



FDA U.S. FOOD & DRUG
ADMINISTRATION

FY 2026

Real Time Report

pursuant to the

Federal Food, Drug, and Cosmetic Act

as amended by the Generic Drug User Fee Amendments of 2022

Acronyms

CDER – Center for Drug Evaluation and Research

FD&C Act – Federal Food, Drug, and Cosmetic Act

FDA – Food and Drug Administration

FDAUFRA 2022 – FDA User Fee Reauthorization Act of 2022

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 September 30, 2022, the FDA User Fee Reauthorization Act of 2022 (FDAUFRA) (Division F of Public Law 117-180) was signed into law. FDAUFRA 2022 amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by revising and extending the user fee programs for human prescription drugs, biologics, generic drugs, medical devices, and biosimilar biological products.

Section 744C(a)(2) of the FD&C Act 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 each quarter of each fiscal year for which fees are collected under this part, 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 2022.”
- “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 2022.”

¹ This report provides information related to human generic drug activities, which are defined by section 744A(9) of the FD&C Act as specified 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 Biosimilar 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 2022. Guidances are listed by the quarter in which they were issued and are provided in a cumulative format for FY 2026.

Table 1: Draft and Final Guidance Documents Related to the Human Generic Drug Activities for FY 2026

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	Abiraterone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202379.pdf	10/1/2025	No	N/A
2	Q1	Abiraterone Acetate; Niraparib Tosylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216793.pdf	10/1/2025	No	N/A
3	Q1	Acetaminophen; Butalbital; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_088831.pdf	10/1/2025	No	N/A
4	Q1	Albuterol Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205636.pdf	10/1/2025	No	N/A
5	Q1	Alectinib Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208434.pdf	10/1/2025	No	N/A
6	Q1	Amantadine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208944.pdf	10/1/2025	No	N/A
7	Q1	Amifampridine Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208078.pdf	10/1/2025	No	N/A
8	Q1	Aspirin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200671.pdf	10/1/2025	No	N/A
9	Q1	Azilsartan Kamedoxomil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200796.pdf	10/1/2025	No	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
10	Q1	Azilsartan Kamedoxomil; Chlorthalidone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202331.pdf	10/1/2025	No	N/A
11	Q1	Betamethasone Acetate; Betamethasone Sodium Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_014602.pdf	10/1/2025	No	N/A
12	Q1	Betaxolol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019845.pdf	10/1/2025	No	N/A
13	Q1	Brimonidine Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021262.pdf	10/1/2025	No	N/A
14	Q1	Brimonidine Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021770.pdf	10/1/2025	No	N/A
15	Q1	Brimonidine Tartrate; Brinzolamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204251.pdf	10/1/2025	No	N/A
16	Q1	Brinzolamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020816.pdf	10/1/2025	No	N/A
17	Q1	Bupivacaine; Meloxicam; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211988.pdf	10/1/2025	No	N/A
18	Q1	Cabotegravir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215499.pdf	10/1/2025	No	N/A
19	Q1	Cabotegravir; Rilpivirine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212888.pdf	10/1/2025	No	N/A
20	Q1	Capivasertib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218197.pdf	10/1/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
21	Q1	Carglumic Acid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022562.pdf	10/1/2025	No	N/A
22	Q1	Clevidipine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022156.pdf	10/1/2025	No	N/A
23	Q1	Clotrimazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017619.pdf	10/1/2025	No	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	Cobicistat; Elvitegravir; Emtricitabine; Tenofovir Disoproxil Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203100.pdf	10/1/2025	No	N/A
25	Q1	Crizotinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217581.pdf	10/1/2025	No	N/A
26	Q1	Cyclobenzaprine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021777.pdf	10/1/2025	No	N/A
27	Q1	Dexmedetomidine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215390.pdf	10/1/2025	No	N/A
28	Q1	Dorzolamide Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020408.pdf	10/1/2025	No	N/A
29	Q1	Ensifentrine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217389.pdf	10/1/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter
30	Q1	Fluticasone Furoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205625.pdf	10/1/2025	No	N/A
31	Q1	Fluticasone Furoate; Umeclidinium Bromide; Vilanterol Trifenatate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209482.pdf	10/1/2025	No	N/A
32	Q1	Fluticasone Furoate; Vilanterol Trifenatate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204275.pdf	10/1/2025	No	N/A
33	Q1	Fluticasone Propionate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208798.pdf	10/1/2025	No	N/A
34	Q1	Fluticasone Propionate; Salmeterol Xinafoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208799.pdf	10/1/2025	No	N/A
35	Q1	Fruquintinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217564.pdf	10/1/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
36	Q1	Glatiramer Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020622.pdf	10/1/2025	No	N/A

