



**FDA** U.S. FOOD & DRUG  
ADMINISTRATION

# **FY 2024**

## ***Real Time Report***

*pursuant to the*

**Federal Food, Drug, and Cosmetic Act**

*as amended by the Generic Drug User Fee Amendments of 2022*

## *Acronyms*

**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***

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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.<sup>1</sup>

### **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.”

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<sup>1</sup> This report provides information related to human generic drug activities, which are defined by section 744A(9) of the FD&C Act as specified activities associated with generic drugs and inspection of facilities associated with generic drugs. This report does not include information regarding biosimilar biologic license applications, which is presented in the ‘Real Time’ report pursuant to the Biosimilar User Fee Act.

# Human Generic Drugs

## Guidance Documents

Pursuant to Section 744C(a)(2) of the FD&C Act, the table below lists the number and titles of draft and final guidances on topics related to human generic drug activities and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2022. Guidances are listed by the quarter in which they were issued and are provided in a cumulative format for Fiscal Year (FY) 2024.

**Table 1: Draft and Final Guidance Documents Related to the Human Generic Drug Activities for FY 2024**

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	Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities; Draft Guidance for Industry <a href="http://www.fda.gov/media/173286/download">www.fda.gov/media/173286/download</a>	10/26/2023	Other	N/A
2	Q1	Albuterol Sulfate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020503.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020503.pdf</a>	11/16/2023	Other	N/A
3	Q1	Azacitidine; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214120.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214120.pdf</a>	11/16/2023	Other	N/A
4	Q1	Betamethasone Acetate; Betamethasone Sodium Phosphate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_014602.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_014602.pdf</a>	11/16/2023	Other	N/A
5	Q1	Budesonide; Formoterol Fumarate Dihydrate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021929.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021929.pdf</a>	11/16/2023	Other	N/A
6	Q1	Chlorhexidine Gluconate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017768.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017768.pdf</a>	11/16/2023	Other	N/A
7	Q1	Cimetidine; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017920.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017920.pdf</a>	11/16/2023	Other	N/A
8	Q1	Citalopram Hydrobromide; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215428.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215428.pdf</a>	11/16/2023	Other	N/A
9	Q1	Deucravacitinib; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214958.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214958.pdf</a>	11/16/2023	Yes	Section III.C.1 of GDUFA II Commitment Letter.
10	Q1	Deutetrabenazine; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216354.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216354.pdf</a>	11/16/2023	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)
11	Q1	Dextroamphetamine; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215401.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215401.pdf</a>	11/16/2023	Other	N/A
12	Q1	Edaravone; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215446.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215446.pdf</a>	11/16/2023	Other	N/A
13	Q1	Emtricitabine; Tenofovir Alafenamide Fumarate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208215.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208215.pdf</a>	11/16/2023	Other	N/A
14	Q1	Ferric Pyrophosphate Citrate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208551.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208551.pdf</a>	11/16/2023	Other	N/A
15	Q1	Ferric Pyrophosphate Citrate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206317.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206317.pdf</a>	11/16/2023	Other	N/A
16	Q1	Ferric Pyrophosphate Citrate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212860.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212860.pdf</a>	11/16/2023	Other	N/A
17	Q1	Ferumoxytol; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022180.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022180.pdf</a>	11/16/2023	Other	N/A
18	Q1	Fingolimod Lauryl Sulfate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214962.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214962.pdf</a>	11/16/2023	Other	N/A
19	Q1	Fluticasone Propionate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021433.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021433.pdf</a>	11/16/2023	Other	N/A
20	Q1	Fluticasone Propionate; Salmeterol Xinafoate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021254.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021254.pdf</a>	11/16/2023	Other	N/A
21	Q1	Fulvestrant; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021344.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021344.pdf</a>	11/16/2023	Other	N/A
22	Q1	Furosemide; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209988.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209988.pdf</a>	11/16/2023	Yes	Section III.C.2.a of GDUFA III Commitment Letter.
23	Q1	Futibatinib; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214801.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214801.pdf</a>	11/16/2023	Yes	Section III.C.1 of GDUFA II Commitment Letter.
24	Q1	Gabapentin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022544.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022544.pdf</a>	11/16/2023	Other	N/A
25	Q1	Ganaxolone; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215904.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215904.pdf</a>	11/16/2023	Yes	Section III.C.1 of GDUFA II Commitment Letter.

