4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6564]

Best Practices for Communication Between Investigational New Drug Application Sponsors and the Food and Drug Administration; 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 guidance for industry and review staff entitled "Best Practices for Communication Between IND Sponsors and FDA During Drug Development." Timely, transparent, and effective communications between investigational new drug application (IND) sponsors and FDA at critical junctures in drug development facilitate earlier availability of safe and effective drugs to the American public. This guidance describes FDA's philosophy regarding timely interactive communication with IND sponsors as a core activity; describes the scope of appropriate interactions between FDA review teams and IND sponsors; outlines the types of advice appropriate for sponsors to seek from FDA in pursuing their drug development programs; describes the general expectations for the timing of FDA responses to IND sponsor inquiries; describes best practices and communication methods to facilitate interactions between FDA review teams and IND sponsors during drug development; and includes expectations on appropriate methods and frequency of such communications. This guidance does not apply to communications or inquiries from industry trade organizations, consumer or patient advocacy

organizations, other government agencies, or other stakeholders not pursuing a development program under an IND. This guidance finalizes the draft guidance issued on December 9, 2015.

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-2017-D-6564 for "Best Practices for Communication Between Investigational New Drug Application Sponsors and the Food and Drug Administration; Guidance for Industry and Review Staff; 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: Rachel B. Kichline, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6312, Silver Spring, MD 20993-0002, 301-796-0319; 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 guidance for industry and review staff entitled "Best Practices for Communication Between IND Sponsors and FDA During Drug Development." As part of the Prescription Drug User Fee Amendments of 2012 (PDUFA V), described in PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017, the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) agreed to publish a joint guidance for industry and review staff on best practices for communication between IND sponsors and FDA during drug development.

To establish the best practices described in this guidance, CDER and CBER gathered the experiences of review staff and incorporated input from interested parties who responded to a notice published in the *Federal Register* of October 29, 2014 (79 FR 64397), or who provided input directly to CDER's Enhanced Communication Team. This guidance was published as a draft guidance on December 9, 2015. The following changes were made to the guidance:

- Biosimilar biological product development information was expanded and Biosimilar User Fee Act (BsUFA) meeting types were added.
- Roles and responsibilities for regulatory project managers were clarified.

- Language describing the formal communication plan for applications in PDUFA Program for Enhanced Review Transparency and Communication for NME NDAs[1] and Original BLAs[2] (also known as *the Program*) and for biologic biosimilar applications reviewed under BsUFA was added.
- Meeting request parameters were revised in alignment with PDUFA VI.
- Additional information was added to the Resources for Sponsors and Additional Contacts sections.

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 best practices for communication between IND sponsors and FDA during drug development. 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. 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 information collection described in 21 CFR part 312 from IND sponsors is approved by OMB under control number 0910-0014. The information collection described in the guidance for industry entitled "Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products" is approved by OMB under control number 0910-0429. The information collection described in the guidance for industry entitled "Formal

[1] New Molecular Entity New Drug Applications
[2] Biologics License Applications

Dispute Resolution: Sponsor Appeals Above the Division Level" (available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM343101.pdf) is approved by OMB under control number 0910-0430. The information collection described in the "Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Acts" is approved by OMB under control number 0910-0746. The information collection described in the guidance for industry entitled "Expedited Programs for Serious Conditions--Drugs and Biologics" (available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf) is approved by OMB under control number 0910-0765. The information collection described in the guidance for industry entitled "Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants" (available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM345649.pdf) is approved by OMB under control number 0910-0802.

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/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or https://www.regulations.gov.

Dated: December 19, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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