4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Review Transparency and Communication in Reviews of 351(k) Biologics License Applications in Biosimilars User Fee Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0746. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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 and 351(k) Biologics License Applications in Biosimilars User Fee Act

OMB Control Number 0910-0746--Extension

This information collection supports the above captioned review program ("the Program"). The Program is part of our performance commitment under the fifth and sixth authorizations of the Prescription Drug User Fee Act (PDUFA), which allows us to collect user fees for the review of human drug and biologics applications for FYs 2013 through 2021, and the second authorization of the Biosimilars User Fee Act (BsUFA II), which applies to 351(k) BLAs for FYs 2018 through 2021. The Program is described in detail in FDA's Commitment Letters for PDUFA VI and BsUFA II, available at https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf and https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf.

The Program goals 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 extension of the Program to BsUFA II is to conduct an interim and final assessment that will evaluate how well the parameters of the Program have achieved the intended goals. The BsUFA

II Commitment Letter specifies that an independent contractor can conduct the assessments and specifies that they include interviews of sponsors who submit 351(k) BLAs to the Program in BsUFA II. In accordance with the PDUFA V and BsUFA II Commitment Letters, we contracted Eastern Research Group, Inc. (ERG) to 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 transparency and communication of reviews during the review process. ERG will anonymize and aggregate sponsor responses before inclusion in the assessments and presentation materials at public meetings. We will publish in the *Federal Register* for public comment ERG's assessments with interview results and findings.

In the *Federal Register* of March 12, 2019 (84 FR 8877), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection 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
Pre-test	5	1	5	1.5	7.5
Interviews	75	1	75	1.5	112.5
Total					120

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

Since the last OMB approval of the information collection, we have adjusted our estimate downward by 60 survey respondents. We base our estimate on the most recent number of annual surveys. ERG interviews between one and three sponsor representatives for each 351(k) BLA first-cycle action issued for applications reviewed under the Program. ERG also conducts a pretest of the interview protocol with five respondents. Assuming it will take 1 to 1.5 hours to complete the pretest, we calculate a total of 7.5 annual burden hours. We estimate that up to 75

respondents will take part in the post-action interviews each year. Assuming each interview will last 1 to 1.5 hours, we calculate a total of 112.5 annual burden hours.

Dated: August 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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