4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-3103]

Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications; Draft Guidance for Industry and Review Staff; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry and review staff entitled "Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications." This draft guidance describes the fundamental values and operational principles that serve as the foundation for the review process. It also clarifies the roles and responsibilities of review staff and identifies ways in which applicants may support a robust and efficient review process. This draft guidance revises the guidance for review staff and industry entitled "Good Review Management Principles and Practices for PDUFA Products" issued April 2005.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-3103 for "Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications." 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: Pinakini Patel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6367, Silver Spring, MD 20993-0002, 301-796-7475; 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 and review staff entitled "Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications." This draft guidance describes good review management principles and practices (GRMPs) for the review of a new drug application (NDA), biologics license application (BLA), or an efficacy supplement/supplement with clinical data. This guidance applies to *human drug applications* (as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379g(1))) and *biosimilar biological product applications* (section 744G(4) of the FD&C Act (21 U.S.C. 379j-51(4))). This guidance also discusses the roles and responsibilities of review staff in managing the review process and identifies ways in which applicants may support an efficient and robust review process.

This draft guidance revises the guidance for review staff and industry entitled "Good Review Management Principles and Practices for PDUFA Products" issued in April 2005. FDA committed to updating the 2005 guidance as part of the Prescription Drug User Fee Act (PDUFA) VI and Biosimilar User Fee Act (BsUFA) II. This draft guidance meets that commitment by reflecting advances in the PDUFA program and implementation of BsUFA. This draft guidance also reflects the evolution of GRMPs to support new regulatory programs such as breakthrough therapy, the Program for Enhanced Review Transparency and Communication for NME (New Molecular Entity) NDAs and Original BLAs, and risk evaluation and mitigation strategies.

In addition, the draft guidance has been consolidated to focus on the fundamental values and operational principles that serve as the foundation for the GRMPs. Details of the review process are covered in other documents referenced by this guidance. Fundamental values and operational principles should remain relatively constant over time, while processes must be able to adapt and respond to scientific advances in product development and evolving public health needs.

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 GRMPs for NDAs and BLAs. 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. Electronic Access

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

Dated: September 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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