



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0684]

Identification of Alternative In Vitro Bioequivalence Pathways Which Can Reliably Ensure In Vivo Bioequivalence of Product Performance and Quality of Non-Systemically Absorbed Drug Products for Animals; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comments; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period related to the use of in vitro methods as a mechanism for assessing the in vivo product bioequivalence (BE) of nonsystemically absorbed drug products intended for use in veterinary species, published in the Federal Register of March 18, 2015 (80 FR 14146). FDA is reopening the comment period to update comments and to receive any new information.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John Harshman, Center for Veterinary Medicine, Food and Drug Administration, HFV-170, MPN2, 7500 Standish Pl., Rockville, MD 20855, 240-402-0845.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of March 18, 2015 (80 FR 14146), FDA announced a public meeting to discuss the use of in vitro methods as a mechanism for assessing the in vivo product bioequivalence (BE) of nonsystemically absorbed drug products intended for use in veterinary species. In the same notice, FDA said that it is seeking additional public comment to the docket. Interested persons were originally given until May 18, 2015, to comment on this issue.

II. Request for Comments

Following publication of the March 18, 2015, notification of public meeting and request for comments, FDA received a request to allow interested persons additional time to comment. The requester asserted that the time period of 60 days was insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues.

III. How to Submit Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: June 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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