FY 2023

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) 2023.

Table 1: Draft and Final Guidance Documents Related to the Human Generic Drug Activities for FY 2023

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	Competitive Generic Therapies; Final Guidance for Industry www.fda.gov/media/136063/download	10/5/2022	Yes	Section 803(b)(1) of the FDA Reauthorization Act of 2017
2	Q1	Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA; Final Guidance for Industry www.fda.gov/media/107626/download	10/5/2022	Other	N/A
3	Q1	Information Requests and Discipline Review Letters Under GDUFA; Final Guidance for Industry www.fda.gov/media/109915/download	10/5/2022	Other	N/A
4	Q1	Post-Complete Response Letter Clarification Teleconferences Between FDA and ANDA Applicants Under GDUFA; Final Guidance for Industry www.fda.gov/media/108337/download	10/5/2022	Other	N/A
5	Q1	Review of Drug Master Files in Advance of Certain ANDA Submissions Under GDUFA; Draft Guidance for Industry www.fda.gov/media/162019/download	10/6/2022	Other	N/A
6	Q1	Facility Readiness: Goal Date Decisions Under GDUFA; Draft Guidance for Industry www.fda.gov/media/162018/download	10/6/2022	Other	N/A
7	Q1	Comparability Protocols for Postapproval Changes to the Chemistry, Manufacturing, and Controls Information in an NDA, ANDA, or BLA; Final Guidance for Industry www.fda.gov/media/162263/download	10/14/2022	Other	N/A
8	Q1	ANDA Submissions – Prior Approval Supplements under GDUFA; Final Guidance for Industry www.fda.gov/media/89263/download	10/14/2022	Other	N/A
9	Q1	Abametapir; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206966.pdf	10/21/2022	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	Acyclovir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021478.pdf	10/21/2022	Other	N/A
11	Q1	Acyclovir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018604.pdf	10/21/2022	Other	N/A
12	Q1	Acyclovir; Hydrocortisone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022436.pdf	10/21/2022	Other	N/A
13	Q1	Adapalene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020380.pdf	10/21/2022	Other	N/A
14	Q1	Adapalene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021753.pdf	10/21/2022	Other	N/A
15	Q1	Adapalene; Benzoyl Peroxide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022320.pdf	10/21/2022	Other	N/A
16	Q1	Adapalene; Benzoyl Peroxide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207917.pdf	10/21/2022	Other	N/A
17	Q1	Benzyl Alcohol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022129.pdf	10/21/2022	Other	N/A
18	Q1	Betamethasone Dipropionate; Calcipotriene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021852.pdf	10/21/2022	Other	N/A
19	Q1	Betamethasone Dipropionate; Calcipotriene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022185.pdf	10/21/2022	Other	N/A
20	Q1	Betamethasone Dipropionate; Calcipotriene; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213422.pdf	10/21/2022	Other	N/A
21	Q1	Bexarotene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021056.pdf	10/21/2022	Other	N/A
22	Q1	Butenafine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020524.pdf	10/21/2022	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)
23	Q1	Butenafine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021307.pdf	10/21/2022	Other	N/A
24	Q1	Calcipotriene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020554.pdf	10/21/2022	Other	N/A
25	Q1	Calcipotriene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020273.pdf	10/21/2022	Other	N/A
26	Q1	Clindamycin Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050782.pdf	10/21/2022	Other	N/A
27	Q1	Clindamycin Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050615.pdf	10/21/2022	Other	N/A
28	Q1	Clindamycin Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050600.pdf	10/21/2022	Other	N/A
29	Q1	Clindamycin Phosphate; Tretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_0050802.pdf	10/21/2022	Other	N/A
30	Q1	Clindamycin Phosphate; Tretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050803.pdf	10/21/2022	Other	N/A
31	Q1	Crisaborole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207695.pdf	10/21/2022	Other	N/A
32	Q1	Crotamiton; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_006927.pdf	10/21/2022	Other	N/A
33	Q1	Crotamiton; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009112.pdf	10/21/2022	Other	N/A
34	Q1	Dapsone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207154.pdf	10/21/2022	Other	N/A
35	Q1	Dapsone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021794.pdf	10/21/2022	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)
