



FDA U.S. FOOD & DRUG
ADMINISTRATION

FY 2020

Real Time Report

pursuant to the

Generic Drug User Fee Amendments

as amended by the FDA Reauthorization Act of 2017

Acronyms

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

FDA – Food and Drug Administration

FDARA – FDA Reauthorization Act of 2017

FY – Fiscal Year (October 1 to September 30)

GDUFA – Generic Drug User Fee Amendments

Q1 – Quarter 1 (October 1 to December 31)

Q2 – Quarter 2 (January 1 to March 31)

Q3 – Quarter 3 (April 1 to June 30)

Q4 – Quarter 4 (July 1 to September 30)

Background

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

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

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

This report is being issued pursuant to the requirement of Section 744C(a)(2) of the FD&C Act, which states:

“Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary [of Health and Human Services] shall post...on the internet website of the Food and Drug Administration...

- “The number and titles of draft and final guidance on topics related to human generic drug activities and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017.”
- “The number and titles of public meetings held on topics related to human generic drug activities and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017.”

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

Human Generic Drugs

Guidance Documents

Pursuant to Section 744C(a)(2) of the FD&C Act, the table below lists the number and titles of draft and final guidances on topics related to human generic drug activities and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017. Guidances are listed by the quarter in which they were issued and are provided in a cumulative format for Fiscal Year (FY) 2020.

Table 1: Draft and Final Guidance Documents Related to the Human Generic Drug Activities for FY 2020

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	Drug Master Files Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-master-files-guidance-industry	10/18/2019	Other	N/A
2	Q1	Assessing User Fees Under the Generic Drug User Fee Amendments of 2017 www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-user-fees-under-generic-drug-user-fee-amendments-2017	11/1/2019	Other	N/A
3	Q1	Transdermal and Topical Delivery Systems - Product Development and Quality Considerations www.fda.gov/regulatory-information/search-fda-guidance-documents/transdermal-and-topical-delivery-systems-product-development-and-quality-considerations	11/20/2019	Other	N/A
4	Q1	Acetaminophen; Benzhydrocodone Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208653.pdf	11/21/2019	Other	N/A
5	Q1	Adapalene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022502.pdf	11/21/2019	Other	N/A
6	Q1	Adapalene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020748.pdf	11/21/2019	Other	N/A
7	Q1	Adapalene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020380.pdf	11/21/2019	Other	N/A
8	Q1	Adapalene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021753.pdf	11/21/2019	Other	N/A
9	Q1	Adapalene; Benzoyl Peroxide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022320.pdf	11/21/2019	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	Adapalene; Benzoyl Peroxide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207917.pdf	11/21/2019	Other	N/A
11	Q1	Azacitidine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050794.pdf	11/21/2019	Other	N/A
12	Q1	Baclofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021589.pdf	11/21/2019	Other	N/A
13	Q1	Benzoyl Peroxide; Clindamycin Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050819.pdf	11/21/2019	Other	N/A
14	Q1	Benzoyl Peroxide; Clindamycin Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050741.pdf	11/21/2019	Other	N/A
15	Q1	Benzoyl Peroxide; Clindamycin Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050756.pdf	11/21/2019	Other	N/A
16	Q1	Benzoyl Peroxide; Erythromycin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050557.pdf	11/21/2019	Other	N/A
17	Q1	Benzoyl Peroxide; Erythromycin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050769.pdf	11/21/2019	Other	N/A
18	Q1	Betamethasone Dipropionate; Calcipotriene; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207589.pdf	11/21/2019	Other	N/A
19	Q1	Capsaicin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022395.pdf	11/21/2019	Other	N/A
20	Q1	Cariprazine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204370.pdf	11/21/2019	Other	N/A
21	Q1	Cefaclor; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050673.pdf	11/21/2019	Other	N/A
22	Q1	Chlorzoxazone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011529-Tab-750MG.pdf	11/21/2019	Other	N/A
23	Q1	Chlorzoxazone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011300.pdf	11/21/2019	Other	N/A
24	Q1	Chlorzoxazone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011529_Tab_500MG.pdf	11/21/2019	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	Clindamycin Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050615.pdf	11/21/2019	Other	N/A
26	Q1	Clindamycin Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050782.pdf	11/21/2019	Other	N/A
27	Q1	Clindamycin Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050600.pdf	11/21/2019	Other	N/A
28	Q1	Clindamycin Phosphate; Tretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050802.pdf	11/21/2019	Other	N/A
29	Q1	Clonidine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018891.pdf	11/21/2019	Other	N/A
30	Q1	Clonidine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017407.pdf	11/21/2019	Other	N/A
31	Q1	Copper; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018680.pdf	11/21/2019	Other	N/A
32	Q1	Dapsone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207154.pdf	11/21/2019	Other	N/A
33	Q1	Dapsone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021794.pdf	11/21/2019	Other	N/A
34	Q1	Diclofenac Epolamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021234.pdf	11/21/2019	Other	N/A
35	Q1	Didanosine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021183.pdf	11/21/2019	Other	N/A
36	Q1	Disopyramide Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017447.pdf	11/21/2019	Other	N/A
37	Q1	Dolutegravir Sodium; Rilpivirine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210192.pdf	11/21/2019	Other	N/A
38	Q1	Doxepin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020126.pdf	11/21/2019	Other	N/A
39	Q1	Doxycycline Hyclate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209844.pdf	11/21/2019	Other	N/A

