

Importance of *In Vitro* Bioequivalence Pathways

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Current Situation

- Hurdles create barriers for demonstrating in vivo bioequivalence (BE) of nonsystemically absorbed drug products:
 - Potential need for multiple clinical endpoint BE studies.
 - Difficulty in obtaining the power to discriminate differences in product response.
 - Expensive, time consuming, difficult to evaluate.

Current Challenge

Identification of a scientifically sound method for evaluating the bioequivalence of nonsystemically absorbed drug products.

This method should provide an incentive for generating safe and effective veterinary drug products:

Generics: demonstration of “sameness”

Innovators: opportunity to address modifications that sometimes occur over the lifetime of a new animal drug product

In Vitro Bioequivalence Approach

- CVM is proposing an *in vitro* approach for evaluating product bioequivalence (generics) or relative bioavailability (innovator products) for nonsystemically absorbed drug products
- Principles underlying this proposal will be described by the next three speakers.
- **FDA/CVM Bioequivalence Regulations:** Ian Hendricks, D.V.M., Ph.D., *Division of Generic Animal Drugs, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, FDA*
- ***In Vitro* Bioequivalence Pathways:** Marilyn Martinez, Ph.D., *Senior Biomedical Research Scientist, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, FDA*
- **Physico-Chemical Characterization :** Raafat Fahmy, Ph.D., *Science Advisor, Division of Manufacturing Technologies*

Why We Are Here Today

- To provide CVM with an opportunity share our proposal for overcoming current regulatory hurdles encountered when evaluating product bioequivalence for nonsystemically absorbed compounds.
- To share points to consider when developing policies covering the proposed *in vitro* bioequivalence approach.
- To provide the public with an opportunity to comment on this proposed approach.

Developing Public Record

- In addition to the opportunity to comment during this meeting, written comments can be submitted to the FDA. Written comments should be submitted to **Docket No. FDA-2015-N-0684 by May 18, 2015.**
- Information and data submitted voluntarily to FDA during the public meeting will become part of the administrative record for the rulemaking .
- The transcript of the proceedings from the public meeting will become part of the administrative record for the rulemaking.

Developing Public Record

The agency will be recording the meeting for subsequent viewing by the public. Once the recording has been made 508 compliant, it will be accessible at FDA's CVM Web site at:

<http://www.fda.gov/AnimalVeterinary/NewsEvents/WorkshopsConferencesMeetings/ucm435459.htm>

We look forward to a lively discussion.
Please provide your thoughts both
during this meeting and during the
open comment period.