UNITED STATES FOOD & DRUG ADMINISTRATION

Section 351(k) Biosimilar Applications – General Licensing Provisions
Biosimilar User Fee Program

OMB Control Number 0910-0719

Non-substantive Change Request to an existing information collection:

I. Background

This information collection helps support 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. Regulations pertaining to applications for biologics licenses and procedures for filing are codified in agency regulations at 21 CFR part 601 (see related OMB control no. 0910-0338).

The Biosimilar User Fee Act of 2012 (BsUFA I), as reauthorized under the FDA Reauthorization Act of 2017 (BsUFA II), permits FDA to establish fees for biologic license applications submitted in accordance with section 351(k). Information collection pertaining to the establishment, submission, reduction, and waiver of fees associated with our BsUFA program is approved under OMB control no. 0910-0718. This collection of information sets forth procedural information and accounts for burden associated with the submission of license applications themselves, along with associated recordkeeping and disclosure burdens resulting from applicable statutory and regulatory requirements.

II. Proposed Changes

The BsUFA requirements discussed above are augmented by what is commonly referred to as a "*goals letter*" or "*commitment letter*," which represents the product of FDA discussions with regulated industry and public stakeholders, as mandated by Congress. We are requesting a non-substantive change to the information collection to incorporate the the document entitled "*BsUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022*" (BsUFA II letter) available on our website at https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf. The performance and procedural goals specified in the letter apply to aspects of the biosimilar biological product review program that are important for facilitating timely access to safe and effective biosimilar medicines for patients. Among those considerations is providing feedback to requests from regulated industry. Each year, FDA review staff participate in many meetings with requesters who seek advice relating to the development and review of a biosimilar or interchangeable product. Because these meetings often represent critical points in the regulatory and development process, it is important that there are clear procedures for the timely and effective conduct of such meetings.

Consistent with *Section I; Part 6* of the BsUFA II letter (see p. 25 of 33) therefore, and together with adherence to agency Good Guidance practice regulations in 21 CFR 10.115, we issued draft guidance articulating current meeting management goals. The guidance provides specific instruction and recommendations regarding the submission of meeting requests and preparing supporting material. In the Federal Register of November 22, 2019 (84 FR 64529) we announced the draft guidance and included an analysis under the PRA attributing 159 annual responses and 3,405 annual hours to the attendant information collection activity. The guidance is available from our website at:

Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products Guidance for Industry | FDA

While we intend to finalize the guidance, we believe that burden associated with the submission of meeting requests and supporting material is ultimately triggered by the BsUFA II letter. At the same time, because the guidance provides procedural instruction helpful to respondents and helps us reach what we believe is a more accurate burden estimate, we are requesting to include reference to the guidance document as well. We have added the 159 annual responses and 3,406 annual hours proffered in our guidance notice as a distinct IC element to this information collection.

Submitted: January 2021