



**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

**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