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
26	Q1	Glatiramer Acetate; Revised Draft Guidance for <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020622.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020622.pdf</a>	11/16/2023	Other	N/A
27	Q1	Glycopyrrolate; Neostigmine Methylsulfate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216903.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216903.pdf</a>	11/16/2023	Other	N/A
28	Q1	Halobetasol Propionate; Tazarotene; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209354.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209354.pdf</a>	11/16/2023	Other	N/A
29	Q1	Latanoprost; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216472.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216472.pdf</a>	11/16/2023	Other	N/A
30	Q1	Levalbuterol Tartrate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021730.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021730.pdf</a>	11/16/2023	Other	N/A
31	Q1	Mometasone Furoate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205641.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205641.pdf</a>	11/16/2023	Other	N/A
32	Q1	Naltrexone; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021897.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021897.pdf</a>	11/16/2023	Other	N/A
33	Q1	Omidenepag Isopropyl; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215092.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215092.pdf</a>	11/16/2023	Yes	Section III.C.1 of GDUFA II Commitment Letter.
34	Q1	Primidone; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009170.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009170.pdf</a>	11/16/2023	Other	N/A
35	Q1	Risperidone; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210655.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210655.pdf</a>	11/16/2023	Other	N/A
36	Q1	Semaglutide; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215256.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215256.pdf</a>	11/16/2023	Other	N/A
37	Q1	Semaglutide; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209637.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209637.pdf</a>	11/16/2023	Other	N/A
38	Q1	Sotorasib; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214665.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214665.pdf</a>	11/16/2023	Other	N/A
39	Q1	Soybean Oil; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017643.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017643.pdf</a>	11/16/2023	Other	N/A
40	Q1	Tapinarof; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215272.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215272.pdf</a>	11/16/2023	Other	N/A
41	Q1	Tiotropium Bromide; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021395.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021395.pdf</a>	11/16/2023	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)
42	Q1	Clindamycin Phosphate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050600.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050600.pdf</a>	11/21/2023	Other	N/A
43	Q1	Inclisiran Sodium; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214012.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214012.pdf</a>	11/21/2023	Other	N/A
44	Q1	Ruxolitinib Phosphate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215309.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215309.pdf</a>	11/21/2023	Other	N/A
45	Q1	Advanced Manufacturing Technologies Designation Program; Draft Guidance for Industry <a href="http://www.fda.gov/media/174651/download">www.fda.gov/media/174651/download</a>	12/13/2023	Other	N/A
46	Q1	Data Standards for Drug and Biological Product Submissions Containing Real-World Data; Final Guidance for Industry <a href="http://www.fda.gov/media/153341/download">www.fda.gov/media/153341/download</a>	12/22/2023	Other	N/A
47	Q1	Real-World Data: Assessing Registries To Support Regulatory Decision-Making for Drug and Biological Products; Final Guidance for Industry <a href="http://www.fda.gov/media/154449/download">www.fda.gov/media/154449/download</a>	12/22/2023	Other	N/A
48	Q1	Quality Considerations for Topical Ophthalmic Drug Products; Draft Guidance for Industry <a href="http://www.fda.gov/media/172937/download">www.fda.gov/media/172937/download</a>	12/27/2023	Other	N/A
49	Q1	Reformulating Drug Products That Contain Carbomers Manufactured With Benzene; Final Guidance for Industry <a href="http://www.fda.gov/media/175083/download">www.fda.gov/media/175083/download</a>	12/28/2023	Other	N/A
50	Q2	Requests for Reconsideration at the Division Level Under GDUFA; Draft Guidance for Industry <a href="http://www.fda.gov/media/108398/download">www.fda.gov/media/108398/download</a>	1/10/2024	Other	N/A
51	Q2	Revising ANDA Labeling Following Revision of the RLD Labeling; Final Guidance for Industry <a href="http://www.fda.gov/media/175654/download">www.fda.gov/media/175654/download</a>	1/24/2024	Other	N/A
52	Q2	ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs; Final Guidance for Industry <a href="http://www.fda.gov/media/119718/download">www.fda.gov/media/119718/download</a>	1/24/2024	Other	N/A
53	Q2	Abacavir Sulfate; Dolutegravir Sodium; Lamivudine; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215413.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215413.pdf</a>	2/15/2024	Other	N/A
54	Q2	Acidinium Bromide; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202450.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202450.pdf</a>	2/15/2024	Other	N/A
55	Q2	Acidinium Bromide; Formoterol Fumarate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210595.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210595.pdf</a>	2/15/2024	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)
56	Q2	Adagrasib; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216340.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216340.pdf</a>	2/15/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
57	Q2	Albuterol Sulfate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205636.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205636.pdf</a>	2/15/2024	Other	N/A
58	Q2	Amoxicillin; Clarithromycin; Vonoprazan Fumarate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215152.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215152.pdf</a>	2/15/2024	Yes	Section III.C.1 of GDUFA II Commitment Letter.
59	Q2	Amoxicillin; Vonoprazan Fumarate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215153.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215153.pdf</a>	2/15/2024	Other	N/A
60	Q2	Aprepitant; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209296.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209296.pdf</a>	2/15/2024	Other	N/A
61	Q2	Baclofen; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215422.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215422.pdf</a>	2/15/2024	Other	N/A
62	Q2	Betamethasone Dipropionate; Clotrimazole; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020010.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020010.pdf</a>	2/15/2024	Other	N/A
63	Q2	Betamethasone Dipropionate; Clotrimazole; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018827.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018827.pdf</a>	2/15/2024	Other	N/A
64	Q2	Budesonide; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021949.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021949.pdf</a>	2/15/2024	Other	N/A
65	Q2	Budesonide; Formoterol Fumarate; Glycopyrrolate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212122.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212122.pdf</a>	2/15/2024	Other	N/A
66	Q2	Caffeine; Ergotamine Tartrate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_086557.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_086557.pdf</a>	2/15/2024	Other	N/A
67	Q2	Dapsone; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207154.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207154.pdf</a>	2/15/2024	Other	N/A
68	Q2	Dapsone; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021794.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021794.pdf</a>	2/15/2024	Other	N/A
69	Q2	Dexamethasone; Neomycin Sulfate; Polymyxin B Sulfate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050023.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050023.pdf</a>	2/15/2024	Other	N/A
70	Q2	Dexamethasone; Tobramycin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050616.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050616.pdf</a>	2/15/2024	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)
71	Q2	Dexamethasone; Tobramycin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050592.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050592.pdf</a>	2/15/2024	Other	N/A
72	Q2	Dexamethasone; Tobramycin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050818.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050818.pdf</a>	2/15/2024	Other	N/A
73	Q2	Diazepam; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211635.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211635.pdf</a>	2/15/2024	Other	N/A
74	Q2	Doxepin Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022036.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022036.pdf</a>	2/15/2024	Other	N/A
75	Q2	Durlobactam Sodium; Durlobactam Sodium; Sulbactam Sodium; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216974.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216974.pdf</a>	2/15/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
76	Q2	Elagolix Sodium, Estradiol, Norethindrone Acetate; Elagolix Sodium; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213388.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213388.pdf</a>	2/15/2024	Other	N/A
77	Q2	Ferric Carboxymaltose; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203565.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203565.pdf</a>	2/15/2024	Other	N/A
78	Q2	Ferric Derisomaltose; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208171.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208171.pdf</a>	2/15/2024	Other	N/A
79	Q2	Finasteride; Tadalafil; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215423.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215423.pdf</a>	2/15/2024	Other	N/A
80	Q2	Flutufolastat F-18 Gallium; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216023.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216023.pdf</a>	2/15/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
81	Q2	Fluorometholone; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016851.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016851.pdf</a>	2/15/2024	Other	N/A
82	Q2	Fluticasone Furoate; Umeclidinium Bromide; Vilanterol Trifenatate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209482.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209482.pdf</a>	2/15/2024	Other	N/A
83	Q2	Fluticasone Propionate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208798.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208798.pdf</a>	2/15/2024	Other	N/A
84	Q2	Fluticasone Propionate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020833.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020833.pdf</a>	2/15/2024	Other	N/A

