FY 2019

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 2019.

Table 1: Draft and Final Guidance Documents Related to the Process for the Review of Biosimilars for FY 2019

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	Questions and Answers on Biosimilar Development and the BPCI Act www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM444661.pdf	12/12/2018	Other	N/A
2	Q1	New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2) www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM273001.pdf	12/12/2018	Pursuant to Commitment Letter	Q.I.20 addresses section II.C
3	Q1	Interpretation of the "Deemed To Be a License" Provision of the Biologics Price Competition and Innovation Act of 2009 www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM490264.pdf	12/12/2018	Other	N/A
4	Q1	The "Deemed to be a License" Provision of the BPCI Act: Questions and Answers www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM628115.pdf	12/12/2018	Other	N/A
5	Q2	Nonproprietary Naming of Biological Products: Update www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM632806.pdf	3/8/2019	Other	N/A
6	Q3	Considerations in Demonstrating Interchangeability with a Reference Product www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-demonstrating-interchangeability-reference-product-guidance-industry	5/10/2019	Pursuant to Commitment Letter	II.A
7	Q3	Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations www.fda.gov/regulatory-information/search-fda-guidance-documents/development-therapeutic-protein-biosimilars-comparative-analytical-assessment-and-other-quality	5/21/2019	Pursuant to Commitment Letter	II.B

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 fiscal year 2019.

Table 2: Public Meetings Held Related to the Process for the Review of Biosimilars for FY 2019

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q3	The Future of Insulin Biosimilars: Increasing Access and Facilitating the Efficient Development of Biosimilar and Interchangeable Insulin Products www.fda.gov/news-events/fda-meetings-conferences-and-workshops/future-insulin-biosimilars-increasing-access-and-facilitating-efficient-development-biosimilar-and	5/13/2019	NA