



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-4096]

Final Assessment of the Program for Enhanced Review Transparency and Communication;
Public Meeting and Establishment of Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and establishment of docket, request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a docket to obtain comments on the final assessment of the Program for Enhanced Review Transparency and Communication for New Molecular Entity (NME) New Drug Applications (NDAs) and Original Biologics License Applications (BLAs) (the Program). FDA is also announcing a public meeting where the final assessment will be discussed and public stakeholders may present their views on the Program to date. The Program is part of the FDA performance commitments under the fifth authorization of the Prescription Drug User Fee Act (PDUFA), which enables FDA to collect user fees for the review of human drug and biologics applications for fiscal years (FYs) 2013-2017. The Program is described in detail in section II.B of the document entitled "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017." The Program is being evaluated by an independent contractor with expertise in assessing the quality and efficiency of pharmaceutical and biopharmaceutical development and regulatory review programs. As part of FDA's performance commitments, FDA is providing a period for public comment on the final assessment of the Program.

DATES: The public meeting will be held on March 27, 2017, from 10 a.m. to 1 p.m. Public comments will be accepted through April 3, 2017. See the ADDRESSES section for information about submitting comments to the public docket. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 2, Conference Room 2047 E, Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For more information on parking and security procedures, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2016-N-4096.

Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1146, Silver Spring, MD 20993, 301-796-5003, FAX: 301-847-8443, Graham.Thompson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The timely review of the safety and efficacy of new drugs and biologics is central to FDA's mission to protect and promote the public health. Since the implementation of PDUFA I in 1993, FDA has used PDUFA resources to improve the timeliness and predictability of new drug review while maintaining FDA's rigorous standards for drug quality, safety and efficacy. With the availability of these additional fee resources, FDA was able to agree to certain review performance goals, including a complete review of NDAs and BLAs and taking regulatory action within specified timeframes. The managed review processes put in place to accomplish this, and the process enhancements including investments in modernized post-market safety and regulatory science over subsequent reauthorizations of PDUFA, have revolutionized the new drug review process, helping to bring critical products to market for patients. The PDUFA program has been reauthorized every 5 years, with the most recent and fifth authorization occurring in 2012. The PDUFA V Performance Goals and Procedures for Fiscal Years 2013 through 2017 can be accessed at <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf>.

PDUFA V introduced a new review program for NME NDAs and original BLAs to enhance review transparency and communication between FDA and applicants on these complex applications. FDA committed to engaging an independent contractor to evaluate the Program to understand the Program's effect on the review of these applications. The interim assessment was published March 31, 2015, and can be accessed at <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM436448.pdf>. The PDUFA V performance commitments also call for a final assessment of the Program to be published by December 31, 2016, for public comment. The final assessment can be accessed

at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm327030.htm>. A public meeting will be held on March 27, 2017, where the final assessment will be discussed and public stakeholders may present their views on the Program.

II. PDUFA V NME NDA and Original BLA Review Program

FDA's performance goals for review of priority and standard new drug applications, 6 and 10 months respectively, have been in place since the late 1990s. Since that time, additional requirements in the review process and scientific advances in product development have made those goals increasingly challenging to meet, particularly for more complex applications like NME NDAs and original BLAs. FDA further recognizes that increasing communication and transparency between the Agency and applicants during FDA's review has the potential to increase efficiency in the review process.

To promote greater transparency and improve communication between the FDA review team and the applicant, FDA implemented a new review model for NME NDAs and original BLAs in PDUFA V. The Program provides opportunities for increased communication between FDA and applicants, including mid-cycle and late-cycle meetings. To accommodate the increased interaction during regulatory review and to address the need for additional time to review these complex applications, FDA's review clock begins after the 60-day administrative filing review period for applications reviewed under the Program.

The goal of the Program is to improve the efficiency and effectiveness of the first-cycle review process by increasing communications during application review. This will provide sponsors with the opportunity to clarify previous submissions and provide additional data and analyses that are readily available, potentially avoiding the need for an additional review cycle when concerns can be promptly resolved without compromising FDA's standards for approval.

III. Meeting Attendance and Participation

FDA is holding the public meeting on March 27, 2017, from 10 a.m. to 1 p.m. If you wish to attend this public meeting, visit: <https://nmemeeting.eventbrite.com>. Please register by March 20, 2017. If you are unable to attend the public meeting in person, you can register to view a live Webcast of the public meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the public meeting will not be possible. If you need special accommodations because of a disability, please contact Graham Thompson (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the public meeting.

FDA will hold an open public comment period to give the public an opportunity to comment during the public meeting. Registration for open public comment will occur at the registration desk on the day of the public meeting on a first-come, first-served basis.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see ADDRESSES). A link to the transcript will also be available on the Internet at <http://www.fda.gov/Drugs/NewsEvents/ucm501389.htm>.

Dated: December 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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