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
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

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)
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
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

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)
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
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

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)
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
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

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)
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
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

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)
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
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

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)
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	Yes	Section III.C.2.c of GDUFA III Commitment Letter
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	Yes	Section III.C.2.c of GDUFA III Commitment Letter
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

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)
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
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	Yes	Section III.C.2.c of GDUFA III Commitment Letter
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	Yes	Section III.C.2.c of GDUFA III Commitment Letter
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

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)
133	Q1	Rifaximin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021361.pdf	11/17/2022	Other	N/A
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	Yes	Section III.C.2.c of GDUFA III Commitment Letter
138	Q1	Tivozanib Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212904.pdf	11/17/2022	Yes	Section III.C.2.c of GDUFA III Commitment Letter
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	Yes	Section III.C.2.c of GDUFA III Commitment Letter
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	Yes	Section III.C.2.c of GDUFA III Commitment Letter
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	Yes	Section III.C.2.c of GDUFA III Commitment Letter
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	Yes	Section III.C.2.c of GDUFA III Commitment Letter
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	Yes	Section III.C.2.c of GDUFA III Commitment Letter
162	Q2	Infigratinib Phosphate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214622.pdf	2/16/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter
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	Yes	Section III.C.2.c of GDUFA III Commitment Letter
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	Yes	Section III.C.2.c of GDUFA III Commitment Letter
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
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

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)
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
180	Q3	Notifying FDA of a Discontinuance or Interruption in Manufacturing of Finished Products or Active Pharmaceutical Ingredients Under Section 506C of the FD&C Act; Draft Guidance for Industry www.fda.gov/media/166837/download	4/5/2023	Other	N/A
181	Q3	Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs Draft Guidance for Industry www.fda.gov/media/167043/download	4/12/2023	Other	N/A
182	Q3	Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs: Draft Guidance for Industry www.fda.gov/media/167073/download	4/13/2023	Other	N/A
183	Q3	Ethinyl Estradiol; Segesterone Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209627.pdf	5/17/2023	Other	N/A
184	Q3	Azelastine Hydrochloride; Fluticasone Propionate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202236.pdf	5/18/2023	Other	N/A
185	Q3	Baloxavir Marboxil; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214410.pdf	5/18/2023	Other	N/A
186	Q3	Baloxavir Marboxil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210854.pdf	5/18/2023	Other	N/A
187	Q3	Belumosudil Mesylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214783.pdf	5/18/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter
188	Q3	Belzutifan; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215383.pdf	5/18/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter
189	Q3	Bimatoprost; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211911.pdf	5/18/2023	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)
190	Q3	Brincidofovir; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214460.pdf	5/18/2023	Other	N/A
191	Q3	Brincidofovir; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214461.pdf	5/18/2023	Other	N/A
192	Q3	Cabotegravir; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215499.pdf	5/18/2023	Other	N/A
193	Q3	Cabozantinib S-Malate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203756.pdf	5/18/2023	Other	N/A
194	Q3	Cabozantinib S-Malate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208692.pdf	5/18/2023	Other	N/A
195	Q3	Casimersen; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213026.pdf	5/18/2023	Other	N/A
196	Q3	Celecoxib; Tramadol Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213426.pdf	5/18/2023	Other	N/A
197	Q3	Citric Acid; Lactic Acid; Potassium Bitartrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208352.pdf	5/18/2023	Other	N/A
198	Q3	Clobetasol Propionate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213691.pdf	5/18/2023	Other	N/A
199	Q3	Defibrotide Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208114.pdf	5/18/2023	Other	N/A
200	Q3	Difelikefalin Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214916.pdf	5/18/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter
201	Q3	Doxepin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016798.pdf	5/18/2023	Other	N/A
202	Q3	Finerenone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215341.pdf	5/18/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter
203	Q3	Fluticasone Furoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022051.pdf	5/18/2023	Other	N/A
204	Q3	Fluticasone Propionate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020121.pdf	5/18/2023	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)
205	Q3	Formoterol Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020831.pdf	5/18/2023	Other	N/A
206	Q3	Formoterol Fumarate; Mometasone Furoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022518.pdf	5/18/2023	Other	N/A
207	Q3	Givosiran Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212194.pdf	5/18/2023	Other	N/A
208	Q3	Glycopyrrolate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207923.pdf	5/18/2023	Other	N/A
209	Q3	Glycopyrrolate; Indacaterol Maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207930.pdf	5/18/2023	Other	N/A
210	Q3	Inclisiran Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214012.pdf	5/18/2023	Other	N/A
211	Q3	Indacaterol Maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022383.pdf	5/18/2023	Other	N/A
212	Q3	Ivacaftor; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207925.pdf	5/18/2023	Other	N/A
213	Q3	Lidocaine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_008048.pdf	5/18/2023	Other	N/A
214	Q3	Lithium Carbonate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018152.pdf	5/18/2023	Other	N/A
215	Q3	Lithium Carbonate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018027.pdf	5/18/2023	Other	N/A
216	Q3	Lithium Carbonate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018558.pdf	5/18/2023	Other	N/A
217	Q3	Lithium Carbonate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017812.pdf	5/18/2023	Other	N/A
218	Q3	Loxapine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022549.pdf	5/18/2023	Other	N/A
219	Q3	Maribavir; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215596.pdf	5/18/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter

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)
220	Q3	Mometasone Furoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020762.pdf	5/18/2023	Other	N/A
221	Q3	Naloxone Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215457.pdf	5/18/2023	Other	N/A
222	Q3	Odevixibat; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215498-Cap.pdf	5/18/2023	Other	N/A
223	Q3	Odevixibat; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215498-Cap Pellets.pdf	5/18/2023	Other	N/A
224	Q3	Paliperidone Palmitate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022264.pdf	5/18/2023	Other	N/A
225	Q3	Pentoxifylline; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018631.pdf	5/18/2023	Other	N/A
226	Q3	Piflufolastat F-18; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214793.pdf	5/18/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter
227	Q3	Rasagiline Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021641.pdf	5/18/2023	Other	N/A
228	Q3	Sirolimus; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213312.pdf	5/18/2023	Other	N/A
229	Q3	Voxelotor; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216157.pdf	5/18/2023	Other	N/A
230	Q3	Cover Letter Attachments for Controlled Correspondences and ANDA Submissions: Guidance for Industry; Final Guidance for Industry www.fda.gov/media/154762/download	6/5/2023	Other	N/A
231	Q3	Assessing User Fees Under the Generic Drug User Fee Amendments of 2022; Final Guidance for Industry www.fda.gov/media/132138/download	6/9/2023	Other	N/A
232	Q4	CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality; Final Guidance for Industry www.fda.gov/media/121305/download	7/26/2023	Other	N/A
233	Q4	Fixed-Combinations and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment or Prevention of Human Immunodeficiency Virus-One Under the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief; Draft Guidance for Industry www.fda.gov/media/72248/download	8/1/2023	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)
234	Q4	Recommended Acceptable Intake Limits for Nitrosamine Drug Substance-Related Impurities; Final Guidance for Industry www.fda.gov/media/170794/download	8/7/2023	Other	N/A
236	Q4	Abrocitinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213871.pdf	8/21/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter
237	Q4	Asciminib Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215358.pdf	8/21/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter
238	Q4	Atogepant; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215206.pdf	8/21/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter
239	Q4	Atropine Sulfate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213581.pdf	8/21/2023	Other	N/A
240	Q4	Avacopan; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214487.pdf	8/21/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter
241	Q4	Beclomethasone Dipropionate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020911.pdf	8/21/2023	Other	N/A
242	Q4	Beclomethasone Dipropionate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207921.pdf	8/21/2023	Other	N/A
243	Q4	Beclomethasone Dipropionate Monohydrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019389.pdf	8/21/2023	Other	N/A
244	Q4	Budesonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020746.pdf	8/21/2023	Other	N/A
245	Q4	Chloroprocaine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216227.pdf	8/21/2023	Other	N/A
246	Q4	Ciclesonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021658.pdf	8/21/2023	Other	N/A
247	Q4	Ciclesonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022004.pdf	8/21/2023	Other	N/A
248	Q4	Clascoterone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213433.pdf	8/21/2023	Other	N/A
249	Q4	Daridorexant Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214985.pdf	8/21/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter

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)
250	Q4	Diclofenac Epolamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021234.pdf	8/21/2023	Other	N/A
251	Q4	Epinephrine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_201739.pdf	8/21/2023	Other	N/A
252	Q4	Epinephrine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205920.pdf	8/21/2023	Other	N/A
253	Q4	Estradiol; Levonorgestrel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021258.pdf	8/21/2023	Other	N/A
254	Q4	Fluvoxamine Maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022033.pdf	8/21/2023	Other	N/A
255	Q4	Glucagon; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212097.pdf	8/21/2023	Other	N/A
256	Q4	Ipratropium Bromide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021527.pdf	8/21/2023	Other	N/A
257	Q4	Lidocaine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_008816.pdf	8/21/2023	Other	N/A
258	Q4	Lumasiran Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214103.pdf	8/21/2023	Other	N/A
259	Q4	Lutetium Lu-177 Vipivotide Tetraxetan; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215833.pdf	8/21/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter
260	Q4	Maralixibat Chloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214662.pdf	8/21/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter
261	Q4	Mavacamten; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214998.pdf	8/21/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter
262	Q4	Midazolam Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216359.pdf	8/21/2023	Other	N/A
263	Q4	Mitapivat Sulfate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216196.pdf	8/21/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter
264	Q4	Mobocertinib Succinate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215310.pdf	8/21/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter

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)
265	Q4	Mometasone Furoate; Olopatadine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211746.pdf	8/21/2023	Other	N/A
266	Q4	Oteseconazole; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215888.pdf	8/21/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter
267	Q4	Pacritinib Citrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208712.pdf	8/21/2023	Yes	Section III.C.2.c of GDUFA III Commitment Letter
268	Q4	Pilocarpine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214028.pdf	8/21/2023	Other	N/A
269	Q4	Ruxolitinib Phosphate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215309.pdf	8/21/2023	Other	N/A
270	Q4	Tirzepatide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215866.pdf	8/21/2023	Other	N/A
271	Q4	Triamcinolone Acetonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020468.pdf	8/21/2023	Other	N/A
272	Q4	Voxelotor; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213137.pdf	8/21/2023	Other	N/A
273	Q4	Vutrisiran Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215515.pdf	8/21/2023	Other	N/A
274	Q4	Post-Warning Letter Meetings Under GDUFA; Draft Guidance for Industry www.fda.gov/media/171785/download	9/5/2023	Other	Section VII.D.12.a. of the GDUFA III commitment letter
275	Q4	Application of Human Factors Engineering Principles for Combination Products: Questions and Answers: Final Guidance for Industry www.fda.gov/media/171855/download	9/7/2023	Other	N/A
276	Q4	Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989 Guidance for Industry; Final Guidance for Industry www.fda.gov/media/172038/download	9/15/2023	Other	N/A
277	Q4	Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies; Final Guidance for Industry www.fda.gov/media/172258/download	9/21/2023	No	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)
278	Q4	Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications; Draft Guidance for Industry www.fda.gov/media/172290/download	9/22/2023	Other	N/A[2]

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	SBIA Webinar: A Deep Dive: FDA Draft Guidance on Statistical Approaches to Establishing Bioequivalence	3/14/2023	No

[2] Issuance of this draft guidance was a goal in the PDUFA VII and BSUFA III commitment letters. However, this guidance is also applicable for GDUFA purposes.