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85	Q2	Fluticasone Propionate; Salmeterol Xinafoate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021077.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021077.pdf</a>	2/15/2024	Other	N/A
86	Q2	Fluticasone Propionate; Salmeterol Xinafoate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208799.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208799.pdf</a>	2/15/2024	Other	N/A
87	Q2	Formoterol Fumarate; Glycopyrrolate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208294.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208294.pdf</a>	2/15/2024	Other	N/A
88	Q2	Hydrocortisone; Neomycin Sulfate; Polymyxin B Sulfate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_060613.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_060613.pdf</a>	2/15/2024	Other	N/A
89	Q2	Lenacapavir Sodium; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215974.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215974.pdf</a>	2/15/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
90	Q2	Lenacapavir Sodium; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215973.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215973.pdf</a>	2/15/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
91	Q2	Loteprednol Etabonate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020583.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020583.pdf</a>	2/15/2024	Other	N/A
92	Q2	Loteprednol Etabonate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200738.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200738.pdf</a>	2/15/2024	Other	N/A
93	Q2	Loteprednol Etabonate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020803.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020803.pdf</a>	2/15/2024	Other	N/A
94	Q2	Loteprednol Etabonate; Tobramycin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050804.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050804.pdf</a>	2/15/2024	Other	N/A
95	Q2	Mannitol; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022368.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022368.pdf</a>	2/15/2024	Other	N/A
96	Q2	Mannitol; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202049.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202049.pdf</a>	2/15/2024	Other	N/A
97	Q2	Mometasone Furoate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021067.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021067.pdf</a>	2/15/2024	Other	N/A
98	Q2	Naloxone Hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208969.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208969.pdf</a>	2/15/2024	Yes	Section III.C.2.a of GDUFA III Commitment Letter.

