



FDA U.S. FOOD & DRUG
ADMINISTRATION

FY 2025

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

Summary

This section provides a summary of the total numbers for each category contained in this report, for certain activities as they relate to human generic drug activities, within the current fiscal year (FY) as of September 30, 2025.

Category	Total
Guidance Documents	936
Public Meetings	18

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 2025.

Table 1: Draft and Final Guidance Documents Related to the Human Generic Drug Activities for FY 2025

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	Requests for Reconsideration at the Division Level Under GDUFA; Final Guidance for Industry www.fda.gov/media/108398/download	10/16/2024	Other	N/A
2	Q1	Review of Drug Master Files in Advance of Certain ANDA Submissions Under GDUFA; Final Guidance for Industry www.fda.gov/media/162019/download	10/17/2024	Yes	GDUFA III Commitment Letter
3	Q1	M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms; Final Guidance for Industry www.fda.gov/media/165049/download	10/30/2024	Other	N/A
4	Q1	Abacavir Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020977.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
5	Q1	Abacavir Sulfate; Dolutegravir Sodium; Lamivudine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205551.pdf	10/30/2024	Other	N/A
6	Q1	Abacavir Sulfate; Dolutegravir Sodium; Lamivudine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215413.pdf	10/30/2024	Other	N/A
7	Q1	Abacavir Sulfate; Lamivudine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021652.pdf	10/30/2024	Other	N/A
8	Q1	Abacavir Sulfate; Lamivudine; Zidovudine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021205.pdf	10/30/2024	Other	N/A
9	Q1	Abemaciclib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208716.pdf	10/30/2024	Other	N/A
10	Q1	Abrocitinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213871.pdf	10/30/2024	Other	N/A
11	Q1	Acalabrutinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210259.pdf	10/30/2024	Other	N/A
12	Q1	Acetaminophen; Aspirin; Caffeine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020802.pdf	10/30/2024	Other	N/A
13	Q1	Acetaminophen; Benzhydrocodone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208653.pdf	10/30/2024	Other	N/A
14	Q1	Acetaminophen; Butalbital; Caffeine; Codeine Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020232.pdf	10/30/2024	Other	N/A
15	Q1	Acetaminophen; Ibuprofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211733.pdf	10/30/2024	Other	N/A
16	Q1	Acetaminophen; Propoxyphene Napsylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017122.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
17	Q1	Acetaminophen; Tramadol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021123.pdf	10/30/2024	Other	N/A
18	Q1	Acetazolamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_008943.pdf	10/30/2024	Other	N/A
19	Q1	Acetylcysteine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207916.pdf	10/30/2024	Other	N/A
20	Q1	Acrivastine; Pseudoephedrine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019806.pdf	10/30/2024	Other	N/A
21	Q1	Acyclovir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018828.pdf	10/30/2024	Other	N/A
22	Q1	Acyclovir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019909.pdf	10/30/2024	Other	N/A
23	Q1	Acyclovir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020089.pdf	10/30/2024	Other	N/A
24	Q1	Adagrasib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216340.pdf	10/30/2024	Other	N/A
25	Q1	Adefovir Dipivoxil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021449.pdf	10/30/2024	Other	N/A
26	Q1	Albuterol Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017853.pdf	10/30/2024	Other	N/A
27	Q1	Allopurinol; Lesinurad; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209203.pdf	10/30/2024	Other	N/A
28	Q1	Almotriptan Malate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021001.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
29	Q1	Alogliptin Benzoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022271.pdf	10/30/2024	Other	N/A
30	Q1	Alogliptin Benzoate; Metformin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203414.pdf	10/30/2024	Other	N/A
31	Q1	Alogliptin Benzoate; Pioglitazone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022426.pdf	10/30/2024	Other	N/A
32	Q1	Alosetron Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021107.pdf	10/30/2024	Other	N/A
33	Q1	Alprazolam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018276.pdf	10/30/2024	Other	N/A
34	Q1	Alprazolam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021726.pdf	10/30/2024	Other	N/A
35	Q1	Amantadine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018101.pdf	10/30/2024	Other	N/A
36	Q1	Amantadine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016020.pdf	10/30/2024	Other	N/A
37	Q1	Ambrisentan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022081.pdf	10/30/2024	Other	N/A
38	Q1	Amifampridine Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208078.pdf	10/30/2024	Other	N/A
39	Q1	Amiloride Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018200.pdf	10/30/2024	Other	N/A
40	Q1	Aminocaproic Acid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_015197.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
41	Q1	Amiodarone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018972.pdf	10/30/2024	Other	N/A
42	Q1	Amitriptyline Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012703.pdf	10/30/2024	Other	N/A
43	Q1	Amitriptyline Hydrochloride; Chlordiazepoxide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016949.pdf	10/30/2024	Other	N/A
44	Q1	Amlodipine Benzoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211340.pdf	10/30/2024	Other	N/A
45	Q1	Amlodipine Besylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019787.pdf	10/30/2024	Other	N/A
46	Q1	Amlodipine Besylate; Atorvastatin Calcium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021540.pdf	10/30/2024	Other	N/A
47	Q1	Amlodipine Besylate; Benazepril Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020364.pdf	10/30/2024	Other	N/A
48	Q1	Amlodipine Besylate; Celecoxib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210045.pdf	10/30/2024	Other	N/A
49	Q1	Amlodipine Besylate; Hydrochlorothiazide; Olmesartan Medoxomil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200175.pdf	10/30/2024	Other	N/A
50	Q1	Amlodipine Besylate; Hydrochlorothiazide; Valsartan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022314.pdf	10/30/2024	Other	N/A
51	Q1	Amlodipine Besylate; Olmesartan Medoxomil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022100.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
52	Q1	Amlodipine Besylate; Perindopril Arginine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205003.pdf	10/30/2024	Other	N/A
53	Q1	Amlodipine Besylate; Valsartan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021990.pdf	10/30/2024	Other	N/A
54	Q1	Amoxicillin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050459.pdf	10/30/2024	Other	N/A
55	Q1	Amoxicillin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050460.pdf	10/30/2024	Other	N/A
56	Q1	Amoxicillin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050760.pdf	10/30/2024	Other	N/A
57	Q1	Amoxicillin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050542.pdf	10/30/2024	Other	N/A
58	Q1	Amoxicillin; Clarithromycin; Vonoprazan Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215152.pdf	10/30/2024	Other	N/A
59	Q1	Amoxicillin; Clavulanate Potassium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050597.pdf	10/30/2024	Other	N/A
60	Q1	Amoxicillin; Clavulanate Potassium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050726.pdf	10/30/2024	Other	N/A
61	Q1	Amoxicillin; Clavulanate Potassium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050725.pdf	10/30/2024	Other	N/A
62	Q1	Amoxicillin; Clavulanate Potassium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050575.pdf	10/30/2024	Other	N/A
63	Q1	Amoxicillin; Clavulanate Potassium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050564.pdf	10/30/2024	Other	N/A

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64	Q1	Amoxicillin; Vonoprazan Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215153.pdf	10/30/2024	Other	N/A
65	Q1	Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011522.pdf	10/30/2024	Other	N/A
66	Q1	Anagrelide Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020333.pdf	10/30/2024	Other	N/A
67	Q1	Anastrozole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020541.pdf	10/30/2024	Other	N/A
68	Q1	Apixaban; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202155.pdf	10/30/2024	Other	N/A
69	Q1	Apremilast; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205437.pdf	10/30/2024	Other	N/A
70	Q1	Aripiprazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021436.pdf	10/30/2024	Other	N/A
71	Q1	Aripiprazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021729.pdf	10/30/2024	Other	N/A
72	Q1	Armodafinil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021875.pdf	10/30/2024	Other	N/A
73	Q1	Aspirin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203697.pdf	10/30/2024	Other	N/A
74	Q1	Aspirin; Butalbital; Caffeine; Codeine Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019429.pdf	10/30/2024	Other	N/A
75	Q1	Atazanavir Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021567.pdf	10/30/2024	Other	N/A

