4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0781]

Final Results of Study of Workload Volume and Full Costs Associated With Review of Biosimilar Biological Product Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the final results of a study of the workload volume and full costs associated with the process for the review of biosimilar biological product applications (final report). This study was conducted by an independent consulting firm, and it fulfills FDA's statutory requirement under the first authorization of the Biosimilar User Fee Act of 2012 (BsUFA), which enables FDA to collect user fees for the review of biosimilar biological applications for fiscal years 2013 to 2017. This notice solicits comments on the final report.

DATES: The report will be released on or before March 17, 2016. Submit either electronic or written comments on the final report by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-0781 for "Final Results of the Study of Workload Volume and Full Costs Associated With Review of Biosimilar Biological Product Applications." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mark Ascione, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1150, Silver Spring, MD 20993-0002, 301-796-7652, FAX: 301-847-8443.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148) amended the Public Health Service Act to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by BsUFA (Title IV of the Food and Drug Administration Safety and Innovation Act, Pub. L. 112-114), authorizes FDA to assess and collect fees for biosimilar biological products from October 2012 through September 2017. FDA uses these fees to expedite the review process for biosimilar biological products. Biosimilar biological products represent an important public health benefit, with the potential to offer life-saving or life-altering benefits at reduced cost to the patient. BsUFA facilitates the development of safe and effective biosimilar products for the American public.

As part of BsUFA, FDA is required to contract with an independent accounting or consulting firm to study the workload volume and full costs associated with the process for the review of biosimilar biological product applications. This notice solicits comments on the final report. The final report is described in section 744I(d) of the FD&C Act (21 U.S.C. 379j-53(d)) (http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section379j-

53&num=0&edition=prelim), as amended by the Food and Drug Administration Safety and Innovation Act enacted in 2012 (http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf). (FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.)

II. Electronic Access

The final report can be accessed at http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/ucm459682.htm.

Dated: March 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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