FY 2018

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 – Food and Drug Administration 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 Food and Drug Administration 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 2018

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	Formal Meetings Between FDA & ANDA Applicants of Complex Products Under GDUFA; Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM578366.pdf	10/03/2017	Pursuant to Commitment Letter	GDUFA II Commitment Letter Section III. A. 1.
2	Q1	ANDA Submissions — Amendments to Abbreviated New Drug Applications Under GDUFA; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM578371.pdf	10/03/2017	Other	N/A
3	Q1	ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM578365.pdf	10/03/2017	Other	N/A
4	Q1	ANDA Submissions — Refuse-to-Receive Standards: Questions and Answers; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM578368.pdf	10/03/2017	Other	N/A
5	Q1	ANDA Submissions – Prior Approval Supplements Under GDUFA; Revised Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM404441.pdf	10/04/2017	Other	N/A
6	Q1	Completeness Assessments for Type II API DMFs Under GDUFA; Revised Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM321884.pdf	10/04/2017	Other	N/A
7	Q1	Requests for Reconsideration at the Division Level Under GDUFA; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM579746.pdf	10/12/2017	Other	N/A
8	Q1	Determining Whether to Submit an ANDA or a 505(b)(2) Application; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM579751.pdf	10/13/2017	Other	N/A

9	Q1	Post-Complete Response Letter Meetings Between FDA and ANDA Applicants Under GDUFA; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM580175.pdf	10/16/2017	Other	N/A
10	Q1	Azelastine Hydrochloride; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM572953.pdf	10/19/2017	Other	N/A
11	Q1	Azithromycin; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM572954.pdf	10/19/2017	Other	N/A
12	Q1	Barium Sulfate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM572955.pdf	10/19/2017	Other	N/A
13	Q1	Betamethasone Dipropionate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM572958.pdf	10/19/2017	Other	N/A
14	Q1	Budesonide; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM572989.pdf	10/19/2017	Other	N/A
15	Q1	Brimonidine Tartrate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm082954.pdf	10/19/2017	Other	N/A
16	Q1	Brimonidine Tartrate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM384649.pdf	10/19/2017	Other	N/A
17	Q1	Bromfenac Sodium; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm116123.pdf	10/19/2017	Other	N/A
18	Q1	Canagliflozin; Metformin Hydrochloride; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM572990.pdf	10/19/2017	Other	N/A
19	Q1	Ciprofloxacin Hydrochloride; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM261517.pdf	10/19/2017	Other	N/A
20	Q1	Cobicistat; Elvitegravir; Emtricitabine; Tenofovir Alafenamide Fumarate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM519690.pdf	10/19/2017	Other	N/A
21	Q1	Dantrolene Sodium; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM572991.pdf	10/19/2017	Other	N/A
22	Q1	Dapsone; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM572994.pdf	10/19/2017	Other	N/A
23	Q1	Dapsone; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM428205.pdf	10/19/2017	Other	N/A
24	Q1	Deflazacort; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM572995.pdf	10/19/2017	Other	N/A

