



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0408]

Microbiology Data for Systemic Antibacterial Drugs--Development, Analysis, and Presentation;
Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled “Microbiology Data for Systemic Antibacterial Drugs--Development, Analysis, and Presentation.” The purpose of this guidance is to assist sponsors in the development, analysis, and presentation of microbiology data during antibacterial drug development. This guidance finalizes the draft guidance of the same name issued on September 17, 2009.

DATES: Submit either electronic or written comments on Agency guidances at any time.

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-2009-D-0408 for "Microbiology Data for Systemic Antibacterial Drugs--Development, Analysis, and Presentation; Guidance for Industry; Availability." 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 this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. 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: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 22, rm. 6244, Silver Spring, MD 20993-0002, 301-796-1400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Microbiology Data for Systemic Antibacterial Drugs--Development, Analysis, and Presentation.” The purpose of this guidance is to assist sponsors in the development, analysis, and presentation of microbiology data during antibacterial drug development. Microbiology data provide important information to guide clinical development of antibacterial drugs and guide clinicians on the use of an antibacterial drug for its intended indication.

This guidance finalizes the draft guidance issued on September 17, 2009 (74 FR 47804). After consideration of comments received in response to the draft guidance, the guidance was restructured to describe general approaches to microbiology data collection in the body of the guidance and to provide more specific recommendations in appendixes (e.g., the format for microbiology data presentation and an example for sections of labeling that pertain to microbiology).

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 the development, analysis, and presentation of microbiology data for systemic antibacterial drugs. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

1. This guidance provides recommendations on the type of information to include in submissions of the clinical microbiology section of investigational new drug applications (INDs) and new drug applications (NDAs) for systemic antibacterial drugs. The microbiology section of an NDA is required under 21 CFR 314.50(d)(4) and this information collection is approved under OMB control number 0910-0001. For INDs, this information is required under 21 CFR 312.23(a) and approved under OMB control number 0910-0014.
2. This guidance also recommends the types of data that should be submitted in a labeling supplement to update the microbiology information in approved labeling if an application holder chooses to update this information without relying on a standard recognized by FDA. The submission of labeling supplements is required under 21 CFR 314.70(b)(2)(v) and 201.56(a)(2) and this information collection is approved under OMB control numbers 0910-0001 and 0910-0572, respectively.

3. Appendix D of this guidance describes the content of the Microbiology subsection of labeling. This labeling is covered under 21 CFR 201.57(c)(13)(i) and the information collection is approved under OMB control number 0910-0572.

4. This guidance also references the guidance for industry entitled “Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices” for updating labeling information. The information collection in this guidance has been approved under OMB control number 0910-0638.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: August 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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