36	Q1	Diclofenac Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022122.pdf	10/21/2022	Other	N/A
37	Q1	Diclofenac Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021005.pdf	10/21/2022	Other	N/A
38	Q1	Docosanol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020941.pdf	10/21/2022	Other	N/A
39	Q1	Doxepin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020126.pdf	10/21/2022	Other	N/A
40	Q1	Erythromycin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050617.pdf	10/21/2022	Other	N/A
41	Q1	Fluocinolone Acetonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012787.pdf	10/21/2022	Other	N/A
42	Q1	Fluorouracil; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022259.pdf	10/21/2022	Other	N/A
43	Q1	Fluorouracil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016988.pdf	10/21/2022	Other	N/A
44	Q1	Fluorouracil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016831-Cre.pdf	10/21/2022	Other	N/A
45	Q1	Gentamicin Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_060462.pdf	10/21/2022	Other	N/A
46	Q1	Gentamicin Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_060463.pdf	10/21/2022	Other	N/A
47	Q1	Halobetasol Propionate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209355.pdf	10/21/2022	Other	N/A
48	Q1	Hydrocortisone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009585.pdf	10/21/2022	Other	N/A
49	Q1	Ivermectin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206255.pdf	10/21/2022	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)
50	Q1	Ivermectin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202736.pdf	10/21/2022	Other	N/A
51	Q1	Ketoconazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021946.pdf	10/21/2022	Other	N/A
52	Q1	Ketoconazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019084.pdf	10/21/2022	Other	N/A
53	Q1	Luliconazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204153.pdf	10/21/2022	Other	N/A
54	Q1	Metronidazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020531.pdf	10/21/2022	Other	N/A
55	Q1	Metronidazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020743.pdf	10/21/2022	Other	N/A
56	Q1	Metronidazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021789.pdf	10/21/2022	Other	N/A
57	Q1	Metronidazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020901.pdf	10/21/2022	Other	N/A
58	Q1	Metronidazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019737.pdf	10/21/2022	Other	N/A
59	Q1	Metronidazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205223.pdf	10/21/2022	Other	N/A
60	Q1	Metronidazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020208.pdf	10/21/2022	Other	N/A
61	Q1	Mupirocin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050591.pdf	10/21/2022	Other	N/A
62	Q1	Mupirocin Calcium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050746.pdf	10/21/2022	Other	N/A
63	Q1	Nitroglycerin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021359.pdf	10/21/2022	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)
64	Q1	Nystatin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_060575.pdf	10/21/2022	Other	N/A
65	Q1	Nystatin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_060571.pdf	10/21/2022	Other	N/A
66	Q1	Nystatin; Triamcinolone Acetonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_060576.pdf	10/21/2022	Other	N/A
67	Q1	Nystatin; Triamcinolone Acetonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_060572.pdf	10/21/2022	Other	N/A
68	Q1	Oxymetazoline Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208552.pdf	10/21/2022	Other	N/A
69	Q1	Ozenoxacin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208945.pdf	10/21/2022	Other	N/A
70	Q1	Penciclovir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020629.pdf	10/21/2022	Other	N/A
71	Q1	Pimecrolimus; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021302.pdf	10/21/2022	Other	N/A
72	Q1	Podofilox; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020529.pdf	10/21/2022	Other	N/A
73	Q1	Silver Sulfadiazine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017381.pdf	10/21/2022	Other	N/A
74	Q1	Spinosad; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022408.pdf	10/21/2022	Other	N/A
75	Q1	Tacrolimus; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050777-Oin-0.1P.pdf	10/21/2022	Other	N/A
76	Q1	Tacrolimus; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050777-Oin-0.03P.pdf	10/21/2022	Other	N/A
77	Q1	Tazarotene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020600-Gel-0.05P.pdf	10/21/2022	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)
