FY 2022

Real Time Report

pursuant to the

Generic Drug User Fee Amendments

as amended by the FDA Reauthorization Act of 2017

Acronyms

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

FDA – Food and Drug Administration

FDARA – FDA Reauthorization Act of 2017

FY – Fiscal Year (October 1 to September 30)

GDUFA – Generic Drug User Fee Amendments

Q1 – Quarter 1 (October 1 to December 31)

Q2 – Quarter 2 (January 1 to March 31)

Q3 – Quarter 3 (April 1 to June 30)

Q4 – Quarter 4 (July 1 to September 30)

Background

On August 18, 2017, the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52) was signed into law. FDARA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to revise and extend the user fee programs for human drugs, biologics, generic drugs, medical devices, and biosimilar biological products.

Section 744C(a)(2) of the FD&C Act, as added by section 903 of FDARA, requires the Food and Drug Administration (FDA) to provide "Real Time" reporting, posted on a quarterly basis, of guidance documents and public meetings related to human generic drug activities.[1]

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

This report is being issued pursuant to the requirement of Section 744C(a)(2) of the FD&C Act, as in effect on September 30, 2022,[2] which stated:

> "Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary [of Health and Human Services] shall post…on the internet website of the Food and Drug Administration…
>
> - "The number and titles of draft and final guidance on topics related to human generic drug activities and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017."
> - "The number and titles of public meetings held on topics related to human generic drug activities and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017."

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

[2] Effective October 1, 2022, section 744C(a)(2) of the FD&C Act was slightly amended by the Generic Drug User Fee Amendments of 2022, as enacted under title III of Division F (FDA User Fee Reauthorization Act of 2022) of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Public Law 117-180).

Human Generic Drugs

Guidance Documents

Pursuant to Section 744C(a)(2) of the FD&C Act, the table below lists the number and titles of draft and final guidances on topics related to human generic drug activities and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017. Guidances are listed by the quarter in which they were issued and are provided in a cumulative format for Fiscal Year (FY) 2022.

