

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 November 2, 2015.

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, 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 November 2, 2015.

Dated: September 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information

Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than December 1, 2015.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: HRSA AIDS Education and Training Centers Evaluation Activities (OMB No. 0915–0281)—Revision.

Abstract: The AIDS Education and Training Centers (AETC) Program, under the title XXVI of the Public Health Service Act, as amended, Ryan White HIV/AIDS Program legislation supports a network of regional and

national centers that conduct targeted, multi-disciplinary education and training programs for health care providers treating persons with HIV/AIDS. The AETC Program’s purpose is to increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat, and medically manage individuals with HIV infection, and to help prevent high risk behaviors that lead to HIV transmission.

Need and Proposed Use of the Information: As part of an ongoing effort to evaluate AETC activities, information is needed on AETC training sessions, consultations, and technical assistance activities. Each regional center collects information on AETC training events, and is required to report aggregate data on their activities to HRSA and the HIV/AIDS Bureau (HAB). These data provide information on the number of training events, including clinical trainings and consultations, as well as technical assistance activities conducted by each regional center, the number of health care providers receiving professional training or consultation, and the time and effort expended on different levels of training and consultation activities. In addition, information is obtained on the populations served by AETC trainees and the increase in capacity achieved through training events. Collection of this information allows HRSA and HAB to provide information on training activities and types of

education and training provided to Ryan White HIV/AIDS Program Grantees; resource allocation; and capacity expansion.

Likely Respondents: Trainees are asked to complete the Participant Information Form (PIF) once a year, and trainers are asked to complete an Event Record (ER) for each training event they conduct during the year. In addition to each regional AETC (8 total), the AETC National Coordinating Resource Center will compile these data into a data set and submit to HAB once a year.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The estimated annual response burden to trainers, as well as attendees of training programs as follows:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Participant Information Form (PIF)	90,193	1	90,193	0.167	15,062
Event Record (ER)	18,070	1	18,070	0.2	3,614
Total	108,263	108,263	18,676

The estimated annual burden to AETCs is as follows:

	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Aggregate Data Set	9	2	18	32	576

The total burden hours are 19,252. HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, (2) the accuracy of the

estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information

technology to minimize the information collection burden.

Jackie Painter,
Director, Division of the Executive Secretariat.
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