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99	Q2	Nilotinib Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022068.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022068.pdf</a>	2/15/2024	Other	N/A
100	Q2	Niraparib Tosylate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214876.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214876.pdf</a>	2/15/2024	Other	N/A
101	Q2	Olutasidenib; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215814.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215814.pdf</a>	2/15/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
102	Q2	Rivaroxaban; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215859.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215859.pdf</a>	2/15/2024	Other	N/A
103	Q2	Salmeterol Xinafoate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020692.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020692.pdf</a>	2/15/2024	Other	N/A
104	Q2	Sertraline Hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215133.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215133.pdf</a>	2/15/2024	Other	N/A
105	Q2	Sodium Phenylbutyrate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214860.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214860.pdf</a>	2/15/2024	Other	N/A
106	Q2	Sodium Phenylbutyrate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216513.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216513.pdf</a>	2/15/2024	Other	N/A
107	Q2	Sodium Phenylbutyrate; Taurursodiol; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216660.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216660.pdf</a>	2/15/2024	Yes	Section III.C.1 of GDUFA II Commitment letter.
108	Q2	Terlipressin Acetate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022231.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022231.pdf</a>	2/15/2024	Yes	Section III.C.1 of GDUFA II Commitment letter.
109	Q2	Testosterone Undecanoate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213953.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213953.pdf</a>	2/15/2024	Other	N/A
110	Q2	Umeclidinium Bromide; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205382.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205382.pdf</a>	2/15/2024	Other	N/A
111	Q2	Umeclidinium Bromide; Vilanterol Trifenatate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203975.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203975.pdf</a>	2/15/2024	Other	N/A
112	Q2	Vandetanib; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022405.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022405.pdf</a>	2/15/2024	Other	N/A
113	Q2	Xenon Xe-129 Hyperpolarized; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214375.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214375.pdf</a>	2/15/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter.