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

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
1	Q1	Q13 Continuous Manufacturing of Drug Substances and Drug Products; Draft Guidance for Industry www.fda.gov/media/153044/download	10/13/2021	Other	N/A
2	Q1	Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act; Draft Guidance for Industry www.fda.gov/media/153665/download	10/29/2021	Other	N/A
3	Q1	Alprazolam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021726.pdf	11/8/2021	Other	N/A
4	Q1	Aripiprazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021729.pdf	11/8/2021	Other	N/A
5	Q1	Artesunate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213036.pdf	11/8/2021	Other	N/A
6	Q1	Beclomethasone Dipropionate Monohydrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019389.pdf	11/8/2021	Other	N/A
7	Q1	Bempedoic Acid; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211616.pdf	11/8/2021	Other	N/A
8	Q1	Bempedoic Acid; Ezetimibe; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211617.pdf	11/8/2021	Other	N/A
9	Q1	Carbidopa; Levodopa; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_076699.pdf	11/8/2021	Other	N/A
10	Q1	Cenobamate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212839.pdf	11/8/2021	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
11	Q1	Cetirizine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022578.pdf	11/8/2021	Other	N/A
12	Q1	Ciclesonide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022004.pdf	11/8/2021	Other	N/A
13	Q1	Clascoterone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213433.pdf	11/8/2021	Other	N/A
14	Q1	Colesevelam Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210895.pdf	11/8/2021	Other	N/A
15	Q1	Colesevelam Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021176.pdf	11/8/2021	Other	N/A
16	Q1	Colesevelam Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022362.pdf	11/8/2021	Other	N/A
17	Q1	Desloratadine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021312.pdf	11/8/2021	Other	N/A
18	Q1	Diclofenac Potassium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020142.pdf	11/8/2021	Other	N/A
19	Q1	Dicyclomine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_007409-Tab.pdf	11/8/2021	Other	N/A
20	Q1	Donepezil Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021720.pdf	11/8/2021	Other	N/A
21	Q1	Glucagon; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212097.pdf	11/8/2021	Other	N/A
22	Q1	Lactitol; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211281.pdf	11/8/2021	Other	N/A
23	Q1	Lansoprazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021428.pdf	11/8/2021	Other	N/A
24	Q1	Lemborexant; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212028.pdf	11/8/2021	Other	N/A
25	Q1	Leuprolide Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021088.pdf	11/8/2021	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
26	Q1	Leuprolide Acetate; Norethindrone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203696.pdf	11/8/2021	Other	N/A
27	Q1	Loratadine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020704.pdf	11/8/2021	Other	N/A
28	Q1	Lurbinectedin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213702.pdf	11/8/2021	Other	N/A
29	Q1	Methylphenidate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205489.pdf	11/8/2021	Other	N/A
30	Q1	Metoclopramide Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022246.pdf	11/8/2021	Other	N/A
31	Q1	Minocycline Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212379.pdf	11/8/2021	Other	N/A
32	Q1	Minocycline Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213690.pdf	11/8/2021	Other	N/A
33	Q1	Minocycline Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209269.pdf	11/8/2021	Other	N/A
34	Q1	Mirtazapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021208.pdf	11/8/2021	Other	N/A
35	Q1	Olanzapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021086.pdf	11/8/2021	Other	N/A
36	Q1	Ondansetron; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020781.pdf	11/8/2021	Other	N/A
37	Q1	Opicapone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212489.pdf	11/8/2021	Other	N/A
38	Q1	Pemigatinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213736.pdf	11/8/2021	Other	N/A
39	Q1	Potassium Phosphate, Dibasic; Potassium Phosphate, Monobasic; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212832.pdf	11/8/2021	Other	N/A
40	Q1	Potassium Phosphate, Dibasic; Potassium Phosphate, Monobasic; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212121.pdf	11/8/2021	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
41	Q1	Remimazolam Besylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212295.pdf	11/8/2021	Other	N/A
42	Q1	Riluzole; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209080.pdf	11/8/2021	Other	N/A
43	Q1	Rimegepant Sulfate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212728.pdf	11/8/2021	Other	N/A
44	Q1	Risperidone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021444.pdf	11/8/2021	Other	N/A
45	Q1	Rizatriptan Benzoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020865.pdf	11/8/2021	Other	N/A
46	Q1	Sodium Iodide I-131; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016517.pdf	11/8/2021	Other	N/A
47	Q1	Tenapanor Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211801.pdf	11/8/2021	Other	N/A
48	Q1	Triamcinolone Acetonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012041.pdf	11/8/2021	Other	N/A
49	Q1	Tucatinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213411.pdf	11/8/2021	Other	N/A
50	Q1	Zolmitriptan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021231.pdf	11/8/2021	Other	N/A
51	Q1	Cover Letter Attachments for Controlled Correspondences and ANDA Submissions; Draft Guidance for Industry www.fda.gov/media/154762/download	12/10/2021	Other	N/A
52	Q1	Inspection of Injectable Products for Visible Particulates; Draft Guidance for Industry www.fda.gov/media/154868/download	12/16/2021	Other	NA
53	Q1	Brilliant Blue G; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209569.pdf	12/17/2021	Other	N/A
54	Q2	Information Requests and Discipline Review Letters Under the Generic Drug User Fee Amendments; Guidance for Industry www.fda.gov/media/109915/download	1/27/2022	Other	N/A
55	Q2	Good ANDA Submission Practices; Guidance for Industry www.fda.gov/media/110689/download	1/27/2022	Other	N/A
56	Q2	Revising ANDA labeling Following Revision of the RLD Labeling; Guidance for Industry www.fda.gov/media/71488/download	1/27/2022	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)
57	Q2	Aclidinium Bromide; Formoterol Fumarate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210595.pdf	2/17/2022	Other	N/A
58	Q2	Apixaban; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202155.pdf	2/17/2022	Other	N/A
59	Q2	Apomorphine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210875.pdf	2/17/2022	Other	N/A
60	Q2	Atropine Sulfate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206289.pdf	2/17/2022	Other	N/A
61	Q2	Capmatinib Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213591.pdf	2/17/2022	Other	N/A
62	Q2	Cladribine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022561.pdf	2/17/2022	Other	N/A
63	Q2	Clozapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203479.pdf	2/17/2022	Other	N/A
64	Q2	Clozapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019758.pdf	2/17/2022	Other	N/A
65	Q2	Clozapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021590.pdf	2/17/2022	Other	N/A
66	Q2	Dicyclomine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_007409-Cap.pdf	2/17/2022	Other	N/A
67	Q2	Dolutegravir Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213983.pdf	2/17/2022	Other	N/A
68	Q2	Enzalutamide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213674.pdf	2/17/2022	Other	N/A
69	Q2	Enzalutamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203415.pdf	2/17/2022	Other	N/A
70	Q2	Estradiol; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021813.pdf	2/17/2022	Other	N/A
71	Q2	Estradiol; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022014.pdf	2/17/2022	Other	N/A
72	Q2	Estradiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022038.pdf	2/17/2022	Other	N/A
73	Q2	Etelcalcetide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208325.pdf	2/17/2022	Other	N/A