25	Q1	Deflazacort; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM572997.pdf	10/19/2017	Other	N/A
26	Q1	Diclofenac Sodium; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm118164.pdf	10/19/2017	Other	N/A
27	Q1	Docosanol; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM572999.pdf	10/19/2017	Other	N/A
28	Q1	Doxycycline Hyclate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM162404.pdf	10/19/2017	Other	N/A
29	Q1	Emtricitabine; Rilpivirine Hydrochloride; Tenofovir Alafenamide Fumarate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM533287.pdf	10/19/2017	Other	N/A
30	Q1	Emtricitabine; Tenofovir Alafenamide Fumarate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM533291.pdf	10/19/2017	Other	N/A
31	Q1	Empagliflozin; Metformin Hydrochloride; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573008.pdf	10/19/2017	Other	N/A
32	Q1	Epinephrine; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573009.pdf	10/19/2017	Other	N/A
33	Q1	Erythromycin; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573010.pdf	10/19/2017	Other	N/A
34	Q1	Esomeprazole Magnesium; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM520173.pdf	10/19/2017	Other	N/A
35	Q1	Everolimus; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573012.pdf	10/19/2017	Other	N/A
36	Q1	Fluorometholone; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573027.pdf	10/19/2017	Other	N/A
37	Q1	Fluticasone Propionate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM581177.pdf	10/19/2017	Other	N/A
38	Q1	Fluticasone Propionate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM581179.pdf	10/19/2017	Other	N/A
39	Q1	Hydrocortisone Acetate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573029.pdf	10/19/2017	Other	N/A
40	Q1	Ivermectin; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573031.pdf	10/19/2017	Other	N/A
41	Q1	Levorphanol Tartrate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573032.pdf	10/19/2017	Other	N/A

42	Q1	Lisdexamfetamine Dimesylate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573033.pdf	10/19/2017	Other	N/A
43	Q1	Lisdexamfetamine Dimesylate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm086296.pdf	10/19/2017	Other	N/A
44	Q1	Mesalamine; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM319999.pdf	10/19/2017	Other	N/A
45	Q1	Methylphenidate Hydrochloride; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM581432.pdf	10/19/2017	Other	N/A
46	Q1	Mometasone Furoate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573090.pdf	10/19/2017	Other	N/A
47	Q1	Mycophenolate Mofetil; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM217148.pdf	10/19/2017	Other	N/A
48	Q1	Nitisinone; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573091.pdf	10/19/2017	Other	N/A
49	Q1	Ofloxacin; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM261523.pdf	10/19/2017	Other	N/A
50	Q1	Olaparib; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573092.pdf	10/19/2017	Other	N/A
51	Q1	Olopatadine Hydrochloride; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm089224.pdf	10/19/2017	Other	N/A
52	Q1	Olopatadine Hydrochloride; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586265.pdf	10/19/2017	Other	N/A
53	Q1	Osimertinib Mesylate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573094.pdf	10/19/2017	Other	N/A
54	Q1	Permethrin; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573095.pdf	10/19/2017	Other	N/A
55	Q1	Pirfenidone; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573096.pdf	10/19/2017	Other	N/A
56	Q1	Ropinirole Hydrochloride; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM194667.pdf	10/19/2017	Other	N/A
57	Q1	Salmeterol Xinafoate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM581189.pdf	10/19/2017	Other	N/A
58	Q1	Sucralfate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573202.pdf	10/19/2017	Other	N/A

59	Q1	Tadalafil; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm090562.pdf	10/19/2017	Other	N/A
60	Q1	Telotristat Etiprate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573097.pdf	10/19/2017	Other	N/A
61	Q1	Terbutaline Sulfate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573098.pdf	10/19/2017	Other	N/A
62	Q1	Tiotropium Bromide; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM581192.pdf	10/19/2017	Other	N/A
63	Q1	Tiotropium Bromide; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM581192.pdf	10/20/2017	Other	N/A
64	Q1	Controlled Correspondence Related to Generic Drug Development; Draft Guidance for Industry www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm583436.pdf	11/03/2017	Other	N/A
65	Q1	ANDAs: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications (Pre-Submission Facility Correspondence); Revised Draft Guidance for Industry www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm563507.pdf	11/06/2017	Other	N/A
66	Q1	General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products; Guidance for Industry www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm492172.pdf	11/22/2017	Other	N/A
67	Q1	Drug Products, Including Biological Products, that Contain Nanomaterials; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM588857.pdf	12/15/2017	Other	N/A
68	Q1	Information Requests and Discipline Review Letters Under the Generic Drug User Fee Amendments; Draft Guidance for Industry www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm588862.pdf	12/18/2017	Other	N/A
69	Q1	Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System; Guidance for Industry www.fda.gov/downloads/Drugs/Guidances/ucm070246.pdf	12/22/2017	Other	N/A
70	Q2	Good ANDA Submission Practices; Draft Guidance for Industry www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm591134.pdf	1/04/2018	Other	N/A
71	Q2	Alcaftadine; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586130.pdf	2/09/2018	Other	N/A
72	Q2	Amitriptyline Hydrochloride; Chlordiazepoxide; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586133.pdf	2/09/2018	Other	N/A
73	Q2	Amphetamine Sulfate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586135.pdf	20/9/2018	Other	N/A

