

Silver Spring, MD 20993-0002, 240-402-7911.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled "Providing Postmarketing Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report)." We are issuing the guidance to describe the conditions under which FDA will exercise its waiver authority to permit the holders of approved new drug applications, abbreviated new drug applications, and biologics license applications (applicants) to use the reporting format of the PBRER to submit periodic safety reports for their marketed products. The harmonized PBRER is intended to promote a consistent approach to periodic postmarketing safety reporting among the ICH regions and to enhance efficiency by reducing the number of reports generated for submissions to the regulatory authorities.

FDA's postmarketing safety reporting regulations require applicants to submit periodic safety reports in the form of a Periodic adverse drug experience report (PADER) (for drugs) or a Periodic adverse experience report (PAER) (for biologics) (21 CFR 314.80(c)(2) and 600.80(c)(2), respectively). FDA has routinely granted waivers under 21 CFR 314.90(b) and 600.90(b) permitting applicants to submit an internationally harmonized Periodic Safety Update Report (PSUR) prepared in accordance with ICH E2C (see 62 FR 27470, May 19, 1997) and 69 FR 5551, February 5, 2004) instead of a PADER/PAER under conditions stated in the waiver. On November 15, 2012, the ICH Steering Committee signed off on the ICH harmonized guideline "Periodic Benefit-Risk Evaluation Report (PBRER) E2C(R2)" and recommended that the PBRER format be adopted by the ICH regulatory bodies of the three regions. Therefore, the new and more comprehensive report format, the PBRER, has superseded the PSUR report format.

This guidance provides information on the steps applicants can take to submit a PBRER to the FDA in place of a PSUR, PADER, or PAER. The guidance discusses: (1) Applicants who have a waiver for their approved product to submit a PSUR instead of a PADER/PAER and (2) applicants who have not obtained a waiver and are currently submitting PADERs/PAERs as required under FDA regulations. Because the PBRER has replaced the PSUR as the ICH E2C harmonized postmarketing safety report format, FDA is permitting

applicants with an existing PSUR waiver to substitute the PBRER for the PSUR without submitting a new waiver request. This guidance describes the steps an applicant should take to submit the PBRER instead of the PSUR. For applicants who do not have a PSUR waiver for their approved application but would like to submit the PBRER instead of the PADER/PAER, this guidance provides information on how to submit a waiver request if they wish to do so.

This guidance describes the content, format, and submission deadlines applicants should follow when submitting the PBRER, as well as U.S.-specific appendices that should be submitted with the PBRER. It also explains how applicants can fulfill FDA's annual reporting requirement while submitting a harmonized PBRER that covers a longer reporting interval. In addition, FDA will consider requests to waive the quarterly reporting requirement.

This guidance finalizes the draft guidance for industry entitled "Providing Postmarket Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report)," which was announced in the **Federal Register** of April 8, 2013 (78 FR 20926). We reviewed the comments received on the draft guidance and revised several sections of the guidance in response to comments and questions on topics such as the submission of the nonexpedited individual case safety reports, waivers of the quarterly reporting requirement, the supplemental information to be provided with the PSUR/PBRER, handling gaps in reporting with changes to the date of the data lock point for the reporting interval, and accepted formats for the periodic safety report. In response to comments, we also clarified the text in the examples that were given in the draft guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on providing postmarketing periodic safety reports in the ICH E2C(R2) PBRER format. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

##### II. Electronic Access

Persons with access to the Internet may obtain the document at <https://www.regulations.gov/>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/>

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

##### III. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). The collections of information related to submission of waiver requests under §§ 314.90(a) and 600.90 have been approved under OMB control numbers 0910-0001 and 0910-0308. The guidance also refers to collections of information that have been approved under OMB control number 0910-0771 related to providing waiver-related materials in accordance with the guidance.

Dated: November 22, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2016-D-2635]

##### The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals; Establishing Appropriate Durations of Therapeutic Administration; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or we) is extending the comment period for a notice that appeared in the **Federal Register** of September 14, 2016. In that notice, FDA requested comments regarding the establishment of appropriately targeted durations of use of antimicrobial drugs of importance to human medicine (*i.e.*, medically important antimicrobial drugs) when they are administered in the feed or water of food-producing animals for therapeutic purposes. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the request for comments

published September 14, 2016 (81 FR 63187). Submit either electronic or written comments by March 13, 2017.  
**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-2016-D-2635 for "Establishing Appropriate Durations of Therapeutic Administration." 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.

**FOR FURTHER INFORMATION CONTACT:** Cindy Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0817, [cindy.burnsteel@fda.hhs.gov](mailto:cindy.burnsteel@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 14, 2016 (81 FR 63187), FDA solicited comments regarding the establishment of appropriate durations of use of antimicrobial drugs of importance to human medicine when administered in the feed or water of food-producing animals for therapeutic purposes with a 90-day comment period.

The Agency has received requests for an extension of the comment period. These requests conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the request for comments.

FDA has considered the requests and is extending the comment period for 90 additional days, until March 13, 2017. The Agency believes that a 90-day extension allows adequate time for interested persons to submit comments without significantly delaying FDA's consideration of these important issues.

Dated: November 22, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2010-N-0067]

#### **Pharmaceutical Science and Clinical Pharmacology Advisory Committee; Establishment of a Public Docket; Request for Comments; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

**DATES:** The meeting will be held on March 15, 2017, from 7:30 a.m. to 3:45 p.m.

**ADDRESSES:** Omni Shoreham Hotel, the Ballroom, 2500 Calvert St. NW., Washington, DC 20008. The hotel telephone number is 202-234-0700. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

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,