FY 2022

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 added 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 specified 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) 2022.

Table 1: Draft and Final Guidance Documents Related to the Human Generic Drug Activities for FY 2022

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	Q13 Continuous Manufacturing of Drug Substances and Drug Products; Draft Guidance for Industry https://www.fda.gov/media/153044/download	10/13/2021	Other	N/A
2	Q1	Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act; Draft Guidance for Industry https://www.fda.gov/media/153665/download	10/29/2021	Yes	Section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act, as added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).
3	Q1	Alprazolam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021726.pdf	11/8/2021	Other	NA
4	Q1	Aripiprazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021729.pdf	11/8/2021	Other	N/A
5	Q1	Artesunate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213036.pdf	11/8/2021	Other	N/A
6	Q1	Beclomethasone Dipropionate Monohydrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019389.pdf	11/8/2021	Other	N/A
7	Q1	Bempedoic Acid; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211616.pdf	11/8/2021	Other	N/A
8	Q1	Bempedoic Acid; Ezetimibe; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211617.pdf	11/8/2021	Other	N/A
9	Q1	Carbidopa; Levodopa; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_076699.pdf	11/8/2021	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	Cenobamate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212839.pdf	11/8/2021	Other	N/A
11	Q1	Cetirizine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022578.pdf	11/8/2021	Other	N/A
12	Q1	Ciclesonide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022004.pdf	11/8/2021	Other	N/A
13	Q1	Clascoterone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213433.pdf	11/8/2021	Other	N/A
14	Q1	Colesevelam Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210895.pdf	11/8/2021	Other	N/A
15	Q1	Colesevelam Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021176.pdf	11/8/2021	Other	N/A
16	Q1	Colesevelam Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022362.pdf	11/8/2021	Other	N/A
17	Q1	Desloratadine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021312.pdf	11/8/2021	Other	N/A
18	Q1	Diclofenac Potassium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020142.pdf	11/8/2021	Other	N/A
19	Q1	Dicyclomine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_007409-Tab.pdf	11/8/2021	Other	N/A
20	Q1	Donepezil Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021720.pdf	11/8/2021	Other	N/A
21	Q1	Glucagon; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212097.pdf	11/8/2021	Other	N/A
22	Q1	Lactitol; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211281.pdf	11/8/2021	Other	N/A
23	Q1	Lansoprazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021428.pdf	11/8/2021	Other	N/A
24	Q1	Lemborexant; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212028.pdf	11/8/2021	Other	N/A
25	Q1	Leuprolide Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021088.pdf	11/8/2021	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)
26	Q1	Leuprolide Acetate; Norethindrone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203696.pdf	11/8/2021	Other	N/A
27	Q1	Loratadine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020704.pdf	11/8/2021	Other	N/A
28	Q1	Lurbinectedin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213702.pdf	11/8/2021	Other	N/A
29	Q1	Methylphenidate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205489.pdf	11/8/2021	Other	N/A
30	Q1	Metoclopramide Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022246.pdf	11/8/2021	Other	N/A
31	Q1	Minocycline Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212379.pdf	11/8/2021	Other	N/A
32	Q1	Minocycline Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213690.pdf	11/8/2021	Other	N/A
33	Q1	Minocycline Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209269.pdf	11/8/2021	Other	N/A
34	Q1	Mirtazapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021208.pdf	11/8/2021	Other	N/A
35	Q1	Olanzapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021086.pdf	11/8/2021	Other	N/A
36	Q1	Ondansetron; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020781.pdf	11/8/2021	Other	N/A
37	Q1	Opicapone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212489.pdf	11/8/2021	Other	N/A
38	Q1	Pemigatinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213736.pdf	11/8/2021	Other	N/A
39	Q1	Potassium Phosphate, Dibasic; Potassium Phosphate, Monobasic; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212832.pdf	11/8/2021	Other	N/A
40	Q1	Potassium Phosphate, Dibasic; Potassium Phosphate, Monobasic; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212121.pdf	11/8/2021	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)
41	Q1	Remimazolam Besylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212295.pdf	11/8/2021	Other	N/A
42	Q1	Riluzole; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209080.pdf	11/8/2021	Other	N/A
43	Q1	Rimegepant Sulfate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212728.pdf	11/8/2021	Other	N/A
44	Q1	Risperidone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021444.pdf	11/8/2021	Other	N/A
45	Q1	Rizatriptan Benzoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020865.pdf	11/8/2021	Other	N/A
46	Q1	Sodium Iodide I-131; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016517.pdf	11/8/2021	Other	N/A
47	Q1	Tenapanor Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211801.pdf	11/8/2021	Other	N/A
48	Q1	Triamcinolone Acetonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012041.pdf	11/8/2021	Other	N/A
49	Q1	Tucatinib; Draft Guidance for Industry https://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213411.pdf	11/8/2021	Other	N/A
50	Q1	Zolmitriptan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021231.pdf	11/8/2021	Other	N/A
51	Q1	Cover Letter Attachments for Controlled Correspondences and ANDA Submissions; Draft Guidance for Industry https://www.fda.gov/media/154762/download	12/10/2021	Other	N/A
52	Q1	Inspection of Injectable Products for Visible Particulates; Draft Guidance for Industry https://www.fda.gov/media/154868/download	12/16/2021	Other	NA
53	Q1	Brilliant Blue G; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209569.pdf	12/17/2021	Other	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 2022.

Table 2: Public Meetings Held on Topics Related to Human Generic Drug Activities for FY 2022

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	FDA and Center for Research on Complex Generics Co-Hosted Workshop: Regulatory Utility of Mechanistic Modeling to Support Alternative Bioequivalence Approaches www.fda.gov/drugs/news-events-human-drugs/fda-and-center-research-complex-generics-co-hosted-workshop-regulatory-utility-mechanistic-modeling	September 30-October 1, 2021	No
2	Q1	Public Meeting on the Reauthorization of Generic Drug User Fee Amendments (GDUFA) www.fda.gov/drugs/news-events-human-drugs/public-meeting-reauthorization-generic-drug-user-fee-amendments-gdufa-11162021-11162021	November 16, 2021	Yes
3	Q1	FDA and Center for Research on Complex Generics Co-Hosted Workshop: Establishing the Suitability of Model-Integrated Evidence to Demonstrate Bioequivalence for Long-Acting Injectable and Implantable Drug Products https://www.fda.gov/drugs/news-events-human-drugs/fda-and-center-research-complex-generics-co-hosted-workshop-establishing-suitability-model	November 30, 2021	No
4	Q1	Drug Permeability: Best Practices for Biopharmaceutics Classification System-Based Biowaivers www.fda.gov/drugs/news-events-human-drugs/drug-permeability-best-practices-biopharmaceutics-classification-system-based-biowaivers-12062021	December 6, 2021	No