



**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**

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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.<sup>1</sup>

### **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.”

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<sup>1</sup> 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 <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-master-files-guidance-industry">www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-master-files-guidance-industry</a>	10/18/2019	Other	N/A
2	Q1	Assessing User Fees Under the Generic Drug User Fee Amendments of 2017 <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-user-fees-under-generic-drug-user-fee-amendments-2017">www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-user-fees-under-generic-drug-user-fee-amendments-2017</a>	11/1/2019	Other	N/A
3	Q1	Transdermal and Topical Delivery Systems - Product Development and Quality Considerations <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/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</a>	11/20/2019	Other	N/A
4	Q1	Acetaminophen; Benzhydrocodone Hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208653.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208653.pdf</a>	11/21/2019	Other	N/A
5	Q1	Adapalene; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022502.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022502.pdf</a>	11/21/2019	Other	N/A
6	Q1	Adapalene; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020748.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020748.pdf</a>	11/21/2019	Other	N/A
7	Q1	Adapalene; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020380.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020380.pdf</a>	11/21/2019	Other	N/A
8	Q1	Adapalene; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021753.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021753.pdf</a>	11/21/2019	Other	N/A
9	Q1	Adapalene; Benzoyl Peroxide; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022320.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022320.pdf</a>	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 <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207917.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207917.pdf</a>	11/21/2019	Other	N/A
11	Q1	Azacitidine; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050794.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050794.pdf</a>	11/21/2019	Other	N/A
12	Q1	Baclofen; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021589.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021589.pdf</a>	11/21/2019	Other	N/A
13	Q1	Benzoyl Peroxide; Clindamycin Phosphate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050819.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050819.pdf</a>	11/21/2019	Other	N/A
14	Q1	Benzoyl Peroxide; Clindamycin Phosphate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050741.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050741.pdf</a>	11/21/2019	Other	N/A
15	Q1	Benzoyl Peroxide; Clindamycin Phosphate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050756.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050756.pdf</a>	11/21/2019	Other	N/A
16	Q1	Benzoyl Peroxide; Erythromycin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050557.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050557.pdf</a>	11/21/2019	Other	N/A
17	Q1	Benzoyl Peroxide; Erythromycin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050769.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050769.pdf</a>	11/21/2019	Other	N/A
18	Q1	Betamethasone Dipropionate; Calcipotriene; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207589.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207589.pdf</a>	11/21/2019	Other	N/A
19	Q1	Capsaicin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022395.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022395.pdf</a>	11/21/2019	Other	N/A
20	Q1	Cariprazine Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204370.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204370.pdf</a>	11/21/2019	Other	N/A
21	Q1	Cefaclor; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050673.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050673.pdf</a>	11/21/2019	Other	N/A
22	Q1	Chlorzoxazone; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011529-Tab-750MG.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011529-Tab-750MG.pdf</a>	11/21/2019	Other	N/A
23	Q1	Chlorzoxazone; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011300.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011300.pdf</a>	11/21/2019	Other	N/A
24	Q1	Chlorzoxazone; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011529_Tab_500MG.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011529_Tab_500MG.pdf</a>	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 <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050615.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050615.pdf</a>	11/21/2019	Other	N/A
26	Q1	Clindamycin Phosphate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050782.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050782.pdf</a>	11/21/2019	Other	N/A
27	Q1	Clindamycin Phosphate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050600.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050600.pdf</a>	11/21/2019	Other	N/A
28	Q1	Clindamycin Phosphate; Tretinoin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050802.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050802.pdf</a>	11/21/2019	Other	N/A
29	Q1	Clonidine; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018891.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018891.pdf</a>	11/21/2019	Other	N/A
30	Q1	Clonidine Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017407.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017407.pdf</a>	11/21/2019	Other	N/A
31	Q1	Copper; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018680.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018680.pdf</a>	11/21/2019	Other	N/A
32	Q1	Dapsone; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207154.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207154.pdf</a>	11/21/2019	Other	N/A
33	Q1	Dapsone; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021794.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021794.pdf</a>	11/21/2019	Other	N/A
34	Q1	Diclofenac Epolamine; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021234.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021234.pdf</a>	11/21/2019	Other	N/A
35	Q1	Didanosine; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021183.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021183.pdf</a>	11/21/2019	Other	N/A
36	Q1	Disopyramide Phosphate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017447.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017447.pdf</a>	11/21/2019	Other	N/A
37	Q1	Dolutegravir Sodium; Rilpivirine Hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210192.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210192.pdf</a>	11/21/2019	Other	N/A
38	Q1	Doxepin Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020126.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020126.pdf</a>	11/21/2019	Other	N/A
39	Q1	Doxycycline Hyclate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209844.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209844.pdf</a>	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)
40	Q1	Encorafenib; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210496.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210496.pdf</a>	11/21/2019	Other	N/A
41	Q1	Estradiol; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022038.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022038.pdf</a>	11/21/2019	Other	N/A