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76	Q1	Atazanavir Sulfate; Cobicistat; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206353.pdf	10/30/2024	Other	N/A
77	Q1	Atenolol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018240.pdf	10/30/2024	Other	N/A
78	Q1	Atenolol; Chlorthalidone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018760.pdf	10/30/2024	Other	N/A
79	Q1	Atomoxetine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021411.pdf	10/30/2024	Other	N/A
80	Q1	Atorvastatin Calcium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213260.pdf	10/30/2024	Other	N/A
81	Q1	Atorvastatin Calcium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020702.pdf	10/30/2024	Other	N/A
82	Q1	Atorvastatin Calcium; Ezetimibe; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200153.pdf	10/30/2024	Other	N/A
83	Q1	Atovaquone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020259.pdf	10/30/2024	Other	N/A
84	Q1	Atovaquone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020500.pdf	10/30/2024	Other	N/A
85	Q1	Auranofin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018689.pdf	10/30/2024	Other	N/A
86	Q1	Avanafil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202276.pdf	10/30/2024	Other	N/A
87	Q1	Avatrombopag Maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210238.pdf	10/30/2024	Other	N/A
88	Q1	Axitinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202324.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
89	Q1	Azilsartan Kamedoxomil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200796.pdf	10/30/2024	Other	N/A
90	Q1	Azilsartan Kamedoxomil; Chlorthalidone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202331.pdf	10/30/2024	Other	N/A
91	Q1	Azithromycin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050711.pdf	10/30/2024	Other	N/A
92	Q1	Azithromycin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050693.pdf	10/30/2024	Other	N/A
93	Q1	Azithromycin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050710.pdf	10/30/2024	Other	N/A
94	Q1	Baclofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021589.pdf	10/30/2024	Other	N/A
95	Q1	Baclofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017851.pdf	10/30/2024	Other	N/A
96	Q1	Baclofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215602.pdf	10/30/2024	Other	N/A
97	Q1	Baclofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215422.pdf	10/30/2024	Other	N/A
98	Q1	Baloxavir Marboxil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210854.pdf	10/30/2024	Other	N/A
99	Q1	Baloxavir Marboxil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214410.pdf	10/30/2024	Other	N/A
100	Q1	Baricitinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207924.pdf	10/30/2024	Other	N/A
101	Q1	Bedaquiline Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204384.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
102	Q1	Belumosudil Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214783.pdf	10/30/2024	Other	N/A
103	Q1	Bempedoic Acid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211616.pdf	10/30/2024	Other	N/A
104	Q1	Bempedoic Acid; Ezetimibe; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211617.pdf	10/30/2024	Other	N/A
105	Q1	Benazepril Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019851.pdf	10/30/2024	Other	N/A
106	Q1	Benazepril Hydrochloride; Hydrochlorothiazide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020033.pdf	10/30/2024	Other	N/A
107	Q1	Benznidazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209570.pdf	10/30/2024	Other	N/A
108	Q1	Berotralstat Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214094.pdf	10/30/2024	Other	N/A
109	Q1	Bexagliflozin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214373.pdf	10/30/2024	Other	N/A
110	Q1	Bicalutamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020498.pdf	10/30/2024	Other	N/A
111	Q1	Binimetinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210498.pdf	10/30/2024	Other	N/A
112	Q1	Bisoprolol Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019982.pdf	10/30/2024	Other	N/A
113	Q1	Bisoprolol Fumarate; Hydrochlorothiazide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020186.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
114	Q1	Boceprevir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202258.pdf	10/30/2024	Other	N/A
115	Q1	Bosentan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021290.pdf	10/30/2024	Other	N/A
116	Q1	Bosentan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209279.pdf	10/30/2024	Other	N/A
117	Q1	Bosutinib Monohydrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203341.pdf	10/30/2024	Other	N/A
118	Q1	Brexpiprazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205422.pdf	10/30/2024	Other	N/A
119	Q1	Brincidofovir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214461.pdf	10/30/2024	Other	N/A
120	Q1	Brivaracetam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205836.pdf	10/30/2024	Other	N/A
121	Q1	Bumetanide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018225.pdf	10/30/2024	Other	N/A
122	Q1	Bupropion Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018644.pdf	10/30/2024	Other	N/A
123	Q1	Buspirone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018731.pdf	10/30/2024	Other	N/A
124	Q1	Cabotegravir Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212887.pdf	10/30/2024	Other	N/A
125	Q1	Calcium Carbonate; Famotidine; Magnesium Hydroxide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020958.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
126	Q1	Canagliflozin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204042.pdf	10/30/2024	Other	N/A
127	Q1	Canagliflozin; Metformin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204353.pdf	10/30/2024	Other	N/A
128	Q1	Candesartan Cilexetil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020838.pdf	10/30/2024	Other	N/A
129	Q1	Candesartan Cilexetil; Hydrochlorothiazide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021093.pdf	10/30/2024	Other	N/A
130	Q1	Capmatinib Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213591.pdf	10/30/2024	Other	N/A
131	Q1	Carbidopa; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017830.pdf	10/30/2024	Other	N/A
132	Q1	Carbidopa; Entacapone; Levodopa; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021485.pdf	10/30/2024	Other	N/A
133	Q1	Carbidopa; Levodopa; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017555.pdf	10/30/2024	Other	N/A
134	Q1	Carbidopa; Levodopa; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_076699.pdf	10/30/2024	Other	N/A
135	Q1	Carglumic Acid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022562.pdf	10/30/2024	Other	N/A
136	Q1	Cariprazine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204370.pdf	10/30/2024	Other	N/A
137	Q1	Carisoprodol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011792.pdf	10/30/2024	Other	N/A
138	Q1	Carvedilol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020297.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
139	Q1	Cefaclor; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050521.pdf	10/30/2024	Other	N/A
140	Q1	Cefadroxil; Cefadroxil Hemihydrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050512.pdf	10/30/2024	Other	N/A
141	Q1	Cefdinir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050739.pdf	10/30/2024	Other	N/A
142	Q1	Cefdinir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050749.pdf	10/30/2024	Other	N/A
143	Q1	Cefditoren Pivoxil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021222.pdf	10/30/2024	Other	N/A
144	Q1	Cefixime; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050621.pdf	10/30/2024	Other	N/A
145	Q1	Cefixime; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203195.pdf	10/30/2024	Other	N/A
146	Q1	Cefixime; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_065380.pdf	10/30/2024	Other	N/A
147	Q1	Cefixime; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050622.pdf	10/30/2024	Other	N/A
148	Q1	Cefpodoxime Proxetil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050675.pdf	10/30/2024	Other	N/A
149	Q1	Cefpodoxime Proxetil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050674.pdf	10/30/2024	Other	N/A
150	Q1	Cefprozil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050664.pdf	10/30/2024	Other	N/A
151	Q1	Cefprozil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050665.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
152	Q1	Cefuroxime Axetil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050672.pdf	10/30/2024	Other	N/A
153	Q1	Cefuroxime Axetil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050605.pdf	10/30/2024	Other	N/A
154	Q1	Celecoxib; Tramadol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213426.pdf	10/30/2024	Other	N/A
155	Q1	Cenobamate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212839.pdf	10/30/2024	Other	N/A
156	Q1	Cephalexin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050405.pdf	10/30/2024	Other	N/A
157	Q1	Cephalexin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050406.pdf	10/30/2024	Other	N/A
158	Q1	Ceritinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211225.pdf	10/30/2024	Other	N/A
159	Q1	Ceritinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205755.pdf	10/30/2024	Other	N/A
160	Q1	Cetirizine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022429.pdf	10/30/2024	Other	N/A
161	Q1	Cetirizine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019835.pdf	10/30/2024	Other	N/A
162	Q1	Cetirizine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021621.pdf	10/30/2024	Other	N/A
163	Q1	Cetirizine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022578.pdf	10/30/2024	Other	N/A
164	Q1	Cevimeline Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020989.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
165	Q1	Chenodiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018513.pdf	10/30/2024	Other	N/A
166	Q1	Chlordiazepoxide Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012249.pdf	10/30/2024	Other	N/A
167	Q1	Chlordiazepoxide Hydrochloride; Clidinium Bromide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012750.pdf	10/30/2024	Other	N/A
168	Q1	Chlorothiazide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011870.pdf	10/30/2024	Other	N/A
169	Q1	Chlorpheniramine Maleate; Ibuprofen; Phenylephrine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022113.pdf	10/30/2024	Other	N/A
170	Q1	Chlorpheniramine Maleate; Ibuprofen; Pseudoephedrine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021441.pdf	10/30/2024	Other	N/A
171	Q1	Chlorpromazine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009149.pdf	10/30/2024	Other	N/A
172	Q1	Chlorthalidone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019574.pdf	10/30/2024	Other	N/A
173	Q1	Chlorthalidone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012283.pdf	10/30/2024	Other	N/A
174	Q1	Chlorzoxazone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011529-Tab-750MG.pdf	10/30/2024	Other	N/A
175	Q1	Cholic Acid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205750.pdf	10/30/2024	Other	N/A
176	Q1	Cimetidine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017920.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
177	Q1	Cinacalcet Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021688.pdf	10/30/2024	Other	N/A
178	Q1	Ciprofloxacin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020780.pdf	10/30/2024	Other	N/A
179	Q1	Ciprofloxacin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019537.pdf	10/30/2024	Other	N/A
180	Q1	Citalopram Hydrobromide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_077668.pdf	10/30/2024	Other	N/A
181	Q1	Citalopram Hydrobromide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215428.pdf	10/30/2024	Other	N/A
182	Q1	Citalopram Hydrobromide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020822.pdf	10/30/2024	Other	N/A
183	Q1	Clarithromycin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050662.pdf	10/30/2024	Other	N/A
184	Q1	Clarithromycin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050698.pdf	10/30/2024	Other	N/A
185	Q1	Clemastine Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017661.pdf	10/30/2024	Other	N/A
186	Q1	Clemastine Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020925.pdf	10/30/2024	Other	N/A
187	Q1	Clindamycin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050162.pdf	10/30/2024	Other	N/A
188	Q1	Clobazam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203993.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
189	Q1	Clobazam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202067.pdf	10/30/2024	Other	N/A
190	Q1	Clomiphene Citrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016131.pdf	10/30/2024	Other	N/A
191	Q1	Clomipramine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019906.pdf	10/30/2024	Other	N/A
192	Q1	Clonazepam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017533.pdf	10/30/2024	Other	N/A
193	Q1	Clonazepam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020813.pdf	10/30/2024	Other	N/A
194	Q1	Clonidine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017407.pdf	10/30/2024	Other	N/A
195	Q1	Clopidogrel Bisulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020839.pdf	10/30/2024	Other	N/A
196	Q1	Clorazepate Dipotassium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017105.pdf	10/30/2024	Other	N/A
197	Q1	Cobicistat; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203094.pdf	10/30/2024	Other	N/A
198	Q1	Cobimetinib Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206192.pdf	10/30/2024	Other	N/A
199	Q1	Colchicine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022352.pdf	10/30/2024	Other	N/A
200	Q1	Colchicine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204820.pdf	10/30/2024	Other	N/A
201	Q1	Crizotinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202570.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
202	Q1	Cyclobenzaprine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017821.pdf	10/30/2024	Other	N/A
203	Q1	Cycloserine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_060593.pdf	10/30/2024	Other	N/A
204	Q1	Daclatasvir Dihydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206843.pdf	10/30/2024	Other	N/A
205	Q1	Dacomitinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211288.pdf	10/30/2024	Other	N/A
206	Q1	Dantrolene Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017443.pdf	10/30/2024	Other	N/A
207	Q1	Dapagliflozin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202293.pdf	10/30/2024	Other	N/A
208	Q1	Dapagliflozin; Saxagliptin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209091.pdf	10/30/2024	Other	N/A
209	Q1	Daprodustat; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216951.pdf	10/30/2024	Other	N/A
210	Q1	Dapsone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_086841.pdf	10/30/2024	Other	N/A
211	Q1	Darolutamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212099.pdf	10/30/2024	Other	N/A
212	Q1	Darunavir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021976.pdf	10/30/2024	Other	N/A
213	Q1	Darunavir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202895.pdf	10/30/2024	Other	N/A
214	Q1	Dasatinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021986.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
215	Q1	Deferiprone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021825.pdf	10/30/2024	Other	N/A
216	Q1	Deflazacort; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208685.pdf	10/30/2024	Other	N/A
217	Q1	Deflazacort; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208684.pdf	10/30/2024	Other	N/A
218	Q1	Delafloxacin meglumine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208610.pdf	10/30/2024	Other	N/A
219	Q1	Delavirdine Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020705.pdf	10/30/2024	Other	N/A
220	Q1	Desipramine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_014399.pdf	10/30/2024	Other	N/A
221	Q1	Desloratadine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021165.pdf	10/30/2024	Other	N/A
222	Q1	Desloratadine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021312.pdf	10/30/2024	Other	N/A
223	Q1	Desmopressin Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019955.pdf	10/30/2024	Other	N/A
224	Q1	Desogestrel; Ethinyl Estradiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020071.pdf	10/30/2024	Other	N/A
225	Q1	Desogestrel; Ethinyl Estradiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021090.pdf	10/30/2024	Other	N/A
226	Q1	Desogestrel; Ethinyl Estradiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020713.pdf	10/30/2024	Other	N/A
227	Q1	Dexamethasone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011664.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
228	Q1	Dexmethylphenidate Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021278.pdf	10/30/2024	Other	N/A
229	Q1	Dexmethylphenidate Hydrochloride; Serdexmethylphenidate Chloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212994.pdf	10/30/2024	Other	N/A
230	Q1	Dextromethorphan Hydrobromide; Quinidine Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021879.pdf	10/30/2024	Other	N/A
231	Q1	Diazepam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_013263.pdf	10/30/2024	Other	N/A
232	Q1	Diazoxide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017453.pdf	10/30/2024	Other	N/A
233	Q1	Dichlorphenamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011366.pdf	10/30/2024	Other	N/A
234	Q1	Diclofenac; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204592.pdf	10/30/2024	Other	N/A
235	Q1	Diclofenac Potassium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022202.pdf	10/30/2024	Other	N/A
236	Q1	Diclofenac Potassium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020142.pdf	10/30/2024	Other	N/A
237	Q1	Dicyclomine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_007409-Cap.pdf	10/30/2024	Other	N/A
238	Q1	Dicyclomine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_007409-Tab.pdf	10/30/2024	Other	N/A
239	Q1	Dienogest; Estradiol Valerate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022252.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
240	Q1	Diflunisal; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018445.pdf	10/30/2024	Other	N/A
241	Q1	Diphenhydramine Citrate; Ibuprofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021394.pdf	10/30/2024	Other	N/A
242	Q1	Diphenhydramine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_005845.pdf	10/30/2024	Other	N/A
243	Q1	Diphenhydramine Hydrochloride; Ibuprofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021393.pdf	10/30/2024	Other	N/A
244	Q1	Diphenhydramine Hydrochloride; Naproxen Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205352.pdf	10/30/2024	Other	N/A
245	Q1	Dipyridamole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012836.pdf	10/30/2024	Other	N/A
246	Q1	Disopyramide Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017447.pdf	10/30/2024	Other	N/A
247	Q1	Disulfiram; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_007883.pdf	10/30/2024	Other	N/A
248	Q1	Dofetilide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020931.pdf	10/30/2024	Other	N/A
249	Q1	Dolasetron Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020623.pdf	10/30/2024	Other	N/A
250	Q1	Dolutegravir Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204790.pdf	10/30/2024	Other	N/A
251	Q1	Dolutegravir Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213983.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
252	Q1	Dolutegravir Sodium; Lamivudine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211994.pdf	10/30/2024	Other	N/A
253	Q1	Dolutegravir Sodium; Rilpivirine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210192.pdf	10/30/2024	Other	N/A
254	Q1	Donepezil Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022568.pdf	10/30/2024	Other	N/A
255	Q1	Donepezil Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020690.pdf	10/30/2024	Other	N/A
256	Q1	Donepezil Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021720.pdf	10/30/2024	Other	N/A
257	Q1	Doxazosin Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019668.pdf	10/30/2024	Other	N/A
258	Q1	Doxepin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022036.pdf	10/30/2024	Other	N/A
259	Q1	Doxepin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016798.pdf	10/30/2024	Other	N/A
260	Q1	Doxycycline; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050641-Cap-100MG.pdf	10/30/2024	Other	N/A
261	Q1	Doxycycline; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050641-Cap-150MG.pdf	10/30/2024	Other	N/A
262	Q1	Doxycycline; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_065070.pdf	10/30/2024	Other	N/A
263	Q1	Doxycycline; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050006.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
264	Q1	Doxycycline Calcium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050480.pdf	10/30/2024	Other	N/A
265	Q1	Doxycycline Hyclate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209844.pdf	10/30/2024	Other	N/A
266	Q1	Doxycycline Hyclate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208253.pdf	10/30/2024	Other	N/A
267	Q1	Doxycycline Hyclate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050007.pdf	10/30/2024	Other	N/A
268	Q1	Doxycycline Hyclate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205931.pdf	10/30/2024	Other	N/A
269	Q1	Doxycycline Hyclate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050533.pdf	10/30/2024	Other	N/A
270	Q1	Dronedarone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022425.pdf	10/30/2024	Other	N/A
271	Q1	Drospirenone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211367.pdf	10/30/2024	Other	N/A
272	Q1	Drospirenone; Estetrol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214154.pdf	10/30/2024	Other	N/A
273	Q1	Drospirenone; Estradiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021355.pdf	10/30/2024	Other	N/A
274	Q1	Drospirenone; Ethinyl Estradiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021676.pdf	10/30/2024	Other	N/A
275	Q1	Drospirenone; Ethinyl Estradiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021098.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
276	Q1	Drospirenone; Ethinyl Estradiol; Levomefolate Calcium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022532.pdf	10/30/2024	Other	N/A
277	Q1	Droxidopa; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203202.pdf	10/30/2024	Other	N/A
278	Q1	Duvelisib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211155.pdf	10/30/2024	Other	N/A
279	Q1	Elacestrant Dihydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217639.pdf	10/30/2024	Other	N/A
280	Q1	Eletriptan Hydrobromide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021016.pdf	10/30/2024	Other	N/A
281	Q1	Eliglustat Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205494.pdf	10/30/2024	Other	N/A
282	Q1	Eltrombopag Olamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022291.pdf	10/30/2024	Other	N/A
283	Q1	Eltrombopag Olamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207027.pdf	10/30/2024	Other	N/A
284	Q1	Eluxadolone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206940.pdf	10/30/2024	Other	N/A
285	Q1	Empagliflozin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204629.pdf	10/30/2024	Other	N/A
286	Q1	Empagliflozin; Linagliptin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206073.pdf	10/30/2024	Other	N/A
287	Q1	Empagliflozin; Metformin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206111.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
288	Q1	Emtricitabine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021500.pdf	10/30/2024	Other	N/A
289	Q1	Emtricitabine; Rilpivirine Hydrochloride; Tenofovir Alafenamide Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208351.pdf	10/30/2024	Other	N/A
290	Q1	Emtricitabine; Rilpivirine Hydrochloride; Tenofovir Disoproxil Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202123.pdf	10/30/2024	Other	N/A
291	Q1	Emtricitabine; Tenofovir Alafenamide Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208215.pdf	10/30/2024	Other	N/A
292	Q1	Emtricitabine; Tenofovir Disoproxil Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021752.pdf	10/30/2024	Other	N/A
293	Q1	Enalapril Maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018998.pdf	10/30/2024	Other	N/A
294	Q1	Enasidenib Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209606.pdf	10/30/2024	Other	N/A
295	Q1	Entacapone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020796.pdf	10/30/2024	Other	N/A
296	Q1	Eplerenone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021437.pdf	10/30/2024	Other	N/A
297	Q1	Eprosartan Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020738.pdf	10/30/2024	Other	N/A
298	Q1	Eprosartan Mesylate; Hydrochlorothiazide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021268.pdf	10/30/2024	Other	N/A
299	Q1	Erdafitinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212018.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
300	Q1	Ertugliflozin; Metformin hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209806.pdf	10/30/2024	Other	N/A
301	Q1	Ertugliflozin; Sitagliptin phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209805.pdf	10/30/2024	Other	N/A
302	Q1	Erythromycin Ethylsuccinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_061904.pdf	10/30/2024	Other	N/A
303	Q1	Erythromycin Ethylsuccinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050207.pdf	10/30/2024	Other	N/A
304	Q1	Erythromycin Ethylsuccinate; Sulfisoxazole Acetyl; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050529.pdf	10/30/2024	Other	N/A
305	Q1	Escitalopram Oxalate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021323.pdf	10/30/2024	Other	N/A
306	Q1	Escitalopram Oxalate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_077660.pdf	10/30/2024	Other	N/A
307	Q1	Eslicarbazepine Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022416.pdf	10/30/2024	Other	N/A
308	Q1	Estradiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_081295.pdf	10/30/2024	Other	N/A
309	Q1	Estradiol; Norethindrone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020907.pdf	10/30/2024	Other	N/A
310	Q1	Estrogens, Esterified; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_083266.pdf	10/30/2024	Other	N/A
311	Q1	Eszopiclone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021476.pdf	10/30/2024	Other	N/A
312	Q1	Ethacrynic Acid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016092.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
313	Q1	Ethambutol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016320.pdf	10/30/2024	Other	N/A
314	Q1	Ethinyl Estradiol; Ethynodiol Diacetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016927.pdf	10/30/2024	Other	N/A
315	Q1	Ethinyl Estradiol; Levonorgestrel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019190.pdf	10/30/2024	Other	N/A
316	Q1	Ethinyl Estradiol; Levonorgestrel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021864.pdf	10/30/2024	Other	N/A
317	Q1	Ethinyl Estradiol; Levonorgestrel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018668.pdf	10/30/2024	Other	N/A
318	Q1	Ethinyl Estradiol; Levonorgestrel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020683.pdf	10/30/2024	Other	N/A
319	Q1	Ethinyl Estradiol; Levonorgestrel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020860.pdf	10/30/2024	Other	N/A
320	Q1	Ethinyl Estradiol; Levonorgestrel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208612.pdf	10/30/2024	Other	N/A
321	Q1	Ethinyl Estradiol; Levonorgestrel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021544.pdf	10/30/2024	Other	N/A
322	Q1	Ethinyl Estradiol; Norethindrone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017576.pdf	10/30/2024	Other	N/A
323	Q1	Ethinyl Estradiol; Norethindrone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018977.pdf	10/30/2024	Other	N/A
324	Q1	Ethinyl Estradiol; Norethindrone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021490.pdf	10/30/2024	Other	N/A
325	Q1	Ethinyl Estradiol; Norethindrone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017735.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
326	Q1	Ethinyl Estradiol; Norethindrone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022573.pdf	10/30/2024	Other	N/A
327	Q1	Ethinyl Estradiol; Norethindrone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022501.pdf	10/30/2024	Other	N/A
328	Q1	Ethinyl Estradiol; Norethindrone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017354.pdf	10/30/2024	Other	N/A
329	Q1	Ethinyl Estradiol; Norethindrone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020130.pdf	10/30/2024	Other	N/A
