Biosimilars User Fee Cover Sheet – Form FDA 3792

0910-0718

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The March 23, 2010, Affordable Care Act contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) that amends the Public Health Service Act (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 (FD&C 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 (CDER) and Center for Biologics Evaluation and Research (CBER) 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, biosimilar biological product INDs, applications, and supplements..

2. Purpose and Use of the Information Collection

Form FDA 3792 requests the minimum necessary information from applicants to determine the amount of the fee required, and to account for and track user fees. Applicants complete the cover sheet to accompany payment. While applicants may submit payment through multiple means, all cover sheets are prepared using FDA's web based electronic User Fee System. Upon submission of the cover sheet, the User Fee System generates a user fee identification number, which is provided to applicants at the bottom of the cover sheet. FDA requests that applicants provide a copy of this completed cover sheet along with the IND, application, and supplement submissions so FDA can verify that the applicant has paid the user fee.

3. Use of Improved Information Technology and Burden Reduction

The Biosimilar User Fee Cover Sheet is completed and submitted electronically. Information such as the applicant's name and address, contact name, telephone number and e-mail of representative are auto-populated if the organization is registered and has a user account in the User Fee System.

4. Efforts to Identify Duplication and Use of Similar Information

The information collection is not available from any other source.

5. Impact on Small Businesses or Other Small Entities

This information collection applies to small and large manufacturers. Although FDA must apply the statutory and regulatory requirements equally to all enterprises, the agency does provide special help to small businesses. The Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach, and Development, Division of Manufacturers Assistance and Training provides assistance to small businesses subject to FDA's regulatory requirements. The Center for Drug Evaluation and Research (CDER), Office of Communication, Division of Drug Information also provides assistance to small businesses.

FDA's proposed biosimilar biological product user fee program includes a waiver provision for small businesses. Small businesses granted waivers of application fees under this provision note their exclusion from fee requirements by utilizing the Biosimilar User Fee Cover Sheet.

6. Consequences of Collecting the Information Less Frequently

Manufacturers of biosimilar biological product candidates are required to complete this form for certain BPD meetings, investigational new drug applications (INDs) intended to support a biosimilar biological product application, and biosimilar biological product applications and supplements. The form provides information necessary for FDA to determine the fee required for submissions, track payments, initiate review of biosimilar biological product INDs, applications, and supplements, and hold

BPD meetings. Less frequent collection of this information could result in potential delays in reviewing INDs, applications, and supplements, and in holding BPD meetings.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for the collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of January 27, 2015 (80 FR 4272). FDA received no comments.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift was provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received by FDA would be handled consistent with the Freedom of Information Act (FOIA) and FDA's published regulations under 21 CFR Part 20, which prohibit FDA from releasing to the public any information that cannot be disclosed.

11. Justification for Sensitive Questions

Questions of a sensitive nature are not applicable to this collection of information.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

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

12b. Annualized Cost Burden Estimate

The estimated annual cost to respondents is $460.

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Reporting	10	$46	$ 460

The cost estimate is based on a regulatory affairs specialist, at a pay rate of $46/hour, who would be responsible for filling out and submitting the form. The estimated average hourly pay rate includes benefits but no overhead costs.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The estimated annual cost to FDA is $920.

Activity	Number of Responses	Hours per Response	Cost per Hour	Total Cost
Form FDA 3792	20	1	$46	$920

The estimated cost is based on FDA office and user fee staff at an average grade of GS 12 Step 5. The estimate of one hour includes the time associated with the support,

review, data entry, and tracking related to the Biosimilar User Fee Cover Sheet. The estimated hourly pay rate includes benefits but no overhead costs.

15. Explanation for Program Changes or Adjustments

The adjustments are based on the number of Form FDA 3792s we have received during the past few years that this form has been in use.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking approval to exempt display of the expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.