4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3155]

Interim 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 interim results of a study of the workload volume and full costs associated with the process for the review of biosimilar biological product applications (interim 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 interim report.

DATES: The interim report will be released on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], and will be available at http://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM459686.pdf. Submit either electronic or written comments on the interim report by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the interim report to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 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. 112-144), 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 interim report, and the final report is due no later than September 30, 2016. The interim 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.

II. Comments

FDA is issuing this notice to request public comment on the interim report. Interested persons may submit either electronic comments 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.

III. Electronic Access

The interim report can be accessed at http://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM459686.pdf.

Dated: September 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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