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37	Q1	Glycopyrrolate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215019.pdf	10/1/2025	No	N/A
38	Q1	Hydroxyurea; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208843.pdf	10/1/2025	No	N/A
39	Q1	Ibrutinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217003.pdf	10/1/2025	No	N/A
40	Q1	Isavuconazonium Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207500.pdf	10/1/2025	No	N/A
41	Q1	Lasmiditan Succinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211280.pdf	10/1/2025	No	N/A
42	Q1	Latanoprost; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206185.pdf	10/1/2025	No	N/A
43	Q1	Levomilnacipran Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204168.pdf	10/1/2025	No	N/A
44	Q1	Lumateperone Tosylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209500.pdf	10/1/2025	No	N/A
45	Q1	Medroxyprogesterone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012541.pdf	10/1/2025	No	N/A
46	Q1	Medroxyprogesterone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020246.pdf	10/1/2025	No	N/A
47	Q1	Metformin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212595.pdf	10/1/2025	No	N/A
48	Q1	Methylprednisolone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011757.pdf	10/1/2025	No	N/A
49	Q1	Metoprolol Succinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210428.pdf	10/1/2025	No	N/A
50	Q1	Miconazole Nitrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017450.pdf	10/1/2025	No	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	Naftifine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019356.pdf	10/1/2025	No	N/A
52	Q1	Naftifine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019599.pdf	10/1/2025	No	N/A
53	Q1	Naftifine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204286.pdf	10/1/2025	No	N/A
54	Q1	Nalmefene Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218590.pdf	10/1/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter
55	Q1	Naloxone Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215487.pdf	10/1/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter
56	Q1	Nirogacestat Hydrobromide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217677.pdf	10/1/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
57	Q1	Oxiconazole Nitrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019828.pdf	10/1/2025	No	N/A
58	Q1	Oxiconazole Nitrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020209.pdf	10/1/2025	No	N/A
59	Q1	Paliperidone Palmitate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207946.pdf	10/1/2025	No	N/A
60	Q1	Pemetrexed Dipotassium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210661.pdf	10/1/2025	No	N/A
61	Q1	Penicillin G Benzathine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050141.pdf	10/1/2025	No	N/A
62	Q1	Phentermine Hydrochloride; Topiramate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022580.pdf	10/1/2025	No	N/A
63	Q1	Ponatinib Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203469.pdf	10/1/2025	No	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)
64	Q1	Posaconazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022003.pdf	10/1/2025	No	N/A
65	Q1	Prednisolone Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017100.pdf	10/1/2025	No	N/A
66	Q1	Progesterone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022057.pdf	10/1/2025	No	N/A
67	Q1	Ranitidine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020251.pdf	10/1/2025	No	N/A
68	Q1	Risperidone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021346.pdf	10/1/2025	No	N/A
69	Q1	Sapropterin Dihydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205065.pdf	10/1/2025	No	N/A
70	Q1	Semaglutide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213051.pdf	10/1/2025	No	N/A
71	Q1	Sofpironium Bromide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217347.pdf	10/1/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter
72	Q1	Topiramate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_201635.pdf	10/1/2025	No	N/A
73	Q1	Topiramate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205122.pdf	10/1/2025	No	N/A
74	Q1	Torseamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213218.pdf	10/1/2025	No	N/A
75	Q1	Trazodone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022411.pdf	10/1/2025	No	N/A
76	Q1	Triamcinolone Acetonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012041.pdf	10/1/2025	No	N/A
77	Q1	Umeclidinium Bromide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205382.pdf	10/1/2025	No	N/A
78	Q1	Umeclidinium Bromide; Vilanterol Trifenatate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203975.pdf	10/1/2025	No	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)
79	Q1	Venlafaxine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020699.pdf	10/1/2025	No	N/A
80	Q1	Vonoprazan Fumarate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215151.pdf	10/1/2025	No	N/A
81	Q1	Zonisamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020789.pdf	10/1/2025	No	N/A
82	Q1	Estrogens, Conjugated; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020216.pdf	11/3/2025	No	N/A
83	Q1	Aclidinium Bromide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202450.pdf	11/6/2025	No	N/A
84	Q1	Formoterol Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210595.pdf	11/6/2025	No	N/A
85	Q1	Ambrisentan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022081.pdf	11/6/2025	No	N/A
86	Q1	Amino Acids; Calcium Chloride; Dextrose; Magnesium Sulfate; Potassium Chloride; Sodium Acetate; Sodium Glycerophosphate; Soyb; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200656.pdf	11/6/2025	No	N/A
87	Q1	Amphetamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204326.pdf	11/6/2025	No	N/A
88	Q1	Aprocitentan; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217686.PDF	11/6/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
89	Q1	Asciminib Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215358.pdf	11/6/2025	No	N/A
90	Q1	Beclomethasone Dipropionate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207921.pdf	11/6/2025	No	N/A
91	Q1	Beclomethasone Dipropionate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020911.pdf	11/6/2025	No	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)
92	Q1	Berdazimer Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217424.pdf	11/6/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter
93	Q1	Bosentan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209279.pdf	11/6/2025	No	N/A
94	Q1	Bosentan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021290.pdf	11/6/2025	No	N/A
95	Q1	Budesonide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213976.pdf	11/6/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter
96	Q1	Budesonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021949.pdf	11/6/2025	No	N/A
97	Q1	Buprenorphine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207932.pdf	11/6/2025	No	N/A
98	Q1	Carbidopa; Levodopa; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214869.PDF	11/6/2025	No	N/A
99	Q1	Carbidopa; Levodopa; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217186.PDF	11/6/2025	No	N/A
100	Q1	Ciclesonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021658.pdf	11/6/2025	No	N/A
101	Q1	Copper Cu-64 Dotatate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213227.pdf	11/6/2025	No	N/A
102	Q1	Crofelemer; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202292.pdf	11/6/2025	No	N/A
103	Q1	Danicopan; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218037.pdf	11/6/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
104	Q1	Dasatinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216099.pdf	11/6/2025	No	N/A
105	Q1	Deuruxolitinib Phosphate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217900.pdf	11/6/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
106	Q1	Dexamethasone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022315.pdf	11/6/2025	No	N/A