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74	Q2	Flortaucipir F-18; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212123.pdf	2/17/2022	Other	N/A
75	Q2	Fluoroestradiol F-18; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212155.pdf	2/17/2022	Other	N/A
76	Q2	Gefitinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206995.pdf	2/17/2022	Other	N/A
77	Q2	Heparin Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017029.pdf	2/17/2022	Other	N/A
78	Q2	Irinotecan Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207793.pdf	2/17/2022	Other	N/A
79	Q2	Leuprolide Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021379.pdf	2/17/2022	Other	N/A
80	Q2	Leuprolide Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021731.pdf	2/17/2022	Other	N/A
81	Q2	Liothyronine Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_010379.pdf	2/17/2022	Other	N/A
82	Q2	Methylprednisolone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011757.pdf	2/17/2022	Other	N/A
83	Q2	Mirabegron; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213801.pdf	2/17/2022	Other	N/A
84	Q2	Mycophenolate Mofetil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050759.pdf	2/17/2022	Other	N/A
85	Q2	Nusinersen Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209531.pdf	2/17/2022	Other	N/A
86	Q2	Osimertinib Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208065.pdf	2/17/2022	Other	N/A
87	Q2	Posaconazole; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214770.pdf	2/17/2022	Other	N/A
88	Q2	Progesterone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_201110.pdf	2/17/2022	Other	N/A
89	Q2	Remdesivir; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214787-Pow.pdf	2/17/2022	Other	N/A

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90	Q2	Remdesivir; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214787-Sol.pdf	2/17/2022	Other	N/A
91	Q2	Ripretinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213973.pdf	2/17/2022	Other	N/A
92	Q2	Ruxolitinib Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202192.pdf	2/17/2022	Other	N/A
93	Q2	Selpercatinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213246.pdf	2/17/2022	Other	N/A
94	Q2	Selumetinib Sulfate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213756.pdf	2/17/2022	Other	N/A
95	Q2	Sodium Chloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019912.pdf	2/17/2022	Other	N/A
96	Q2	Valbenazine Tosylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209241.pdf	2/17/2022	Other	N/A
97	Q2	Vasopressin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204485.pdf	2/17/2022	Other	N/A
98	Q2	Viloxazine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211964.pdf	2/17/2022	Other	N/A
99	Q3	Considerations for Waiver Requests for pH Adjusters in Generic Drug Products Intended for Parenteral, Ophthalmic, or Otic Use; Draft Guidance for Industry www.fda.gov/media/157655/download	4/14/2022	Other	N/A
100	Q3	Drug Products, Including Biological Products, that Contain Nanomaterials; Guidance for Industry www.fda.gov/media/157812/download	4/21/2022	Other	N/A
101	Q3	Testosterone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_080911.pdf	5/6/2022	Other	N/A
102	Q3	Risk Management Plans to Mitigate the Potential for Drug Shortages; Draft Guidance for Industry www.fda.gov/media/158487/download	5/19/2022	Other	N/A
103	Q3	Acarbose; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020482.pdf	5/20/2022	Other	N/A
104	Q3	Acetaminophen; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018337.pdf	5/20/2022	Other	N/A
105	Q3	Arsenic Trioxide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021248.pdf	5/20/2022	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	Q3	Asenapine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212268.pdf	5/20/2022	Other	N/A
107	Q3	Bupivacaine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204803.pdf	5/20/2022	Other	N/A
108	Q3	Cedazuridine; Decitabine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212576.pdf	5/20/2022	Other	N/A
109	Q3	Chlorhexidine Gluconate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020774.pdf	5/20/2022	Other	N/A
110	Q3	Cocaine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209575.pdf	5/20/2022	Other	N/A
111	Q3	Doxorubicin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050718.pdf	5/20/2022	Other	N/A
112	Q3	Exenatide Synthetic; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022200.pdf	5/20/2022	Other	N/A
113	Q3	Exenatide Synthetic; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209210.pdf	5/20/2022	Other	N/A
114	Q3	Flunisolide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018148.pdf	5/20/2022	Other	N/A
115	Q3	Halobetasol Propionate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210566.pdf	5/20/2022	Other	N/A
116	Q3	Hydrocortisone; Neomycin Sulfate; Polymyxin B Sulfate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_060613.pdf	5/20/2022	Other	N/A
117	Q3	Ibuprofen; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020812.pdf	5/20/2022	Other	N/A
118	Q3	Linaclotide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202811.pdf	5/20/2022	Other	N/A
119	Q3	Lorazepam; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214826.pdf	5/20/2022	Other	N/A
120	Q3	Metoprolol Succinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210428.pdf	5/20/2022	Other	N/A
121	Q3	Midostaurin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207997.pdf	5/20/2022	Other	N/A