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114	Q2	Zanamivir; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021036.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021036.pdf</a>	2/15/2024	Other	N/A
115	Q2	Q2(R2) Validation of Analytical Procedures; Final Guidance for Industry <a href="http://www.fda.gov/media/161201/download">www.fda.gov/media/161201/download</a>	3/6/2024	Other	N/A
116	Q2	Q14 Analytical Procedure Development; Final Guidance for Industry <a href="http://www.fda.gov/media/161202/download">www.fda.gov/media/161202/download</a>	3/7/2024	Other	N/A
117	Q2	Annual Reportable Labeling Changes for New Drug Applications and Abbreviated New Drug Applications for Nonprescription Drug Products; Draft Guidance for Industry <a href="http://www.fda.gov/media/176915/download">www.fda.gov/media/176915/download</a>	3/13/2024	Other	N/A
118	Q2	Controlled Correspondence Related to Generic Drug Development; Final Guidance for Industry <a href="http://www.fda.gov/media/164111/download">www.fda.gov/media/164111/download</a>	3/18/2024	Other	N/A
119	Q2	Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products; Draft Guidance for Industry <a href="http://www.fda.gov/media/177128/download">www.fda.gov/media/177128/download</a>	3/21/2024	Other	N/A
120	Q2	Handling and Retention of Bioavailability BA and Bioequivalence BE Testing Samples; Draft Guidance for Industry <a href="http://www.fda.gov/media/71393/download">www.fda.gov/media/71393/download</a>	3/27/2024	Other	N/A
121	Q3	Oxymetazoline hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212520.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212520.pdf</a>	4/2/2024	Other	N/A
122	Q3	Electronic Submission of Expedited Safety Reports from Investigational New Drug-Exempt Bioavailability/Bioequivalence Studies <a href="http://www.fda.gov/media/177371/download">www.fda.gov/media/177371/download</a>	4/2/2024	Other	N/A
123	Q3	Data Integrity for In Vivo Bioavailability and Bioequivalence Studies <a href="http://www.fda.gov/media/177404/download">www.fda.gov/media/177404/download</a>	4/3/2024	Other	N/A
124	Q3	Content and Format of Composition Statement and Corresponding Statement of Ingredients in Labeling in NDAs and ANDAs; Draft Guidance for Industry <a href="http://www.fda.gov/media/178099/download">www.fda.gov/media/178099/download</a>	4/29/2024	Other	N/A
125	Q3	REMS Logic Model: A Framework to Link Program Design With Assessment; Draft Guidance for Industry <a href="http://www.fda.gov/media/178291/download">www.fda.gov/media/178291/download</a>	5/7/2024	Other	PDUFA VII I.M.1.a.
126	Q3	Atorvastatin Calcium; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213260.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213260.pdf</a>	5/16/2024	Other	N/A
127	Q3	Baclofen; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215602.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215602.pdf</a>	5/16/2024	Other	N/A
128	Q3	Benzoyl Peroxide; Erythromycin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050557.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050557.pdf</a>	5/16/2024	Other	N/A

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129	Q3	Benzoyl Peroxide; Erythromycin' Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050769.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050769.pdf</a>	5/16/2024	Other	N/A
130	Q3	Bexagliflozin; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214373.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214373.pdf</a>	5/16/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
131	Q3	Daprodustat; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216951.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216951.pdf</a>	5/16/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
132	Q3	Elacestrant Dihydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217639.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217639.pdf</a>	5/16/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter.
133	Q3	Fluticasone Furoate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205625.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205625.pdf</a>	5/16/2024	Other	N/A
134	Q3	Fluticasone Furoate; Vilanterol Trifenatate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204275.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204275.pdf</a>	5/16/2024	Other	N/A
135	Q3	Gadopiclenol; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216986.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216986.pdf</a>	5/16/2024	Yes	Section III.C.1 of GDUFA II Commitment letter.
136	Q3	Ganciclovir; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022211.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022211.pdf</a>	5/16/2024	Other	N/A
137	Q3	Ganirelix Acetate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021057.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021057.pdf</a>	5/16/2024	Other	N/A
138	Q3	Indomethacin; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018332.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018332.pdf</a>	5/16/2024	Other	N/A
139	Q3	Lacosamide; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216185.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216185.pdf</a>	5/16/2024	Other	N/A
140	Q3	Levodopa; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209184.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209184.pdf</a>	5/16/2024	Other	N/A
141	Q3	Lidocaine Hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022221.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022221.pdf</a>	5/16/2024	Other	N/A
142	Q3	Liraglutide; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206321.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206321.pdf</a>	5/16/2024	Other	N/A
143	Q3	Lotilaner; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217603.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217603.pdf</a>	5/16/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter

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144	Q3	Nalmefene Hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217470.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217470.pdf</a>	5/16/2024	Yes	Section III.C.2.a of GDUFA III Commitment Letter.
145	Q3	Nitrofurantoin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009175.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009175.pdf</a>	5/16/2024	Other	N/A
146	Q3	Omaveloxolone; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216718.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216718.pdf</a>	5/16/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter
147	Q3	Oxazepam; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_015539-Cap.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_015539-Cap.pdf</a>	5/16/2024	Other	N/A
148	Q3	Pegcetacoplan; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215014.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215014.pdf</a>	5/16/2024	Other	N/A
149	Q3	Perfluorohexyloctane; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216675.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216675.pdf</a>	5/16/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter
150	Q3	Pirtobrutinib; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216059.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216059.pdf</a>	5/16/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter
151	Q3	Rezafungin Acetate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217417.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217417.pdf</a>	5/16/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter
152	Q3	Sodium Oxybate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214755.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214755.pdf</a>	5/16/2024	Other	N/A
153	Q3	Sparsentan; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216403.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216403.pdf</a>	5/16/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter
154	Q3	Tasimelteon; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214517.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214517.pdf</a>	5/16/2024	Other	N/A
155	Q3	Tobramycin; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_201688.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_201688.pdf</a>	5/16/2024	Other	N/A
156	Q3	Tretinoin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020475.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020475.pdf</a>	5/16/2024	Other	N/A
157	Q3	Zavegepant Hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216386.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216386.pdf</a>	5/16/2024	Yes	Section III.C.2.a of GDUFA III Commitment Letter.
158	Q3	Processes and Practices Applicable to Bioresearch Monitoring Inspections; Draft Guidance for Industry <a href="http://www.fda.gov/media/179027/download">www.fda.gov/media/179027/download</a>	6/5/2024	Other	N/A

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159	Q3	Q&A Manufacturing and Testing Controls for Ophthalmic Sterility <a href="http://www.fda.gov/drugs/guidances-drugs/questions-and-answers-current-good-manufacturing-practice-regulations-production-and-process#23">www.fda.gov/drugs/guidances-drugs/questions-and-answers-current-good-manufacturing-practice-regulations-production-and-process#23</a>	5/24/2024	No	N/A
160	Q3	Facility Readiness: Goal Date Decisions Under GDUFA; Final Guidance for Industry <a href="http://www.fda.gov/media/162018/download">www.fda.gov/media/162018/download</a>	6/18/2024	Yes	Section I.A.3 of GDUFA III Commitment Letter
161	Q3	Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies; Draft Guidance for Industry <a href="http://www.fda.gov/media/179593/download">www.fda.gov/media/179593/download</a>	6/26/2024	Other	N/A
162	Q3	Essential Drug Delivery Outputs for Devices Intended to Deliver Drugs and Biological Products; Draft Guidance for Industry <a href="http://www.fda.gov/media/179545/download">www.fda.gov/media/179545/download</a>	6/28/2024	Other	N/A
163	Q4	M14 General Principles on Plan, Design, and Analysis of Pharmacoepidemiological Studies That Utilize Real-World Data for Safety Assessment of Medicines; Draft Guidance for Industry <a href="http://www.fda.gov/media/179795/download">www.fda.gov/media/179795/download</a>	7/5/2024	No	N/A
168	Q4	Product-Specific Guidance Meetings Between FDA and ANDA Applicants Under GDUFA; Final Guidance for Industry <a href="http://www.fda.gov/media/165468/download">www.fda.gov/media/165468/download</a>	8/20/2024	Other	N/A
169	Q4	Air Polymer-Type A; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212279.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212279.pdf</a>	8/22/2024	Other	N/A
170	Q4	Albuterol Sulfate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_2020503.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_2020503.pdf</a>	8/22/2024	Other	N/A
171	Q4	Albuterol Sulfate; Ipratropium Bromide; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_2021747.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_2021747.pdf</a>	8/22/2024	Other	N/A
172	Q4	Apalutamide; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210951.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210951.pdf</a>	8/22/2024	Other	N/A
173	Q4	Azelaic Acid; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_2020428.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_2020428.pdf</a>	8/22/2024	Other	N/A
174	Q4	Bempedoic Acid; Ezetimibe; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211617.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211617.pdf</a>	8/22/2024	Other	N/A
175	Q4	Budesonide; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_2021949.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_2021949.pdf</a>	8/22/2024	Other	N/A
176	Q4	Bupropion Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_2020358.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_2020358.pdf</a>	8/22/2024	Other	N/A