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107	Q1	Diazepam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_013263.pdf	11/6/2025	No	N/A
108	Q1	Eltrombopag Choline; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216774.pdf	11/6/2025	No	N/A
109	Q1	Epinephrine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020800.pdf	11/6/2025	No	N/A
110	Q1	Epinephrine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207534.pdf	11/6/2025	No	N/A
111	Q1	Fish Oil Triglycerides; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210589.pdf	11/6/2025	No	N/A
112	Q1	Fish Oil; Medium Chain Triglycerides; Olive Oil; Soybean Oil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207648.pdf	11/6/2025	No	N/A
113	Q1	Fludrocortisone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_010060.pdf	11/6/2025	No	N/A
114	Q1	Flunisolide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021247.pdf	11/6/2025	No	N/A
115	Q1	Gabapentin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020882.pdf	11/6/2025	No	N/A
116	Q1	Gallium Ga-68 Edotreotide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210828.pdf	11/6/2025	No	N/A
117	Q1	Givinostat Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217865.pdf	11/6/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
118	Q1	Glucagon; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020928.pdf	11/6/2025	No	N/A
119	Q1	Glycopyrrolate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207923.pdf	11/6/2025	No	N/A
120	Q1	Indacaterol Maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207930.pdf	11/6/2025	No	N/A
121	Q1	Hydroxychloroquine Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009768.pdf	11/6/2025	No	N/A

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122	Q1	Inavolisib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_219249.pdf	11/6/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
123	Q1	Indacaterol Maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022383.pdf	11/6/2025	No	N/A
124	Q1	Ipratropium Bromide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021527.pdf	11/6/2025	No	N/A
125	Q1	Iron Dextran; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017441.pdf	11/6/2025	No	N/A
126	Q1	Isotretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018662.pdf	11/6/2025	No	N/A
127	Q1	Lazertinib Mesylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_219008.pdf	11/6/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
128	Q1	Macitentan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204410.pdf	11/6/2025	No	N/A
129	Q1	Macitentan; Tadalafil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218490.pdf	11/6/2025	No	N/A
130	Q1	Mavoxifafor; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218709.pdf	11/6/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
131	Q1	Metronidazole; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216755.pdf	11/6/2025	No	N/A
132	Q1	Metronidazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012623.pdf	11/6/2025	No	N/A
133	Q1	Metronidazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020334.pdf	11/6/2025	No	N/A
134	Q1	Minocycline Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_219015.pdf	11/6/2025	No	N/A
135	Q1	Minocycline Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050781.pdf	11/6/2025	No	N/A

