AAPS WORKSHOP

Co-sponsored with PQRI and FIP

Challenges and Opportunities in Establishing Scientific and Regulatory Standards for Assuring Therapeutic Equivalence of Modified Release Product

October 1-2, 2009 ● Bethesda, MD

Background

Modified release (MR) drug products are complex dosage forms designed to release drug in a controlled manner to achieve desired efficacy and safety profiles. With continued advances in pharmaceutical science and technology, modern technological process for controlled release is leveraged extensively to achieve optimal target product profiles via novel MR dosage forms and drug delivery systems. Upon expiry of patent exclusivity of such products, generic versions are introduced in the market based on the evidence of bioequivalence to the reference listed drugs (innovator products). Demonstration of bioequivalence between drug products can be made using blood level measurements, pharmacodynamic studies, clinical trials, and/or *in vitro* studies. The U.S. regulations deem drug products therapeutic equivalents if they are both pharmaceutically equivalent and bioequivalent.

Inadequate control of drug release from such products may result in reduced efficacy or increased toxicity. In this regard, there were incidences of dose dumping due to product failure or triggered by the extrinsic factors such as heat. There were also concerns about possible therapeutic inequivalence between controlled release formulations. Given the unique feature and complexity of these products, challenges have been presented to industry and regulatory scientists in ensuring pharmaceutical equivalence, bioequivalence, and therapeutic equivalence.

Goals and Objectives

- Review current regulations/regulatory guidance and industry practices for demonstrating pharmaceutical equivalence, bioequivalence, and therapeutic equivalence of modified release (MR) products;
- review advances in pharmaceutical science and technology for MR dosage forms and assess their potential impacts on the establishment of scientific and regulatory approaches to evaluating therapeutic equivalence of these products;

continued

Detailed program information will be available at:

www.aapspharmaceutica.com/modifiedreleaseproduct

Call 1 *877- 998-AAPS* or email *meetings@aaps.org* for more information.

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- examine current and emerging issues regarding equivalence determination of MR formulations, and provide systematic analyses for problem-solving;
- elucidate critical factors governing MR product performance *in vivo* and consider innovative approaches for demonstrating or supporting therapeutic equivalence of these products; and
- identify the critical paths to establishing scientific and regulatory standards for ensuring therapeutic equivalence of MR products.

The objective of this workshop is to convene pharmaceutical scientists from academia, industry, and regulatory agencies to have open discussions on current regulatory expectations and industry practices for demonstrating bioequivalence of MR products, and identify the critical paths to establishing scientific and regulatory standards for ensuring therapeutic equivalence of MR products. Key messages from this meeting may be published as a workshop report for the scientific community towards demonstrating bioequivalency of MR products to ensure the highest level of their safety and efficacy.

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