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122	Q3	Naloxone Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212045.pdf	5/20/2022	Other	N/A
123	Q3	Oliceridine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210730.pdf	5/20/2022	Other	N/A
124	Q3	Oseltamivir Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021087.pdf	5/20/2022	Other	N/A
125	Q3	Palbociclib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212436.pdf	5/20/2022	Other	N/A
126	Q3	Pralsetinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213721.pdf	5/20/2022	Other	N/A
127	Q3	Risdiplam; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213535.pdf	5/20/2022	Other	N/A
128	Q3	Secretin Synthetic Human; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021256.pdf	5/20/2022	Other	N/A
129	Q3	Selinexor; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212306.pdf	5/20/2022	Other	N/A
130	Q3	Solifenacin Succinate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209529.pdf	5/20/2022	Other	N/A
131	Q3	Solifenacin Succinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021518.pdf	5/20/2022	Other	N/A
132	Q3	Tegaserod Maleate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021200.pdf	5/20/2022	Other	N/A
133	Q3	Theophylline; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_085328.pdf	5/20/2022	Other	N/A
134	Q3	Tiopronin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211843.pdf	5/20/2022	Other	N/A
135	Q3	Torsemide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213218.pdf	5/20/2022	Other	N/A
136	Q3	Torsemide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020136.pdf	5/20/2022	Other	N/A
137	Q3	Trametinib Dimethyl Sulfoxide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204114.pdf	5/20/2022	Other	N/A

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138	Q3	Triheptanoin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213687.pdf	5/20/2022	Other	N/A
139	Q3	Uridine Triacetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208159.pdf	5/20/2022	Other	N/A
140	Q3	Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination; Draft Guidance for Industry www.fda.gov/media/159358/download	06/24/2022	Other	N/A
141	Q4	Evaluation of Therapeutic Equivalence; Draft Guidance for Industry www.fda.gov/media/160054/download	7/20/22	Other	N/A
142	Q4	Conducting Remote Regulatory Assessments Questions and Answers; Draft Guidance for Industry www.fda.gov/media/160173/download	7/22/22	Other	NA
143	Q4	Orange Book Questions and Answers; Guidance for Industry www.fda.gov/media/160167/download	7/22/22	Other	N/A
144	Q4	Failure to Respond to an ANDA Complete Response Letter Within the Regulatory Timeframe; Guidance for Industry www.fda.gov/media/160166/download	7/22/22	Other	N/A
145	Q4	Acetaminophen; Ibuprofen; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211733.pdf	8/2/2022	Other	N/A
146	Q4	Amoxicillin; Clavulanate Potassium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050726.pdf	8/2/2022	Other	N/A
147	Q4	Amphetamine; Amphetamine Aspartate/Dextroamphetamine Sulfate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210526.pdf	8/2/2022	Other	N/A
148	Q4	Ampicillin/Ampicillin Trihydrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_064082.pdf	8/2/2022	Other	N/A
149	Q4	Azelastine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213872.pdf	8/2/2022	Other	N/A
150	Q4	Azelastine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020114.pdf	8/2/2022	Other	N/A
151	Q4	Berotralstat Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214094.pdf	8/2/2022	Other	N/A