78	Q1	Tazarotene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021184-Cre-0.1P.pdf	10/21/2022	Other	N/A
79	Q1	Tazarotene; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211882.pdf	10/21/2022	Other	N/A
80	Q1	Tazarotene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020600-Gel-0.1P.pdf	10/21/2022	Other	N/A
81	Q1	Tirbanibulin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213189.pdf	10/21/2022	Other	N/A
82	Q1	Tretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_0017579.pdf	10/21/2022	Other	N/A
83	Q1	Tretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_0022070.pdf	10/21/2022	Other	N/A
84	Q1	Tretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_0017955.pdf	10/21/2022	Other	N/A
85	Q1	Triamcinolone Acetonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011602.pdf	10/21/2022	Other	N/A
86	Q1	Triamcinolone Acetonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011600.pdf	10/21/2022	Other	N/A
87	Q1	Triamcinolone Acetonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011601.pdf	10/21/2022	Other	N/A
88	Q1	Triamcinolone Acetonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011600-Oin-0.05P.pdf	10/21/2022	Other	N/A
89	Q1	Physicochemical and Structural (Q3) Characterization of Topical Drug Products Submitted in ANDAs; Draft Guidance for Industry www.fda.gov/media/162471/download	10/24/2022	Other	N/A
90	Q1	In Vitro Release Test Studies for Topical Products Submitted in ANDAs; Draft Guidance for Industry www.fda.gov/media/162476/download	10/24/2022	Other	N/A
91	Q1	In Vitro Permeation Test Studies for Topical Products Submitted in ANDAs; Draft Guidance for Industry www.fda.gov/media/162475/download	10/24/2022	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)
92	Q1	Topical Dermatologic Corticosteroids: In Vivo Bioequivalence; Draft Guidance for Industry www.fda.gov/media/162457/download	10/24/2022	Other	N/A
93	Q1	Sameness Evaluations in an ANDA – Active Ingredients; Draft Guidance for Industry www.fda.gov/media/163018/download	11/9/2022	Other	N/A
94	Q1	Acyclovir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203791.pdf	11/17/2022	Other	N/A
95	Q1	Ammonium Lactate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020508.pdf	11/17/2022	Other	N/A
96	Q1	Ammonium Lactate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019155.pdf	11/17/2022	Other	N/A
97	Q1	Baricitinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207924.pdf	11/17/2022	Other	N/A
98	Q1	Budesonide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215935.pdf	11/17/2022	Other	N/A
99	Q1	Calcitonin Salmon; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017769.pdf	11/17/2022	Other	N/A
100	Q1	Calcium Carbonate; Famotidine; Magnesium Hydroxide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020958.pdf	11/17/2022	Other	N/A
101	Q1	Clindamycin Phosphate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215650.pdf	11/17/2022	Other	N/A
102	Q1	Daunorubicin Citrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050704.pdf	11/17/2022	Other	N/A
103	Q1	Deferiprone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021825.pdf	11/17/2022	Other	N/A
104	Q1	Deferiprone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212269.pdf	11/17/2022	Other	N/A
105	Q1	Drospirenone; Estetrol; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214154.pdf	11/17/2022	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)
106	Q1	Eteplirsen; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206488.pdf	11/17/2022	Other	N/A
107	Q1	Ethinyl Estradiol; Norethindrone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021065.pdf	11/17/2022	Other	N/A
108	Q1	Ferric Oxyhydroxide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020955.pdf	11/17/2022	Other	N/A
109	Q1	Ferric Oxyhydroxide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017441.pdf	11/17/2022	Other	N/A
110	Q1	Fidaxomicin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213138.pdf	11/17/2022	Other	N/A
111	Q1	Fosdenopterin Hydrobromide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214018.pdf	11/17/2022	Other	N/A
112	Q1	Goserelin Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020578.pdf	11/17/2022	Other	N/A
113	Q1	Goserelin Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019726.pdf	11/17/2022	Other	N/A
114	Q1	Hydrocortisone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016199.pdf	11/17/2022	Other	N/A
115	Q1	Hydroxyurea; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208843.pdf	11/17/2022	Other	N/A
116	Q1	Icosapent Ethyl; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202057.pdf	11/17/2022	Other	N/A