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136	Q1	Mometasone Furoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021067.pdf	11/6/2025	No	N/A
137	Q1	Neratinib maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208051.pdf	11/6/2025	No	N/A
138	Q1	Nilotinib Tartrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_219293.pdf	11/6/2025	No	N/A
139	Q1	Olive Oil; Soybean Oil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204508.pdf	11/6/2025	No	N/A
140	Q1	Oxaprozin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217927.pdf	11/6/2025	No	N/A
141	Q1	Palbociclib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212436.pdf	11/6/2025	No	N/A
142	Q1	Pexidartinib Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211810.pdf	11/6/2025	No	N/A
143	Q1	Probenecid; Sulopenem Etzadroxil; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213972.pdf	11/6/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
144	Q1	Resmetirom; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217785.pdf	11/6/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
145	Q1	Rifampin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050420.pdf	11/6/2025	No	N/A
146	Q1	Sacubitril; Valsartan; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218591.pdf	11/6/2025	No	N/A
147	Q1	Seladelpar Lysine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217899.pdf	11/6/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
148	Q1	Sodium Ferric Gluconate Complex; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020955.pdf	11/6/2025	No	N/A
149	Q1	Soybean Oil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017643.pdf	11/6/2025	No	N/A

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150	Q1	Tirzepatide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217806.pdf	11/6/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter
151	Q1	Tovorafenib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217700.pdf	11/6/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
152	Q1	Tovorafenib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218033.pdf	11/6/2025	No	N/A
153	Q1	Travoprost; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218010.pdf	11/6/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter
154	Q1	Trospium Chloride; Xanomeline Tartrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216158.pdf	11/6/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
155	Q1	Vadadustat; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215192.pdf	11/6/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
156	Q1	Valbenazine Tosylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218390.pdf	11/6/2025	No	N/A
157	Q1	Valbenazine Tosylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209241.pdf	11/6/2025	No	N/A
158	Q1	Vorasidenib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218784.pdf	11/6/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
159	Q1	Considerations for Waiver Requests for pH Adjusters in Generic Drug Products Intended for Parenteral, Ophthalmic, or Otic Use; Final Guidance for Industry www.fda.gov/media/157655/download	11/14/2025	No	N/A
160	Q1	Q3E Guideline for Extractables and Leachables: Supporting Documentation: Class 3 Leachable Monographs; Draft Guidance for Industry www.fda.gov/media/189891/download	11/28/2025	No	N/A
161	Q1	Q3E Guideline for Extractables and Leachables; Draft Guidance for Industry www.fda.gov/media/189890/download	11/28/2025	No	N/A
162	Q1	Medical Gases — Current Good Manufacturing Practice: Draft Guidance for Industry www.fda.gov/media/70973/download	11/28/2025	No	N/A

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163	Q1	Acoramidis Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216540.pdf	12/4/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
164	Q1	Apomorphine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214056.pdf	12/4/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter
165	Q1	Arimocloamol Citrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214927.pdf	12/4/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
166	Q1	Baclofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017851.pdf	12/4/2025	No	N/A
167	Q1	Baricitinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207924.pdf	12/4/2025	No	N/A
168	Q1	Birch Triterpenes; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215064.pdf	12/4/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter
169	Q1	Brigatinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208772.pdf	12/4/2025	No	N/A
170	Q1	Budesonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215935-REV-2025-12.pdf	12/4/2025	No	N/A
171	Q1	Budesonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020929.pdf	12/4/2025	No	N/A
172	Q1	Bupropion Hydrochloride; Dextromethorphan Hydrobromide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215430.pdf	12/4/2025	No	N/A
173	Q1	Cabergoline; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020664.pdf	12/4/2025	No	N/A
174	Q1	Calcitonin Salmon; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017808.pdf	12/4/2025	No	N/A
175	Q1	Carbinoxamine Maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022556.pdf	12/4/2025	No	N/A
176	Q1	Carvedilol Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022012.pdf	12/4/2025	No	N/A