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152	Q4	Cabotegravir Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212887.pdf	8/2/2022	Other	N/A
153	Q4	Carbamazepine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018281.pdf	8/2/2022	Other	N/A
154	Q4	Caspofungin Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021227.pdf	8/2/2022	Other	N/A
155	Q4	Cetirizine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021621.pdf	8/2/2022	Other	N/A
156	Q4	Cobicistat; Darunavir; Emtricitabine; Tenofovir Alafenamide Fumarate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210455.pdf	8/2/2022	Other	N/A
157	Q4	Cyclosporine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214965.pdf	8/2/2022	Other	N/A
158	Q4	Cytarabine; Daunorubicin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209401.pdf	8/2/2022	Other	N/A
159	Q4	Dantrolene Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205579.pdf	8/2/2022	Other	N/A
160	Q4	Dasiglucagon Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214231.pdf	8/2/2022	Other	N/A
161	Q4	Doxycycline Hyclate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050751.pdf	8/2/2022	Other	N/A
162	Q4	Ethinyl Estradiol; Norethindrone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021490.pdf	8/2/2022	Other	N/A
163	Q4	Ethinyl Estradiol; Norethindrone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203667.pdf	8/2/2022	Other	N/A
164	Q4	Etonogestrel; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021529.pdf	8/2/2022	Other	N/A
165	Q4	Famotidine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020801.pdf	8/2/2022	Other	N/A
166	Q4	Gallium Ga-68 Gozetotide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212642.pdf	8/2/2022	Other	N/A

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167	Q4	Ibuprofen; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020601.pdf	8/2/2022	Other	N/A
168	Q4	Ketoprofen; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018754.pdf	8/2/2022	Other	N/A
169	Q4	Lamotrigine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020764.pdf	8/2/2022	Other	N/A
170	Q4	Lanthanum Carbonate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021468.pdf	8/2/2022	Other	N/A
171	Q4	Lonafarnib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213969.pdf	8/2/2022	Other	N/A
172	Q4	Loperamide Hydrochloride; Simethicone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020606.pdf	8/2/2022	Other	N/A
173	Q4	Loratadine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021891.pdf	8/2/2022	Other	N/A
174	Q4	Loteprednol Etabonate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210933.pdf	8/2/2022	Other	N/A
175	Q4	Medroxyprogesterone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012541.pdf	8/2/2022	Other	N/A
176	Q4	Medroxyprogesterone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020246.pdf	8/2/2022	Other	N/A
177	Q4	Meloxicam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210583.pdf	8/2/2022	Other	N/A
178	Q4	Methylphenidate Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021475.pdf	8/2/2022	Other	N/A
179	Q4	Mometasone Furoate; Olopatadine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211746.pdf	8/2/2022	Other	N/A
180	Q4	Nicotine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020385.pdf	8/2/2022	Other	N/A
181	Q4	Nifurtimox; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213464.pdf	8/2/2022	Other	N/A
182	Q4	Olopatadine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021861.pdf	8/2/2022	Other	N/A

