DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0194]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biosimilars User Fee Cover Sheet; Form FDA 3792

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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.

Biosimilars User Fee Cover Sheet; Form FDA 3792

OMB Control Number 0910-0718--Extension

The Patient Protection and Affordable Care Act (Pub. L. 111-148) contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (Title VII Subtitle A) (BPCI Act) that amends the Public Health Service Act (42 U.S.C 262) (PHS Act) and other statutes to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Section 351(k) of the PHS Act, added by the BPCI Act, allows a company to submit an application for licensure of a biosimilar or interchangeable biological product. The BPCI Act also amends section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) to include 351(k) applications in the definition of "human drug application" for the purposes of the prescription drug user fee provisions. The BPCI Act directs FDA to develop recommendations for a biosimilar biological product user fee program for fiscal years 2013 through 2017. FDA's recommendations for a biosimilar biological product user fee program were submitted to Congress on January 13, 2012.

FDA's biosimilar biological product user fee program requires FDA to assess and collect user fees for certain meetings concerning biosimilar biological product development (BPD meetings), investigational new drug applications (INDs) intended to support a biosimilar biological product application, and biosimilar biological product applications and supplements. Form FDA 3792, the Biosimilars User Fee Cover Sheet, requests the minimum necessary information to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fees submitted for a submission with the actual

submission by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research to initiate the administrative screening of biosimilar biological product INDs, applications, and supplements, and to account for and track user fees associated with BPD meetings.

In the Federal Register of January 27, 2015 (80 FR 4272), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Respondents to this collection of information are manufacturers of biosimilar biological product candidates. Based on the number of Form FDA 3792s we have received, we estimate the burden of this collection of information as follows:

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

FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Biosimilars User Fee Cover Sheet; Form FDA 3792	20	1	20	0.50 (30 minutes)	10

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

Dated: May 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

BILLING CODE 4164-01-P

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