



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0093]

Interim 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 interim 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 interim 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 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 interim assessment of the Program.

DATES: See Section III, "How to Participate in the Public Meeting" in the SUPPLEMENTARY INFORMATION section of this document for dates and times of the public meeting, closing dates for advance registration, requesting special accommodations due to disability, and information on deadlines for submitting either electronic or written comments to FDA's Division of Dockets Management.

ADDRESSES: See Section III, "How to Participate in the Public Meeting" in the SUPPLEMENTARY INFORMATION section of this document.

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 significantly reduce the time it takes to evaluate new drugs without compromising FDA's rigorous standards for drug safety and efficacy. In return for these additional resources, FDA agreed to certain review performance goals, such as completing reviews of NDAs and BLAs and taking regulatory actions on them within predictable timeframes. These changes revolutionized the review process and enabled FDA to improve the efficiency of the application review process for new drugs and biologics without compromising

the Agency's high standards for demonstration of safety, efficacy, and quality of new drugs and biologics prior to approval.

PDUFA provides FDA with a source of stable, consistent funding that has made possible our efforts to focus on promoting innovative therapies and helping to bring to market critical products for patients. The PDUFA program has been reauthorized every 5 years, with the most recent reauthorization occurring in 2012 for FYs 2013-2017 (PDUFA V).¹

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. The PDUFA V performance commitments call for an interim assessment of the Program to be published by March 31, 2015, for public comment. The interim assessment can be accessed at <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM436448.pdf>.

II. PDUFA V NME NDA and Original BLA Review Program

FDA's review performance goals for priority and standard 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 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

¹ This document is available on the Internet at <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf>.

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 but without compromising FDA's standards for approval.

To understand the Program's effect on the review of these applications, the Program is being evaluated by an independent contractor. In addition to publishing an interim assessment and opening a docket for public comments, a public meeting will be held on May 20, 2015, where the interim assessment will be discussed and public stakeholders may present their views on the Program to date. The final assessment of the Program will be published for public comment by December 31, 2016, and will be followed by a public meeting by March 30, 2017.

III. How to Participate in the Public Meeting

FDA is holding the public meeting on May 20, 2015, from 10 a.m. to 1 p.m. Due to limited space and time, we encourage all persons who wish to attend the meeting to register in advance. There is no fee to register for the public meeting, and registration will be on a first-come, first-served basis.

Table 1 of this document provides information on participation in the public meeting.

Table 1.--Information on Participating in the Meeting and on Submitting Comments to the Docket¹

	Dates	Electronic addresses	Addresses	Other information
Attend public meeting	May 20, 2015, from 10 a.m. to 1 p.m.	Please preregister at https://www.nmepdufa.eventbrite.com .	FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Section A of the Great Room (rm. 1503) Silver Spring, MD 20993.	Participants must enter through Building 1 and undergo security screening. For more information on parking and security procedures, please visit http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm
Preregister	Register by May 13, 2015.	Individuals who wish to participate in person are asked to preregister at https://www.nmepdufa.eventbrite.com .	We encourage the use of electronic registration, if possible. ¹	There is no registration fee for the public meeting.
View Web cast	May 20, 2015, from 10 a.m. to 1 p.m.	Individuals who are unable to attend the meeting in person, can register to view a live Web cast. You will be asked to indicate in your registration whether you plan to attend in person or via the Web cast.		The Web cast will have closed captioning
Request special accommodations due to disability	Request at least 7 days before the meeting	Graham Thompson, email: Graham.Thompson@fda.hhs.gov	See FOR FURTHER INFORMATION CONTACT	
Submit electronic or written comments.	Submit comments by June 30, 2015.	Federal eRulemaking Portal: http://www.regulations.gov . Follow the instructions for submitting comments.	Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.	Identify your comments with the docket number listed in brackets in the heading of this document. We encourage you to submit electronic comments by using the Federal eRulemaking Portal.

¹You may also register via email, mail, or fax. Please include your name, title, firm name, address, and phone and fax numbers in your registration information and send to: 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.

IV. Comments and Transcripts

Regardless of attendance at the public meeting, interested persons may submit to FDA's Division of Dockets Management (see Addresses in table 1) either electronic or written comments on the interim assessment of the Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs. You only need to send one set of comments. Identify the comments with the docket number provided in brackets in the heading of this document.

With respect to transcripts, please be advised that as soon as a transcript is available, it will be accessible at

www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm327030.htm.

Dated: April 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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