



FDA U.S. FOOD & DRUG
ADMINISTRATION

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 2019.

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; Guidance for Industry 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.accessdata.fda.gov/drugsatfda_docs/psg/Buprenorphine_transdermal%20extended%20release%20film_NDA%20021306_RV10-18.pdf	10/9/2018	Other	N/A
6	Q1	Capsaicin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Capsaicin_draft_Topical%20patch_RLD%20022395_RC10-18.pdf	10/9/2018	Other	N/A
7	Q1	Clonidine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Clonidine%20transdermal%20extended%20release%20film%20NDA%20018891%20PSG%20Page%20RV10-18.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)
8	Q1	Diclofenac Epolamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Diclofenac%20Epolamine_draft_Topical%20patch_RLD%2021234_RC10-18.pdf	10/9/2018	Other	N/A
9	Q1	Estradiol; (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Estradiol_draft_Transdermal%20film%20ER_RLD%2019081_RC10-18.pdf	10/9/2018	Other	N/A
10	Q1	Estradiol; (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Estradiol_draft_Transdermal%20film%20ER_RLD%2020375%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%2021674_RC10-18.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.accessdata.fda.gov/drugsatfda_docs/psg/Ethinyl%20estradiol;%20Norethindrone%20acetate_draft_Oral%20cap_RLD%20204426_RC07-18.pdf	10/9/2018	Other	N/A
14	Q1	Ethinyl Estradiol; Norelgestromin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Ethinyl%20Estradiol;%20Norelgestromin_draft_Transdermal%20film%20ER_RLD%2021180_RC10-18.pdf	10/9/2018	Other	N/A
15	Q1	Fentanyl; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Fentanyl_transdermal%20extended%20release%20film_NDA%20019813_RV10-18.pdf	10/9/2018	Other	N/A
16	Q1	Granisetron; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Granisetron_transdermal%20extended%20release%20film_NDA%20022198_RV10-18.pdf	10/9/2018	Other	N/A
17	Q1	Lidocaine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Lidocaine_draft_Topical%20patch_RLD%20020612_RC10-18.pdf	10/9/2018	Other	N/A
18	Q1	Menthol; Methyl Salicylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Menthol;%20Methyl%20Salicylate_draft_Topical%20patch_RLD%2022029_RC10-18.pdf	10/9/2018	Other	N/A
19	Q1	Methylphenidate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Methylphenidate_draft_Transdermal%20film%20ER_RLD%2021514_RC10-18.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)
20	Q1	Nicotine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Nicotine_transdermal%20NDA%20020076%20and%20NDA%20020165_RV10-18.pdf	10/9/2018	Other	N/A
21	Q1	Nitroglycerin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Nitroglycerin_transdermal%20extended%20release%20film_NDA%20020145_RV10-18.pdf	10/9/2018	Other	N/A
22	Q1	Nitroglycerin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Nitroglycerin_transdermal%20extended%20release%20film_NDA%20020144_RV10-18.pdf	10/9/2018	Other	N/A
23	Q1	Oxybutynin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Oxybutynin_transdermal%20extended%20release%20film_NDA%200202211_RV10-18.pdf	10/9/2018	Other	N/A
24	Q1	Oxybutynin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Oxybutynin%20transdermal%20extended%20release%20film%20NDA%20021351%20PSG%20Page%20RV10-18.pdf	10/9/2018	Other	N/A
25	Q1	Rivastigmine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Rivastigmine_transdermal%20extended%20release%20film_NDA%20022083_RV10-18.pdf	10/9/2018	Other	N/A
26	Q1	Rotigotine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Rotigotine_transdermal%20extended%20release%20film_NDA%20021829_RV10-18.pdf	10/9/2018	Other	N/A
27	Q1	Scopolamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Scopolamine_transdermal%20extended%20release%20film_NDA%20017874_RV10-18.pdf	10/9/2018	Other	N/A
28	Q1	Selegiline; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Selegiline_transdermal%20extended%20release%20film_NDA%20021336_RV10-18.pdf	10/9/2018	Other	N/A
29	Q1	Testosterone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Testosterone_transdermal%20extended%20release%20film_NDA%20020489_RV10-18.pdf	10/9/2018	Other	N/A
30	Q1	Acetaminophen; Butalbital; Caffeine (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Acetaminophen;Butalbital;Caffeine_A89007%20A0885%20A40885_RV%20Oct%202018.pdf	11/28/2018	Other	N/A