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177	Q1	Cefepime Hydrochloride; Enmetazobactam; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216165.pdf	12/4/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
178	Q1	Cenobamate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212839.pdf	12/4/2025	No	N/A
179	Q1	Crinecerfont; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218808.pdf	12/4/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
180	Q1	Crinecerfont; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218820.pdf	12/4/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
181	Q1	Dabrafenib Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202806.pdf	12/4/2025	No	N/A
182	Q1	Dasiglucagon Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214231.pdf	12/4/2025	No	N/A
183	Q1	Desmopressin Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017922.pdf	12/4/2025	No	N/A
184	Q1	Deutivacaftor; Tezacaftor; Vanzacaftor Calcium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218730.pdf	12/4/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
185	Q1	Diltiazem Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020062.pdf	12/4/2025	No	N/A
186	Q1	Docetaxel; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218711.pdf	12/4/2025	No	N/A
187	Q1	Elafibranor; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218860.pdf	12/4/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
188	Q1	Elexacaftor, Ivacaftor, Tezacaftor; Ivacaftor; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217660.pdf	12/4/2025	No	N/A
189	Q1	Ensartinib Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218171.pdf	12/4/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter

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190	Q1	Epinephrine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019430.pdf	12/4/2025	No	N/A
191	Q1	Epinephrine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214697.pdf	12/4/2025	No	N/A
192	Q1	Escitalopram Oxalate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021323-ODT.pdf	12/4/2025	No	N/A
193	Q1	Estradiol; Norethindrone Acetate; Relugolix; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214846.pdf	12/4/2025	No	N/A
194	Q1	Estradiol; Progesterone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210132.pdf	12/4/2025	No	N/A
195	Q1	Etodolac; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018922-Tab.pdf	12/4/2025	No	N/A
196	Q1	Fenfluramine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212102.pdf	12/4/2025	No	N/A
197	Q1	Flurpiridaz F-18; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215168.pdf	12/4/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
198	Q1	Fluticasone Propionate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020121.pdf	12/4/2025	No	N/A
199	Q1	Gepotidacin Mesylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218230.pdf	12/4/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
200	Q1	Glucagon; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212097.pdf	12/4/2025	No	N/A
201	Q1	Glucagon; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210134.pdf	12/4/2025	No	N/A
202	Q1	Hydrochlorothiazide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_219141.pdf	12/4/2025	No	N/A
203	Q1	Hydrochlorothiazide; Metoprolol Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018303.pdf	12/4/2025	No	N/A
204	Q1	Hydroxychloroquine Sulfate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214581.pdf	12/4/2025	No	N/A

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205	Q1	lomeprol; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216016.pdf	12/4/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
206	Q1	lomeprol; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216017.pdf	12/4/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
207	Q1	Isotretinoin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211913.pdf	12/4/2025	No	N/A
208	Q1	Ixazomib Citrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208462.pdf	12/4/2025	No	N/A
209	Q1	Ketorolac Tromethamine; Phenylephrine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205388.pdf	12/4/2025	No	N/A
210	Q1	Levacetylleucine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_219132.pdf	12/4/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
211	Q1	Liraglutide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022341.pdf	12/4/2025	No	N/A
212	Q1	Liraglutide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206321.pdf	12/4/2025	No	N/A
213	Q1	Mesalamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022000.pdf	12/4/2025	No	N/A
214	Q1	Omeprazole; Sodium Bicarbonate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213593.pdf	12/4/2025	No	N/A
215	Q1	Omeprazole; Sodium Bicarbonate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021636.pdf	12/4/2025	No	N/A
216	Q1	Pegcetacoplan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215014.pdf	12/4/2025	No	N/A
217	Q1	Pegcetacoplan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217171.pdf	12/4/2025	No	N/A
218	Q1	Pegulicianine Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214511.pdf	12/4/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter

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219	Q1	Pivmecillinam Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216483.pdf	12/4/2025	No	N/A
220	Q1	Posaconazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214770.pdf	12/4/2025	No	N/A
221	Q1	Potassium Chloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019561.pdf	12/4/2025	No	N/A
222	Q1	Prednisolone Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017469.pdf	12/4/2025	No	N/A
223	Q1	Primidone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009170-ODT.pdf	12/4/2025	No	N/A
224	Q1	Pyridostigmine Bromide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_015193.pdf	12/4/2025	No	N/A
225	Q1	Pyridostigmine Bromide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217604.pdf	12/4/2025	No	N/A
226	Q1	Pyridostigmine Bromide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009829.pdf	12/4/2025	No	N/A
227	Q1	Revumenib Citrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218944.pdf	12/4/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
228	Q1	Roflumilast; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217242.pdf	12/4/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter
229	Q1	Selpercatinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218160.pdf	12/4/2025	No	N/A
230	Q1	Semaglutide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215256.pdf	12/4/2025	No	N/A
231	Q1	Sunitinib Malate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021938.pdf	12/4/2025	No	N/A
232	Q1	Suzetrigine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_219209.pdf	12/4/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
233	Q1	Talazoparib Tosylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217439.pdf	12/4/2025	No	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)
234	Q1	Tapinarof; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215272.pdf	12/4/2025	No	N/A
235	Q1	Tenapanor Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213931.pdf	12/4/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter
236	Q1	Teriparatide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021318.pdf	12/4/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter
237	Q1	Testosterone Undecanoate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208088.pdf	12/4/2025	No	N/A
238	Q1	Tirzepatide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215866.pdf	12/4/2025	No	N/A
239	Q1	Treosulfan; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214759.pdf	12/4/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter
240	Q1	Treprostinil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214324.pdf	12/4/2025	No	N/A
241	Q1	Tretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017340.pdf	12/4/2025	No	N/A
242	Q1	Trospium Chloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022103.pdf	12/4/2025	No	N/A
243	Q1	Vosoritide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214938.pdf	12/4/2025	No	N/A
244	Q1	Estradiol; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208564.pdf	12/8/2025	No	N/A
245	Q1	Estradiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020908.pdf	12/8/2025	No	N/A
246	Q1	ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs; Final Guidance for Industry www.fda.gov/media/119718/download	12/16/2025	No	N/A
247	Q2	Aceclidine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218585.pdf	2/26/2026	Yes	Section III.C.2.c of GDUFA III Commitment Letter

