



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 receive new information.

DATES: Submit either electronic or written comments by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

<http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-N-0684 for 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. Received comments will be placed in

the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions – To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION”. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: John Harshman, CVM, Food and Drug Administration, HFV-170, MPN2, 7500 Standish Place, 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 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. Following publication of that notice, FDA received a request to allow interested persons additional time to comment. In response to that request, FDA published a Federal Register notice on June 10, 2015, reopening the comment period for 60 days, until August 10, 2015.

##### II. Request for Comments

Following publication of the June 10, 2015, notice reopening the comment period for 60 days, FDA received a request to allow interested persons an additional 30 days to comment.

FDA has considered the request and is reopening the comment period for 30 days, until  
[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER], 2015.

Dated: September 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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