FY 2021

Real Time Report

pursuant to the

Generic Drug User Fee Amendments

as amended by the FDA Reauthorization Act of 2017

Acronyms

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)

GDUFA – Generic Drug User Fee Amendments

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 744C(a)(2) 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 related to human generic drug activities.[1]

Real Time Reporting Under Section 744C(a)(2) of the FD&C Act

This report is being issued pursuant to the requirement of Section 744C(a)(2) of the FD&C Act, which states:

> "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…
>
> - "The number and titles of draft and final guidance on topics related to human generic drug activities and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017."
> - "The number and titles of public meetings held on topics related to human generic drug activities and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017."

[1] This report provides information related to human generic drug activities, which are defined by section 744A(9) of the FD&C Act as activities associated with generic drugs and inspection of facilities associated with generic drugs. This report does not include information regarding biosimilar biologic license applications, which is presented in the 'Real Time' report pursuant to the Biosimilars User Fee Act.

Human Generic Drugs

Guidance Documents

Pursuant to Section 744C(a)(2) of the FD&C Act, the table below lists the number and titles of draft and final guidances on topics related to human generic drug activities and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017. Guidances are listed by the quarter in which they were issued and are provided in a cumulative format for Fiscal Year (FY) 2021.

Table 1: Draft and Final Guidance Documents Related to the Human Generic Drug Activities for FY 2021

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	The Use of Physiologically Based Pharmacokinetic Analyses — Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls www.fda.gov/media/142500/download	10/1/2020	Other	NA
2	Q1	Referencing Approved Drug Products in ANDA Submissions; Final Guidance for Industry www.fda.gov/media/102360/download	10/27/2020	None	N/A
3	Q1	Tiotropium Bromide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021936.pdf	11/18/2020	Other	N/A
4	Q1	Azelaic Acid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207071.pdf	11/19/2020	Other	N/A
5	Q1	Budesonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205613.pdf	11/19/2020	Other	N/A
6	Q1	Bupropion Hydrochloride; Naltrexone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200063.pdf	11/19/2020	Other	N/A
7	Q1	Calcipotriene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022563.pdf	11/19/2020	Other	N/A
8	Q1	Ceritinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211225.pdf	11/19/2020	Other	N/A
9	Q1	Clobazam; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210833.pdf	11/19/2020	Other	N/A

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)
10	Q1	Clobetasol Propionate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022013.pdf	11/19/2020	Other	N/A
11	Q1	Crofelemer; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202292.pdf	11/19/2020	Other	N/A
12	Q1	Desonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021978.pdf	11/19/2020	Other	N/A
13	Q1	Diazepam; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211635.pdf	11/19/2020	Other	N/A
14	Q1	Epinephrine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205920.pdf	11/19/2020	Other	N/A
15	Q1	Erythromycin Ethylsuccinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_061904.pdf	11/19/2020	Other	N/A
16	Q1	Erythromycin Ethylsuccinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050207.pdf	11/19/2020	Other	N/A
17	Q1	Erythromycin Ethylsuccinate; Sulfisoxazole Acetyl; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050529.pdf	11/19/2020	Other	N/A
18	Q1	Fluorodopa F-18; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200655.pdf	11/19/2020	Other	N/A
19	Q1	Fluphenazine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011751.pdf	11/19/2020	Other	N/A
20	Q1	Hydrocortisone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017351.pdf	11/19/2020	Other	N/A
21	Q1	Isotretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021951.pdf	11/19/2020	Other	N/A

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)
22	Q1	Isotretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018662.pdf	11/19/2020	Other	N/A
23	Q1	Lefamulin Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211672.pdf	11/19/2020	Other	N/A
24	Q1	Levorphanol Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_008720.pdf	11/19/2020	Other	N/A
25	Q1	Lomitapide Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203858.pdf	11/19/2020	Other	N/A
26	Q1	Methylphenidate Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207960.pdf	11/19/2020	Other	N/A
27	Q1	Naloxone Hydrochloride; Oxycodone Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205777.pdf	11/19/2020	Other	N/A
28	Q1	Pimavanserin Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207318.pdf	11/19/2020	Other	N/A
29	Q1	Pretomanid; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212862.pdf	11/19/2020	Other	N/A
30	Q1	Prochlorperazine Maleate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_010571.pdf	11/19/2020	Other	N/A
31	Q1	Propranolol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016418.pdf	11/19/2020	Other	N/A
32	Q1	Propranolol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021438.pdf	11/19/2020	Other	N/A

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)
33	Q1	Propranolol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018553.pdf	11/19/2020	Other	N/A
34	Q1	Tafamidis Meglumine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211996.pdf	11/19/2020	Other	N/A
35	Q1	Tiotropium Bromide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021936.pdf	11/19/2020	Other	N/A
36	Q1	Tofacitinib Citrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208246.pdf	11/19/2020	Other	N/A
37	Q1	Vancomycin Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208910.pdf	11/19/2020	Other	N/A
38	Q1	Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA; Final Guidance for Industry www.fda.gov/media/107626/download	11/24/2020	Yes	GDUFA Commitment Letter Section III (Pre-ANDA Program)
39	Q1	Controlled Correspondence Related to Generic Drug Development; Final Guidance for Industry www.fda.gov/media/109232/download	12/16/2020	Other	NA
40	Q1	Review Timelines for Applicant Responses to Complete Response Letters When a Facility Assessment Is Needed During the COVID-19 Public Health Emergency Guidance for Industry www.fda.gov/media/144690/download	12/21/2020	Other	NA
41	Q1	Protecting Participants in Bioequivalence Studies for Abbreviated New Drug Applications During the COVID-19 Public Health Emergency; Final Guidance for Industry www.fda.gov/media/145162/download	01/15/2021	None	N/A

Public Meetings

Pursuant to Section 744C(a)(2) of the FD&C Act, the table below lists the number and titles of public meetings held on topics related to human generic drug activities and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug 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 2021.

Table 2: Public Meetings Held on Topics Related to Human Generic Drug Activities for FY 2021

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	The FDA/DIA Complex Generic Drug-Device Combination Products Conference 2020 www.fda.gov/drugs/news-events-human-drugs/fdadia-complex-generic-drug-device-combination-products-conference-2020-10192020-10202020	October 19-20, 2020	No
2	Q1	Regulatory Education for Industry: Celebrating 40 Years: An In-Depth Examination of the FDA Orange Book www.fda.gov/drugs/news-events-human-drugs/regulatory-education-industry-celebrating-40-years-depth-examination-fda-orange-book-10272020	October 27-28, 2020	No