



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-2032]

Limited Population Pathway for Antibacterial and Antifungal Drugs; 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 final guidance for industry entitled “Limited Population Pathway for Antibacterial and Antifungal Drugs.” This guidance provides information on the implementation of the limited population pathway provision of the 21st Century Cures Act (Cures Act), which established the limited population pathway for antibacterial and antifungal drugs (LPAD pathway). This guidance finalizes the draft guidance of the same name issued on June 13, 2018.

DATES: The announcement of the guidance is published in the *Federal Register* on **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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-2018-D-2032 for "Limited Population Pathway for Antibacterial and Antifungal Drugs." 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, 240-402-7500.

- 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.govinfo.gov/content/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, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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., Hillendale Building, 4th Floor, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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: Sarah Walinsky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993-0002, 240-402-4075; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled “Limited Population Pathway for Antibacterial and Antifungal Drugs.” Section 3042 of the Cures Act added section 506(h) to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356(h)(5)) to create the LPAD pathway. The LPAD pathway is intended to encourage the development of certain antibacterial and antifungal drugs to help address the critical public health and patient care concern that has resulted from the current decline in antibacterial drug research and development as serious antibacterial and antifungal drug-resistant infections increase. FDA is committed to using the tools at its disposal, including the LPAD pathway, to help encourage the development of safe and effective drugs that address unmet needs of patients with serious bacterial and fungal infections.

Section 506(h)(5) of the FD&C Act requires FDA to issue guidance that describes criteria, processes, and other general considerations for demonstrating the safety and effectiveness of limited population antibacterial and antifungal drugs. This guidance provides this information and is intended to assist sponsors in the development of certain new antibacterial and antifungal drugs for approval under the LPAD pathway. This guidance also is intended to assist sponsors in developing labeling, including prescribing information, patient labeling, and carton/container labeling, that incorporates certain statements required by section 506(h) of the FD&C Act. This guidance satisfies the requirements under section 506(h)(5) of the FD&C Act.

This guidance finalizes the draft guidance of the same name issued on June 13, 2018 (83 FR 27616). Changes made to the guidance were based on the comments submitted to the docket on the draft guidance and public comments received during the FDA public meeting entitled “Limited Population Pathway for Antibacterial and Antifungal Drugs,” which was held on July 12, 2019 (84 FR 12621) (meeting transcript available at <https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fda-public-meeting-limited-population-pathway-antibacterial-and-antifungal-drugs-07122019-07122019>). Based on the comments received, FDA made clarifying changes to this guidance, included examples of labeling and explanations of the meaning of limited population, and provided further information about presubmission of promotional materials.

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 “Limited Population Pathway for Antibacterial and Antifungal 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. Paperwork Reduction Act of 1995

This guidance contains no new collection of information. Therefore, additional clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3521) is not required.

However, this guidance refers to previously approved FDA collections of information. These collections of information were reviewed by OMB under the PRA. The collections of information in 21 CFR part 314 for the submission of new drug applications (NDAs) under the LPAD pathway, including the submission of labeling under § 314.50(e)(2)(ii) and (l)(1)(i) and advertisements and promotional labeling under § 314.81(b)(3)(i), have been approved under OMB control number 0910-0001. The submission of biologics license applications (BLAs) under the LPAD pathway has been approved under OMB control number 0910-0338.

The submission of prescription drug labeling in 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910-0572. The submission of medication guides in 21 CFR part 208 has been approved under OMB control number 0910-0393. The submission of prescription drug advertisements in 21 CFR 202.1 has been approved under OMB control number 0910-0686.

The collections of information in 21 CFR part 312, including submissions under subpart E, have been approved under OMB control number 0910-0014. The collections of information in FDA's draft guidance for industry entitled "Formal Meetings Between the FDA and Sponsors and Applicants for PDUFA Products" (available at <https://www.fda.gov/media/109951/download>), including requests for pre-NDA and pre-BLA meetings and other meetings pertaining to the LPAD pathway, have been approved under OMB control number 0910-0429.

The collections of information in FDA's final guidance for industry entitled "Expedited Programs for Serious Conditions--Drugs and Biologics" (available at <https://www.fda.gov/media/86377/download>) have been approved under OMB control number 0910-0765.

III. Electronic Access

Persons with access to the internet may obtain the guidance at

<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,

<https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: July 31, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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