74	Q2	Aspirin; Omeprazole; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM566376.pdf	2/09/2018	Other	N/A
75	Q2	Barium Sulfate (Multiple Reference Listed Drugs); Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586138.pdf	2/09/2018	Other	N/A
76	Q2	Barium Sulfate (Multiple Reference Listed Drugs); Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586142.pdf	2/09/2018	Other	N/A
77	Q2	Betamethasone Dipropionate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586156.pdf	2/09/2018	Other	N/A
78	Q2	Bimatoprost (Multiple Reference Listed Drugs); Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586159.pdf	2/09/2018	Other	N/A
79	Q2	Bimatoprost (Multiple Reference Listed Drugs); Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586161.pdf	2/09/2018	Other	N/A
80	Q2	Bimatoprost (Multiple Reference Listed Drugs); Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586170.pdf	2/09/2018	Other	N/A
81	Q2	Bupivacaine; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586176.pdf	2/09/2018	Other	N/A
82	Q2	Buprenorphine Hydrochloride; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586185.pdf	2/09/2018	Other	N/A
83	Q2	Cabozantinib S-malate (Multiple Reference Listed Drugs); Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586187.pdf	2/09/2018	Other	N/A
84	Q2	Cabozantinib S-malate (Multiple Reference Listed Drugs); Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586188.pdf	2/09/2018	Other	N/A
85	Q2	Crisaborole; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586273.pdf	2/09/2018	Other	N/A
86	Q2	Cysteamine Bitartrate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM460993.pdf	2/09/2018	Other	N/A
87	Q2	Daclatasvir Dihydrochloride; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM494883.pdf	2/09/2018	Other	N/A
88	Q2	Desonide; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586287.pdf	2/09/2018	Other	N/A

89	Q2	Dexlansoprazole; (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM520165.pdf	20/9/2018	Other	N/A
90	Q2	Dexlansoprazole; (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM261519.pdf	2/09/2018	Other	N/A
91	Q2	Doxycycline Hyclate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586288.pdf	2/09/2018	Other	N/A
92	Q2	Esomeprazole Magnesium (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM201301.pdf	2/09/2018	Other	N/A
93	Q2	Esomeprazole Magnesium (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm086251.pdf	2/09/2018	Other	N/A
94	Q2	Felbamate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm086175.pdf	2/09/2018	Other	N/A
95	Q2	Felbamate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm086176.pdf	2/09/2018	Other	N/A
96	Q2	Fluconazole; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm086187.pdf	2/09/2018	Other	N/A
97	Q2	Fluocinonide; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586294.pdf	2/09/2018	Other	N/A
98	Q2	Gatifloxacin; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm086200.pdf	2/09/2018	Other	N/A
99	Q2	Gentamicin Sulfate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM406271.pdf	2/09/2018	Other	N/A
100	Q2	Hydrocortisone Valerate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586300.pdf	2/09/2018	Other	N/A
101	Q2	Ixazomib Citrate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586302.pdf	2/09/2018	Other	N/A
102	Q2	Ketoconazole; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586304.pdf	2/09/2018	Other	N/A
103	Q2	Ketorolac Tromethamine; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM347003.pdf	2/09/2018	Other	N/A
104	Q2	Lansoprazole; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm086284.pdf	2/09/2018	Other	N/A
105	Q2	Leuprolide Acetate; Norethindrone Acetate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586315.pdf	2/09/2018	Other	N/A