330	Q1	Ethinyl Estradiol; Norethindrone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021065.pdf	10/30/2024	Other	N/A
331	Q1	Ethinyl Estradiol; Norethindrone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203667.pdf	10/30/2024	Other	N/A
332	Q1	Ethinyl Estradiol; Norethindrone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204654.pdf	10/30/2024	Other	N/A
333	Q1	Ethinyl Estradiol; Norgestimate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019653.pdf	10/30/2024	Other	N/A
334	Q1	Ethinyl Estradiol; Norgestrel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016672.pdf	10/30/2024	Other	N/A
335	Q1	Ethionamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_013026.pdf	10/30/2024	Other	N/A
336	Q1	Ethosuximide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012380.pdf	10/30/2024	Other	N/A
337	Q1	Etodolac; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018922-Cap.pdf	10/30/2024	Other	N/A
338	Q1	Etodolac; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018922-Tab.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
339	Q1	Exemestane; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020753.pdf	10/30/2024	Other	N/A
340	Q1	Ezetimibe; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021445.pdf	10/30/2024	Other	N/A
341	Q1	Ezetimibe; Simvastatin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021687.pdf	10/30/2024	Other	N/A
342	Q1	Ezogabine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022345.pdf	10/30/2024	Other	N/A
343	Q1	Famciclovir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020363.pdf	10/30/2024	Other	N/A
344	Q1	Famotidine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019462.pdf	10/30/2024	Other	N/A
345	Q1	Famotidine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020801.pdf	10/30/2024	Other	N/A
346	Q1	Famotidine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020752.pdf	10/30/2024	Other	N/A
347	Q1	Famotidine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019527.pdf	10/30/2024	Other	N/A
348	Q1	Famotidine; Ibuprofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022519.pdf	10/30/2024	Other	N/A
349	Q1	Febuxostat; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021856.pdf	10/30/2024	Other	N/A
350	Q1	Fedratinib Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212327.pdf	10/30/2024	Other	N/A
351	Q1	Fenofibric Acid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022418.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
352	Q1	Fenoprofen Calcium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017604.pdf	10/30/2024	Other	N/A
353	Q1	Fexofenadine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020625.pdf	10/30/2024	Other	N/A
354	Q1	Fexofenadine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_201373.pdf	10/30/2024	Other	N/A
355	Q1	Fexofenadine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021963.pdf	10/30/2024	Other	N/A
356	Q1	Fexofenadine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020872.pdf	10/30/2024	Other	N/A
357	Q1	Finasteride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020180.pdf	10/30/2024	Other	N/A
358	Q1	Finerenone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215341.pdf	10/30/2024	Other	N/A
359	Q1	Fingolimod Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022527.pdf	10/30/2024	Other	N/A
360	Q1	Fingolimod Lauryl Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214962.pdf	10/30/2024	Other	N/A
361	Q1	Flavoxate Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016769.pdf	10/30/2024	Other	N/A
362	Q1	Flecainide Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018830.pdf	10/30/2024	Other	N/A
363	Q1	Flibanserin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022526.pdf	10/30/2024	Other	N/A
364	Q1	Fluconazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019949.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
365	Q1	Flucytosine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017001.pdf	10/30/2024	Other	N/A
366	Q1	Fludrocortisone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_010060.pdf	10/30/2024	Other	N/A
367	Q1	Fluoxetine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202133.pdf	10/30/2024	Other	N/A
368	Q1	Fluoxetine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021860.pdf	10/30/2024	Other	N/A
369	Q1	Fluoxetine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020974.pdf	10/30/2024	Other	N/A
370	Q1	Fluoxetine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018936.pdf	10/30/2024	Other	N/A
371	Q1	Fluoxetine Hydrochloride; Olanzapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021520.pdf	10/30/2024	Other	N/A
372	Q1	Fluphenazine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011751.pdf	10/30/2024	Other	N/A
373	Q1	Flutamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018554.pdf	10/30/2024	Other	N/A
374	Q1	Fluvastatin Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020261.pdf	10/30/2024	Other	N/A
375	Q1	Fosamprenavir Calcium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021548.pdf	10/30/2024	Other	N/A
376	Q1	Fosinopril Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019915.pdf	10/30/2024	Other	N/A
377	Q1	Fosinopril Sodium; Hydrochlorothiazide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020286.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
378	Q1	Frovatriptan Succinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021006.pdf	10/30/2024	Other	N/A
379	Q1	Furosemide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016273.pdf	10/30/2024	Other	N/A
380	Q1	Futibatinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214801.pdf	10/30/2024	Other	N/A
381	Q1	Gabapentin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020882.pdf	10/30/2024	Other	N/A
382	Q1	Gabapentin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020235.pdf	10/30/2024	Other	N/A
383	Q1	Galantamine Hydrobromide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021169.pdf	10/30/2024	Other	N/A
384	Q1	Ganaxolone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215904.pdf	10/30/2024	Other	N/A
385	Q1	Ganciclovir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020460.pdf	10/30/2024	Other	N/A
386	Q1	Gefitinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206995.pdf	10/30/2024	Other	N/A
387	Q1	Gemifloxacin Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021158.pdf	10/30/2024	Other	N/A
388	Q1	Gilteritinib Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211349.pdf	10/30/2024	Other	N/A
389	Q1	Glasdegib Maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210656.pdf	10/30/2024	Other	N/A
390	Q1	Glimepiride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020496.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
391	Q1	Glimepiride; Pioglitazone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021925.pdf	10/30/2024	Other	N/A
392	Q1	Glimepiride; Rosiglitazone Maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021700.pdf	10/30/2024	Other	N/A
393	Q1	Glipizide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017783.pdf	10/30/2024	Other	N/A
394	Q1	Glipizide; Metformin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021460.pdf	10/30/2024	Other	N/A
395	Q1	Glyburide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020051.pdf	10/30/2024	Other	N/A
396	Q1	Glyburide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017498.pdf	10/30/2024	Other	N/A
397	Q1	Glyburide; Metformin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021178.pdf	10/30/2024	Other	N/A
398	Q1	Granisetron Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020305.pdf	10/30/2024	Other	N/A
399	Q1	Griseofulvin; Microcrystalline; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_062279.pdf	10/30/2024	Other	N/A
400	Q1	Guanfacine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019032.pdf	10/30/2024	Other	N/A
401	Q1	Haloperidol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_015921.pdf	10/30/2024	Other	N/A
402	Q1	Hydralazine Hydrochloride; Isosorbide Dinitrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020727.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
403	Q1	Hydrochlorothiazide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011835.pdf	10/30/2024	Other	N/A
404	Q1	Hydrochlorothiazide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020504.pdf	10/30/2024	Other	N/A
405	Q1	Hydrochlorothiazide; Lisinopril; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019778.pdf	10/30/2024	Other	N/A
406	Q1	Hydrochlorothiazide; Losartan Potassium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020387.pdf	10/30/2024	Other	N/A
407	Q1	Hydrochlorothiazide; Metoprolol Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018303.pdf	10/30/2024	Other	N/A
408	Q1	Hydrochlorothiazide; Olmesartan Medoxomil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021532.pdf	10/30/2024	Other	N/A
409	Q1	Hydrochlorothiazide; Quinapril Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020125.pdf	10/30/2024	Other	N/A
410	Q1	Hydrochlorothiazide; Spironolactone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012616.pdf	10/30/2024	Other	N/A
411	Q1	Hydrochlorothiazide; Triamterene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019129.pdf	10/30/2024	Other	N/A
412	Q1	Hydrochlorothiazide; Triamterene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016042.pdf	10/30/2024	Other	N/A
413	Q1	Hydrochlorothiazide; Valsartan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020818.pdf	10/30/2024	Other	N/A
414	Q1	Hydrochlorothiazide; Irbesartan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020758.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
415	Q1	Hydrocodone Bitartrate; Ibuprofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020716.pdf	10/30/2024	Other	N/A
416	Q1	Hydrocortisone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_008697.pdf	10/30/2024	Other	N/A
417	Q1	Hydromorphone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019892.pdf	10/30/2024	Other	N/A
418	Q1	Hydroxychloroquine Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009768.pdf	10/30/2024	Other	N/A
419	Q1	Hydroxyzine Pamoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011795.pdf	10/30/2024	Other	N/A
420	Q1	Hydroxyzine Pamoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011459.pdf	10/30/2024	Other	N/A
421	Q1	Ibrexafungerp Citrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214900.pdf	10/30/2024	Other	N/A
422	Q1	Ibrutinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210563.pdf	10/30/2024	Other	N/A
423	Q1	Ibrutinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205552.pdf	10/30/2024	Other	N/A
424	Q1	Ibuprofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020402.pdf	10/30/2024	Other	N/A
425	Q1	Ibuprofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021472.pdf	10/30/2024	Other	N/A
426	Q1	Ibuprofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019842.pdf	10/30/2024	Other	N/A
427	Q1	Ibuprofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020516.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
428	Q1	Ibuprofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017463.pdf	10/30/2024	Other	N/A
429	Q1	Ibuprofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019012.pdf	10/30/2024	Other	N/A
430	Q1	Ibuprofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020812.pdf	10/30/2024	Other	N/A
431	Q1	Ibuprofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020601.pdf	10/30/2024	Other	N/A
432	Q1	Ibuprofen Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_201803.pdf	10/30/2024	Other	N/A
433	Q1	Ibuprofen; Phenylephrine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022565.pdf	10/30/2024	Other	N/A
434	Q1	Ibuprofen; Pseudoephedrine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021128.pdf	10/30/2024	Other	N/A
435	Q1	Ibuprofen; Pseudoephedrine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021374.pdf	10/30/2024	Other	N/A
436	Q1	Ibuprofen; Pseudoephedrine hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019771.pdf	10/30/2024	Other	N/A
437	Q1	Icosapent Ethyl; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202057.pdf	10/30/2024	Other	N/A
438	Q1	Idelalisib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205858.pdf	10/30/2024	Other	N/A
439	Q1	Iloperidone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022192.pdf	10/30/2024	Other	N/A
440	Q1	Imipramine Pamoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017090.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
441	Q1	Indapamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018538.pdf	10/30/2024	Other	N/A
442	Q1	Indinavir Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020685.pdf	10/30/2024	Other	N/A
443	Q1	Indomethacin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204768.pdf	10/30/2024	Other	N/A
444	Q1	Indomethacin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016059.pdf	10/30/2024	Other	N/A
445	Q1	Indomethacin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018332.pdf	10/30/2024	Other	N/A
446	Q1	Irbesartan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020757.pdf	10/30/2024	Other	N/A
447	Q1	Isavuconazonium Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207500.pdf	10/30/2024	Other	N/A
448	Q1	Isocarboxazid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011961.pdf	10/30/2024	Other	N/A
449	Q1	Isosorbide Dinitrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012093-Tab-40MG.pdf	10/30/2024	Other	N/A
450	Q1	Isosorbide Dinitrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012093-Tab-30MG.pdf	10/30/2024	Other	N/A
451	Q1	Isradipine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019546.pdf	10/30/2024	Other	N/A
452	Q1	Istradefylline; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022075.pdf	10/30/2024	Other	N/A
453	Q1	Ivabradine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206143.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
454	Q1	Ketoconazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018533.pdf	10/30/2024	Other	N/A
455	Q1	Ketoprofen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018754.pdf	10/30/2024	Other	N/A
456	Q1	Ketorolac Tromethamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019645.pdf	10/30/2024	Other	N/A
457	Q1	Lacosamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022253.pdf	10/30/2024	Other	N/A
458	Q1	Lamivudine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021003.pdf	10/30/2024	Other	N/A
459	Q1	Lamivudine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020564.pdf	10/30/2024	Other	N/A
460	Q1	Lamivudine; Tenofovir Disoproxil Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211284.pdf	10/30/2024	Other	N/A
461	Q1	Lamivudine; Tenofovir Disoproxil Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022344.pdf	10/30/2024	Other	N/A
462	Q1	Lamivudine; Tenofovir Disoproxil Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022141.pdf	10/30/2024	Other	N/A
463	Q1	Lamivudine; Zidovudine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020857.pdf	10/30/2024	Other	N/A
464	Q1	Lamotrigine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020241.pdf	10/30/2024	Other	N/A
465	Q1	Lamotrigine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020764.pdf	10/30/2024	Other	N/A
466	Q1	Lamotrigine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022251.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
467	Q1	Larotrectinib Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210861.pdf	10/30/2024	Other	N/A
468	Q1	Lasmiditan Succinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211280.pdf	10/30/2024	Other	N/A
469	Q1	Leflunomide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020905.pdf	10/30/2024	Other	N/A
470	Q1	Lemborexant; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212028.pdf	10/30/2024	Other	N/A
471	Q1	Lenalidomide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021880.pdf	10/30/2024	Other	N/A
472	Q1	Lesinurad; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207988.pdf	10/30/2024	Other	N/A
473	Q1	Letermovir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209939.pdf	10/30/2024	Other	N/A
474	Q1	Letrozole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020726.pdf	10/30/2024	Other	N/A
475	Q1	Letrozole; Ribociclib Succinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209935.pdf	10/30/2024	Other	N/A
476	Q1	Leucovorin Calcium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018342.pdf	10/30/2024	Other	N/A
477	Q1	Levetiracetam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021035.pdf	10/30/2024	Other	N/A
478	Q1	Levetiracetam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207958.pdf	10/30/2024	Other	N/A
479	Q1	Levocarnitine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018948.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
480	Q1	Levocetirizine Dihydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022064.pdf	10/30/2024	Other	N/A
481	Q1	Levocetirizine Dihydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209089.pdf	10/30/2024	Other	N/A
482	Q1	Levofloxacin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020634.pdf	10/30/2024	Other	N/A
483	Q1	Levonorgestrel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021045.pdf	10/30/2024	Other	N/A
484	Q1	Levorphanol Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_008720.pdf	10/30/2024	Other	N/A
485	Q1	Linagliptin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_201280.pdf	10/30/2024	Other	N/A
486	Q1	Linagliptin; Metformin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_201281.pdf	10/30/2024	Other	N/A
487	Q1	Linezolid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021130.pdf	10/30/2024	Other	N/A
488	Q1	Linezolid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021132.pdf	10/30/2024	Other	N/A
489	Q1	Lisdexamfetamine Dimesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208510.pdf	10/30/2024	Other	N/A
490	Q1	Lisdexamfetamine Dimesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021977.pdf	10/30/2024	Other	N/A
491	Q1	Lisinopril; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019777.pdf	10/30/2024	Other	N/A
492	Q1	Lofexidine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209229.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
493	Q1	Loperamide Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021855.pdf	10/30/2024	Other	N/A
494	Q1	Loperamide Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017694.pdf	10/30/2024	Other	N/A
495	Q1	Loperamide Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019487.pdf	10/30/2024	Other	N/A
496	Q1	Loperamide Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020448.pdf	10/30/2024	Other	N/A
497	Q1	Loperamide Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019860.pdf	10/30/2024	Other	N/A
498	Q1	Loperamide Hydrochloride; Simethicone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020606.pdf	10/30/2024	Other	N/A
499	Q1	Loratadine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021891.pdf	10/30/2024	Other	N/A
500	Q1	Loratadine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020704.pdf	10/30/2024	Other	N/A
501	Q1	Loratadine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019658.pdf	10/30/2024	Other	N/A
502	Q1	Lorazepam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017794.pdf	10/30/2024	Other	N/A
503	Q1	Lumateperone Tosylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209500.pdf	10/30/2024	Other	N/A
504	Q1	Lurasidone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200603.pdf	10/30/2024	Other	N/A
505	Q1	Lusutrombopag; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210923.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
506	Q1	Macitentan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204410.pdf	10/30/2024	Other	N/A
507	Q1	Maraviroc; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022128.pdf	10/30/2024	Other	N/A
508	Q1	Maribavir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215596.pdf	10/30/2024	Other	N/A
509	Q1	Mavacamten; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214998.pdf	10/30/2024	Other	N/A
510	Q1	Mecamylamine hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_010251.pdf	10/30/2024	Other	N/A
511	Q1	Medroxyprogesterone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011839.pdf	10/30/2024	Other	N/A
512	Q1	Mefenamic Acid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_015034.pdf	10/30/2024	Other	N/A
513	Q1	Megestrol Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020264.pdf	10/30/2024	Other	N/A
514	Q1	Meloxicam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021530.pdf	10/30/2024	Other	N/A
515	Q1	Meloxicam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207233.pdf	10/30/2024	Other	N/A
516	Q1	Meloxicam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020938.pdf	10/30/2024	Other	N/A
517	Q1	Meloxicam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211210.pdf	10/30/2024	Other	N/A
518	Q1	Memantine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021487.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
519	Q1	Mesna; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020855.pdf	10/30/2024	Other	N/A
520	Q1	Mestranol; Norethindrone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016659.pdf	10/30/2024	Other	N/A
521	Q1	Metformin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020357.pdf	10/30/2024	Other	N/A
522	Q1	Metformin Hydrochloride; Pioglitazone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021842.pdf	10/30/2024	Other	N/A
523	Q1	Metformin Hydrochloride; Repaglinide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022386.pdf	10/30/2024	Other	N/A
524	Q1	Metformin Hydrochloride; Sitagliptin Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022044.pdf	10/30/2024	Other	N/A
525	Q1	Methazolamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011721.pdf	10/30/2024	Other	N/A
526	Q1	Methenamine Hippurate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017681.pdf	10/30/2024	Other	N/A
527	Q1	Methimazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_007517.pdf	10/30/2024	Other	N/A
528	Q1	Methoxsalen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009048.pdf	10/30/2024	Other	N/A
529	Q1	Methoxsalen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019600.pdf	10/30/2024	Other	N/A
530	Q1	Methsuximide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_010596.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
531	Q1	Methylergonovine Maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_006035.pdf	10/30/2024	Other	N/A
532	Q1	Methylphenidate Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_010187.pdf	10/30/2024	Other	N/A
533	Q1	Methylphenidate Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021475.pdf	10/30/2024	Other	N/A
534	Q1	Methylprednisolone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011153.pdf	10/30/2024	Other	N/A
535	Q1	Methyltestosterone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_083976.pdf	10/30/2024	Other	N/A
536	Q1	Metoclopramide Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017854.pdf	10/30/2024	Other	N/A
537	Q1	Metoclopramide Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022246.pdf	10/30/2024	Other	N/A
538	Q1	Metolazone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017386.pdf	10/30/2024	Other	N/A
539	Q1	Metoprolol Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017963.pdf	10/30/2024	Other	N/A
540	Q1	Metyrosine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017871.pdf	10/30/2024	Other	N/A
541	Q1	Mexiletine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018873.pdf	10/30/2024	Other	N/A
542	Q1	Midodrine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019815.pdf	10/30/2024	Other	N/A
543	Q1	Miglustat; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021348.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
544	Q1	Milnacipran Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022256.pdf	10/30/2024	Other	N/A
545	Q1	Minocycline Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050451.pdf	10/30/2024	Other	N/A
546	Q1	Minocycline Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050649.pdf	10/30/2024	Other	N/A
547	Q1	Minoxidil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018154.pdf	10/30/2024	Other	N/A
548	Q1	Mirtazapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020415.pdf	10/30/2024	Other	N/A
549	Q1	Mirtazapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021208.pdf	10/30/2024	Other	N/A
550	Q1	Mitapivat Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216196.pdf	10/30/2024	Other	N/A
551	Q1	Modafinil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020717.pdf	10/30/2024	Other	N/A
552	Q1	Molindone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017111.pdf	10/30/2024	Other	N/A
553	Q1	Montelukast Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020829.pdf	10/30/2024	Other	N/A
554	Q1	Montelukast Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020830.pdf	10/30/2024	Other	N/A
555	Q1	Montelukast Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021409.pdf	10/30/2024	Other	N/A
556	Q1	Morphine Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022207.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
557	Q1	Moxidectin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210867.pdf	10/30/2024	Other	N/A
558	Q1	Moxifloxacin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021085.pdf	10/30/2024	Other	N/A
559	Q1	Mycophenolate Mofetil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050722.pdf	10/30/2024	Other	N/A
560	Q1	Mycophenolate Mofetil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050759.pdf	10/30/2024	Other	N/A
561	Q1	Mycophenolate Mofetil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050723.pdf	10/30/2024	Other	N/A
562	Q1	Nabumetone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019583.pdf	10/30/2024	Other	N/A
563	Q1	Nadolol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018063.pdf	10/30/2024	Other	N/A
564	Q1	Naldemedine Tosylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208854.pdf	10/30/2024	Other	N/A
565	Q1	Naltrexone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018932.pdf	10/30/2024	Other	N/A
566	Q1	Naproxen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017581.pdf	10/30/2024	Other	N/A
567	Q1	Naproxen; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018965.pdf	10/30/2024	Other	N/A
568	Q1	Naproxen Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018164.pdf	10/30/2024	Other	N/A
569	Q1	Naproxen Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020204.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
570	Q1	Naproxen Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021920.pdf	10/30/2024	Other	N/A
571	Q1	Naratriptan Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020763.pdf	10/30/2024	Other	N/A
572	Q1	Nateglinide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021204.pdf	10/30/2024	Other	N/A
573	Q1	Nebivolol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021742.pdf	10/30/2024	Other	N/A
574	Q1	Nebivolol hydrochloride; Valsartan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206302.pdf	10/30/2024	Other	N/A
575	Q1	Neratinib maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208051.pdf	10/30/2024	Other	N/A
576	Q1	Netupitant; Palonosetron Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205718.pdf	10/30/2024	Other	N/A
577	Q1	Nevirapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020636.pdf	10/30/2024	Other	N/A
578	Q1	Nevirapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020933.pdf	10/30/2024	Other	N/A
579	Q1	Nicardipine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019488.pdf	10/30/2024	Other	N/A
580	Q1	Nimodipine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018869.pdf	10/30/2024	Other	N/A
581	Q1	Nitisinone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206356.pdf	10/30/2024	Other	N/A
582	Q1	Nitisinone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209449.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
583	Q1	Nitrofurantoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009175.pdf	10/30/2024	Other	N/A
584	Q1	Nitrofurantoin Macrocrystalline; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016620.pdf	10/30/2024	Other	N/A
585	Q1	Nitrofurantoin; Nitrofurantoin Macrocrystalline; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020064.pdf	10/30/2024	Other	N/A
586	Q1	Norethindrone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017060.pdf	10/30/2024	Other	N/A
587	Q1	Norethindrone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016954.pdf	10/30/2024	Other	N/A
588	Q1	Norethindrone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018405.pdf	10/30/2024	Other	N/A
589	Q1	Nortriptyline Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018013.pdf	10/30/2024	Other	N/A