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177	Q4	Carvedilol Phosphate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022012.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022012.pdf</a>	8/22/2024	Other	N/A
178	Q4	Ciprofloxacin Hydrochloride; Hydrocortisone; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020805.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020805.pdf</a>	8/22/2024	Other	N/A
179	Q4	Ciprofloxacin; Dexamethasone; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021537.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021537.pdf</a>	8/22/2024	Other	N/A
180	Q4	Cladribine; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022561.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022561.pdf</a>	8/22/2024	Other	N/A
181	Q4	Dalfampridine; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022250.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022250.pdf</a>	8/22/2024	Other	N/A
182	Q4	Dapagliflozin; Metformin Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205649.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205649.pdf</a>	8/22/2024	Other	N/A
183	Q4	Donepezil Hydrochloride; Memantine Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206439.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206439.pdf</a>	8/22/2024	Other	N/A
184	Q4	Fentanyl Citrate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022569.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022569.pdf</a>	8/22/2024	Other	N/A
185	Q4	Ferric Citrate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205874.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205874.pdf</a>	8/22/2024	Other	N/A
186	Q4	Fezolinetant; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216578.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216578.pdf</a>	8/22/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter
187	Q4	Fluticasone Furoate; Umeclidinium Bromide; Vilanterol Trifenatate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209482.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209482.pdf</a>	8/22/2024	Other	N/A
188	Q4	Fluticasone Propionate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021433.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021433.pdf</a>	8/22/2024	Other	N/A
189	Q4	Fluticasone Propionate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020833.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020833.pdf</a>	8/22/2024	Other	N/A
190	Q4	Fluticasone Propionate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208798.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208798.pdf</a>	8/22/2024	Other	N/A



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191	Q4	Fluticasone Propionate; Salmeterol Xinafoate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208799.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208799.pdf</a>	8/22/2024	Other	N/A
192	Q4	Fluticasone Propionate; Salmeterol Xinafoate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021254.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021254.pdf</a>	8/22/2024	Other	N/A
193	Q4	Fluticasone Propionate; Salmeterol Xinafoate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021077.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021077.pdf</a>	8/22/2024	Other	N/A
194	Q4	Halobetasol Propionate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019968.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019968.pdf</a>	8/22/2024	Other	N/A
195	Q4	Heparin Sodium; Taurolidine; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214520.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214520.pdf</a>	8/22/2024	Yes	Section III.C.2.a of GDUFA III Commitment Letter
196	Q4	Hydrochlorothiazide; Metoprolol Succinate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021956.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021956.pdf</a>	8/22/2024	Other	N/A
197	Q4	Hydromorphone Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021217.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021217.pdf</a>	8/22/2024	Other	N/A
198	Q4	Ibrutinib; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210563.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210563.pdf</a>	8/22/2024	Other	N/A
199	Q4	Leniolisib Phosphate; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217759.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217759.pdf</a>	8/22/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter
200	Q4	Levalbuterol Tartrate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021730.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021730.pdf</a>	8/22/2024	Other	N/A
201	Q4	Levomilnacipran Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204168.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204168.pdf</a>	8/22/2024	Other	N/A
202	Q4	Memantine Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022525.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022525.pdf</a>	8/22/2024	Other	N/A
203	Q4	Metformin Hydrochloride; Saxagliptin Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200678.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200678.pdf</a>	8/22/2024	Other	N/A
204	Q4	Metformin Hydrochloride; Sitagliptin Phosphate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202270.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202270.pdf</a>	8/22/2024	Other	N/A