		www.fda.gov/drugs/news-events-human-drugs/deep-dive-fda-draft-guidance-statistical-approaches-establishing-bioequivalence-03142023		
5	Q3	Generic Drugs Forum (GDF) 2023: Celebrating 10 Years of the GDF www.fda.gov/drugs/news-events-human-drugs/generic-drugs-forum-gdf-2023-celebrating-10-years-gdf-04122023	4/12/2013 – 4/13/2023	No
6	Q3	FDA and Center for Research on Complex Generics Co-Hosted Workshop: Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products www.fda.gov/drugs/news-events-human-drugs/fdacrcg-considerations-and-alternatives-comparative-clinical-endpoint-and-pharmacodynamic	4/20/2023 – 4/21/2023	No
7	Q3	SBIA Webinar: Electronic Systems, Electronic Records, and Electronic Signatures www.fda.gov/drugs/news-events-human-drugs/electronic-systems-electronic-records-and-electronic-signatures-webinar-04252023	4/25/2023	No
8	Q3	SBIA Webinar: Navigating the First ICH Generic Drug Draft Guideline "M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms" www.fda.gov/drugs/news-events-human-drugs/navigating-first-ich-generic-drug-draft-guideline-m13a-bioequivalence-immediate-release-solid-oral	5/2/2023	No
9	Q3	FDA and Center for Research on Complex Generics Co-Hosted Workshop: DDCP 101 – Identifying, Developing, and Evaluating Generic Drug Device Combination Products (DDCP) www.fda.gov/drugs/news-events-human-drugs/fdacrcg-drug-device-combination-products-101-identifying-developing-and-evaluating-drug-device	5/10/2023	No
10	Q3	Fiscal Year 2023 Generic Drug Science and Research Initiatives Public Workshop www.fda.gov/drugs/fiscal-year-2023-generic-drug-science-and-research-initiatives-public-workshop-05112023	5/11/2023 – 5/12/2023	Yes
11	Q3	SBIA Webinar: A Deep Dive: GDUFA III Scientific Meetings www.fda.gov/drugs/news-events-human-drugs/deep-dive-gdufa-iii-scientific-meetings-05152023	5/15/2023	No
12	Q3	Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches www.federalregister.gov/documents/2023/04/24/2023-08545/advancing-the-utilization-and-supporting-the-implementation-of-innovative-manufacturing-approaches	6/8/2023	No
13	Q3	2023 Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments www.fda.gov/drugs/news-events-human-drugs/2023-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act	6/8/2023	Yes
14	Q3	Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches; Public Workshop www.federalregister.gov/documents/2023/04/24/2023-08545/advancing-the-utilization-and-supporting-the-implementation-of-innovative-manufacturing-approaches	6/8/2023	No
15	Q3	The FDA Science Forum www.fda.gov/science-research/about-science-research-fda/fda-science-forum	6/13/2023	No
16	Q3	FDA and Center for Research on Complex Generics Co-Hosted Workshop: Mitigation Strategies for Nitrosamine Drug	6/15/2023	No

		Substance Related Impurities: Quality and Bioequivalence Considerations for Generic Products www.fda.gov/drugs/mitigation-strategies-nitrosamine-drug-substance-related-impurities-quality-and-bioequivalence		
17	Q4	FDA and University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) Workshop: Physiologically Based Biopharmaceutics Modeling (PBBM) Best Practices for Drug Product Quality www.cersi.umd.edu/physiologically-based-biopharmaceutics-modeling-pbbm-best-practices-drug-product-quality	8/29/2023-8/31/2023	No
18	Q4	Understanding FDA Inspections and Data www.fda.gov/drugs/news-events-human-drugs/understanding-fda-inspections-and-data-09062023	9/6/2023	No
19	Q4	SBIA Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023 www.fda.gov/drugs/news-events-human-drugs/advancing-generic-drug-development-translating-science-approval-2023-09132023	9/13/2023-9/14/2023	No
20	Q4	FDA/PQRI Workshop on the Regulatory Framework for the Utilization of Artificial Intelligence in Pharmaceutical Manufacturing www.fda.gov/drugs/fdapqri-workshop-regulatory-framework-utilization-artificial-intelligence-pharmaceutical	9/26/2023-9/27/2023	No