590	Q1	Obeticholic Acid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207999.pdf	10/30/2024	Other	N/A
591	Q1	Olanzapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020592.pdf	10/30/2024	Other	N/A
592	Q1	Olanzapine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021086.pdf	10/30/2024	Other	N/A
593	Q1	Olanzapine; Samidorphan L-Malate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213378.pdf	10/30/2024	Other	N/A
594	Q1	Olmesartan Medoxomil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021286.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
595	Q1	Omaveloxolone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216718.pdf	10/30/2024	Other	N/A
596	Q1	Omega-3-Acid Ethyl Esters Type A; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204977.pdf	10/30/2024	Other	N/A
597	Q1	Ondansetron; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020781.pdf	10/30/2024	Other	N/A
598	Q1	Ondansetron Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020103.pdf	10/30/2024	Other	N/A
599	Q1	Osetamivir Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021087.pdf	10/30/2024	Other	N/A
600	Q1	Osetamivir Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021246.pdf	10/30/2024	Other	N/A
601	Q1	Osilodrostat Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212801.pdf	10/30/2024	Other	N/A
602	Q1	Osimertinib Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208065.pdf	10/30/2024	Other	N/A
603	Q1	Ospemifene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203505.pdf	10/30/2024	Other	N/A
604	Q1	Oteseconazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215888.pdf	10/30/2024	Other	N/A
605	Q1	Oxaprozin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018841.pdf	10/30/2024	Other	N/A
606	Q1	Oxazepam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_015539-Cap.pdf	10/30/2024	Other	N/A
607	Q1	Oxcarbazepine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021285.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
608	Q1	Oxcarbazepine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021014.pdf	10/30/2024	Other	N/A
609	Q1	Oxybutynin Chloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017577.pdf	10/30/2024	Other	N/A
610	Q1	Oxycodone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021011.pdf	10/30/2024	Other	N/A
611	Q1	Oxycodone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200534.pdf	10/30/2024	Other	N/A
612	Q1	Oxymetholone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016848.pdf	10/30/2024	Other	N/A
613	Q1	Ozanimod Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209899.pdf	10/30/2024	Other	N/A
614	Q1	Pacritinib Citrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208712.pdf	10/30/2024	Other	N/A
615	Q1	Palbociclib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207103.pdf	10/30/2024	Other	N/A
616	Q1	Palonosetron Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022233.pdf	10/30/2024	Other	N/A
617	Q1	Panobinostat Lactate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205353.pdf	10/30/2024	Other	N/A
618	Q1	Paroxetine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020031.pdf	10/30/2024	Other	N/A
619	Q1	Paroxetine mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021299.pdf	10/30/2024	Other	N/A
620	Q1	Paroxetine Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204516.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
621	Q1	Pemigatinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213736.pdf	10/30/2024	Other	N/A
622	Q1	Penbutolol Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018976.pdf	10/30/2024	Other	N/A
623	Q1	Penicillin V Potassium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_060003.pdf	10/30/2024	Other	N/A
624	Q1	Perampanel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202834.pdf	10/30/2024	Other	N/A
625	Q1	Perampanel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208277.pdf	10/30/2024	Other	N/A
626	Q1	Perindopril Erbumine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020184.pdf	10/30/2024	Other	N/A
627	Q1	Perphenazine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_010775.pdf	10/30/2024	Other	N/A
628	Q1	Phenelzine Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011909.pdf	10/30/2024	Other	N/A
629	Q1	Phentermine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202088.pdf	10/30/2024	Other	N/A
630	Q1	Pilocarpine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020237.pdf	10/30/2024	Other	N/A
631	Q1	Pimavanserin Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210793.pdf	10/30/2024	Other	N/A
632	Q1	Pimavanserin Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207318.pdf	10/30/2024	Other	N/A
633	Q1	Pimozide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017473.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
634	Q1	Pindolol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018285.pdf	10/30/2024	Other	N/A
635	Q1	Pioglitazone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021073.pdf	10/30/2024	Other	N/A
636	Q1	Pirfenidone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208780.pdf	10/30/2024	Other	N/A
637	Q1	Pirfenidone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022535.pdf	10/30/2024	Other	N/A
638	Q1	Piroxicam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018147.pdf	10/30/2024	Other	N/A
639	Q1	Pitavastatin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022363.pdf	10/30/2024	Other	N/A
640	Q1	Pitavastatin Magnesium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208379.pdf	10/30/2024	Other	N/A
641	Q1	Pitavastatin sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209875.pdf	10/30/2024	Other	N/A
642	Q1	Pitolisant Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211150.pdf	10/30/2024	Other	N/A
643	Q1	Pomalidomide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204026.pdf	10/30/2024	Other	N/A
644	Q1	Ponesimod; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213498.pdf	10/30/2024	Other	N/A
645	Q1	Pramipexole Dihydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020667.pdf	10/30/2024	Other	N/A
646	Q1	Prasugrel Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022307.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
647	Q1	Pravastatin Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019898.pdf	10/30/2024	Other	N/A
648	Q1	Praziquantel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018714.pdf	10/30/2024	Other	N/A
649	Q1	Prazosin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017442.pdf	10/30/2024	Other	N/A
650	Q1	Prednisolone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009987.pdf	10/30/2024	Other	N/A
651	Q1	Prednisolone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022067.pdf	10/30/2024	Other	N/A
652	Q1	Prednisolone Sodium Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021959.pdf	10/30/2024	Other	N/A
653	Q1	Pregabalin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021446.pdf	10/30/2024	Other	N/A
654	Q1	Primaquine Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_008316.pdf	10/30/2024	Other	N/A
655	Q1	Prochlorperazine Maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_010571.pdf	10/30/2024	Other	N/A
656	Q1	Promethazine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_007935.pdf	10/30/2024	Other	N/A
657	Q1	Propafenone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019151.pdf	10/30/2024	Other	N/A
658	Q1	Propranolol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016418.pdf	10/30/2024	Other	N/A
659	Q1	Propylthiouracil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_006188.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
660	Q1	Protriptyline Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016012.pdf	10/30/2024	Other	N/A
661	Q1	Prucalopride Succinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210166.pdf	10/30/2024	Other	N/A
662	Q1	Pyrazinamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_080157.pdf	10/30/2024	Other	N/A
663	Q1	Pyridostigmine Bromide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009829.pdf	10/30/2024	Other	N/A
664	Q1	Pyrimethamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_008578.pdf	10/30/2024	Other	N/A
665	Q1	Quetiapine Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020639.pdf	10/30/2024	Other	N/A
666	Q1	Quinapril Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019885.pdf	10/30/2024	Other	N/A
667	Q1	Raloxifene Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020815.pdf	10/30/2024	Other	N/A
668	Q1	Ramelteon; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021782.pdf	10/30/2024	Other	N/A
669	Q1	Ramipril; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022021.pdf	10/30/2024	Other	N/A
670	Q1	Ramipril; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019901.pdf	10/30/2024	Other	N/A
671	Q1	Ranitidine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020095.pdf	10/30/2024	Other	N/A
672	Q1	Ranitidine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020520.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
673	Q1	Ranitidine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018703.pdf	10/30/2024	Other	N/A
674	Q1	Ranitidine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020251.pdf	10/30/2024	Other	N/A
675	Q1	Relugolix; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214621.pdf	10/30/2024	Other	N/A
676	Q1	Repaglinide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020741.pdf	10/30/2024	Other	N/A
677	Q1	Reserpine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009838.pdf	10/30/2024	Other	N/A
678	Q1	Ribavirin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021511.pdf	10/30/2024	Other	N/A
679	Q1	Ribavirin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020903.pdf	10/30/2024	Other	N/A
680	Q1	Ribociclib succinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209092.pdf	10/30/2024	Other	N/A
681	Q1	Rifapentine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021024.pdf	10/30/2024	Other	N/A
682	Q1	Rilpivirine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202022.pdf	10/30/2024	Other	N/A
683	Q1	Rimegepant Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212728.pdf	10/30/2024	Other	N/A
684	Q1	Riociguat; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204819.pdf	10/30/2024	Other	N/A
685	Q1	Risperidone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020272.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
686	Q1	Risperidone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021444.pdf	10/30/2024	Other	N/A
687	Q1	Rivastigmine Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020823.pdf	10/30/2024	Other	N/A
688	Q1	Rizatriptan Benzoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020864.pdf	10/30/2024	Other	N/A
689	Q1	Rizatriptan Benzoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020865.pdf	10/30/2024	Other	N/A
690	Q1	Roflumilast; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022522.pdf	10/30/2024	Other	N/A
691	Q1	Rolapitant Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206500.pdf	10/30/2024	Other	N/A
692	Q1	Ropinirole Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020658.pdf	10/30/2024	Other	N/A
693	Q1	Rosiglitazone Maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021071.pdf	10/30/2024	Other	N/A
694	Q1	Rosuvastatin Calcium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021366.pdf	10/30/2024	Other	N/A
695	Q1	Rufinamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021911.pdf	10/30/2024	Other	N/A
696	Q1	Rufinamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_201367.pdf	10/30/2024	Other	N/A
697	Q1	Ruxolitinib Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202192.pdf	10/30/2024	Other	N/A
698	Q1	Sacubitril; Valsartan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207620.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
699	Q1	Safinamide Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207145.pdf	10/30/2024	Other	N/A
700	Q1	Sapropterin Dihydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022181.pdf	10/30/2024	Other	N/A
701	Q1	Sarecycline Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209521.pdf	10/30/2024	Other	N/A
702	Q1	Saxagliptin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022350.pdf	10/30/2024	Other	N/A
703	Q1	Selegiline Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020647.pdf	10/30/2024	Other	N/A
704	Q1	Selegiline Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021479.pdf	10/30/2024	Other	N/A
705	Q1	Selexipag; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207947.pdf	10/30/2024	Other	N/A
706	Q1	Selpercatinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213246.pdf	10/30/2024	Other	N/A
707	Q1	Sertraline Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215133.pdf	10/30/2024	Other	N/A
708	Q1	Sertraline Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019839.pdf	10/30/2024	Other	N/A
709	Q1	Sibutramine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020632.pdf	10/30/2024	Other	N/A
710	Q1	Sildenafil Citrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020895.pdf	10/30/2024	Other	N/A
711	Q1	Sildenafil Citrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203109.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
712	Q1	Silodosin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022206.pdf	10/30/2024	Other	N/A
713	Q1	Simvastatin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019766.pdf	10/30/2024	Other	N/A
714	Q1	Simvastatin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021961.pdf	10/30/2024	Other	N/A
715	Q1	Simvastatin; Sitagliptin Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202343.pdf	10/30/2024	Other	N/A
716	Q1	Siponimod Fumaric Acid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209884.pdf	10/30/2024	Other	N/A
717	Q1	Sitagliptin Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021995.pdf	10/30/2024	Other	N/A
718	Q1	Sodium Phenylbutyrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020572.pdf	10/30/2024	Other	N/A
719	Q1	Sodium Phenylbutyrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020573.pdf	10/30/2024	Other	N/A
720	Q1	Sodium Phenylbutyrate; Taurursodiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216660.pdf	10/30/2024	Other	N/A
721	Q1	Sofosbuvir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204671.pdf	10/30/2024	Other	N/A
722	Q1	Solifenacin Succinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021518.pdf	10/30/2024	Other	N/A
723	Q1	Solriamfetol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211230.pdf	10/30/2024	Other	N/A
724	Q1	Sotalol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019865.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
725	Q1	Sotalol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021151.pdf	10/30/2024	Other	N/A
726	Q1	Sotorasib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214665.pdf	10/30/2024	Other	N/A
727	Q1	Sparsentan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216403.pdf	10/30/2024	Other	N/A
728	Q1	Spirolactone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209478.pdf	10/30/2024	Other	N/A
729	Q1	Spirolactone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012151.pdf	10/30/2024	Other	N/A
730	Q1	Stavudine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020412.pdf	10/30/2024	Other	N/A
731	Q1	Stiripentol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206709.pdf	10/30/2024	Other	N/A
732	Q1	Stiripentol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207223.pdf	10/30/2024	Other	N/A
733	Q1	Succimer; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019998.pdf	10/30/2024	Other	N/A
734	Q1	Sulfadiazine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_004122.pdf	10/30/2024	Other	N/A
735	Q1	Sulfamethoxazole; Trimethoprim; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017377.pdf	10/30/2024	Other	N/A
736	Q1	Sulfamethoxazole; Trimethoprim; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017560.pdf	10/30/2024	Other	N/A
737	Q1	Sumatriptan Succinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020132.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
738	Q1	Tadalafil; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021368.pdf	10/30/2024	Other	N/A
739	Q1	Tafenoquine Succinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210795.pdf	10/30/2024	Other	N/A
740	Q1	Tafenoquine Succinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210607.pdf	10/30/2024	Other	N/A
741	Q1	Tamoxifen Citrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017970.pdf	10/30/2024	Other	N/A
742	Q1	Tapentadol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022304.pdf	10/30/2024	Other	N/A
743	Q1	Tasimelteon; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214517.pdf	10/30/2024	Other	N/A
744	Q1	Tecovirimat; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208627.pdf	10/30/2024	Other	N/A
745	Q1	Tedizolid Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205435.pdf	10/30/2024	Other	N/A
746	Q1	Telbivudine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022011.pdf	10/30/2024	Other	N/A
747	Q1	Telithromycin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021144.pdf	10/30/2024	Other	N/A
748	Q1	Telotristat Etiprate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208794.pdf	10/30/2024	Other	N/A
749	Q1	Temazepam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018163.pdf	10/30/2024	Other	N/A
750	Q1	Tenofovir Alafenamide Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208464.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
751	Q1	Tenofovir Disoproxil Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021356.pdf	10/30/2024	Other	N/A
752	Q1	Tenofovir Disoproxil Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022577.pdf	10/30/2024	Other	N/A
753	Q1	Tepotinib Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214096.pdf	10/30/2024	Other	N/A
754	Q1	Terazosin Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020347.pdf	10/30/2024	Other	N/A
755	Q1	Terbinafine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020539.pdf	10/30/2024	Other	N/A
756	Q1	Terbinafine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022071.pdf	10/30/2024	Other	N/A
757	Q1	Terbutaline Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017849.pdf	10/30/2024	Other	N/A
758	Q1	Teriflunomide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202992.pdf	10/30/2024	Other	N/A
759	Q1	Testosterone Undecanoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213953.pdf	10/30/2024	Other	N/A
760	Q1	Tetrabenazine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021894.pdf	10/30/2024	Other	N/A
761	Q1	Tetracycline Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050278.pdf	10/30/2024	Other	N/A
762	Q1	Thioridazine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011808.pdf	10/30/2024	Other	N/A
763	Q1	Thiothixene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016584.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
764	Q1	Tiagabine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020646.pdf	10/30/2024	Other	N/A
765	Q1	Ticagrelor; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022433.pdf	10/30/2024	Other	N/A
766	Q1	Ticlopidine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019979.pdf	10/30/2024	Other	N/A
767	Q1	Timolol Maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018017.pdf	10/30/2024	Other	N/A
768	Q1	Tivozanib Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212904.pdf	10/30/2024	Other	N/A
769	Q1	Tizanidine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020397.pdf	10/30/2024	Other	N/A
770	Q1	Tofacitinib Citrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203214.pdf	10/30/2024	Other	N/A
771	Q1	Tolcapone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020697.pdf	10/30/2024	Other	N/A
772	Q1	Tolterodine Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020771.pdf	10/30/2024	Other	N/A
773	Q1	Topiramate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020505.pdf	10/30/2024	Other	N/A
774	Q1	Topiramate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020844.pdf	10/30/2024	Other	N/A
775	Q1	Toremifene Citrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020497.pdf	10/30/2024	Other	N/A
776	Q1	Torseamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020136.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
777	Q1	Torseamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213218.pdf	10/30/2024	Other	N/A
778	Q1	Trandolapril; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020528.pdf	10/30/2024	Other	N/A
779	Q1	Tranylcypromine Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_012342.pdf	10/30/2024	Other	N/A
780	Q1	Trazodone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018207.pdf	10/30/2024	Other	N/A
781	Q1	Triamterene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_013174.pdf	10/30/2024	Other	N/A
782	Q1	Triazolam; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017892.pdf	10/30/2024	Other	N/A
783	Q1	Triclabendazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208711.pdf	10/30/2024	Other	N/A
784	Q1	Trimethoprim; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018679.pdf	10/30/2024	Other	N/A
785	Q1	Trimipramine Maleate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016792.pdf	10/30/2024	Other	N/A
786	Q1	Ubrogepant; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211765.pdf	10/30/2024	Other	N/A
787	Q1	Ulipristal Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022474.pdf	10/30/2024	Other	N/A
788	Q1	Uridine Triacetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208159.pdf	10/30/2024	Other	N/A
789	Q1	Ursodiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020675.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
790	Q1	Ursodiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019594.pdf	10/30/2024	Other	N/A
791	Q1	Valacyclovir Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020487.pdf	10/30/2024	Other	N/A
792	Q1	Valbenazine Tosylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209241.pdf	10/30/2024	Other	N/A
793	Q1	Valganciclovir Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021304.pdf	10/30/2024	Other	N/A
794	Q1	Valsartan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021283.pdf	10/30/2024	Other	N/A
795	Q1	Vandetanib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022405.pdf	10/30/2024	Other	N/A
796	Q1	Vardenafil Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021400.pdf	10/30/2024	Other	N/A
797	Q1	Vardenafil Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200179.pdf	10/30/2024	Other	N/A
798	Q1	Varenicline Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021928.pdf	10/30/2024	Other	N/A
799	Q1	Vericiguat; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214377.pdf	10/30/2024	Other	N/A
800	Q1	Vibegron; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213006.pdf	10/30/2024	Other	N/A
801	Q1	Vilazodone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022567.pdf	10/30/2024	Other	N/A
802	Q1	Vismodegib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203388.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
803	Q1	Vorapaxar Sulfate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204886.pdf	10/30/2024	Other	N/A
804	Q1	Vortioxetine Hydrobromide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204447.pdf	10/30/2024	Other	N/A
805	Q1	Voxelotor; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213137.pdf	10/30/2024	Other	N/A
806	Q1	Voxelotor; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216157.pdf	10/30/2024	Other	N/A
807	Q1	Zalcitabine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020199.pdf	10/30/2024	Other	N/A
808	Q1	Zaleplon; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020859.pdf	10/30/2024	Other	N/A
809	Q1	Zidovudine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019655.pdf	10/30/2024	Other	N/A
810	Q1	Zidovudine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020518.pdf	10/30/2024	Other	N/A
811	Q1	Zileuton; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020471.pdf	10/30/2024	Other	N/A
812	Q1	Ziprasidone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020825.pdf	10/30/2024	Other	N/A
813	Q1	Ziprasidone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021483.pdf	10/30/2024	Other	N/A
814	Q1	Zolmitriptan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020768.pdf	10/30/2024	Other	N/A
815	Q1	Zolmitriptan; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021231.pdf	10/30/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
816	Q1	Zolpidem Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019908.pdf	10/30/2024	Other	N/A
817	Q1	Zonisamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020789.pdf	10/30/2024	Other	N/A
818	Q1	Acalabrutinib Maleate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216387.pdf	11/19/2024	Other	N/A
819	Q1	Adapalene; Benzoyl Peroxide; Clindamycin Phosphate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216632.pdf	11/19/2024	Yes	Section III.C.2.a of GDUFA III Commitment Letter.
820	Q1	Allopurinol; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016084-Sus.pdf	11/19/2024	Other	N/A
821	Q1	Allopurinol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016084.pdf	11/19/2024	Other	N/A
822	Q1	Aripiprazole Lauroxil; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209830.pdf	11/19/2024	Other	N/A
823	Q1	Aripiprazole; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217006.pdf	11/19/2024	Yes	Section III.C.2.a of GDUFA III Commitment Letter.
824	Q1	Azelaic Acid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021470.pdf	11/19/2024	Other	N/A
825	Q1	Bictegravir Sodium; Emtricitabine; Tenofovir Alafenamide Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210251.pdf	11/19/2024	Other	N/A
826	Q1	Budesonide; Formoterol Fumarate Dihydrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021929.pdf	11/19/2024	Other	N/A
827	Q1	Buspirone Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021190.pdf	11/19/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
828	Q1	Cantharidin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212905.pdf	11/19/2024	Other	N/A
829	Q1	Cefazolin Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211413.pdf	11/19/2024	Other	N/A
830	Q1	Clonazepam; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017533-Sus.pdf	11/19/2024	Other	N/A
831	Q1	Cyclosporine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217469.pdf	11/19/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
832	Q1	Dexamethsone; Neomycin Sulfate; Polymyxin B Sulfate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050065.pdf	11/19/2024	Other	N/A
833	Q1	Enfuvirtide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021481.pdf	11/19/2024	Other	N/A
834	Q1	Enzalutamide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213674.pdf	11/19/2024	Other	N/A
835	Q1	Eplontersen Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217388.pdf	11/19/2024	Yes	Section III.C.2.a of GDUFA III Commitment Letter.
836	Q1	Estrogens, Conjugated; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020216.pdf	11/19/2024	Other	N/A
837	Q1	Ferric Carboxymaltose; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203565.pdf	11/19/2024	Other	N/A
838	Q1	Ferumoxytol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022180.pdf	11/19/2024	Other	N/A
839	Q1	Fluticasone Propionate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020833.pdf	11/19/2024	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
840	Q1	Fluticasone Propionate; Salmeterol Xinafoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021077.pdf	11/19/2024	Other	N/A
841	Q1	Formoterol Fumarate; Mometasone Furoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022518.pdf	11/19/2024	Other	N/A
842	Q1	Formoterol Fumarate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020831.pdf	11/19/2024	Other	N/A
843	Q1	Icatibant Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022150.pdf	11/19/2024	Other	N/A
844	Q1	Labetalol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018687.pdf	11/19/2024	Other	N/A
845	Q1	Lenvatinib Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206947.pdf	11/19/2024	Other	N/A
846	Q1	Levonorgestrel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203159.pdf	11/19/2024	Other	N/A
847	Q1	Liraglutide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022341.pdf	11/19/2024	Other	N/A
848	Q1	Losartan Potassium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020386.pdf	11/19/2024	Other	N/A
849	Q1	Macitentan; Tadalafil; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218490.pdf	11/19/2024	Other	N/A
850	Q1	Magnesium sulfate; Polyethylene glycol 3350; Potassium chloride; Sodium chloride; Sodium sulfate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215344.pdf	11/19/2024	Yes	Section III.C.2.a of GDUFA III Commitment Letter.
851	Q1	Memantine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021487-ODT.pdf	11/19/2024	Other	N/A