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40	Q1	Encorafenib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210496.pdf	11/21/2019	Other	N/A
41	Q1	Estradiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022038.pdf	11/21/2019	Other	N/A
42	Q1	Estradiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203752.pdf	11/21/2019	Other	N/A
43	Q1	Estradiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019081.pdf	11/21/2019	Other	N/A
44	Q1	Estradiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020375.pdf	11/21/2019	Other	N/A
45	Q1	Estradiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020538.pdf	11/21/2019	Other	N/A
46	Q1	Estradiol; Levonorgestrel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021258.pdf	11/21/2019	Other	N/A
47	Q1	Estradiol; Norethindrone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020870.pdf	11/21/2019	Other	N/A
48	Q1	Ethinyl Estradiol; Norelgestromin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021180.pdf	11/21/2019	Other	N/A
49	Q1	Fentanyl; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019813.pdf	11/21/2019	Other	N/A
50	Q1	Flavoxate Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016769.pdf	11/21/2019	Other	N/A
51	Q1	Granisetron; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022198.pdf	11/21/2019	Other	N/A
52	Q1	Indapamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018538.pdf	11/21/2019	Other	N/A
53	Q1	Indocyanine Green; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211580.pdf	11/21/2019	Other	N/A
54	Q1	Isoniazid; Pyrazinamide; Rifampin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050705.pdf	11/21/2019	Other	N/A
55	Q1	Isosorbide Dinitrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019790.pdf	11/21/2019	Other	N/A

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56	Q1	Latanoprost; Netarsudil Dimesylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208259.pdf	11/21/2019	Other	N/A
57	Q1	Lidocaine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207962.pdf	11/21/2019	Other	N/A
58	Q1	Lidocaine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020612.pdf	11/21/2019	Other	N/A
59	Q1	Lithium Carbonate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017812.pdf	11/21/2019	Other	N/A
60	Q1	Lorlatinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210868.pdf	11/21/2019	Other	N/A
61	Q1	Lutetium Dotatate Lu-177; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208700.pdf	11/21/2019	Other	N/A
62	Q1	Medroxyprogesterone Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011839.pdf	11/21/2019	Other	N/A
63	Q1	Meloxicam; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211210.pdf	11/21/2019	Other	N/A
64	Q1	Menthol; Methyl Salicylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022029.pdf	11/21/2019	Other	N/A
65	Q1	Metformin Hydrochloride; Repaglinide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022386.pdf	11/21/2019	Other	N/A
66	Q1	Methylphenidate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021514.pdf	11/21/2019	Other	N/A
67	Q1	Mifepristone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020687.pdf	11/21/2019	Other	N/A
68	Q1	Mifepristone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202107.pdf	11/21/2019	Other	N/A
69	Q1	Migalastat Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208623.pdf	11/21/2019	Other	N/A
70	Q1	Molindone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017111.pdf	11/21/2019	Other	N/A

