FY 2020

Real Time Report

pursuant to the

Biosimilar User Fee Act

as amended by the FDA Reauthorization Act of 2017

Acronyms

BLA – Biologics License Application

BsUFA – Biosimilar User Fee Act

CBER – Center for Biologics Evaluation and Research

CDER – Center for Drug Evaluation and Research

FD&C Act – Federal Food, Drug, and Cosmetic Act

FDA – Food and Drug Administration

FDARA – FDA Reauthorization Act of 2017

FY – Fiscal Year (October 1 to September 30)

Q1 – Quarter 1 (October 1 to December 31)

Q2 – Quarter 2 (January 1 to March 31)

Q3 – Quarter 3 (April 1 to June 30)

Q4 – Quarter 4 (July 1 to September 30)

Background

On August 18, 2017, the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52) was signed into law. FDARA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to revise and extend the user fee programs for human drugs, biologics, generic drugs, medical devices, and biosimilar biological products.

Section 744I(a)(3) of the FD&C Act, as amended by Section 903 of FDARA, requires the Food and Drug Administration (FDA) to provide 'Real Time' reporting, posted on a quarterly basis, of guidance documents and public meetings pertaining to the process for the review of biosimilars.

Real Time Reporting Under Section 744I(a)(3) of the FD&C Act

This report provides the BsUFA real time reporting metrics, required under Section 744I(a)(3) of the FD&C Act:

> Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary of Health and Human Services shall post on the internet website of the Food and Drug Administration:
>
> 1) The number and titles of draft and final guidance on topics related to the process for the review of biosimilars, and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017.
> 2) The number and titles of public meetings held on topics related to the process for the review of biosimilars, and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017.

Biosimilars

Guidance Documents

Pursuant to Section 744I(a)(3) of the FD&C Act, the table below lists the number and titles of draft and final guidance on topics related to the process for the review of biosimilars, and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017. Guidance documents are listed by the quarter in which they were issued and are provided in a cumulative format for Fiscal Year (FY) 2020.

Table 1: Draft and Final Guidance Documents Related to the Process for the Review of Biosimilars for FY 2020

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
1	Q1	Draft guidance for industry Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-immunogenicity-considerations-biosimilar-and-interchangeable-insulin-products	11/29/2019	Other	NA
2	Q2	Draft guidance for industry Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/promotional-labeling-and-advertising-considerations-prescription-biological-reference-and-biosimilar	2/4/2020	Other	NA
3	Q2	Draft guidance for industry Biosimilars and Interchangeable Biosimilars: Licensure for Fewer Than All Conditions of Use for Which the Reference Product Has Been Licensed www.fda.gov/regulatory-information/search-fda-guidance-documents/biosimilars-and-interchangeable-biosimilars-licensure-fewer-all-conditions-use-which-reference	2/7/2020	Other	NA
4	Q2	The "Deemed" to be a License" Provision of the Biologics Price Competition and Innovation Act: Questions and Answers www.federalregister.gov/documents/2020/03/05/2020-04537/the-deemed-to-be-a-license-provision-of-the-biologics-price-competition-and-innovation-act-questions	3/5/2020	Other	NA

Public Meetings

Pursuant to Section 744I(a)(3) of the FD&C Act, the table below lists the number and titles of public meetings held on topics related to the process for the review of biosimilars, and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017. Public meetings are listed by the quarter in which they were held and are provided in a cumulative format for FY 2020.

Table 2: Public Meetings Held Related to the Process for the Review of Biosimilars for FY 2020

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q2	Public Workshop: FDA/FTC Workshop on a Competitive Marketplace for Biosimilars	3/9/2020	NA
2	Q3	Financial Transparency and Efficiency of the Prescription Drug User Fee, Biosimilar User Fee Act and Generic User Fee Amendments	6/10/2020	NA