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183	Q4	Oxymetazone Hydrochloride; Tetracaine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208032.pdf	8/2/2022	Other	N/A
184	Q4	Pafolacianine Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214907.pdf	8/2/2022	Other	N/A
185	Q4	Prednisone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202020.pdf	8/2/2022	Other	N/A
186	Q4	Relugolix; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214621.pdf	8/2/2022	Other	N/A
187	Q4	Setmelanotide Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213793.pdf	8/2/2022	Other	N/A
188	Q4	Tacrolimus; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210115.pdf	8/2/2022	Other	N/A
189	Q4	Technetium Tc-99m Sodium Pertechnetate Generator; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202158.pdf	8/2/2022	Other	N/A
190	Q4	Upadacitinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211675.pdf	8/2/2022	Other	N/A
191	Q4	Vericiguat; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214377.pdf	8/2/2022	Other	N/A
192	Q4	Vibegron; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213006.pdf	8/2/2022	Other	N/A
193	Q4	Electronic Submission of Expedited Safety Reports from IND-Exempt BA/BE Studies; Draft Guidance for Industry www.fda.gov/media/160561/download	8/3/2022	Other	N/A

Public Meetings

Pursuant to Section 744C(a)(2) of the FD&C Act, the table below lists the number and titles of public meetings held on topics related to human generic drug activities and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017. Public meetings are listed by the quarter in which they were held and are provided in a cumulative format for FY 2022.

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

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	FDA and Center for Research on Complex Generics Co-Hosted Workshop: Regulatory Utility of Mechanistic Modeling to Support Alternative Bioequivalence Approaches www.fda.gov/drugs/news-events-human-drugs/fda-and-center-research-complex-generics-co-hosted-workshop-regulatory-utility-mechanistic-modeling	9/30-10/1/2021	No
2	Q1	Public Meeting on the Reauthorization of Generic Drug User Fee Amendments (GDUFA) www.fda.gov/drugs/news-events-human-drugs/public-meeting-reauthorization-generic-drug-user-fee-amendments-gdufa-11162021-11162021	11/16/2021	Yes
3	Q1	FDA and Center for Research on Complex Generics Co-Hosted Workshop: Establishing the Suitability of Model-Integrated Evidence to Demonstrate Bioequivalence for Long-Acting Injectable and Implantable Drug Products www.fda.gov/drugs/news-events-human-drugs/fda-and-center-research-complex-generics-co-hosted-workshop-establishing-suitability-model	11/30/2021	No
4	Q1	Drug Permeability: Best Practices for Biopharmaceutics Classification System-Based Biowaivers www.fda.gov/drugs/news-events-human-drugs/drug-permeability-best-practices-biopharmaceutics-classification-system-based-biowaivers-12062021	12/6/2021	No
5	Q2	SBIA Webinar: Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA www.fda.gov/drugs/news-events-human-drugs/bioequivalence-studies-pharmacokinetic-endpoints-drugs-submitted-under-anda-02242022	2/24/2022	No
6	Q3	Generic Drugs Forum 2022: The Current State of Generic Drugs www.fda.gov/drugs/news-events-human-drugs/generic-drugs-forum-2022-current-state-generic-drugs-04262022	4/26-4/27/2022	No
7	Q3	FY 2022 Generic Drug Science and Research Initiatives Public Workshop www.fda.gov/drugs/news-events-human-drugs/fy-2022-generic-drug-science-and-research-initiatives-public-workshop-05092022	5/9-5/10/2022	Yes
8	Q3	FDA and Center for Research on Complex Generics Co-Hosted Workshop: In Vitro Release Test and In Vitro-In Vivo Correlation of Complex Generic Ophthalmic, Injectable, Implantable, and Inserted Products complexgenerics.org/IVRT-IVIVC/	6/29/2022	No
9	Q4	SBIA Webinar: Decoding the Guidance: Considerations for Waiver Requests for pH Adjusters in Generic Drug Products Intended for Parenteral, Ophthalmic, or Otic Use https://www.fda.gov/drugs/news-events-human-drugs/decoding-guidance-considerations-waiver-requests-ph-adjusters-generic-drug-products-intended	8/10/2022	No
10	Q4	SBIA Webinar: Best Practices for Topical Generic Product Development and ANDA Submission www.fda.gov/drugs/news-events-human-drugs/best-practices-topical-generic-product-development-and-anda-submission-08112022	8/11/2022	No

11	Q4	SBIA Workshop: Advancing Generic Drug Development: Translating Science to Approval www.fda.gov/drugs/news-events-human-drugs/advancing-generic-drug-development-translating-science-approval-09202022	9/20-9/21/2022	No