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Joint Meeting

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Overview of submission of summary Bioequivalence data for ANDAs

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The Food and Drug Administration (FDA) amended its regulations on the submission of bioequivalence data to require an abbreviated new drug application (ANDA) applicant to submit data from all bioequivalence (BE) studies the applicant conducts on a drug product formulation submitted for approval. In the past, ANDA applicants submitted BE studies demonstrating that a generic product meets bioequivalence criteria in order for FDA to approve the ANDA, but have not typically submitted additional BE studies conducted on the same drug product formulation, such as studies that do not show that the product meets these criteria. In some cases, firms may conduct pilot studies on formulations other than the same drug product formulation. The presentation will focus on how to determine if a formulation is considered to be a "same drug product formulation" and, if so, how to submit the study in the ANDA.

Biography

Ethan M. Stier, R.Ph., Ph.D., is currently acting Deputy Director in the Division of Bioequivalence II in the Office of Generic Drugs, CDER, FDA. Dr. Stier earned his Ph.D. in Pharmaceutics from the University of Michigan and pharmacy degree from the University of Connecticut. His graduate work focused on protein delivery using liposomal delivery. His current research interests focus on the use of computer simulation to predict bioequivalence and on establishing bioequivalence approaches for complex dosage forms.