117	Q1	Inotersen Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211172.pdf	11/17/2022	Other	N/A
118	Q1	Ketotifen Fumarate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021066.pdf	11/17/2022	Other	N/A
119	Q1	Lapatinib Ditosylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022059.pdf	11/17/2022	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)
120	Q1	Lidocaine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207962.pdf	11/17/2022	Other	N/A
121	Q1	Magnesium Sulfate; Potassium Chloride; Sodium Sulfate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213135.pdf	11/17/2022	Other	N/A
122	Q1	Melphalan Flufenamide Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214383.pdf	11/17/2022	Other	N/A
123	Q1	Miconazole Nitrate; White Petrolatum; Zinc Oxide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021026.pdf	11/17/2022	Other	N/A
124	Q1	Mometasone Furoate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215712.pdf	11/17/2022	Other	N/A
125	Q1	Nicardipine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019488.pdf	11/17/2022	Other	N/A
126	Q1	Omeprazole Magnesium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_078878.pdf	11/17/2022	Other	N/A
127	Q1	Oxycodone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208090.pdf	11/17/2022	Other	N/A
128	Q1	Patisiran Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210922.pdf	11/17/2022	Other	N/A
129	Q1	Ponesimod; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213498.pdf	11/17/2022	Other	N/A
130	Q1	Progesterone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020701.pdf	11/17/2022	Other	N/A
131	Q1	Ranolazine (Tablet, Extended Release); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021526.pdf	11/17/2022	Other	N/A
132	Q1	Ranolazine (Granules, Extended Release); Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216018.pdf	11/17/2022	Other	N/A
133	Q1	Rifaximin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021361.pdf	11/17/2022	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)
134	Q1	Sodium Phosphate, Dibasic, Anhydrous; Sodium Phosphate, Monobasic, Monohydrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021892.pdf	11/17/2022	Other	N/A
135	Q1	Sumatriptan Succinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020080-Vial.pdf	11/17/2022	Other	N/A
136	Q1	Sumatriptan Succinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020080-Autoinj.pdf	11/17/2022	Other	N/A
137	Q1	Tepotinib Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214096.pdf	11/17/2022	Other	N/A
138	Q1	Tivozanib Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212904.pdf	11/17/2022	Other	N/A
139	Q1	Triamcinolone Acetonide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208845.pdf	11/17/2022	Other	N/A
140	Q1	Trilaciclib Dihydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214200.pdf	11/17/2022	Other	N/A
141	Q1	Varenicline Tartrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213978.pdf	11/17/2022	Other	N/A
142	Q1	Voclosporin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213716.pdf	11/17/2022	Other	N/A
143	Q1	Statistical Approaches to Establishing Bioequivalence; Draft Guidance for Industry www.fda.gov/media/163638/download	12/5/2022	Other	N/A
144	Q1	ANDAs: Pre-Submission Facility Correspondence Related to Prioritized Generic Drug Submissions; Revised Draft Guidance for Industry www.fda.gov/media/163643/download	12/5/2022	Other	N/A
145	Q1	Failure to Respond to an ANDA Complete Response Letter Within the Regulatory Timeframe; Final Guidance for Industry www.fda.gov/media/160166/download	12/15/2022	Other	N/A
146	Q1	Controlled Correspondence Related to Generic Drug Development; Draft Guidance for Industry www.fda.gov/media/164111/download	12/21/2022	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)
147	Q2	M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms; Draft Guidance for Industry www.fda.gov/media/165049/download	1/31/2023	Other	N/A
148	Q2	Afamelanotide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210797.pdf	2/16/2023	Other	N/A
149	Q2	Benzoyl Peroxide; Clindamycin Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050819.pdf	2/16/2023	Other	N/A
150	Q2	Benzoyl Peroxide; Clindamycin Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050741.pdf	2/16/2023	Other	N/A
151	Q2	Benzoyl Peroxide; Clindamycin Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050756.pdf	2/16/2023	Other	N/A
152	Q2	Bismuth Subsalicylate; Metronidazole; Tetracycline Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050719.pdf	2/16/2023	Other	N/A
