FY 2024

Real Time Report

pursuant to the

Federal Food, Drug, and Cosmetic Act

as amended by the Generic Drug User Fee Amendments of 2022

Acronyms

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

FDA – Food and Drug Administration

FDAUFRA 2022 – FDA User Fee Reauthorization Act of 2022

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 September 30, 2022, the FDA User Fee Reauthorization Act of 2022 (FDAUFRA) (Division F of Public Law 117-180) was signed into law. FDAUFRA 2022 amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by revising and extending the user fee programs for human prescription drugs, biologics, generic drugs, medical devices, and biosimilar biological products.

Section 744C(a)(2) of the FD&C Act 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 each quarter of each fiscal year for which fees are collected under this part, 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 2022."
> - "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 2022."

[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 Biosimilar 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 2022. Guidances are listed by the quarter in which they were issued and are provided in a cumulative format for Fiscal Year (FY) 2024.

Table 1: Draft and Final Guidance Documents Related to the Human Generic Drug Activities for FY 2024

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	Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities; Draft Guidance for Industry www.fda.gov/media/173286/download	10/26/2023	Other	N/A
2	Q1	Albuterol Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020503.pdf	11/16/2023	Other	N/A
3	Q1	Azacitidine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214120.pdf	11/16/2023	Other	N/A
4	Q1	Betamethasone Acetate; Betamethasone Sodium Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_014602.pdf	11/16/2023	Other	N/A
5	Q1	Budesonide; Formoterol Fumarate Dihydrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021929.pdf	11/16/2023	Other	N/A
6	Q1	Chlorhexidine Gluconate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017768.pdf	11/16/2023	Other	N/A
7	Q1	Cimetidine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017920.pdf	11/16/2023	Other	N/A
8	Q1	Citalopram Hydrobromide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215428.pdf	11/16/2023	Other	N/A
9	Q1	Deucravacitinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214958.pdf	11/16/2023	Yes	Section III.C.1 of GDUFA II commitment letter".
10	Q1	Deutetrabenazine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216354.pdf	11/16/2023	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)
11	Q1	Dextroamphetamine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215401.pdf	11/16/2023	Other	N/A
12	Q1	Edaravone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215446.pdf	11/16/2023	Other	N/A
13	Q1	Emtricitabine; Tenofovir Alafenamide Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208215.pdf	11/16/2023	Other	N/A
14	Q1	Ferric Pyrophosphate Citrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208551.pdf	11/16/2023	Other	N/A
15	Q1	Ferric Pyrophosphate Citrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206317.pdf	11/16/2023	Other	N/A
16	Q1	Ferric Pyrophosphate Citrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212860.pdf	11/16/2023	Other	N/A
17	Q1	Ferumoxytol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022180.pdf	11/16/2023	Other	N/A
18	Q1	Fingolimod Lauryl Sulfate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214962.pdf	11/16/2023	Other	N/A
19	Q1	Fluticasone Propionate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021433.pdf	11/16/2023	Other	N/A
20	Q1	Fluticasone Propionate; Salmeterol Xinafoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021254.pdf	11/16/2023	Other	N/A
21	Q1	Fulvestrant; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021344.pdf	11/16/2023	Other	N/A
22	Q1	Furosemide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209988.pdf	11/16/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter
23	Q1	Futibatinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214801.pdf	11/16/2023	Yes	Section III.C.1 of GDUFA II commitment letter".
24	Q1	Gabapentin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022544.pdf	11/16/2023	Other	N/A
25	Q1	Ganaxolone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215904.pdf	11/16/2023	Yes	Section III.C.1 of GDUFA II commitment letter".
26	Q1	Glatiramer Acetate; Revised Draft Guidance for www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020622.pdf	11/16/2023	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)
27	Q1	Glycopyrrolate; Neostigmine Methylsulfate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216903.pdf	11/16/2023	Other	N/A
28	Q1	Halobetasol Propionate; Tazarotene; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209354.pdf	11/16/2023	Other	N/A
29	Q1	Latanoprost; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216472.pdf	11/16/2023	Other	N/A
30	Q1	Levalbuterol Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021730.pdf	11/16/2023	Other	N/A
31	Q1	Mometasone Furoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205641.pdf	11/16/2023	Other	N/A
32	Q1	Naltrexone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021897.pdf	11/16/2023	Other	N/A
33	Q1	Omidenepag Isopropyl; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215092.pdf	11/16/2023	Yes	Section III.C.1 of GDUFA II commitment letter".
34	Q1	Primidone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009170.pdf	11/16/2023	Other	N/A
35	Q1	Risperidone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210655.pdf	11/16/2023	Other	N/A
36	Q1	Semaglutide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215256.pdf	11/16/2023	Other	N/A
37	Q1	Semaglutide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209637.pdf	11/16/2023	Other	N/A
38	Q1	Sotorasib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214665.pdf	11/16/2023	Other	N/A
39	Q1	Soybean Oil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017643.pdf	11/16/2023	Other	N/A
40	Q1	Tapinarof; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215272.pdf	11/16/2023	Other	N/A
41	Q1	Tiotropium Bromide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021395.pdf	11/16/2023	Other	N/A
42	Q1	Clindamycin Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050600.pdf	11/21/2023	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)
43	Q1	Inclisiran Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214012.pdf	11/21/2023	Other	N/A
44	Q1	Ruxolitinib Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215309.pdf	11/21/2023	Other	N/A
45	Q1	Advanced Manufacturing Technologies Designation Program; Draft Guidance for Industry www.fda.gov/media/174651/download	12/13/2023	Other	N/A
46	Q1	Data Standards for Drug and Biological Product Submissions Containing Real-World Data; Final Guidance for Industry www.fda.gov/media/153341/download	12/22/2023	Other	N/A
47	Q1	Real-World Data: Assessing Registries To Support Regulatory Decision-Making for Drug and Biological Products; Final Guidance for Industry www.fda.gov/media/154449/download	12/22/2023	Other	N/A
48	Q1	Quality Considerations for Topical Ophthalmic Drug Products; Draft Guidance for Industry www.fda.gov/media/172937/download	12/27/2023	Other	N/A
49	Q1	Reformulating Drug Products That Contain Carbomers Manufactured With Benzene; Final Guidance for Industry www.fda.gov/media/175083/download	12/28/2023	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 2022. Public meetings are listed by the quarter in which they were held and are provided in a cumulative format for FY 2024.

