



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0744]

Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases; 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 "Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases." The purpose of the guidance is to assist sponsors in the development of new antibacterial drugs to treat serious bacterial diseases in patients with an unmet medical need, including patients who have a serious bacterial disease for which effective antibacterial drugs are limited or lacking. This guidance finalizes the draft guidance of the same name issued July 2, 2013.

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: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2013-D-0744 for "Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases." Received comments will be placed in the docket and, except for

those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 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, 301-796-1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases." The purpose of this guidance is to assist sponsors in the development of new antibacterial drugs for the treatment of serious bacterial diseases in patients with an unmet medical need, including patients who have a serious bacterial disease for which effective antibacterial drugs are limited or lacking.

Efforts to develop new antibacterial drugs have diminished in the past few decades. Because bacteria continue to develop resistance to available antibacterial drugs, a situation of unmet medical need has arisen in which patients with serious bacterial diseases have limited or

in some cases no alternative antibacterial drugs available for treatment. To foster new antibacterial drug development that will have the potential to keep pace with continued selective pressures of antibacterial resistance, FDA is exploring approaches to help streamline development programs for new antibacterial drugs. This guidance outlines approaches for streamlined development programs that are consistent with FDA's longstanding commitment to regulatory flexibility regarding the evidence required to support drug approval for patient populations with serious disease and limited or no treatment options, while meeting appropriate standards for safety and effectiveness (see, for example, 21 CFR 312, subpart E, Drugs Intended to Treat Life-threatening and Severely-debilitating Illnesses).

This guidance finalizes the draft guidance of the same name issued July 2, 2013 (78 FR 39737). After consideration of comments received in response to the draft guidance, FDA updated the guidance to include clarifications about trial designs for streamlined development programs and statistical approaches. In addition, the guidance outlines development approaches for antibacterial drugs that are pathogen-focused (i.e., drugs that are intended to treat a single species or a few species of bacteria) and, accordingly, fulfills the requirements of section 806(a), Title VIII (entitled "Generating Antibiotic Incentives Now") of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144).

FDA notes that section 3042 of the 21st Century Cures Act (Pub. L. 114-255), which establishes a limited population pathway for certain antibacterial and antifungal drugs (LPAD) that are intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs, was enacted shortly before publication of this guidance. Some antibacterial drugs that are candidates for a streamlined development program may also be

candidates for LPAD. FDA intends to issue separate guidance regarding LPAD. Sponsors are encouraged to discuss proposed approaches with the Division of Anti-Infective Products.

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 this topic. 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. This is not a significant regulatory action subject to Executive Order 12866.

II. 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 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively.

III. Electronic Access

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

Dated: July 27, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-16228 Filed: 8/1/2017 8:45 am; Publication Date: 8/2/2017]