DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–24270 Filed 9–23–15; 8:45 am]

BILLING CODE 4184–01–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 September 24, 2015, 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 October 26, 2015.

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:U.S.C.-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.

[FR Doc. 2015–24227 Filed 9–23–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1837]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic User Fee Payment Request Forms

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 October 26, 2015.

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 title Electronic User Fee Payment Request Forms. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455