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852	Q1	Mitomycin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211728.pdf	11/19/2024	Other	N/A
853	Q1	Mometasone Furoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205641.pdf	11/19/2024	Other	N/A
854	Q1	Nepafenac; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021862.pdf	11/19/2024	Other	N/A
855	Q1	Nepafenac; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203491.pdf	11/19/2024	Other	N/A
856	Q1	Nitroglycerin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021359.pdf	11/19/2024	Other	N/A
857	Q1	Olaparib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208558.pdf	11/19/2024	Other	N/A
858	Q1	Paclitaxel; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216338.pdf	11/19/2024	Yes	Section III.C.2.a of GDUFA III Commitment Letter.
859	Q1	Palovarotene; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215559.pdf	11/19/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
860	Q1	Pemetrexed Disodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215179.pdf	11/19/2024	Other	N/A
861	Q1	Phentolamine Mesylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217064.pdf	11/19/2024	Other	N/A
862	Q1	Phytonadione; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_083722.pdf	11/19/2024	Other	N/A
863	Q1	Phytonadione; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_087954.pdf	11/19/2024	Other	N/A
864	Q1	Phytonadione; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_010104.pdf	11/19/2024	Other	N/A

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865	Q1	Phytonadione; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011745.pdf	11/19/2024	Other	N/A
866	Q1	Primidone; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009170.pdf	11/19/2024	Other	N/A
867	Q1	Quizartinib Dihydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216993.pdf	11/19/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
868	Q1	Rasagiline Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021641.pdf	11/19/2024	Other	N/A
869	Q1	Risperidone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213586.pdf	11/19/2024	Yes	Section III.C.2.a of GDUFA III Commitment Letter.
870	Q1	Ritlecitinib Tosylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215830.pdf	11/19/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
871	Q1	Ruxolitinib Phosphate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215309.pdf	11/19/2024	Other	N/A
872	Q1	Salmeterol Xinafoate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020692.pdf	11/19/2024	Other	N/A
873	Q1	Tacrolimus; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050777.pdf	11/19/2024	Other	N/A
874	Q1	Tazarotene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021184-Cre-0.05P.pdf	11/19/2024	Other	N/A
875	Q1	Tiotropium Bromide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021395.pdf	11/19/2024	Other	N/A
876	Q1	Tramadol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020281.pdf	11/19/2024	Other	N/A

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877	Q1	Treprostinil; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214324.pdf	11/19/2024	Other	N/A
878	Q1	Advanced Manufacturing Technologies Designation Program; Final Guidance for Industry www.fda.gov/media/174651/download	12/31/2024	Yes	FD&C Act section 506L
879	Q2	Considerations for Complying with 21 CFR 211.110; Draft Guidance for Industry www.fda.gov/media/184825/download	1/6/2025	Other	N/A
880	Q3	Albuterol Sulfate; Budesonide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214070.pdf	5/20/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter.
881	Q3	Aripiprazole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202971.pdf	5/20/2025	Other	N/A
882	Q3	Benzgalantamine Gluconate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218549.pdf	5/20/2025	Other	N/A
883	Q3	Brimonidine Tartrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218424.pdf	5/20/2025	Other	N/A
884	Q3	Budesonide; Formoterol Fumarate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216579.pdf	5/20/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter.
885	Q3	Carbinoxamine Maleate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_008955-ODT.pdf	5/20/2025	Other	N/A
886	Q3	Ceftobiprole Medocaril Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218275.pdf	5/20/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
887	Q3	Celecoxib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020998.pdf	5/20/2025	Other	N/A
888	Q3	Clobetasol Propionate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218158.pdf	5/20/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter.

