4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6209]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Assessing User Fees Under the Biosimilar User Fee Amendments of 2017

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 0910-0718. 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.

Guidance for Industry: Assessing User Fees Under the Biosimilar User Fee Amendments of 2017

OMB Control Number 0910-0718--Revision

This information collection supports the above captioned Agency guidance and implementation of the Biosimilar User Fee Amendments of 2017 (BsUFA II). Under BsUFA II, FDA's authority is extended to collect user fees from fiscal years 2018-2022 and includes a number of technical revisions that affect what fees and how fees are collected. Fees authorized by this legislation help fund the review process for biosimilar biological product applications and play an important role in expediting the review and approval process.

We have developed the guidance document entitled "Assessing User Fees Under the Biosimilar User Fee Amendments of 2017" to assist industry in understanding when these fees are incurred and the process by which applicants can submit payments. The guidance also provides information on the consequences of failing to pay BsUFA II fees, as well as processes for submitting reconsideration and appeal requests. The guidance document is available on our website at:

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM584984.pdf.

In the *Federal Register* of November 16, 2017 (82 FR 53505), we published a notice announcing availability of the subject guidance document, including a 60-day notice requesting public comment on the information collection. One comment was received in response to the

notice from a trade organization indicating that interested persons "have reviewed the draft guidance and appreciate(s) FDA applying the user fee provisions consistent with the BsUFA II negotiations and Commitment Letter." In addition, and upon our own review, we believe it is appropriate to include the guidance document under the existing information collection "Biosimilar User Fee Cover Sheet" currently approved under OMB control number 0910-0718 rather than to establish a new collection. FDA is preparing to renew OMB control number 0910-0718 and will include the guidance document accordingly.

We estimate the burden of the information collection as follows:

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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Request for discontinuation from biological product development program	2	1	2	1	2
Request to move products to discontinued section of the biosimilar list	5	1	5	0.5 (30 minutes)	2.5
Small business waiver of the BsUFA application fee	1	1	1	16	16
Small business waiver reconsiderations	1	1	1	24	24
Small business waiver appeals	1	1	1	12	12
Annual Fee Determination Survey	35	1	35	1	35
Annual BsUFA Fees Correspondence	35	1	35	2	70
Total					161.5

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

Our estimate is based on the number of Biosimilars User Fee submissions we have received since establishing the program.

Dated: June 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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