42	Q1	Estradiol; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203752.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203752.pdf</a>	11/21/2019	Other	N/A
43	Q1	Estradiol; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019081.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019081.pdf</a>	11/21/2019	Other	N/A
44	Q1	Estradiol; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020375.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020375.pdf</a>	11/21/2019	Other	N/A
45	Q1	Estradiol; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020538.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020538.pdf</a>	11/21/2019	Other	N/A
46	Q1	Estradiol; Levonorgestrel; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021258.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021258.pdf</a>	11/21/2019	Other	N/A
47	Q1	Estradiol; Norethindrone Acetate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020870.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020870.pdf</a>	11/21/2019	Other	N/A
48	Q1	Ethinyl Estradiol; Norelgestromin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021180.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021180.pdf</a>	11/21/2019	Other	N/A
49	Q1	Fentanyl; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019813.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019813.pdf</a>	11/21/2019	Other	N/A
50	Q1	Flavoxate Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016769.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016769.pdf</a>	11/21/2019	Other	N/A
51	Q1	Granisetron; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022198.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022198.pdf</a>	11/21/2019	Other	N/A
52	Q1	Indapamide; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018538.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018538.pdf</a>	11/21/2019	Other	N/A
53	Q1	Indocyanine Green; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211580.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211580.pdf</a>	11/21/2019	Other	N/A
54	Q1	Isoniazid; Pyrazinamide; Rifampin; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050705.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050705.pdf</a>	11/21/2019	Other	N/A
55	Q1	Isosorbide Dinitrate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019790.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019790.pdf</a>	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)
56	Q1	Latanoprost; Netarsudil Dimesylate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208259.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208259.pdf</a>	11/21/2019	Other	N/A
57	Q1	Lidocaine; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207962.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207962.pdf</a>	11/21/2019	Other	N/A
58	Q1	Lidocaine; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020612.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020612.pdf</a>	11/21/2019	Other	N/A
59	Q1	Lithium Carbonate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017812.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017812.pdf</a>	11/21/2019	Other	N/A
60	Q1	Lorlatinib; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210868.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210868.pdf</a>	11/21/2019	Other	N/A
61	Q1	Lutetium Dotatate Lu-177; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208700.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208700.pdf</a>	11/21/2019	Other	N/A
62	Q1	Medroxyprogesterone Acetate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011839.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011839.pdf</a>	11/21/2019	Other	N/A
63	Q1	Meloxicam; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211210.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211210.pdf</a>	11/21/2019	Other	N/A
64	Q1	Menthol; Methyl Salicylate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022029.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022029.pdf</a>	11/21/2019	Other	N/A
65	Q1	Metformin Hydrochloride; Repaglinide; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022386.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022386.pdf</a>	11/21/2019	Other	N/A
66	Q1	Methylphenidate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021514.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021514.pdf</a>	11/21/2019	Other	N/A
67	Q1	Mifepristone; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020687.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020687.pdf</a>	11/21/2019	Other	N/A
68	Q1	Mifepristone; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202107.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202107.pdf</a>	11/21/2019	Other	N/A
69	Q1	Migalastat Hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208623.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208623.pdf</a>	11/21/2019	Other	N/A
70	Q1	Molindone Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017111.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017111.pdf</a>	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)
71	Q1	Mycophenolate Mofetil; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050759.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050759.pdf</a>	11/21/2019	Other	N/A
72	Q1	Nicotine; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020076.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020076.pdf</a>	11/21/2019	Other	N/A
73	Q1	Nitrofurantoin, Macrocrystalline; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016620.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016620.pdf</a>	11/21/2019	Other	N/A
74	Q1	Nitrofurantoin; Nitrofurantoin, Macrocrystalline; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020064.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020064.pdf</a>	11/21/2019	Other	N/A
75	Q1	Nitroglycerin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020145.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020145.pdf</a>	11/21/2019	Other	N/A
76	Q1	Nitroglycerin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020144.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020144.pdf</a>	11/21/2019	Other	N/A
77	Q1	Omadacycline Tosylate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209816.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209816.pdf</a>	11/21/2019	Other	N/A
78	Q1	Omadacycline Tosylate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209817.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209817.pdf</a>	11/21/2019	Other	N/A
79	Q1	Oxybutynin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202211.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202211.pdf</a>	11/21/2019	Other	N/A
80	Q1	Oxybutynin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021351.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021351.pdf</a>	11/21/2019	Other	N/A
81	Q1	Oxymetazoline Hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208522.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208522.pdf</a>	11/21/2019	Other	N/A
82	Q1	Pimavanserin Tartrate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210793.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210793.pdf</a>	11/21/2019	Other	N/A
83	Q1	Pimecrolimus; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021302.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021302.pdf</a>	11/21/2019	Other	N/A
84	Q1	Prednisolone Sodium Phosphate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021959.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021959.pdf</a>	11/21/2019	Other	N/A
85	Q1	Rivastigmine; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022083.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022083.pdf</a>	11/21/2019	Other	N/A
86	Q1	Roflumilast; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022522.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022522.pdf</a>	11/21/2019	Other	N/A