153	Q2	Cabotegravir; Rilpivirine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212888.pdf	2/16/2023	Other	N/A
154	Q2	Dexmethylphenidate Hydrochloride; Serdexmethylphenidate Chloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212994.pdf	2/16/2023	Other	N/A
155	Q2	Dihydroergotamine Mesylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213436.pdf	2/16/2023	Other	N/A
156	Q2	Donepezil Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212304.pdf	2/16/2023	Other	N/A
157	Q2	Fexinidazole; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214429.pdf	2/16/2023	Other	N/A
158	Q2	Glucagon; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210134.pdf	2/16/2023	Other	N/A
159	Q2	Golodirsen; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211970.pdf	2/16/2023	Other	N/A
160	Q2	Hydroxyurea; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016295.pdf	2/16/2023	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)
161	Q2	Ibrexafungerp Citrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214900.pdf	2/16/2023	Other	N/A
162	Q2	Infigratinib Phosphate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214622.pdf	2/16/2023	Other	N/A
163	Q2	Leuprolide Mesylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211488.pdf	2/16/2023	Other	N/A
164	Q2	Mechlorethamine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202317.pdf	2/16/2023	Other	N/A
165	Q2	Mirabegron; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202611.pdf	2/16/2023	Other	N/A
166	Q2	Naproxen Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020353.pdf	2/16/2023	Other	N/A
167	Q2	Olanzapine; Samidorphan L-Malate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213378.pdf	2/16/2023	Other	N/A
168	Q2	Siponimod Fumaric Acid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209884.pdf	2/16/2023	Other	N/A
169	Q2	Sirolimus; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213478.pdf	2/16/2023	Other	N/A
170	Q2	Sotorasib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214665.pdf	2/16/2023	Other	N/A
171	Q2	Sucralfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018333.pdf	2/16/2023	Other	N/A
172	Q2	Sucralfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019183.pdf	2/16/2023	Other	N/A
173	Q2	Testosterone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205488.pdf	2/16/2023	Other	N/A
174	Q2	Triamcinolone Acetonide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211950.pdf	2/16/2023	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)
175	Q2	Venlafaxine Besylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215429.pdf	2/16/2023	Other	N/A
176	Q2	Viltolarsen; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212154.pdf	2/16/2023	Other	N/A
177	Q2	Vosoritide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214938.pdf	2/16/2023	Other	N/A
178	Q2	Product-Specific Guidance Meetings Between the Food and Drug Administration and Abbreviated New Drug Applicants Under the Generic Drug User Fee Act; Draft Guidance for Industry www.fda.gov/media/165468/download	2/17/2023	Other	N/A
178	Q2	Q13 Continuous Manufacturing of Drug Substances and Drug Products; Final Guidance for Industry www.fda.gov/media/165775/download	3/1/2023	Other	N/A
179	Q2	Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers; Draft Guidance for Industry www.fda.gov/media/166215/download	3/15/2023	No	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 2023.

Table 2: Public Meetings Held on Topics Related to Human Generic Drug Activities for FY 2023

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: Best Practices for Utilizing Modeling Approaches to Support Generic Product Development www.fda.gov/drugs/news-events-human-drugs/best-practices-utilizing-modeling-approaches-support-generic-product-development-10272022	10/27/2022 – 10/28/2022	No

2	Q1	FDA and Center for Research on Complex Generics Co-Hosted Workshop: Formulation Characterization and Cutaneous Pharmacokinetics to Facilitate Generic Topical Product Development www.fda.gov/drugs/news-events-human-drugs/formulation-characterization-and-cutaneous-pharmacokinetics-facilitate-generic-topical-product	11/3/2022	No
3	Q1	FDA and Center for Research on Complex Generics Co-Hosted Workshop: Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned www.fda.gov/drugs/excipients-and-formulation-assessments-complex-generic-products-best-practices-and-lessons-learned	12/6/2022	No
4	Q2	A Deep Dive: FDA Draft Guidance on Statistical Approaches to Establishing Bioequivalence www.fda.gov/drugs/news-events-human-drugs/deep-dive-fda-draft-guidance-statistical-approaches-establishing-bioequivalence-03142023	3/14/2023	N/A