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71	Q1	Mycophenolate Mofetil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050759.pdf	11/21/2019	Other	N/A
72	Q1	Nicotine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020076.pdf	11/21/2019	Other	N/A
73	Q1	Nitrofurantoin, Macrocrystalline; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016620.pdf	11/21/2019	Other	N/A
74	Q1	Nitrofurantoin; Nitrofurantoin, Macrocrystalline; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020064.pdf	11/21/2019	Other	N/A
75	Q1	Nitroglycerin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020145.pdf	11/21/2019	Other	N/A
76	Q1	Nitroglycerin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020144.pdf	11/21/2019	Other	N/A
77	Q1	Omadacycline Tosylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209816.pdf	11/21/2019	Other	N/A
78	Q1	Omadacycline Tosylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209817.pdf	11/21/2019	Other	N/A
79	Q1	Oxybutynin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202211.pdf	11/21/2019	Other	N/A
80	Q1	Oxybutynin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021351.pdf	11/21/2019	Other	N/A
81	Q1	Oxymetazoline Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208522.pdf	11/21/2019	Other	N/A
82	Q1	Pimavanserin Tartrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210793.pdf	11/21/2019	Other	N/A
83	Q1	Pimecrolimus; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021302.pdf	11/21/2019	Other	N/A
84	Q1	Prednisolone Sodium Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021959.pdf	11/21/2019	Other	N/A
85	Q1	Rivastigmine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022083.pdf	11/21/2019	Other	N/A
86	Q1	Roflumilast; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022522.pdf	11/21/2019	Other	N/A

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87	Q1	Rotigotine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021829.pdf	11/21/2019	Other	N/A
88	Q1	Scopolamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017874.pdf	11/21/2019	Other	N/A
89	Q1	Selegiline; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021336.pdf	11/21/2019	Other	N/A
90	Q1	Sulfacetamide Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019931.pdf	11/21/2019	Other	N/A
91	Q1	Sulfadiazine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_004122.pdf	11/21/2019	Other	N/A
92	Q1	Sumatriptan Succinate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020080.pdf	11/21/2019	Other	N/A
93	Q1	Tazarotene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202428.pdf	11/21/2019	Other	N/A
94	Q1	Tazarotene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020600-Gel-0.1P.pdf	11/21/2019	Other	N/A
95	Q1	Terazosin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020347.pdf	11/21/2019	Other	N/A
96	Q1	Testosterone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020489.pdf	11/21/2019	Other	N/A
97	Q1	Tetracaine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208135.pdf	11/21/2019	Other	N/A
98	Q1	Timolol Maleate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020330.pdf	11/21/2019	Other	N/A
99	Q1	Tinidazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021618.pdf	11/21/2019	Other	N/A
100	Q1	Tipiracil Hydrochloride; Trifluridine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207981.pdf	11/21/2019	Other	N/A
101	Q1	Tretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020475-Gel-0.1P.pdf	11/21/2019	Other	N/A
102	Q1	Tretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020475-Gel-0.04P.pdf	11/21/2019	Other	N/A
103	Q1	Tretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017340.pdf	11/21/2019	Other	N/A

