

Meal Choice: Fish, Chicken or Vegetarian	First Name	Sur (Last) Name	Company

MAIL CONFIRMATION WILL BE SENT
CPDG ACCEPTS CASH AND CHECKS (PERSONAL OR COMPANY) ONLY!!!
STUDENTS FREE RETIREE-REGISTRATION 50% DISCOUNTED
PLEASE MAKE RESERVATIONS EARLY NO-SHOWS WILL BE BILLED ACCORDINGLY
MORE INFORMATION CAN BE FOUND ON THE AAPS WEBPAGE:
http://www.aaps.org/Chicagoland/

Firm Registration Deadline of 12:00 p.m., Tuesday, October 17, 2017

DIRECTIONS TO THE OCTOBER 19, 2017, CPDG MEETING AT CROWN PLAZA NORTHBROOK
2875 N. MILWAUKEE AVE, NORTHBROOK, IL

- **EXIT I-294 AT WILLOW RD.**
- **WEST 0.5 MILES TO SANDERS ROAD**
- **SOUTH 0.6 MILES TO WINKELMAN ROAD**
- **WEST 0.4 MILES TO THE CROWN PLAZ NORTHBROOK**