4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2012-N-0129]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Licensing Provisions; Section 351(k) Biosimilar Applications

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 0910-0719. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, 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.

General Licensing Provisions; Section 351(k) Biosimilar Applications

OMB Control Number 0910-0719--Extension

The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) amended the Public Health Service Act (PHS Act) and other statutes to create an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference product. Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, 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 meet the standard for interchangeability, an applicant must provide sufficient information to demonstrate biosimilarity and also to demonstrate that the biological product can be expected to

produce the same clinical result as the reference product in any given patient and, if the 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 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 healthcare provider (see section 351(i)(3) of the PHS Act) In estimating the information collection burden for 351(k) biosimilar product applications and interchangeable product applications or supplements, we reviewed the number of 351(k) applications FDA has received in fiscal years 2015, 2016, and 2017, considered responses to a survey of biosimilar sponsors and applicants regarding projected future 351(k) submission volumes, as well as the collection of information regarding the general licensing provisions for biologics license applications under section 351(a) of the PHS Act submitted to OMB (approved under OMB control number 0910-0338).

To submit an application seeking licensure of a proposed biosimilar product under sections 351(k)(2)(A)(i) and (iii) of the PHS Act, the estimated burden hours (FDA believes) would be approximately the same as noted under OMB control number 0910-0338 for a 351(a) application--860 hours. The burden estimates for seeking licensure of a proposed biosimilar product that meets the standards for interchangeability under sections 351(k)(2)(B) and (k)(4) would also be 860 hours per application. FDA believes these estimates are appropriate for 351(k) applications because the paperwork burden for a 351(k) application is expected to be comparable to the paperwork burden for a 351(a) application.

In addition to the collection of information regarding the submission of a 351(k) application for a proposed biosimilar or interchangeable biological product, section 351(l) of the BPCI Act establishes procedures for identifying and resolving patent disputes involving applications submitted under section 351(k) of the PHS Act. The burden estimate for the patent notification provisions under section 351(l)(6)(C) of the BPCI Act are included in table 1 and are based on the estimated number of 351(k) applicants. Based on similar reporting requirements, FDA estimates this notification will take 2 hours.

In the *Federal Register* of July 3, 2018 (83 FR 31152), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

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.

Based on a review of the information collection since our last request for OMB approval, the estimated burden for the information collection reflects an overall increase in total hours and responses. We attribute this adjustment to an increase in the number of submissions received over the last few years and additional interest in the biosimilars program.

Dated: November 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-25232 Filed: 11/19/2018 8:45 am; Publication Date: 11/20/2018]