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889	Q3	Clonidine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217645.pdf	5/20/2025	Other	N/A
890	Q3	Daridorexant Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214985.pdf	5/20/2025	Other	N/A
891	Q3	Deutetrabenazine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216354.pdf	5/20/2025	Other	N/A
892	Q3	Diazepam; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218623.pdf	5/20/2025	Other	N/A
893	Q3	Epinephrine; Draft Guidance of Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214697.pdf	5/20/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter.
894	Q3	Epinephrine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215875.pdf	5/20/2025	Other	N/A
895	Q3	Epinephrine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205920.pdf	5/20/2025	Other	N/A
896	Q3	Ertugliflozin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209803.pdf	5/20/2025	Other	N/A
897	Q3	Etrasimod Arginine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216956.pdf	5/20/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
898	Q3	Fluticasone Propionate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209022.pdf	5/20/2025	Other	N/A
899	Q3	Gepirone Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021164.pdf	5/20/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
900	Q3	Iptacopan Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218276.pdf	5/20/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter.

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901	Q3	Levoketoconazole; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214133.pdf	5/20/2025	Other	N/A
902	Q3	Levonorgestrel; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208224.pdf	5/20/2025	Other	N/A
903	Q3	Loratadine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021952.pdf	5/20/2025	Other	N/A
904	Q3	Melphalan Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_201848.pdf	5/20/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter.
905	Q3	Metformin Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020357-TabC.pdf	5/20/2025	Other	N/A
906	Q3	Migalastat Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208623.pdf	5/20/2025	Other	N/A
907	Q3	Momelotinib Dihydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216873.pdf	5/20/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
908	Q3	Motixafortide Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217159.pdf	5/20/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
909	Q3	Norgestrel; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017031.pdf	5/20/2025	Other	N/A
910	Q3	Paclitaxel; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211875.pdf	5/20/2025	Other	N/A
911	Q3	Pemetrexed Disodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214218.pdf	5/20/2025	Other	N/A
912	Q3	Pemetrexed Ditromethamine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208746.pdf	5/20/2025	Other	N/A
913	Q3	Pilocarpine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217836.pdf	5/20/2025	Other	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
914	Q3	Repotrectinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_218213.pdf	5/20/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
915	Q3	Risperidone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214835.pdf	5/20/2025	Yes	Section III.C.2.a of GDUFA III Commitment Letter.
916	Q3	Roflumilast; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215985.pdf	5/20/2025	Other	N/A
917	Q3	Selenium Sulfide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_007936.pdf	5/20/2025	Other	N/A
918	Q3	Terbinafine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021958.pdf	5/20/2025	Other	N/A
919	Q3	Terbinafine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021124.pdf	5/20/2025	Other	N/A
920	Q3	Terbinafine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020980.pdf	5/20/2025	Other	N/A
921	Q3	Thalidomide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020785.pdf	5/20/2025	Other	N/A
922	Q3	Tipiracil Hydrochloride; Trifluridine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207981.pdf	5/20/2025	Other	N/A
923	Q3	Tizanidine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021447.pdf	5/20/2025	Other	N/A
924	Q3	Trientine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019194.pdf	5/20/2025	Other	N/A
925	Q3	Vamorolone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215239.pdf	5/20/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter.

