



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Limited Population Pathway for Antibacterial and Antifungal Drugs; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Limited Population Pathway for Antibacterial and Antifungal Drugs.”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).

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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; Draft Guidance for Industry; Availability." 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.

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

Submit written requests for single copies of the draft 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, or 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 draft 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 draft guidance for industry entitled “Limited Population Pathway for Antibacterial and Antifungal Drugs.” Section 506(h)(5) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356(h)(5)) requires FDA to issue guidance “describing 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, added by section 3042 of the Cures Act. This guidance satisfies the requirements under section 506(h)(5) of the FD&C Act.

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 drug products that address unmet needs of patients with serious bacterial and fungal infections.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the LPAD pathway. 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 guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft 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 (PRA) (44 U.S.C.

3501-3520). The collection 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), has 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 under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910-0572. The submission of medication guides under 21 CFR part 208 has been approved under OMB control number 0910-0393. The submission of prescription drug advertisements under 21 CFR 202.1 has been approved under OMB control number 0910-0686.

The collection of information in the draft guidance for industry entitled “Formal Meetings Between the FDA and Sponsors and Applicants for PDUFA Products” (available at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm590547.pdf>), including requests for pre-NDA and pre-BLA meetings and other meetings pertaining to the LPAD pathway, has been approved under OMB control number 0910-0429.

The collection of information in the guidance for industry entitled “Expedited Programs for Serious Conditions--Drugs and Biologics” (available at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm358301.pdf>), including fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation has been approved under OMB control number 0910-0765.

The collection of information in 21 CFR part 312, including submissions under subpart E, has been approved under OMB control number 0910-0014. In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: June 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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