



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

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)
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

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)
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

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)
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

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)
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

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)
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

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)
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

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)
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

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)
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

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)
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

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)
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

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