FY 2019

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 2018.

Table 1: Draft and Final Guidance Documents Related to the Human Generic Drug Activities for FY 2019

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	Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM622235.pdf	10/2/2018	Other	N/A
2	Q1	Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM468228.pdf	10/2/2018	Other	N/A
3	Q1	Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM622672.pdf	10/9/2018	Other	N/A
4	Q1	Assessing Adhesion with Transdermal Delivery Systems and Topical Patches for ANDAs; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM504157.pdf	10/9/2018	Other	N/A
5	Q1	Buprenorphine; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM384107.pdf	10/9/2018	Other	N/A
6	Q1	Capsaicin; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM622436.pdf	10/9/2018	Other	N/A
7	Q1	Clonidine; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM191775.pdf	10/9/2018	Other	N/A
8	Q1	Diclofenac Epolamine; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM296889.pdf	10/9/2018	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)
9	Q1	Estradiol; (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM234961.pdf	10/9/2018	Other	N/A
10	Q1	Estradiol; (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM234963.pdf	10/9/2018	Other	N/A
11	Q1	Estradiol; (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM384116.pdf	10/9/2018	Other	N/A
12	Q1	Estradiol; (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM234962.pdf	10/9/2018	Other	N/A
13	Q1	Estradiol; Norethindrone Acetate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM622439.pdf	10/9/2018	Other	N/A
14	Q1	Ethinyl Estradiol; Norelgestromin; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM162407.pdf	10/9/2018	Other	N/A
15	Q1	Fentanyl; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM162427.pdf	10/9/2018	Other	N/A
16	Q1	Granisetron; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM296900.pdf	10/9/2018	Other	N/A
17	Q1	Lidocaine; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm086293.pdf	10/9/2018	Other	N/A
18	Q1	Menthol; Methyl Salicylate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM406333.pdf	10/9/2018	Other	N/A
19	Q1	Methylphenidate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM220196.pdf	10/9/2018	Other	N/A
20	Q1	Nicotine; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM373700.pdf	10/9/2018	Other	N/A
21	Q1	Nitroglycerin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM194644.pdf	10/9/2018	Other	N/A
22	Q1	Nitroglycerin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM194647.pdf	10/9/2018	Other	N/A
23	Q1	Oxybutynin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM194654.pdf	10/9/2018	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)
24	Q1	Oxybutynin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM452848.pdf	10/9/2018	Other	N/A
25	Q1	Rivastigmine; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM201278.pdf	10/9/2018	Other	N/A
26	Q1	Rotigotine; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM308070.pdf	10/9/2018	Other	N/A
27	Q1	Scopolamine; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM179189.pdf	10/9/2018	Other	N/A
28	Q1	Selegiline; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM179190.pdf	10/9/2018	Other	N/A
29	Q1	Testosterone; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM428222.pdf	10/9/2018	Other	N/A
30	Q1	Acetaminophen; Butalbital; Caffeine (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM204374.pdf	11/28/2018	Other	N/A
31	Q1	Acetaminophen; Butalbital; Caffeine (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM204373.pdf	11/28/2018	Other	N/A
32	Q1	Acetaminophen; Oxycodone HCL; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM194590.pdf	11/28/2018	Other	N/A
33	Q1	Adapalene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM191958.pdf	11/28/2018	Other	N/A
34	Q1	Adapalene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM191959.pdf	11/28/2018	Other	N/A
35	Q1	Adapalene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM191960.pdf	11/28/2018	Other	N/A
36	Q1	Adapalene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM244365.pdf	11/28/2018	Other	N/A
37	Q1	Adapalene; Benzoyl Peroxide (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM533014.pdf	11/28/2018	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)
38	Q1	Adapalene; Benzoyl Peroxide (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM191957.pdf	11/28/2018	Other	N/A
39	Q1	Amphetamine; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626426.pdf	11/28/2018	Other	N/A
40	Q1	Asenapine Maleate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358110.pdf	11/28/2018	Other	N/A
41	Q1	Atropine Sulfate; Diphenoxylate Hydrochloride; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626429.pdf	11/28/2018	Other	N/A
42	Q1	Benzoyl Peroxide; Clindamycin Phosphate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM224140.pdf	11/28/2018	Other	N/A
43	Q1	Benzoyl Peroxide; Clindamycin Phosphate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM224142.pdf	11/28/2018	Other	N/A
44	Q1	Benzoyl Peroxide; Clindamycin Phosphate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM240967.pdf	11/28/2018	Other	N/A
45	Q1	Benzoyl Peroxide; Erythromycin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM212603.pdf	11/28/2018	Other	N/A
46	Q1	Benzoyl Peroxide; Erythromycin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM212604.pdf	11/28/2018	Other	N/A
47	Q1	Clindamycin Phosphate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM252720.pdf	11/28/2018	Other	N/A