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

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104	Q1	Tretinoin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017522.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017522.pdf</a>	11/21/2019	Other	N/A
105	Q1	Tretinoin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019049.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019049.pdf</a>	11/21/2019	Other	N/A
106	Q1	Tretinoin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017579.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017579.pdf</a>	11/21/2019	Other	N/A
107	Q1	Tretinoin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017955.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017955.pdf</a>	11/21/2019	Other	N/A
108	Q1	Tretinoin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022070.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022070.pdf</a>	11/21/2019	Other	N/A
109	Q1	Cocaine Hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209963.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209963.pdf</a>	12/13/2019	Other	N/A
110	Q2	Levonorgestrel; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021225.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021225.pdf</a>	1/22/2020	Other	N/A
111	Q2	Competitive Generic Therapies; Final Guidance <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/competitive-generic-therapies">www.fda.gov/regulatory-information/search-fda-guidance-documents/competitive-generic-therapies</a>	3/16/2020	Required by Statute	FDA Reauthorization Act of 2017 Section 803(b)(1)
112	Q2	Albuterol Sulfate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019604.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019604.pdf</a>	3/3/2020	Other	N/A
113	Q2	Albuterol Sulfate; Revised Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020503.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020503.pdf</a>	3/3/2020	Other	N/A
114	Q2	Albuterol Sulfate; Revised Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205636.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205636.pdf</a>	3/3/2020	Other	N/A
115	Q2	Amifampridine Phosphate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208078.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208078.pdf</a>	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 <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200656.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200656.pdf</a>	3/3/2020	Other	N/A
117	Q2	Beclomethasone Dipropionate; Revised Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020911.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020911.pdf</a>	3/3/2020	Other	N/A
118	Q2	Besifloxacin Hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022308.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022308.pdf</a>	3/3/2020	Other	N/A

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119	Q2	Binimetinib; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210498.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210498.pdf</a>	3/3/2020	Other	N/A
120	Q2	Budesonide; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211929.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211929.pdf</a>	3/3/2020	Other	N/A
121	Q2	Calcitonin Salmon; Revised Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020313.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020313.pdf</a>	3/3/2020	Other	N/A
122	Q2	Clevidipine; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022156.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022156.pdf</a>	3/3/2020	Other	N/A
123	Q2	Dacomitinib; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211288.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211288.pdf</a>	3/3/2020	Other	N/A
124	Q2	Dapagliflozin; Metformin Hydrochloride; Revised Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205649.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205649.pdf</a>	3/3/2020	Other	N/A
125	Q2	Dapagliflozin; Metformin Hydrochloride; Saxagliptin Hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210874.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210874.pdf</a>	3/3/2020	Other	N/A
126	Q2	Diltiazem Hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018602.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018602.pdf</a>	3/3/2020	Other	N/A
127	Q2	Doravirine; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210806.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210806.pdf</a>	3/3/2020	Other	N/A
128	Q2	Doravirine; Lamivudine; Tenofovir Disoproxil Fumarate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210807.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210807.pdf</a>	3/3/2020	Other	N/A
129	Q2	Duloxetine Hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212516.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212516.pdf</a>	3/3/2020	Other	N/A
130	Q2	Edaravone; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209176.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209176.pdf</a>	3/3/2020	Other	N/A
131	Q2	Edoxaban Tosylate; Revised Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206316.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206316.pdf</a>	3/3/2020	Other	N/A
132	Q2	Elagolix Sodium; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210450.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210450.pdf</a>	3/3/2020	Other	N/A
133	Q2	Granisetron; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022445.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022445.pdf</a>	3/3/2020	Other	N/A
134	Q2	Ibrutinib; Revised Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205552.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205552.pdf</a>	3/3/2020	Other	N/A
135	Q2	Ivacaftor; Lumacaftor; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211358.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211358.pdf</a>	3/3/2020	Other	N/A

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136	Q2	Levalbuterol Tartrate; Revised Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021730.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021730.pdf</a>	3/3/2020	Other	N/A
137	Q2	Liraglutide; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022341.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022341.pdf</a>	3/3/2020	Other	N/A
138	Q2	Lusutrombopag; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210923.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210923.pdf</a>	3/3/2020	Other	N/A
139	Q2	Mexiletine Hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018873.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018873.pdf</a>	3/3/2020	Other	N/A
140	Q2	Moxidectin; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210867.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210867.pdf</a>	3/3/2020	Other	N/A
141	Q2	Olsalazine Sodium; Revised Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019715.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019715.pdf</a>	3/3/2020	Other	N/A
142	Q2	Propranolol Hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021438.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021438.pdf</a>	3/3/2020	Other	N/A
143	Q2	Rifamycin Sodium; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210910.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210910.pdf</a>	3/3/2020	Other	N/A
144	Q2	Selenious Acid; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209379.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209379.pdf</a>	3/3/2020	Other	N/A
145	Q2	Selexipag; Revised Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207947.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207947.pdf</a>	3/3/2020	Other	N/A
146	Q2	Semaglutide; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209637.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209637.pdf</a>	3/3/2020	Other	N/A
147	Q2	Stiripentol; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206709.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206709.pdf</a>	3/3/2020	Other	N/A
148	Q2	Stiripentol; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207223.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207223.pdf</a>	3/3/2020	Other	N/A
149	Q2	Sumatriptan Succinate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206099.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206099.pdf</a>	3/3/2020	Other	N/A
150	Q2	Tacrolimus; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210115.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210115.pdf</a>	3/3/2020	Other	N/A
151	Q2	Tioprozin; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211843.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211843.pdf</a>	3/3/2020	Other	N/A
152	Q2	Tolvaptan; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204441.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204441.pdf</a>	3/3/2020	Other	N/A



**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