4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Proposed Collection; Comment Request; 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 Act.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed information collection involving interviews of pharmaceutical manufacturers who submit new molecular entity (NME) new drug applications (NDAs) and original biologics license applications (BLAs) to FDA under the Program for Enhanced Review Transparency and Communication ("the Program") during fiscal years (FYs) 2013-2017. The Program is part of the FDA performance commitments under the fifth authorization of the Prescription Drug User Fee Act (PDUFA), which allows FDA to collect user fees for the review of human drug and biologics applications for FYs 2013-2017.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL

REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Ila S. Mizrachi,

Office of Information Management,

Food and Drug Administration,

1350 Piccard Dr.,

PI50-400B,

Rockville, MD 20850,

301-796-7726.

Ila.Mizrachi@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in PDUFA V: Interviews of Applicants in the Program (OMB Control Number 0910-New)

As part of its commitments in PDUFA V, FDA has established a new review Program to promote greater transparency and increased communication between the FDA review team and the applicant on the most innovative products reviewed by the Agency. The Program applies to all NME NDAs and original BLAs that are received from October 1, 2012, through September 30, 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 "Commitment Letter") (available at http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.

The goals of the Program are to increase the efficiency and effectiveness of the first review cycle and decrease the number of review cycles necessary for approval so that patients have timely access to safe, effective, and high-quality new drugs and biologics. A key aspect of the Program is an interim and final assessment that will evaluate how well the parameters of the Program have achieved the intended goals. The PDUFA V Commitment Letter specifies that the

assessments be conducted by an independent contractor and that they include interviews of pharmaceutical manufacturers who submit NME NDAs and original BLAs to the Program in PDUFA V. The contractor for the assessments of the Program is Eastern Research Group, Inc. (ERG), and the statement of work for the assessments is available at http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM304793.pdf.

Therefore, in accordance with the PDUFA V Commitment Letter, FDA proposes to have ERG conduct independent interviews of applicants after FDA issues a first-cycle action for applications reviewed under the Program. The purpose of these interviews is to collect feedback from applicants on the success of the Program in increasing review transparency and communication during the review process. ERG will anonymize and aggregate sponsor responses prior to inclusion in the assessments and any presentation materials at public meetings. FDA will publish ERG's assessments (with interview results and findings) in the Federal Register for public comment.

FDA typically reviews approximately 40 to 45 NME NDAs and original BLAs per year. ERG will interview 1 to 3 sponsor representatives at a time for each application that receives a first-cycle action from FDA--up to 135 sponsor representatives per year. Thus, FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Portion of Study	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pretest	5	1	5	1.5	7.50
Interviews	135	1	135	1.5	202.50
Total					210

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

ERG will conduct a pretest of the interview protocol with five respondents. FDA estimates that it will take 1.0 to 1.5 hours to complete the pretest, for a total of a maximum of 7.5 hours. We estimate that up to 135 respondents will take part in the post-action interviews each year, with each interview lasting 1.0 to 1.5 hours, for a total of a maximum of 202.5 hours. Thus, the total estimated annual burden is 210 hours. FDA's burden estimate is based on prior experience with similar interviews with the regulated community.

Dated: February 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-03705 Filed 02/15/2013 at 8:45 am; Publication Date: 02/19/2013]