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104	Q1	Tretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017522.pdf	11/21/2019	Other	N/A
105	Q1	Tretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019049.pdf	11/21/2019	Other	N/A
106	Q1	Tretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017579.pdf	11/21/2019	Other	N/A
107	Q1	Tretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017955.pdf	11/21/2019	Other	N/A
108	Q1	Tretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022070.pdf	11/21/2019	Other	N/A
109	Q1	Cocaine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209963.pdf	12/13/2019	Other	N/A
110	Q2	Levonorgestrel; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021225.pdf	1/22/2020	Other	N/A
111	Q2	Competitive Generic Therapies; Final Guidance www.fda.gov/regulatory-information/search-fda-guidance-documents/competitive-generic-therapies	3/16/2020	Required by Statute	FDA Reauthorization Act of 2017 Section 803(b)(1)
112	Q2	Albuterol Sulfate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019604.pdf	3/3/2020	Other	N/A
113	Q2	Albuterol Sulfate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020503.pdf	3/3/2020	Other	N/A
114	Q2	Albuterol Sulfate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205636.pdf	3/3/2020	Other	N/A
115	Q2	Amifampridine Phosphate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208078.pdf	3/3/2020	Other	N/A
116	Q2	Amino Acids; Calcium Chloride; Dextrose; Magnesium Sulfate; Potassium Chloride; Sodium Acetate; Sodium Glycerophosphate; Soybean Oil; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200656.pdf	3/3/2020	Other	N/A
117	Q2	Beclomethasone Dipropionate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020911.pdf	3/3/2020	Other	N/A
118	Q2	Besifloxacin Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022308.pdf	3/3/2020	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)
119	Q2	Binimetinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210498.pdf	3/3/2020	Other	N/A
120	Q2	Budesonide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211929.pdf	3/3/2020	Other	N/A
121	Q2	Calcitonin Salmon; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020313.pdf	3/3/2020	Other	N/A
122	Q2	Clevidipine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022156.pdf	3/3/2020	Other	N/A
123	Q2	Dacomitinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211288.pdf	3/3/2020	Other	N/A
124	Q2	Dapagliflozin; Metformin Hydrochloride; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205649.pdf	3/3/2020	Other	N/A
125	Q2	Dapagliflozin; Metformin Hydrochloride; Saxagliptin Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210874.pdf	3/3/2020	Other	N/A
126	Q2	Diltiazem Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018602.pdf	3/3/2020	Other	N/A
127	Q2	Doravirine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210806.pdf	3/3/2020	Other	N/A
128	Q2	Doravirine; Lamivudine; Tenofovir Disoproxil Fumarate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210807.pdf	3/3/2020	Other	N/A
129	Q2	Duloxetine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212516.pdf	3/3/2020	Other	N/A
130	Q2	Edaravone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209176.pdf	3/3/2020	Other	N/A
131	Q2	Edoxaban Tosylate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206316.pdf	3/3/2020	Other	N/A
132	Q2	Elagolix Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210450.pdf	3/3/2020	Other	N/A
133	Q2	Granisetron; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022445.pdf	3/3/2020	Other	N/A
134	Q2	Ibrutinib; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205552.pdf	3/3/2020	Other	N/A
135	Q2	Ivacafator; Lumacaftor; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211358.pdf	3/3/2020	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)
136	Q2	Levalbuterol Tartrate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021730.pdf	3/3/2020	Other	N/A
137	Q2	Liraglutide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022341.pdf	3/3/2020	Other	N/A
138	Q2	Lusutrombopag; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210923.pdf	3/3/2020	Other	N/A
139	Q2	Mexiletine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018873.pdf	3/3/2020	Other	N/A
140	Q2	Moxidectin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210867.pdf	3/3/2020	Other	N/A
141	Q2	Olsalazine Sodium; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019715.pdf	3/3/2020	Other	N/A
142	Q2	Propranolol Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021438.pdf	3/3/2020	Other	N/A
143	Q2	Rifamycin Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210910.pdf	3/3/2020	Other	N/A
144	Q2	Selenious Acid; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209379.pdf	3/3/2020	Other	N/A
145	Q2	Selexipag; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207947.pdf	3/3/2020	Other	N/A
146	Q2	Semaglutide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209637.pdf	3/3/2020	Other	N/A
