TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Type of submission	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Promotional labeling submitted for advisory comments, including resubmissions and amendments	199	2.5	499	50	24,950
General correspondence submitted to FDA	200	2.5	500	2	1,000
Requests to withdraw a previous submission to FDA	6	1	6	2	12
Responses to untitled or warning letters	26	2	52	12	624
Responses to information requests	4	1.5	6	12	72
Reference documents	7	1	7	12	84
Complaints submitted to OPDP	60	1	60	12	720
Total					27,462

This draft guidance also refers to previously approved collections of information found in FDA regulations and collections of information that are currently under OMB review. The collections of information in 21 CFR 202.1, including requests for advisory comments, resubmissions, and amendments for advertisements, have been approved under OMB control number 0910–0686; the collections of information in 21 CFR 601.45 (presubmission of promotional materials for accelerated approval products under part 601) have been approved under OMB control number 0910–0338; the collections of information for FDA Form 2253 and the presubmission of promotional materials for accelerated approval products under part 314 have been approved under OMB control number 0910–0001. FDA has also published in the **Federal Register** a 60-day notice soliciting public comments on the collections of information that result from the submission of television advertisements under section 503C of the FD&C Act (21 U.S.C. 353c) (77 FR 14811, March 13, 2012). These burden estimates do not change as a result of this guidance. This is because new burdens for establishing the means for submitting materials in electronic form to comply with this guidance would be negated by the savings in burden from not having to print out the materials and mail them to FDA.

Some firms may incur costs associated with upgrading technology or changing the method of submitting information to FDA, and these have been described in the **Federal Register** notice for the revised draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the Electronic Common Technical Document Specifications'' (79 FR 43494, July 25, 2014).

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: April 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–09297 Filed 4–21–15; 8:45 am]

BILLING CODE 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 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' 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 DOCKET [1]

	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.

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

TABLE 1—INFORMATION ON PARTICIPATING IN THE MEETING AND ON SUBMITTING COMMENTS TO THE DOCKET [1]—Continued

	Dates	Electronic addresses	Addresses	Other information
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.

[1] You 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.

[FR Doc. 2015–09300 Filed 4–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Ebola Virus Disease Therapeutics

ACTION: Notice of Declaration Under the Public Readiness and Emergency Preparedness Act.

SUMMARY: The Secretary is issuing a Declaration pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) to provide liability protection for activities related to Ebola Virus Disease Therapeutics consistent with the terms of the Declaration.

DATES: The Declaration is effective as of February 27, 2015.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, MD, MSPH, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201, Telephone (202) 205–2882 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The Public Readiness and Emergency Preparedness Act (''PREP Act'') authorizes the Secretary of Health and Human Services (''the Secretary'') to issue a Declaration to provide liability immunity to certain individuals and entities (''Covered Persons'') against any claim of loss caused by, arising out of, relating to, or resulting from the administration or use of medical countermeasures (''Covered Countermeasures''), except for claims that meet the PREP Act's definition of willful misconduct. Using this authority, the Secretary is issuing a Declaration to provide liability immunity to Covered Persons for activities related to the Covered Countermeasures, Ebola Virus Disease Therapeutics as listed in Section VI of the Declaration, consistent with the terms of this Declaration.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (''PHS'') Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified in the U.S. Code as 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the Federal Food, Drug, and Cosmetic (FD&C) Act to provide new emergency authorities for dispensing approved products in emergencies and products held for emergency use.

PAHPRA accordingly amended the definitions of ''Covered Countermeasures'' and ''qualified pandemic and epidemic products'' in section 319F–3 of the Public Health Service Act (the PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act Declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products that may be covered under a PREP Act Declaration to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

The Ebola virus causes an acute, serious illness that is often fatal. Since March 2014, West Africa has been experiencing the largest and most complex Ebola outbreak since the Ebola