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)
248	Q2	Acetaminophen; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206968.pdf	2/26/2026	No	N/A
249	Q2	Acetaminophen; Ibuprofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211733.pdf	2/26/2026	No	N/A
250	Q2	Acoltremon; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217370.pdf	2/26/2026	Yes	Section III.C.2.c of GDUFA III Commitment Letter
251	Q2	Alpelisib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218466.pdf	2/26/2026	No	N/A
252	Q2	Alpelisib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215039.pdf	2/26/2026	No	N/A
253	Q2	Alpelisib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212526.pdf	2/26/2026	No	N/A
254	Q2	Amoxicillin; Omeprazole Magnesium; Rifabutin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213004.pdf	2/26/2026	No	N/A
255	Q2	Apixaban; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_220073.pdf	2/26/2026	No	N/A
256	Q2	Apixaban; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202155.pdf	2/26/2026	No	N/A
257	Q2	Asenapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212268.pdf	2/26/2026	No	N/A
258	Q2	Avacincaptad Pegol Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217225.pdf	2/26/2026	Yes	Section III.C.2.a of GDUFA III Commitment Letter
259	Q2	Baclofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215602.pdf	2/26/2026	No	N/A
260	Q2	Baloxavir Marboxil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214410.pdf	2/26/2026	No	N/A
261	Q2	Barium Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208036.pdf	2/26/2026	No	N/A
262	Q2	Barium Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208143.pdf	2/26/2026	No	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)
263	Q2	Bisoprolol Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019982.pdf	2/26/2026	No	N/A
264	Q2	Buprenorphine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210136.pdf	2/26/2026	No	N/A
265	Q2	Buprenorphine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021306.pdf	2/26/2026	Yes	Section III.C.2.a of GDUFA III Commitment Letter
266	Q2	Buspirone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018731.pdf	2/26/2026	No	N/A
267	Q2	Capsaicin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022395.pdf	2/26/2026	No	N/A
268	Q2	Cephalexin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050440.pdf	2/26/2026	No	N/A
269	Q2	Chlorthalidone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012283.pdf	2/26/2026	No	N/A
270	Q2	Clonidine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018891.pdf	2/26/2026	No	N/A
271	Q2	Clozapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203479.pdf	2/26/2026	No	N/A
272	Q2	Clozapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019758.pdf	2/26/2026	No	N/A
273	Q2	Clozapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021590.pdf	2/26/2026	No	N/A
274	Q2	Cobicistat; Darunavir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205395.pdf	2/26/2026	No	N/A
275	Q2	Dabrafenib Mesylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217514.pdf	2/26/2026	No	N/A
276	Q2	Dasatinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021986.pdf	2/26/2026	No	N/A
277	Q2	Dextroamphetamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215401.pdf	2/26/2026	No	N/A
278	Q2	Diazoxide Choline; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216665.pdf	2/26/2026	No	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)
279	Q2	Diclofenac Epolamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021234.pdf	2/26/2026	No	N/A
280	Q2	Donepezil Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212304.pdf	2/26/2026	No	N/A
281	Q2	Duloxetine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021427.pdf	2/26/2026	No	N/A
282	Q2	Duloxetine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212516.pdf	2/26/2026	No	N/A
283	Q2	Entrectinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218550.pdf	2/26/2026	No	N/A
284	Q2	Estradiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020538.pdf	2/26/2026	No	N/A
285	Q2	Estradiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019081.pdf	2/26/2026	No	N/A
286	Q2	Estradiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020375.pdf	2/26/2026	No	N/A
287	Q2	Estradiol; Levonorgestrel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021258.pdf	2/26/2026	No	N/A
288	Q2	Estradiol; Norethindrone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020870.pdf	2/26/2026	No	N/A
289	Q2	Ethinyl Estradiol; Levonorgestrel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204017.pdf	2/26/2026	No	N/A
290	Q2	Ethinyl Estradiol; Norelgestromin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021180.pdf	2/26/2026	No	N/A
291	Q2	Fentanyl; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019813.pdf	2/26/2026	No	N/A
292	Q2	Ferric Derisomaltose; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208171.pdf	2/26/2026	No	N/A
293	Q2	Formoterol Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020831.pdf	2/26/2026	No	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)
294	Q2	Foscarbidopa; Foslevodopa; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216962.pdf	2/26/2026	Yes	Section III.C.2.a of GDUFA III Commitment Letter
295	Q2	Glecaprevir; Pibrentasvir; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215110.pdf	2/26/2026	No	N/A
296	Q2	Granisetron; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022198.pdf	2/26/2026	No	N/A
297	Q2	Imatinib Mesylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_219097.pdf	2/26/2026	No	N/A
298	Q2	Imatinib Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021588.pdf	2/26/2026	No	N/A
299	Q2	Ketoconazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019927.pdf	2/26/2026	No	N/A
300	Q2	Ketoconazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020310.pdf	2/26/2026	No	N/A
301	Q2	Landiolol Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217202.pdf	2/26/2026	Yes	Section III.C.2.c of GDUFA III Commitment Letter
302	Q2	Letermovir; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_219104.pdf	2/26/2026	No	N/A
303	Q2	Lidocaine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207962.pdf	2/26/2026	No	N/A
304	Q2	Lidocaine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020612.pdf	2/26/2026	No	N/A
305	Q2	Lorazepam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214826.pdf	2/26/2026	No	N/A
306	Q2	Lorlatinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210868.pdf	2/26/2026	No	N/A
307	Q2	Loxapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022549.pdf	2/26/2026	No	N/A
308	Q2	Meloxicam; Rizatriptan Benzoate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215431.pdf	2/26/2026	No	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)
309	Q2	Menthol; Methyl Salicylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022029.pdf	2/26/2026	No	N/A
310	Q2	Metformin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020357-TabC.pdf	2/26/2026	No	N/A
311	Q2	Methylphenidate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021514.pdf	2/26/2026	No	N/A
312	Q2	Mometasone Furoate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209310.pdf	2/26/2026	No	N/A
313	Q2	Nicotine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020076.pdf	2/26/2026	No	N/A
314	Q2	Nitroglycerin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020145.pdf	2/26/2026	No	N/A
315	Q2	Nitroglycerin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020144.pdf	2/26/2026	No	N/A
316	Q2	Octreotide Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213224.pdf	2/26/2026	Yes	Section III.C.2.a of GDUFA III Commitment Letter
317	Q2	Oxybutynin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202211.pdf	2/26/2026	No	N/A
318	Q2	Oxybutynin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021351.pdf	2/26/2026	No	N/A
319	Q2	Paliperidone Palmitate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216352.pdf	2/26/2026	Yes	Section III.C.2.a of GDUFA III Commitment Letter
320	Q2	Paliperidone Palmitate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022264.pdf	2/26/2026	No	N/A
321	Q2	Perfluorohexyloctane; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216675.pdf	2/26/2026	No	N/A
322	Q2	Phenylephrine Hydrochloride; Tropicamide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215352.pdf	2/26/2026	Yes	Section III.C.2.a of GDUFA III Commitment Letter

