UNITED STATES FOOD AND DRUG ADMINISTRATION

Section 351(k) Biosimilar Applications – General Licensing Provisions
Biosimilar User Fee Program
OMB Control Number 0910-0719

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The BPCI Act amended the Public Health Service Act (PHS Act) to establish an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, a Food and Drug Administration (FDA)-licensed biological reference product. Section 351(k) of the PHS Act (42 U.S.C. 262(k)), sets forth the requirements for an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product. Section 351(k) defines biosimilarity to mean "*that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components*" and that "*there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product*." (See section 351(i)(2) of the PHS Act.)

A 351(k) application must contain, among other things, information demonstrating that the biological product is biosimilar to a reference product based upon data derived from analytical studies, animal studies, and clinical studies, unless FDA determines, in its discretion, that certain studies are unnecessary in a 351(k) application. (See section 351(k)(2) of the PHS Act.) To demonstrate interchangeability, an applicant must provide sufficient information to demonstrate biosimilarity and that the biosimilar biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biosimilar biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biosimilar biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch. (See section 351(k)(4) of the PHS Act.) Interchangeable products may be substituted for the reference product without the intervention of the prescribing health care provider. (See section 351(i)(3) of the PHS Act.)

We therefore request extension of OMB approval for the information collection provisions associated with section 351(k) biosimilar applications, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The information collection establishes an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product, and sets forth the requirements for an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product. We use the information

submitted in a 351(k) application or supplement to make a determination of biosimilarity or interchangeability of a proposed 351(k) product.

3. Use of Improved Information Technology and Burden Reduction

One of our continuing objectives is to improve the timing and quality of our review and approval programs. To make the review process more efficient for industry and FDA, we utilize electronic information systems technology and currently accepts the submission of electronic license applications and other similar submissions. To assist respondents, we offer guidance documents describing the process for submitting applications to FDA in electronic format on our website at:

- http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064994.htm; and
- http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/ucm218518.htm

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. While have established and administer user fee programs associated with the review of other FDA-regulated products, this information collection specifically supports information collection associated biosimilar applications filed under section 351(k) of the PHS.

5. Impact on Small Businesses or Other Small Entities

The information collection imposes no undue burden on small entities. At the same time, we provide assistance to small businesses through our Center for Biologics Evaluation and Research (CBER) Office of Communications, Outreach and Development, Division of Manufacturer's Assistance and Training; and our Center for Drug Evaluation and Research (CDER) Office of Communication, Division of Drug Information.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

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

There are no special circumstances for this 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), we published a 60-day notice inviting public comment in the Federal Register of July 3, 2018 (83 FR 31152). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No gifts or payments are provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received is protected consistent with applicable provisions of the Freedom of Information Act (FOIA) and FDA's published regulations under 21 CFR Part 20, 21 CFR 601.51, and 601.70(e).

11. Justification for Sensitive Questions

There are no questions of a sensitive nature applicable to this collection of information.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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

351(k) Applications (42 U.S.C. 262(k))	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
351(k)(2)(A)(i) and 351(k)(2)(A)(iii) Biosimilar Product Applications	4	2.25	9	860	7,740
351(k)(2)(B) and (k)(4) Interchangeable Product Applications or Supplements	2	1	2	860	1,720
351(l)(6)(C) Patent Infringement Notifications	4	2.25	9	2	18
Total					9,478

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

12b. Annualized Cost Burden Estimate

Assuming a regulatory affairs specialist, at a pay rate of $50/hour, would be responsible for preparing an submitting an application, supplement, or other similar submission, and multiplying that figure by the total annual burden hours (9,478), we estimate an annual cost to respondents of $ 473,900.

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

We estimate an annualized cost to FDA of $250,000. This estimate assumes 2 full-time equivalent employees (FTEs) will be responsible for the review of license applications including supplemental applications. The amount of time and expense incurred by the Federal government includes the time to the review of all material submitted with an application or supplement. The estimated average annual salary for FDA reviewers includes benefits but no overhead costs.

15. Explanation for Program Changes or Adjustments

Although we adjusted the estimated number of respondents downward, we have increased the number of submissions per respondent, reflecting an overall increase since last OMB approval. The increase corresponds to an increase in applications we have received over the last three years.

16. Plans for Tabulation and Publication and Project Time Schedule

We do not intend to publish tabulated results of these information collection requirements.

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

We will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.