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926	Q3	Verapamil Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018593.pdf	5/20/2025	Other	N/A
927	Q3	Zilucoplan Sodium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216834.pdf	5/20/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
928	Q3	Zonisamide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214273.pdf	5/20/2025	Other	N/A
929	Q3	Zuranolone; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217369.pdf	5/20/2025	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
930	Q3	Replacing Color Additives in Approved or Marketed Drug Products; Draft Guidance for Industry www.fda.gov/media/186692/download	5/29/2025	Other	N/A
931	Q3	M13B Bioequivalence for Immediate-Release Solid Oral Dosage Forms: Additional Strengths Biowaiver; Draft Guidance for Industry www.fda.gov/media/186703/download	5/30/2025	Other	N/A
932	Q3	ANDAs: Pre-Submission Facility Correspondence Related to Prioritized Generic Drug Submissions; Final Guidance for Industry www.fda.gov/media/187029/download	6/16/2025	Yes	Section II.F.1.a of GDUFA III Commitment Letter
933	Q3	Post-Warning Letter Meetings Under GDUFA; Final Guidance for Industry www.fda.gov/media/171785/download	6/20/2025	Yes	Section VII.D.12.a of GDUFA III Commitment Letter
934	Q3	Q1 Stability Testing of Drug Substances and Drug Products; Draft Guidance for Industry www.fda.gov/media/187161/download	6/23/2025	Other	N/A
935	Q4	Iron Sucrose; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021135.pdf	08/08/2025	Other	N/A
936	Q4	Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications; Final Guidance for Industry www.fda.gov/media/172290/download	9/11/2025	Other	N/A

Public Meetings

Pursuant to section 744C(a)(2) of the FD&C Act, the table below lists the number and titles of public meetings held on topics related to human generic drug activities and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2022. Public meetings are listed by the quarter in which they were held and are provided in a cumulative format for FY 2025.

Table 2: Public Meetings Held on Topics Related to Human Generic Drug Activities for FY 2025

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	Guidance Development and Regulatory Assessment of Generic Topical and Dermal Drug Products Workshop www.fda.gov/drugs/news-events-human-drugs/guidance-development-and-regulatory-assessment-generic-topical-and-dermal-drug-products-10032024	10/3/2024	No
2	Q1	Scientific and Regulatory Considerations for Assessment of Immunogenicity Risk for Generic Peptide and Oligonucleotide Drug Products www.fda.gov/drugs/news-events-human-drugs/scientific-and-regulatory-considerations-assessment-immunogenicity-risk-generic-peptide-and	10/7/2024-10/8/2024	No
3	Q1	FDA-CDER and HESI Nitrosamine Ames Data Review and Method Development Workshop www.fda.gov/drugs/fda-cder-and-hesi-nitrosamine-ames-data-review-and-method-development-workshop-10152024	10/15/2024-10/16/2024	No
4	Q1	Global IDMP Implementation - Getting Closer to the Goal www.fda.gov/drugs/news-events-human-drugs/global-idmp-implementation-getting-closer-goal-10162024	10/16/2024	No
5	Q1	FDA and Center for Research on Complex Generics Co-Hosted Workshop: Updates on Approaches to Acceptable Intakes of Nitrosamine Drug Substance Related Impurities and Bioequivalence Assessment for Reformulated Drug Products www.fda.gov/drugs/news-events-human-drugs/updates-approaches-acceptable-intakes-nitrosamine-drug-substance-related-impurities-and	11/6/2024-11/7/2024	No
6	Q1	Putting the Pieces Together: REMS Logic Model in REMS Design, Implementation, and Evaluation www.fda.gov/drugs/news-events-human-drugs/putting-pieces-together-rems-logic-model-rems-design-implementation-and-evaluation-11072024	11/7/2024	No
7	Q1	M13A: Bioequivalence for Immediate-Release Solid Oral Dosage Forms - Implementing the Final Guidance www.fda.gov/drugs/news-events-human-drugs/m13a-bioequivalence-immediate-release-solid-oral-dosage-forms-implementing-final-guidance-11212024	11/21/2024	No
8	Q1	FDA and Center for Research on Complex Generics Co-Hosted Workshop: Navigating the Transition to Low Global Warming Potential Propellants www.complexgenerics.org/education-training/navigating-the-transition-to-low-global-warming-potential-propellants/	12/4/2024-12/5/2024	No

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
9	Q2	Navigating Controlled Correspondences to Support Generic Drug Development www.fda.gov/drugs/news-events-human-drugs/navigating-controlled-correspondences-support-generic-drug-development-02272025	2/27/2025	No
10	Q2	Model Master Files: Advancing Modeling and Simulation in Generic Drug Development and Regulatory Submissions www.fda.gov/drugs/news-events-human-drugs/model-master-files-advancing-modeling-and-simulation-generic-drug-development-and-regulatory	3/13/2025	No
11	Q2	Generic Drugs Forum (GDF) 2025 www.fda.gov/drugs/news-events-human-drugs/generic-drugs-forum-gdf-2025-04092025	4/9/2025-4/10/2025	No
12	Q2	FDA and Center for Research on Complex Generics Co-Hosted Workshop: Implementing FDA's IVPT Guidance Recommendations: A Step-By-Step Illustration www.fda.gov/drugs/news-events-human-drugs/implementing-fdas-ivpt-guidance-recommendations-step-step-illustration-04292025	4/29/2025-4/30/2025	No
13	Q3	Fiscal Year 2025 Generic Drug Science and Research Initiatives Public Workshop www.fda.gov/drugs/news-events-human-drugs/fiscal-year-2025-generic-drug-science-and-research-initiatives-public-workshop-06032025	6/3/2025-6/4/2025	Yes
14	Q4	Public Meeting on the Reauthorization of Generic Drug User Fee Amendments (GDUFA) www.fda.gov/drugs/news-events-human-drugs/public-meeting-reauthorization-generic-drug-user-fee-amendments-gdufa-07112025	7/11/2025	Yes
15	Q4	ICH M13B Webinar: Navigating the Draft ICH M13B Additional Strengths Biowaiver Guideline www.fda.gov/drugs/news-events-human-drugs/ich-m13b-webinar-navigating-draft-ich-m13b-additional-strengths-biowaiver-guideline-09112025	9/11/2025	No
16	Q4	FDA/Center for Research on Complex Generics (CRCG) Workshop on Mastering Particle Size Analysis: A Step-By-Step Illustration of Techniques and Best Practices www.fda.gov/drugs/news-events-human-drugs/fda-center-research-complex-generics-crcg-workshop-mastering-particle-size-analysis-step-step	9/23/2025-9/24/2025	No
17	Q4	Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and	9/30/2025	Yes
18	Q4	FDA Public Meeting: Onshoring Manufacturing of Drugs and Biological Products www.fda.gov/drugs/news-events-human-drugs/fda-public-meeting-onshoring-manufacturing-drugs-and-biological-products-09302025	9/30/2025	Yes