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31	Q1	Acetaminophen; Butalbital; Caffeine (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Acetaminophen;%20Butalbital;%20Caffeine_Oraltablet_ANDA%20040511_RV%20Oct%202018.pdf	11/28/2018	Other	N/A
32	Q1	Acetaminophen; Oxycodone HCL; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Acetaminophen;OxycodoneHCL_Oral%20tablet_ANDA%2040330_RV%20Oct%202018.pdf	11/28/2018	Other	N/A
33	Q1	Adapalene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Adapalene_Topical%20lotion_NDA%20022502_RV%20Nov%202018.pdf	11/28/2018	Other	N/A
34	Q1	Adapalene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Adapalene_Topical%20cream_NDA%20020748_RV%20Nov%202018.pdf	11/28/2018	Other	N/A
35	Q1	Adapalene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Adapalene_Topical%20gel_NDA%2020380_RV%20Oct%202018.pdf	11/28/2018	Other	N/A
36	Q1	Adapalene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Adapalene_Topical%20gel_NDA%20021753_RV%20Nov%202018.pdf	11/28/2018	Other	N/A
37	Q1	Adapalene; Benzoyl Peroxide (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Adapalene_Benzoyl_Peroxide_Gel_0.1_2.5_NDA_22320_RV_Nov_2018.pdf	11/28/2018	Other	N/A
38	Q1	Adapalene; Benzoyl Peroxide (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Adapalene_Benzoyl_Peroxide_Gel_NDA_207917_RV_Nov_2018.pdf	11/28/2018	Other	N/A
39	Q1	Amphetamine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Amphetamine_orally_disintegrating_ER_tablet_RLD_204326_RC_03-17.pdf	11/28/2018	Other	N/A
40	Q1	Asenapine Maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Asenapine%20maleate_Sublingual%20tablet_NDA%20022117_RV%20Oct%202018.pdf	11/28/2018	Other	N/A
41	Q1	Atropine Sulfate; Diphenoxylate Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Atropine%20Sulfate;%20DiphenoxylateHCl_NDA%20012462_RC%20Nov%202018.pdf	11/28/2018	Other	N/A

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42	Q1	Benzoyl Peroxide; Clindamycin Phosphate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Benzoyl_Clindamycin_Gel_25_12_NDA_050819_RV_Nov_2018.pdf	11/28/2018	Other	N/A
43	Q1	Benzoyl Peroxide; Clindamycin Phosphate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Benzoyl_Clindomycin_Gel_5_1_NDA_050741_RV_Nov_2018.pdf	11/28/2018	Other	N/A
44	Q1	Benzoyl Peroxide; Clindamycin Phosphate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Benzoyl_Clindamycin_Gel_5_1_NDA_050756_RV_Nov_2018.pdf	11/28/2018	Other	N/A
45	Q1	Benzoyl Peroxide; Erythromycin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Benzoyl_Peroxide_Erythromycin_Gel_5_3_NDA_50557_RV_Nov_2018.pdf	11/28/2018	Other	N/A
46	Q1	Benzoyl Peroxide; Erythromycin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Benzoyl_Peroxide_Erythromycin_Topical_Gel_5_3_50769_RV_Nov_2018.pdf	11/28/2018	Other	N/A
47	Q1	Clindamycin Phosphate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Clindamycin%20phosphate_Topical%20gel_NDA%20050615_RV%20Nov%202018.pdf	11/28/2018	Other	N/A
48	Q1	Clindamycin Phosphate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Clindamycin%20Phosphate_Topical%20gel_NDA%2050782%20RV%20Nov%202018.pdf	11/28/2018	Other	N/A
49	Q1	Clindamycin Phosphate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Clindamycin%20Phosphate_Topical%20lotion_NDA%20050600_RV%20Nov%202018.pdf	11/28/2018	Other	N/A
50	Q1	Clindamycin Phosphate; Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Clindamycin%20Phosphate:Tretinoin%20Gel%20gel%201.2%200.025%20PSG%20Page%20RV%20Nov%202018.pdf	11/28/2018	Other	N/A
51	Q1	Dapsone (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Dapsone_Topical%20gel_NDA%20021794_RV%20Nov%202018.pdf	11/28/2018	Other	N/A

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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.accessdata.fda.gov/drugsatfda_docs/psg/Dapsone_Topical%20gel_NDA%20207154_RV%20Nov%202018.pdf	11/28/2018	Other	N/A
54	Q1	Doxepin Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Doxepin%20Hydrochloride_Topical%20cream_NDA%20020126_RC%20Oct%202018.pdf	11/28/2018	Other	N/A
55	Q1	Ertugliflozin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Ertugliflozin_Oral%20tablet_NDA%20209803_RC%20Oct%202018.pdf	11/28/2018	Other	N/A
56	Q1	Ertugliflozin; Metformin Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Ertugliflozin;%20Metformin%20Hydrochloride_Oral%20tablet_NDA%20209806_RC%20Oct%202018.pdf	11/28/2018	Other	N/A
57	Q1	Ertugliflozin; Sitagliptin Phosphate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Ertugliflozin;%20Sitagliptin%20Phosphateoral_Oral%20tablet_NDA%20209805_RC%20Oct%202018.pdf	11/28/2018	Other	N/A
58	Q1	Estradiol; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Estradiol_Transdermal%20gel_NDA%20022038_RC%20Oct%202018.pdf	11/28/2018	Other	N/A
59	Q1	Everolimus; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Everolimus_draft_Oral%20tab_RLD%2022334_RC11-18.pdf	11/28/2018	Other	N/A
60	Q1	Isosorbide Dinitrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Isosorbide%20Dinitrate_Oral%20tablet_NDA%20012093_RV%20Nov%202018.pdf	11/28/2018	Other	N/A
61	Q1	Latanoprostene Bunod; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Latanoprostene%20Bunod_Ophthalmic%20solution%20drops_NDA%20207795_RC%20Oct%202018.pdf	11/28/2018	Other	N/A
62	Q1	Letermovir (Multiple Reference Listed Drugs); Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Letermovir_IV_infusion_solution_NDA_209940_RC_Oct_2018.pdf	11/28/2018	Other	N/A
63	Q1	Letermovir (Multiple Reference Listed Drugs); Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Letermovir_Oral%20tablet_NDA%20209939_RC%20Oct%202018.pdf	11/28/2018	Other	N/A

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64	Q1	Levothyroxine Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Levothyroxine_Sodium%20capsules_NDA%20021924_RC%20Oct%202018.pdf	11/28/2018	Other	N/A
65	Q1	Lifitegrast; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Lifitegrast_Ophthalmic%20solution%20drops_NDA%20208073_RC%20Oct%202018.pdf	11/28/2018	Other	N/A
66	Q1	Macimorelin Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Macimorelin%20Acetate_Oral%20solution_NDA%20205598_RC%20Oct%202018.pdf	11/28/2018	Other	N/A
67	Q1	Metaxalone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Metaxalone_draft_Oral%20tab_RLD%2013217_RC11-18.pdf	11/28/2018	Other	N/A
68	Q1	Metoprolol Succinate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Metoprolol%20succinate_Oral%20extended%20release%20capsule_NDA%20210428_RC%20Nov%202018.pdf	11/28/2018	Other	N/A
69	Q1	Mycophenolic Acid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Mycophenolic%20Acid_draft_Oral%20tab%20DR_RLD%2050791_RC11-18.pdf	11/28/2018	Other	N/A
70	Q1	Netarsudil Dimesylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Netarsudil%20Dimesylate_Ophthalmic%20solution%20drops_NDA%20208254_RC%20Oct%202018.pdf	11/28/2018	Other	N/A
71	Q1	Nitazoxanide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Nitazoxanide_Oral%20suspension_NDA%20021498_RC%20Oct%202018.pdf	11/28/2018	Other	N/A
72	Q1	Nitazoxanide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Nitazoxanide_Oral%20tablet_NDA%20021497_RV%20Oct%202018.pdf	11/28/2018	Other	N/A
73	Q1	Penicillamine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Penicillamine_Oral%20Tablet_NDA%2019854_RC%20Oct%202018.pdf	11/28/2018	Other	N/A
74	Q1	Plecanatide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Plecanatide_Oral%20tablet_NDA%20208745_RC%20Oct%202018.pdf	11/28/2018	Other	N/A
75	Q1	Reserpine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Reserpine_Oral%20tablets_NDA%20009838_RC%20Oct%202018.pdf	11/28/2018	Other	N/A
76	Q1	Ribociclib Succinate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Ribociclib%20Succinate_Oral%20tablet_NDA%20209092_RC%20Oct%202018.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)
77	Q1	Sulfacetamide Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Sulfacetamide%20Sodium_Topical%20lotion%20or%20Suspension_NDA%2019931%20RV%20Nov%202018.pdf	11/28/2018	Other	N/A
78	Q1	Sulfamethoxazole; Trimethoprim; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Sulfamethoxazole%20Trimethoprim_Oral%20suspension_NDA%20017560_RV%20Oct%202018.pdf	11/28/2018	Other	N/A
79	Q1	Sumatriptan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Sumatriptan_Nasal%20spray_NDA%20020626_RV%20Nov%202018.pdf	11/28/2018	Other	N/A
80	Q1	Tazarotene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Tazarotene_draft_Topical%20foam_RLD%20202428_RC11-18.pdf	11/28/2018	Other	N/A
81	Q1	Tazarotene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Tazarotene_Topical%20gel_NDA%20020600_RV%20Nov%202018.pdf	11/28/2018	Other	N/A
82	Q1	Thiothixene; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Thiothixene_Oral%20capsule_NDA%20016584_RC%20Oct%202018.pdf	11/28/2018	Other	N/A
83	Q1	Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Tretinoin_Topical%20gel%200.1_NDA%20020475_RV%20Nov%202018.pdf	11/28/2018	Other	N/A
84	Q1	Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Tretinoin_Topical%20gel%200.4_NDA%20020475_RV%20Nov%202018.pdf	11/28/2018	Other	N/A
85	Q1	Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Tretinoin_Topical%20cream_NDA%20017340_RV%20Nov%202018.pdf	11/28/2018	Other	N/A
86	Q1	Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Tretinoin_Topical%20cream_NDA%20017522_RV%20Nov%202018.pdf	11/28/2018	Other	N/A
87	Q1	Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Tretinoin_Topical%20cream_NDA%20019049_RV%20Nov%202018.pdf	11/28/2018	Other	N/A

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88	Q1	Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Tretinoin_Topical%20gel_NDA%20017579_RV%20Nov%202018.pdf	11/28/2018	Other	N/A
89	Q1	Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Tretinoin_Topical%20gel_NDA%20017955_RV%20Nov%202018.pdf	11/28/2018	Other	N/A
90	Q1	Tretinoin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Tretinoin_Topical%20gel_NDA%20022070_RV%20Nov%202018.pdf	11/28/2018	Other	N/A
91	Q1	Triamterene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Triamterene_Oral%20capsule_NDA%20013174_RV%20Oct%202018.pdf	11/28/2018	Other	N/A
92	Q1	Zolmitriptan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Zolmitriptan_Nasal%20spray_NDA%20021450_RV%20Oct%202018.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/regulatory-information/search-fda-guidance-documents/post-complete-response-letter-meetings-between-food-and-drug-administration-and-abbreviated-new-drug	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.accessdata.fda.gov/drugsatfda_docs/psg/Linaclotide-Capsule-NDA-202811-Page-RC-12-2018.pdf	12/27/2018	Other	N/A
96	Q2	ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs; Draft Guidance for Industry www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm629489.pdf	1/16/2019	Other	N/A
97	Q2	REMS Assessment: Planning and Reporting; Draft Guidance for Industry www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm629743.pdf	1/24/2019	Other	N/A
98	Q2	Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format; Draft Guidance for Industry www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm630099.pdf	1/30/2019	Other	N/A

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99	Q2	CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality; Draft Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/cders-program-recognition-voluntary-consensus-standards-related-pharmaceutical-quality	2/13/2019	Other	N/A
100	Q2	Competitive Generic Therapies; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM631401.pdf	2/15/2019	Required by Statute	FDA Reauthorization Act of 2017 Section 803(b)(1)
101	Q2	Acalabrutinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Acalabrutinib%20Oral%20Capsules%20NDA%20210259%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
102	Q2	Acetaminophen; Butalbital; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Acetaminophen%20Butalbital%20Oral%20Tablet%20ANDA%2089987%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
103	Q2	Acetaminophen; Caffeine; Dihydrocodeine Bitartrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Acetaminophen;%20Caffeine;%20Dihydrocodeine%20Bitartrate%20Oral%20Capsule%20ANDA%20204785%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
104	Q2	Angiotensin II Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/ANGIOTENSIN%20II%20ACETATE%20IV%20infusion%20solution%20NDA%20209360%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
105	Q2	Aripiprazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Aripiprazole%20Oral%20Tablet%20NDA%20021436%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
106	Q2	Azelastine Hydrochloride; Fluticasone Propionate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Azelastine%20hydrochloride;%20Fluticasone%20propionate%20nasal%20metered%20spray%20NDA%20202236%20PSG%20Page%20RV%2002-2019.pdf	2/22/2019	Other	N/A
107	Q2	Betamethasone Dipropionate; Calcipotriene Hydrate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Betamethasone;%20Calcipotriene%20Ointment%20NDA%20021852%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
108	Q2	Betamethasone Dipropionate; Calcipotriene Hydrate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Betamethasone;%20Calcipotriene%20Suspension%20NDA%20022185%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A

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109	Q2	Betamethasone dipropionate; Clotrimazole (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Betamethasone%20Dipropionate;%20Clotrimazole%20Lotion%20NDA%20020010%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
110	Q2	Betamethasone dipropionate; Clotrimazole (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Betamethasone%20Dipropionate;%20Clotrimazole%20Cream%20NDA%20018827%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
111	Q2	Bexarotene; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Bexarotene%20topical%20gel%20NDA%20021056%20RC%202019.pdf	2/22/2019	Other	N/A
112	Q2	Bosentan; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Bosentan%20Tablets%20for%20oral%20suspension%20NDA%20209279%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
113	Q2	Bromocriptine Mesylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Bromocriptine%20Mesylate%20Tablets%20NDA20866%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
114	Q2	Butenafine Hydrochloride (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Butenafine%20HCl%20Cream%20NDA%2020524%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
115	Q2	Butenafine Hydrochloride (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Butenafine%20HCl%20Cream%20NDA%20021307%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
116	Q2	Butoconazole Nitrate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Butoconazole%20Nitrate%20Vaginal%20Cream%20NDA%20200923%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
117	Q2	Butoconazole Nitrate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Butoconazole%20Nitrate%20Vaginal%20Cream%20NDA%20020421%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
118	Q2	Calcipotriene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Calcipotriene%20Topical%20Aerosol%20Foam%20NDA%20022563%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
119	Q2	Calcipotriene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Calcipotriene%20Topical%20Emulsion%20Cream%20NDA%20020554%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A

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120	Q2	Calcipotriene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Calcipotriene%20Topical%20Ointment%20NDA%20020273%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
121	Q2	Ceritinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Ceritinib%20Oral%20Capsule%20NDA%20205755%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
122	Q2	Chlorothiazide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Chlorothiazide%20Oral%20Suspension%20NDA%20011870%20PSG%20Page%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
123	Q2	Ciclopirox (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Ciclopirox%20Topical%20Suspension%20NDA%20019824%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
124	Q2	Ciclopirox (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Ciclopirox%20Topical%20Cream%20NDA%20018748%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
125	Q2	Ciclopirox (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Ciclopirox%20Topical%20Gel%20NDA%20020519%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
126	Q2	Clotrimazole (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Clotrimazole%20Topical%20Solution%20NDA%20018181%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
127	Q2	Clotrimazole (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Clotrimazole%20Topical%20Cream%20ANDA%20072640%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
128	Q2	Clotrimazole (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Clotrimazole%20Vaginal%20Cream%20NDA%20018052%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
129	Q2	Clotrimazole (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Clotrimazole%20Vaginal%20Cream%20NDA%20020574%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
130	Q2	Clotrimazole (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Clotrimazole%20Vaginal%20Tablet%20NDA%20017717%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A

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131	Q2	Clotrimazole (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Clotrimazole%20Vaginal%20Tablet%20NDA%20020525%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
132	Q2	Crisaborole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Crisaborole-NDA-207695.pdf	2/22/2019	Other	N/A
133	Q2	Daptomycin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/DAPTOMYCIN%20IV%20infusion%20powder%20NDA%20209949%20&%20NDA%20208385%20Page%20Feb%202019.pdf	2/22/2019	Other	N/A
134	Q2	Dexamethasone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Dexamethasone%20Oral%20Concentrate%20Solution%20NDA%20088252%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
135	Q2	Dexamethasone; Tobramycin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM199633.pdf	2/22/2019	Other	N/A
136	Q2	Dexamethasone; Tobramycin (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Dexamethasone%20Tobramycin_ophthalmic%20suspension%20NDA%2050818%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
137	Q2	Diclofenac Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Diclofenac%20Sodium%20Topical%20Gel%20NDA%20021005%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
138	Q2	Dihydroergotamine Mesylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Dihydroergotamine%20Mesylate%20Nasal%20Spray%20Meted%20NDA%20020148%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
139	Q2	Diltiazem Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Diltiazem%20Hydrochloride%20oral%20extended%20release%20capsule%20NDA%20019471%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
140	Q2	Doxycycline Calcium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Doxycycline%20Calcium%20Oral%20Suspension%20NDA%20050480%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
141	Q2	Econazole Nitrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Econazole%20Nitrate%20Topical%20Cream%20NDA%20018751%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A

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142	Q2	Doxylamine Succinate; Pyridoxine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Doxylamine%20succinate%20and%20pyridoxine%20hydrochloride%20oral%20ER%20tablet%20NDA%20209661%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
143	Q2	Fish Oil; Medium Chain Triglycerides; Olive Oil; Soybean Oil; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Fish%20oil;%20Medium%20chain%20triglycerides;%20Olive%20oil;%20Soybean%20oil%20NDA%20207648%20Feb%202019.pdf	2/22/2019	Other	N/A
144	Q2	Fluorouracil (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Fluorouracil%20Topical%20Cream%20NDA%20016988%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
145	Q2	Fluorouracil (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Fluorouracil%20Topical%20Cream%20NDA%20020985%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
146	Q2	Fluorouracil (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Fluorouracil%20Topical%20Cream%20NDA%20016831%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
147	Q2	Fluticasone Propionate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Fluticasone%20propionate%20nasal%20spray%20NDA%20020121%20RV%2002-2019.pdf	2/22/2019	Other	N/A
148	Q2	Haloperidol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Haloperidol%20Oral%20Tablets%20NDA%20015921%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
149	Q2	Imiquimod (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Imiquimod%20Topical%20Cream%202.5%20NDA%20022483%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
150	Q2	Imiquimod (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Imiquimod%20Topical%20Cream%203.75%20NDA%20022483%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
151	Q2	Imiquimod (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Imiquimod%20Topical%20Cream%20NDA%20020723%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A

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152	Q2	Ingenol Mebutate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Ingenol%20Mebutate%20Topical%20Gel%200.05_NDA%20202833%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
153	Q2	Ingenol Mebutate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Ingenol%20Mebutate%20Topical%20Gel%200.015_NDA%20202833%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
154	Q2	Isocarboxazid; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Isocarboxazid%20Oral%20Tablet%20NDA%20011961%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
155	Q2	Ivacaftor; Tezacaftor; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Ivacaftor;%20Tezacaftor%20Oral%20Tablet%20NDA%20210491%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
156	Q2	Ketoconazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Ketoconazole%20Topical%20Cream%20NDA%20019084%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
157	Q2	Letrozole; Ribociclib Succinate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Letrozole%20and%20Ribociclib%20Succinate%20Copackaged%20Oral%20Tablet%20NDA%20209935%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
158	Q2	Loratadine; Pseudoephedrine Sulfate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Loratadine%20Pseudoephedrine%20Oral%20Extended%20Release%20Tablet%20NDA%20020470%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
159	Q2	Lumacaftor; Ivacaftor; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Ivacaftor-Lumacaftor%20Oral%20Tablet%20NDA%20206038%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
160	Q2	Methsuximide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Methsuximide%20Oral%20Capsules%20NDA%20010596%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
161	Q2	Miconazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Miconazole_Buccal_Tablet_50mg_NDA_22404_RV_Feb_2019.pdf	2/22/2019	Other	N/A
162	Q2	Mometasone Furoate Monohydrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Mometasone%20furoate%20nasal%20spray%20NDA%20020762%20RV%2002-2019.pdf	2/22/2019	Other	N/A

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163	Q2	Oxiconazole Nitrate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Oxiconazole%20Nitrate%20Cream%20NDA%20019828%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
164	Q2	Oxiconazole Nitrate (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Oxiconazole%20Nitrate%20Lotion%20NDA%20020209%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
165	Q2	Ozenoxacin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Ozenoxacin%20topical%20cream%20NDA%20208945%20RC%202019.pdf	2/22/2019	Other	N/A
166	Q2	Paroxetine Mesylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Paroxetine%20Mesylate%20Oral%20Tablets%20NDA%20NDA%20021299%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
167	Q2	Succimer; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Succimer%20Oral%20Capsule%20100%20mg%20NDA%20019998%20RC%20Feb%202019.pdf	2/22/2019	Other	N/A
168	Q2	Tazarotene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Tazarotene%20Cream%200.1_NDA%20021184%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
169	Q2	Tazarotene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/TazaroteneTopicalGel0.05NDA020600RVFeb2019.pdf	2/22/2019	Other	N/A
170	Q2	Tazarotene (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Tazarotene%20Topical%200.05_Cream%20NDA%20021184%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
171	Q2	Terbinafine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Terbinafine%20Hydrochloride%20Topical%20Cream%20NDA%20020980%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
172	Q2	Treprostinil Diolamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Treprostinil%20diolamine%20oral%20extended%20release%20tablet%20NDA%20203496%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
173	Q2	Tretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Tretinoin%20Topical%20Cream%20ANDA%20090098%20RV%20Feb%202019.pdf	2/22/2019	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)
174	Q2	Triamcinolone Acetonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Triamcinolone%20acetonide%20nasal%20spray%20NDA%20020468%20RV%20Feb%202019.pdf	2/22/2019	Other	N/A
175	Q2	Quality Considerations for Continuous Manufacturing; Draft Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM632033.pdf	2/26/2019	Other	N/A
176	Q3	Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles; Guidance for Government Public Health and Emergency Response Stakeholders www.federalregister.gov/documents/2019/04/25/2019-08349/extending-expiration-dates-of-doxycycline-tablets-and-capsules-in-strategic-stockpiles-guidance-for	4/25/2019	Other	N/A
177	Q3	Determining Whether to Submit an ANDA or a 505(b)(2) Application; Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/determining-whether-submit-anda-or-505b2-application	5/9/2019	Other	N/A
178	Q3	Acetaminophen; Codeine Phosphate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Acetaminophen;%20Codeine%20Phosphate%20Tablet%20ANDA%20085055%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
179	Q3	Apalutamide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Apalutamide%20Oral%20Tablets%20NDA%20210951%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
180	Q3	Beclomethasone Dipropionate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Beclomethasone%20dipropionate%20Inhalation%20Aerosol%20Metered%20NDA%20207921%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
181	Q3	Benoxinate hydrochloride; Fluorescein sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Benoxinate%20hydrochloride;%20Fluorescein%20sodium%20Ophthalmic%20solution%20drops%200.25-0.45%20NDA%20208582%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
182	Q3	Bictegravir Sodium; Emtricitabine; Tenofovir Alafenamide Fumarate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Bictegravir%20Sodium,%20Emtricitabin,%20Tenofovir%20Alafenamide%20Fumarate%20Oral%20Tablet%20NDA%20210251%20page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
183	Q3	Brimonidine Tartrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Brimonidine%20tartrate%20Ophthalmic%20solution%200.025%20NDA%20208144%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A

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184	Q3	Budesonide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Budesonide%20Nasal%20Spray%20Metered%20NDA%2020746%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
185	Q3	Chlorpheniramine Maleate; Ibuprofen; Pseudoephedrine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Chlorpheniramine%20maleate;%20Ibuprofen;%20Pseudoephedrine%20HCl%20Tablet%202mg;%20200mg;%2030mg%20NDA%20021441%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
186	Q3	Cyclosporine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Cyclosporine%20ophthalmic%20solution%200.09%20NDA%20210913%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
187	Q3	Desloratadine; Pseudoephedrine Sulfate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Desloratadine_Pseudoephedrine_Oral_Extended_Release_Tablet_NDA_021313_PSG_Page_RC_May_2019.pdf	5/16/2019	Other	N/A
188	Q3	Desmopressin Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Desmopressin%20acetate%20Sublingual%20Tablets%20NDA%20022517%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
189	Q3	Efavirenz; Lamivudine; Tenofovir Disoproxil Fumarate (Multiple Reference Listed Drugs); Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Efavirenz%20Lamivudine%20Tenofovir%20Disoproxil%20Fumarate%20Tablets%20NDA208255%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
190	Q3	Efavirenz; Lamivudine; Tenofovir Disoproxil Fumarate (Multiple Reference Listed Drugs); Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Efavirenz-Lamivudine-Tenofovir%20Disoproxil%20Fumarate%20Oral%20Tablet%20NDA%20022142%20page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
191	Q3	Eravacycline Dihydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/ERAVACYCLINE%20DIHYDROCHLORIDE%20POWDER%20INTRAVENOUS%20NDA%20211109%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
192	Q3	Estradiol; Levonorgestrel; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Estradiol%20Levonorgestrel%20transdermal%20extended%20release%20film%20NDA%20021258%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A

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193	Q3	Fluticasone Furoate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Fluticasone%20furoate%20nasal%20spray%20metered%20NDA%20022051%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
194	Q3	Fluticasone Propionate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Fluticasone%20Propionate%20Inhalation%20Powder%20NDA%20208798%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
195	Q3	Fluticasone Propionate; Salmeterol Xinafoate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Fluticasone%20Propionate;%20Salmeterol%20Xinafoate%20Inhalation%20Aerosol%20Metered%20NDA%20021254%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
196	Q3	Fosnetupitant Chloride Hydrochloride; Palonosetron Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Fosnetupitant%20and%20Palonosetron%20Hydrochloride.%20powder%20for%20injection%20NDA%20210493%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
197	Q3	Halcinonide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Halcinonide%20topical%20ointment%20NDA%20017824%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
198	Q3	Lamivudine; Tenofovir Disoproxil Fumarate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Lamivudine-Tenofovir%20Disoproxil%20Fumarate%20Oral%20Tablet%20NDA%20022141%20PSG%20page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
199	Q3	Naproxen; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Naproxen%20Oral%20Suspension%20NDA%20018965%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
200	Q3	Omeprazole Magnesium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Omeprazole%20magnesium%20oral%20delayed%20release%20suspension%20NDA%20022056%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
201	Q3	Primidone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Primidone%20Tablets%20NDA%20009170%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
202	Q3	Timolol Maleate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Timolol%20Maleate%20Ophthalmic%20Solution%20NDA%20018086%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A

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203	Q3	Tobramycin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Tobramycin%20ophthalmic%20ointment%200.3%20NDA%20050555%20PSG%20Page%20RC%20May%202019.pdf	5/16/2019	Other	N/A
204	Q3	Azelaic Acid (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Azelaic%20Acid%20Cream%2020%20NDA%20020428%20PSG%20Page%20RV%20May%202019.pdf	5/16/2019	Other	N/A
205	Q3	Azelaic Acid (Multiple Reference Listed Drugs); Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Azelaic%20Acid%20Gel%2015%20NDA%20021470%20PSG%20Page%20RV%20May%202019.pdf	5/16/2019	Other	N/A
206	Q3	Betaxolol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/BETA%20XOLOL%20HYDROCHLORIDE%20ophthalmic%20suspensiondrops%20NDA%20019845%20PSG%20Page%20RV%20May%202019.pdf	5/16/2019	Other	N/A
207	Q3	Brimonidine Tartrate; Brinzolamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/BRIMONIDINE%20TARTRATE%20BRINZOLAMIDE%20ophthalmic%20suspension%20drops%20NDA%200204251%20PSG%20Page%20RV%20May%202019.pdf	5/16/2019	Other	N/A
208	Q3	Brinzolamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/BRINZOLAMIDE%20ophthalmic%20suspension%20drops%20NDA%20020816%20PSG%20Page%20RV%20May%202019.pdf	5/16/2019	Other	N/A
209	Q3	Fosfomycin Tromethamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Fosfomycin%20Tromethamine%20Oral%20Solution%20NDA%20050717%20PSG%20Page%20RV%20May%202019.pdf	5/16/2019	Other	N/A
210	Q3	Ivermectin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Ivermectin%20Topical%20Cream%201%20NDA%20206255%20PSG%20Page%20RV%20May%202019.pdf	5/16/2019	Other	N/A
211	Q3	Methylprednisolone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Methylprednisolone%20Oral%20Tablet%20NDA%2011153%20PSG%20Page%20RV%20May%202019.pdf	5/16/2019	Other	N/A
212	Q3	Prednisolone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Prednisolone%20acetate%20Ophthalmic%20suspension%20ORLD%20017011%20PSG%20Page%20RV%20May%202019.pdf	5/16/2019	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)
213	Q3	Tofacitinib Citrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/Tofacitinib%20Citrate%20Oral%20Tablet%20NDA%20203214%20PSG%20Page%20RV%20May%202019.pdf	5/16/2019	Other	N/A
214	Q3	ANDA Submissions – Content and Format Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/anda-submissions-content-and-format-abbreviated-new-drug-applications	6/12/2019	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 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
1	Q1	FDA-DIA Workshop on Complex Generic Drug-Device Combination Products	10/9/2018 to 10/10/2019	No
2	Q3	CDER Small Business and Industry Assistance (SBIA) Regulatory Education for Industry (REdI): Generic Drugs Forum	4/3/2019 to 4/4/2019	No
3	Q3	FY2019 Generic Drug Regulaory Science Initiatives Public Workshop	5/1/2019	Yes