106	Q2	Levetiracetam; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586318.pdf	2/09/2018	Other	N/A
107	Q2	Levocetirizine Dihydrochloride; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586352.pdf	2/09/2018	Other	N/A
108	Q2	Loteprednol Etabonate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586354.pdf	2/09/2018	Other	N/A
109	Q2	Loteprednol Etabonate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM249244.pdf	2/09/2018	Other	N/A
110	Q2	Mebendazole; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586355.pdf	2/09/2018	Other	N/A
111	Q2	Morphine Sulfate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm088709.pdf	2/09/2018	Other	N/A
112	Q2	Naldemedine Tosylate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586356.pdf	2/09/2018	Other	N/A
113	Q2	Naloxegol Oxalate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM452840.pdf	2/09/2018	Other	N/A
114	Q2	Naproxen Sodium; Pseudoephedrine Hydrochloride; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586358.pdf	2/09/2018	Other	N/A
115	Q2	Niraparib Tosylate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586359.pdf	2/09/2018	Other	N/A
116	Q2	Olopatadine Hydrochloride; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586360.pdf	2/09/2018	Other	N/A
117	Q2	Oxycodone; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM533407.pdf	2/09/2018	Other	N/A
118	Q2	Pantoprazole Sodium; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM194659.pdf	2/09/2018	Other	N/A
119	Q2	Potassium Citrate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM224224.pdf	2/09/2018	Other	N/A
120	Q2	Prasterone; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586361.pdf	2/09/2018	Other	N/A
121	Q2	Rucaparib Camsylate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586364.pdf	2/09/2018	Other	N/A
122	Q2	Safinamide Mesylate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586365.pdf	2/09/2018	Other	N/A

123	Q2	Simvastatin; Sitagliptin Phosphate; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586366.pdf	2/09/2018	Other	N/A
124	Q2	Soybean Oil (Multiple Reference Listed Drugs); Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586367.pdf	2/09/2018	Other	N/A
125	Q2	Sulfamethoxazole; Trimethoprim; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm090384.pdf	2/09/2018	Other	N/A
126	Q2	Triamcinolone Acetonide; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM249256.pdf	2/09/2018	Other	N/A
127	Q2	Regulatory Classification of Pharmaceutical Co-Crystals; Revised Guidance for Industry www.fda.gov/downloads/Drugs/Guidances/UCM281764.pdf	2/14/2018	Other	N/A
128	Q2	Q11 Development and Manufacture of Drug Substances--Questions and Answers (Chemical Entities and Biotechnological/Biological Entities); Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM542176.pdf	2/23/2018	Other	N/A
129	Q2	Doxycycline Hyclate; Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM162404.pdf	3/29/2018	Other	N/A
130	Q3	Development of a Shared System REMS; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609045.pdf	5/31/2018	Other	N/A
131	Q3	Waivers of the Single, Shared System REMS Requirement; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609048.pdf	5/31/2018	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 2018.

Table 2: Public Meetings Held on Topics Related to Human Generic Drug Activities for FY 2018

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	Leveraging Quantitative Methods and Modeling to Modernize Generic Drug Development and Review; Public Workshop	10/2/2017 to 10/3/2017	Other
2	Q1	Demonstrating Equivalence of Generic Complex Drug Substances and Formulations	10/6/2017	Other
3	Q1	Overcoming Barriers to Product Development, Regulatory Approval and Commercialization of Affordable, High Quality, Generic Topical Dermatological Drug Products; Public Workshop	10/20/2017	Other
4	Q2	New Insights for Product Development and Bioequivalence Assessments of Generic Orally Inhaled and Nasal Drug Products	1/9/2018	Other
5	Q3	FY 2018 Generic Drug Regulatory Science Initiatives Public Workshop	5/24/2017	GDUFA II Commitment Letter Section III. H. 1.