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)
323	Q2	Ribavirin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018859.pdf	2/26/2026	No	N/A
324	Q2	Rilpivirine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_219016.pdf	2/26/2026	No	N/A
325	Q2	Rivastigmine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022083.pdf	2/26/2026	No	N/A
326	Q2	Rotigotine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021829.pdf	2/26/2026	No	N/A
327	Q2	Sacubitril; Valsartan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207620.pdf	2/26/2026	No	N/A
328	Q2	Scopolamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017874.pdf	2/26/2026	No	N/A
329	Q2	Selegiline; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021336.pdf	2/26/2026	No	N/A
330	Q2	Selinexor; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212306.pdf	2/26/2026	No	N/A
331	Q2	Semaglutide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218316.pdf	2/26/2026	Yes	Section III.C.2.a of GDUFA III Commitment Letter
332	Q2	Sofosbuvir; Velpatasvir; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214187.pdf	2/26/2026	No	N/A
333	Q2	Tadalafil; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214522.pdf	2/26/2026	No	N/A
334	Q2	Testosterone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020489.pdf	2/26/2026	No	N/A
335	Q2	Testosterone Cypionate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216318.pdf	2/26/2026	No	N/A
336	Q2	Testosterone Cypionate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_085635.pdf	2/26/2026	No	N/A
337	Q2	Testosterone Undecanoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213953.pdf	2/26/2026	No	N/A
338	Q2	Testosterone Undecanoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206089.pdf	2/26/2026	No	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)
339	Q2	Tiopronin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211843.pdf	2/26/2026	No	N/A
340	Q2	Tizanidine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021447.pdf	2/26/2026	No	N/A
341	Q2	Tolmetin Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017628.pdf	2/26/2026	No	N/A
342	Q2	Tolmetin Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018084.pdf	2/26/2026	No	N/A
343	Q2	Venlafaxine Besylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215429.pdf	2/26/2026	No	N/A
344	Q2	Venlafaxine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020151.pdf	2/26/2026	No	N/A
345	Q2	E2D(R1) Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports; Final Guidance for Industry www.fda.gov/media/176977/download	3/3/2026	No.	N/A
346	Q2	M14 General Principles on Planning, Designing, Analyzing, and Reporting of Non-interventional Studies That Utilize Real-World Data for Safety Assessment of Medicines; Final Guidance for Industry www.fda.gov/media/179795/download	3/3/2026	No	N/A
347	Q2	New Clinical Investigation Exclusivity (3-Year Exclusivity) for Drug Products: Questions and Answers Guidance for Industry www.fda.gov/media/191368/download	3/3/2026	No	N/A
348	Q2	Responding to FDA Form 483 Observations at the Conclusion of a Drug CGMP Inspection; Draft Guidance for Industry www.fda.gov/media/191427/download	3/6/2026	No.	N/A
349	Q2	Pyrogen and Endotoxins Testing: Questions and Answers: Final Guidance for Industry www.fda.gov/media/83477/download	3/18/2026	No.	N/A
350	Q2	Physicochemical and Structural (Q3) Characterization of Topical Drug Products Submitted in ANDAs Guidance for Industry www.fda.gov/media/162471/download	3/18/2026	No	N/A
351	Q2	General Considerations for the Use of New Approach Methodologies in Drug Development; Draft Guidance for Industry www.fda.gov/media/191589/download	3/18/2026	No	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 2022. Public meetings are listed by the quarter in which they were held and are provided in a cumulative format for FY 2026.

Table 2: Public Meetings Held on Topics Related to Human Generic Drug Activities for FY 2026

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	Advancing Generic Drug Development: Translating Science to Approval 2025 www.fda.gov/drugs/news-events-human-drugs/advancing-generic-drug-development-translating-science-approval-2025-10072025	10/7/2025-10/8/2025	No
2	Q1	FDA/Center for Research on Complex Generics (CRCG) Workshop on Modeling and Artificial Intelligence (AI) in Generic Drug Development and Product Lifecycle Management: Regulatory Insights and Future Trends www.fda.gov/drugs/news-events-human-drugs/fdacenter-research-complex-generics-crcg-workshop-modeling-and-artificial-intelligence-ai-generic	10/15/2025-10/16/2025	No
3	Q1	FDA/Center for Research on Complex Generics (CRCG) Workshop on Visionary Standards: Advancing Science and Regulation in Generic Ophthalmic Products www.fda.gov/drugs/news-events-human-drugs/fdacenter-research-complex-generics-crcg-workshop-visionary-standards-advancing-science-and	11/19/2025-11/20/2025	No
4	Q1	Quality and Regulatory Predictability: Shaping USP Standards www.fda.gov/drugs/news-events-human-drugs/quality-and-regulatory-predictability-shaping-usp-standards-12112025	12/11/2025	No
5	Q2	FDA Information Session on Generic Drug Research Needs & Opportunities for FY 2026 www.fda.gov/drugs/news-events-human-drugs/fda-information-session-generic-drug-research-needs-opportunities-fy-2026-01212026	1/21/2026	No