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 non-systemically 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 August 10, 2015.

ADDITIONAL INFORMATION: On April 23, 2015, the Agency submitted a proposed collection of information entitled, “Comparative Price Information in Direct-to-Consumer and Professional Prescription Drug Advertisements” to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0791. The approval expires on May 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at http://www.reginfo.gov/public/do/PRAMain.

Dated: June 4, 2015.

Leslie Kux,
Associate Commissioner for Policy.

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 non-systemically 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[docket No. FDA–2014–N–1533]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishment of a Tobacco User Panel

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 10, 2015.

ADDITIONAL INFORMATION: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–NEW and title “Establishment of a Tobacco User Panel”. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Establishment of a Tobacco User Panel—(OMB Control Number 0910–NEW)

The Food and Drug Administration’s Center for Tobacco Products (CTP) proposes to establish a high-quality, probability-based, primarily Web-based, panel of 4,000 tobacco users. The panel will include individuals who can participate in up to 8 studies over a 3-year period to assess consumers’ responses to tobacco marketing, warning statements, product labels, and other communications about tobacco products. CTP proposed the establishment of the panel of consumers