48	Q1	Clindamycin Phosphate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM252719.pdf	11/28/2018	Other	N/A
49	Q1	Clindamycin Phosphate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM252723.pdf	11/28/2018	Other	N/A
50	Q1	Clindamycin Phosphate; Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM333014.pdf	11/28/2018	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)
51	Q1	Dapsone (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM428205.pdf	11/28/2018	Other	N/A
52	Q1	Dapsone (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM572994.pdf	11/28/2018	Other	N/A
53	Q1	Dichlorphenamide; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626431.pdf	11/28/2018	Other	N/A
54	Q1	Doxepin Hydrochloride; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626433.pdf	11/28/2018	Other	N/A
55	Q1	Ertugliflozin; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626508.pdf	11/28/2018	Other	N/A
56	Q1	Ertugliflozin; Metformin Hydrochloride; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626506.pdf	11/28/2018	Other	N/A
57	Q1	Ertugliflozin; Sitagliptin Phosphate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626507.pdf	11/28/2018	Other	N/A
58	Q1	Estradiol; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626509.pdf	11/28/2018	Other	N/A
59	Q1	Everolimus; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM249239.pdf	11/28/2018	Other	N/A
60	Q1	Isosorbide Dinitrate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM436834.pdf	11/28/2018	Other	N/A
61	Q1	Latanoprostene Bunod; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626510.pdf	11/28/2018	Other	N/A
62	Q1	Letermovir (Multiple Reference Listed Drugs); Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626512.pdf	11/28/2018	Other	N/A
63	Q1	Letermovir (Multiple Reference Listed Drugs); Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626511.pdf	11/28/2018	Other	N/A
64	Q1	Levothyroxine Sodium; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626514.pdf	11/28/2018	Other	N/A
65	Q1	Lifitegrast; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626515.pdf	11/28/2018	Other	N/A
66	Q1	Macimorelin Acetate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626517.pdf	11/28/2018	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)
67	Q1	Metaxalone; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm088669.pdf	11/28/2018	Other	N/A
68	Q1	Metoprolol Succinate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626518.pdf	11/28/2018	Other	N/A
69	Q1	Mycophenolic Acid; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm082268.pdf	11/28/2018	Other	N/A
70	Q1	Netarsudil Dimesylate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626519.pdf	11/28/2018	Other	N/A
71	Q1	Nitazoxanide; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626520.pdf	11/28/2018	Other	N/A
72	Q1	Nitazoxanide; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM179184.pdf	11/28/2018	Other	N/A
73	Q1	Penicillamine; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626521.pdf	11/28/2018	Other	N/A
74	Q1	Plecanatide; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626522.pdf	11/28/2018	Other	N/A
75	Q1	Reserpine; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626523.pdf	11/28/2018	Other	N/A
76	Q1	Ribociclib Succinate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626524.pdf	11/28/2018	Other	N/A
77	Q1	Sulfacetamide Sodium; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM212625.pdf	11/28/2018	Other	N/A
78	Q1	Sulfamethoxazole; Trimethoprim; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm090381.pdf	11/28/2018	Other	N/A
79	Q1	Sumatriptan; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM296987.pdf	11/28/2018	Other	N/A
80	Q1	Tazarotene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM495426.pdf	11/28/2018	Other	N/A
81	Q1	Tazarotene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM283489.pdf	11/28/2018	Other	N/A
82	Q1	Thiothixene; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM626525.pdf	11/28/2018	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)
83	Q1	Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM296991.pdf	11/28/2018	Other	N/A
84	Q1	Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM296992.pdf	11/28/2018	Other	N/A
85	Q1	Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM296993.pdf	11/28/2018	Other	N/A
86	Q1	Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM296996.pdf	11/28/2018	Other	N/A
87	Q1	Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM296995.pdf	11/28/2018	Other	N/A
88	Q1	Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM320047.pdf	11/28/2018	Other	N/A
89	Q1	Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM296997.pdf	11/28/2018	Other	N/A
90	Q1	Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM320044.pdf	11/28/2018	Other	N/A
91	Q1	Triamterene; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm090716.pdf	11/28/2018	Other	N/A
92	Q1	Zolmitriptan; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM406345.pdf	11/28/2018	Other	N/A
93	Q1	Post-Complete Response Letter Meetings Between FDA and ANDA Applicants Under GDUFA; Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM580175.pdf	12/3/2018	Other	N/A
94	Q1	Data Integrity and Compliance With Drug CGMP www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM495891.pdf	12/12/2018	Other	N/A
95	Q1	Linaclotide; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM629200.pdf	12/27/2018	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 fiscal year 2019.

Table 2: Public Meetings Held on Topics Related to Human Generic Drug Activities for FY 2019

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter