Biosimilar User Fee Cover Sheet – Form FDA 3792
0910-NEW
SUPPORTING STATEMENT

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. Sections 744G, 744H, and 744I of the Federal Food, Drug, and Cosmetic Act, as amended by the Biosimilar User Fee Act of 2012 (BsUFA), authorizes FDA to assess and collect fees for certain meetings concerning biosimilar biological product development (BPD meetings), investigational new drug (IND) applications (INDs) for biosimilar biological products, and biosimilar biological product applications and supplements. Under BsUFA, fees are due upon submission of the IND, application, and supplement.

2. Purpose and Use of the Information Collection

Proposed Form FDA 3792, the Biosimilar User Fee Cover Sheet, requests the minimum necessary information from applicants to determine the amount of the fee required, and to account for and track user fees. Applicants will fill out 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.

The information collected would be 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.

3. Use of Improved Information Technology and Burden Reduction

The Biosimilar User Fee Cover Sheet would be 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. The review and financial systems are not currently integrated. Therefore, some duplication of effort is inherent in this collection. FDA is exploring ways to integrate the IT systems such that it would address this two-step approach. However, FDA must weigh the costs of system integration with the size of FDA's user fee programs, and other agency priorities. FDA

will consider alternate processes to eliminate the need for applicants to include the coversheet with the application submission, and report to OMB on this status by the next OMB submission.

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 requirements.

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 March 13, 2012 (77 FR 14809). FDA received the following comments:

Comment 1: Suggests FDA use the term "Biosimilar Biological Product Licensing Application (BBLA)" or "Interchangeable Biosimilar Biological Product Application (IBLA)" for a biosimilar application instead of Biologics License Application (BLA) to avoid confusion and provide greater clarity.

Response: FDA notes the Biosimilar User Fee Cover Sheet serves a billing and collections purpose, and does not indicate FDA's position on reference terms. However, to maintain consistency throughout the document and avoid any confusion, FDA refers to a biologics license application submitted under section 351(k) of the Public Health Service Act as a "351(k) application". Under FDA's proposed biosimilar biological product user fee program, user fees would be assessed only for those 351(k) applications that fall within the scope of the defined term "biosimilar biological product application." Accordingly, FDA has made changes to the Biosimilar User Fee Cover Sheet to clarify that Form 3792 need not be submitted for certain specified types of 351(k) applications. Additionally, to address the need for greater clarity, FDA has added definitions of several other key terms to the Biosimilar User Fee Cover Sheet.

Comment 2: Requests FDA to ask for all available product names, including the product's code name in addition to trade and proper names, because the Biosimilar User Fee Cover Sheet should be consistent with Form FDA 1571. Further, requests FDA to amend the "Product Name" information field to "Product Name(s)."

Response: We agree that the Biosimilar User Fee Cover sheet should be consistent with Form 1571, where applicable. Accordingly, FDA amended the instructions to request proper name, trade or proprietary name, and code name, as applicable, and amended the "Product Name" information field to "Product Name(s)".

Comment 3: Requests FDA to remove the question about whether the application requires clinical data, other than comparative bioavailability studies, for approval because this information does not affect the fee amount.

Response: FDA notes this question applies only to fees for biosimilar biological product applications, and not to fees for biosimilar biological products in development. Under FDA's proposed biosimilar biological product user fee program, the fee amount for a biosimilar biological product application depends on whether clinical data with respect to safety or effectiveness are required. Specifically:

- a full fee is assessed for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required for approval;

- a half fee is assessed for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required for approval;

- a half fee is assessed for a supplement for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required for approval; and

- no fee is assessed for a supplement for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required for approval.

Therefore, FDA has retained the question on the Biosimilar User Fee Cover Sheet concerning whether clinical data are required because it requests information necessary to determine the fee amount for a biosimilar biological product application or supplement.

Comment 4: Requests FDA to decline to require a patent certification as part of a 351(k) application.

Response: FDA notes this comment is outside the scope of the proposed collection of information, Form FDA 3792, the Biosimilar User Fee Cover Sheet.

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 proposed collection of information would be manufacturers of biosimilar biological product candidates. Based on FDA's database system, there are an estimated 18 manufacturers that fall into this category. However, not all manufacturers will have submissions in a given year and some may have multiple submissions. FDA estimates 9 annual responses that include the following: 6 INDs or BPD meetings, 2 applications, and 1 supplement. The estimated hours per response are based on FDA's past experience with other submissions, and average 30 minutes. This estimate includes the time associated with including the cover sheet with the IND, application, or supplement submission.

The total estimated annual burden for this collection of information is 4.5 hours.

Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3792	9	1	9	0.5	4.5

12b. Annualized Cost Burden Estimate

The estimated annual cost to respondents is $207.

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	4.5	$46	$ 207

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 costs or operating and maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

The estimated annual cost to FDA is $414.

Activity	Number of Responses	Hours per Response	Cost per Hour	Total Cost
Form FDA 3792	9	1.0	$46	$414

The estimated cost is based on FDA office and user fee staff at an average grade of GS12-5. 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

This is a new collection of information.

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.