147	Q2	Stiripentol; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206709.pdf	3/3/2020	Other	N/A
148	Q2	Stiripentol; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207223.pdf	3/3/2020	Other	N/A
149	Q2	Sumatriptan Succinate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206099.pdf	3/3/2020	Other	N/A
150	Q2	Tacrolimus; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210115.pdf	3/3/2020	Other	N/A
151	Q2	Tioprozin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211843.pdf	3/3/2020	Other	N/A
152	Q2	Tolvaptan; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204441.pdf	3/3/2020	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)
153	Q2	Umeclidinium Bromide; Vilanterol Trifenatate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203975.pdf	3/3/2020	Other	N/A
154	Q2	Upadacitinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211675.pdf	3/3/2020	Other	N/A
155	Q3	Hydroxychloroquine Sulfate; Final Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009768.pdf	4/13/2020	Other	N/A
156	Q3	Chloroquine Phosphate; Final Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_006002.pdf	4/13/2020	Other	N/A
157	Q3	Orange Book Questions and Answers Guidance www.fda.gov/regulatory-information/search-fda-guidance-documents/orange-book-questions-and-answers-guidance-industry	5/27/2020	Other	N/A
158	Q3	Abiraterone Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210308.pdf	6/3/2020	Other	N/A
159	Q3	Albendazole; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020666.pdf	6/3/2020	Other	N/A
160	Q3	Amoxicillin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050542.pdf	6/3/2020	Other	N/A
161	Q3	Aprepitant; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209296.pdf	6/3/2020	Other	N/A
162	Q3	Azelastine Hydrochloride; Fluticasone Propionate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202236.PDF	6/3/2020	Other	N/A
163	Q3	Brexanolone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211371.pdf	6/3/2020	Other	N/A
164	Q3	Buprenorphine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209819.pdf	6/3/2020	Other	N/A
165	Q3	Buprenorphine; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021306.pdf	6/3/2020	Other	N/A
166	Q3	Carglumic Acid; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022562.pdf	6/3/2020	Other	N/A
167	Q3	Clindamycin Phosphate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050537-Sol.pdf	6/3/2020	Other	N/A
168	Q3	Clindamycin Phosphate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050537-Sw a.pdf	6/3/2020	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)
169	Q3	Clindamycin Phosphate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050782.pdf	6/3/2020	Other	N/A
170	Q3	Clindamycin Phosphate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050801.pdf	6/3/2020	Other	N/A
171	Q3	Clindamycin Phosphate; Tretinoin; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050802.pdf	6/3/2020	Other	N/A
172	Q3	Clindamycin Phosphate; Tretinoin; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050803.pdf	6/3/2020	Other	N/A
173	Q3	Dapagliflozin; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202293.pdf	6/3/2020	Other	N/A
174	Q3	Dapagliflozin; Saxagliptin Hydrochloride; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209091.pdf	6/3/2020	Other	N/A
175	Q3	Desvenlafaxine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204683.pdf	6/3/2020	Other	N/A
176	Q3	Desvenlafaxine; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204150.pdf	6/3/2020	Other	N/A
177	Q3	Desvenlafaxine Fumarate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205583.pdf	6/3/2020	Other	N/A
178	Q3	Desvenlafaxine Succinate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021992.pdf	6/3/2020	Other	N/A
179	Q3	Dihydroergotamine Mesylate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020148.pdf	6/3/2020	Other	N/A
180	Q3	Diltiazem Hydrochloride; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019471.pdf	6/3/2020	Other	N/A
181	Q3	Diltiazem Hydrochloride; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020092.pdf	6/3/2020	Other	N/A
182	Q3	Diltiazem Hydrochloride; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020062.pdf	6/3/2020	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)
183	Q3	Diltiazem Hydrochloride; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020401.pdf	6/3/2020	Other	N/A
184	Q3	Diltiazem Hydrochloride; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021392.pdf	6/3/2020	Other	N/A
185	Q3	Dolutegravir Sodium; Lamivudine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211994.pdf	6/3/2020	Other	N/A
186	Q3	Efavirenz; Lamivudine; Tenofovir Disoproxil Fumarate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210649.pdf	6/3/2020	Other	N/A
187	Q3	Estradiol; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020472.pdf	6/3/2020	Other	N/A
188	Q3	Everolimus; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021560.pdf	6/3/2020	Other	N/A
189	Q3	Ferric Citrate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205874.pdf	6/3/2020	Other	N/A