Table 2: Public Meetings Held on Topics Related to Human Generic Drug Activities for FY 2024

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	2023 NanoDay Symposium: Continuous Manufacturing of Nanomaterials www.fda.gov/drugs/news-events-human-drugs/2023-nanoday-symposium-continuous-manufacturing-nanomaterials-10112023	10/11/2023	No

2	Q1	FDA and Center for Research on Complex Generics Co-Hosted Workshop: Advances in PBPK Modeling and its Regulatory Utility for Oral Drug Product Development www.fda.gov/news-events/advances-pbpk-modeling-and-its-regulatory-utility-oral-drug-product-development-10122023	10/12/2023	No
3	Q1	Pharmaceutical Quality Symposium 2023: Quality, Supply Chain & Advanced Manufacturing www.fda.gov/drugs/news-events-human-drugs/pharmaceutical-quality-symposium-2023-quality-supply-chain-advanced-manufacturing-10312023	10/31/2023-11/1/2023	No
4	Q1	Positron Emission Tomography: Product Quality Regulatory Submissions, Facility Inspections, and Benefit-Risk Considerations www.fda.gov/drugs/news-events-human-drugs/positron-emission-tomography-product-quality-regulatory-submissions-facility-inspections-and-benefit	11/13/2023-11/14/2023	No
5	Q1	FDA and Center for Research on Complex Generics Co-Hosted Workshop: Characterization of Complex Excipients and Formulations www.complexgenerics.org/education-training/characterization-of-complex-excipients-formulations/	12/07/2023	No