FY 2018

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 – Food and Drug Administration 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 Food and Drug Administration Reauthorization Act (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 2018.

Table 1: Draft and Final Guidance Documents Related to the Process for the Review of Biosimilars for FY 2018

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	Assessing User Fees Under the Biosimilar User Fee Amendments of 2017 www.federalregister.gov/documents/2017/11/16/2017-24831/assessing-user-fees-under-the-biosimilar-user-fee-amendments-of-2017-draft-guidance-for-industry	11/16/2017	Other	N/A
2	Q1	Drug Products, Including Biological Products, that Contain Nanomaterials - Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM588857.pdf	12/15/2017	Other	N/A
3	Q1	Best Practices for Communication Between IND Sponsors and FDA www.fda.gov/downloads/drugs/guidancecompliancere gulatoryinformation/guidances/ucm475586.pdf	12/28/2017	Pursuant to Commitment Letter	I.I.6.b
4	Q2	Q11 Development and Manufacture of Drug Substances--Questions and Answers (Chemical Entities and Biotechnological/Biological Entities) www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM542176.pdf	2/23/2018	Other	N/A
5	Q3	Special Protocol Assessment; Guidance for Industry: Final www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM498793.pdf	4/16/2018	Other	N/A
6	Q3	Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Biosimilar User Fee Act Products: Draft www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609662.pdf	6/5/2018	Pursuant to Commitment Letter	I.I.6.a.
7	Q3	Assessing User Fees Under the Biosimilar User Fee Amendments of 2017: Final www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM584984.pdf	6/29/2018	Other	N/A
8	Q4	Labeling for Biosimilar Products: Final www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM493439.pdf	7/19/2018	Pursuant to Commitment Letter	II.D.3

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)
9	Q4	Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications: Draft www.fda.gov/downloads/Drugs/.../Guidances/ucm079748.pdf	9/24/2018	Pursuant to Commitment Letter	I.D

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 2018.

Table 2: Public Meetings Held Related to the Process for the Review of Biosimilars for FY 2018

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q4	Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments www.federalregister.gov/documents/2018/07/25/2018-15859/facilitating-competition-and-innovation-in-the-biological-products-marketplace-public-hearing	9/4/2018	Other