190	Q3	Fish Oil Triglycerides; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210589.pdf	6/3/2020	Other	N/A
191	Q3	Fluorometholone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019216.pdf	6/3/2020	Other	N/A
192	Q3	Fluticasone Furoate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022051.pdf	6/3/2020	Other	N/A
193	Q3	Fluticasone Propionate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020121.pdf	6/3/2020	Other	N/A
194	Q3	Fluticasone Propionate; Salmeterol Xinafoate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021254.pdf	6/3/2020	Other	N/A
195	Q3	Gilteritinib Fumarate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211349.pdf	6/3/2020	Other	N/A
196	Q3	Glycopyrrolate; Indacaterol Maleate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207930.pdf	6/3/2020	Other	N/A
197	Q3	Ivosidenib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211192.pdf	6/3/2020	Other	N/A
198	Q3	Latanoprost; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206185.pdf	6/3/2020	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)
199	Q3	Metformin Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212595.pdf	6/3/2020	Other	N/A
200	Q3	Methylphenidate Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212038.pdf	6/3/2020	Other	N/A
201	Q3	Methylphenidate Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209311.pdf	6/3/2020	Other	N/A
202	Q3	Methylphenidate Hydrochloride; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205831.pdf	6/3/2020	Other	N/A
203	Q3	Methylphenidate Hydrochloride; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021284.pdf	6/3/2020	Other	N/A
204	Q3	Methylphenidate Hydrochloride; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021259.pdf	6/3/2020	Other	N/A
205	Q3	Methylphenidate Hydrochloride; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018029.pdf	6/3/2020	Other	N/A
206	Q3	Metoprolol Tartrate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017963.pdf	6/3/2020	Other	N/A
207	Q3	Metronidazole; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205223.pdf	6/3/2020	Other	N/A
208	Q3	Metronidazole; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020208.pdf	6/3/2020	Other	N/A
209	Q3	Mometasone Furoate; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020762.pdf	6/3/2020	Other	N/A
210	Q3	Prucalopride Succinate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210166.pdf	6/3/2020	Other	N/A
211	Q3	Revefenacin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210598.pdf	6/3/2020	Other	N/A
212	Q3	Sodium Zirconium Cyclosilicate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207078.pdf	6/3/2020	Other	N/A
213	Q3	Tafenoquine Succinate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210795.pdf	6/3/2020	Other	N/A
214	Q3	Talazoparib Tosylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211651.pdf	6/3/2020	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)
215	Q3	Tretinoin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209353.pdf	6/3/2020	Other	N/A
216	Q3	Tretinoin; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022070.pdf	6/3/2020	Other	N/A
217	Q3	Tretinoin; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021108.pdf	6/3/2020	Other	N/A
218	Q3	Tretinoin; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020475.pdf	6/3/2020	Other	N/A
219	Q3	Tretinoin; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019963.pdf	6/3/2020	Other	N/A
220	Q3	Tretinoin; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019049.pdf	6/3/2020	Other	N/A
221	Q3	Tretinoin; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017955.pdf	6/3/2020	Other	N/A
222	Q3	Tretinoin; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017579.pdf	6/3/2020	Other	N/A
223	Q3	Tretinoin; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017522.pdf	6/3/2020	Other	N/A
224	Q3	Tretinoin; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017340.pdf	6/3/2020	Other	N/A
225	Q3	Triamcinolone Acetonide; Revised Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020468.pdf	6/3/2020	Other	N/A
226	Q3	Triclabendazole; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208711.pdf	6/3/2020	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 2020.

Table 2: Public Meetings Held on Topics Related to Human Generic Drug Activities for FY 2020

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q3	Regulatory Education for Industry (REdI): Generic Drugs Forum www.fda.gov/drugs/news-events-human-drugs/regulatory-education-industry-redi-generic-drugs-forum-april-15-16-2020-04152020-04162020	April 15-16, 2020	No
2	Q3	FY2020 Generic Drug Regulatory Science Initiatives Public Workshop www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fy-2020-generic-drug-regulatory-science-initiatives-public-workshop-05042020-05042020	May 4, 2020	Yes
3	Q3	Financial Transparency and Efficiency of the Prescription Drug User Fee, Biosimilar User Fee Act and Generic User Fee Amendments www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and	6/10/2020	Yes