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205	Q4	Mometasone Furoate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021067.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021067.pdf</a>	8/22/2024	Other	N/A
206	Q4	Morphine Sulfate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019516.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019516.pdf</a>	8/22/2024	Other	N/A
207	Q4	Morphine Sulfate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021260.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021260.pdf</a>	8/22/2024	Other	N/A
208	Q4	Morphine Sulfate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020616.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020616.pdf</a>	8/22/2024	Other	N/A
209	Q4	Naloxone Hydrochloride; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217722.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217722.pdf</a>	8/22/2024	Yes	Section III.C.2.a of GDUFA III Commitment Letter
210	Q4	Naloxone Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208411.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208411.pdf</a>	8/22/2024	Other	N/A
211	Q4	Nedosiran Sodium; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215842.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215842.pdf</a>	8/22/2024	Yes	Section III.C.2.a of GDUFA III Commitment Letter
212	Q4	Nirmatrelvir; Ritonavir; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217188.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217188.pdf</a>	8/22/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter
213	Q4	Olodaterol Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203108.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203108.pdf</a>	8/22/2024	Other	N/A
214	Q4	Olodaterol Hydrochloride; Tiotropium Bromide; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206756.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206756.pdf</a>	8/22/2024	Other	N/A
215	Q4	Oxcarbazepine; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202810.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202810.pdf</a>	8/22/2024	Other	N/A
216	Q4	Oxymorphone Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021610.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021610.pdf</a>	8/22/2024	Other	N/A
217	Q4	Pegcetacoplan; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217171.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217171.pdf</a>	8/22/2024	Yes	Section III.C.2.a of GDUFA III Commitment Letter
218	Q4	Phentermine Hydrochloride; Topiramate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022580.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022580.pdf</a>	8/22/2024	Other	N/A

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219	Q4	Posaconazole; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205053.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205053.pdf</a>	8/22/2024	Other	N/A
220	Q4	Pramipexole Dihydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022421.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022421.pdf</a>	8/22/2024	Other	N/A
221	Q4	Progesterone; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022057.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022057.pdf</a>	8/22/2024	Other	N/A
222	Q4	Promethazine Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_010926.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_010926.pdf</a>	8/22/2024	Other	N/A
223	Q4	Quetiapine Fumarate; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022047.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022047.pdf</a>	8/22/2024	Other	N/A
224	Q4	Risperidone; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212849.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212849.pdf</a>	8/22/2024	Yes	Section III.C.2.a of GDUFA III Commitment Letter
225	Q4	Sotagliflozin; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216203.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_216203.pdf</a>	8/22/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter
226	Q4	Tacrolimus; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206406.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206406.pdf</a>	8/22/2024	Other	N/A
227	Q4	Tafuprost; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202514.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202514.pdf</a>	8/22/2024	Other	N/A
228	Q4	Tapentadol Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200533.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200533.pdf</a>	8/22/2024	Other	N/A
229	Q4	Teriparatide; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021318.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021318.pdf</a>	8/22/2024	Other	N/A
230	Q4	Tiotropium Bromide; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021936.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021936.pdf</a>	8/22/2024	Other	N/A
231	Q4	Tofersen; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215887.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_215887.pdf</a>	8/22/2024	Yes	Section III.C.2.a of GDUFA III Commitment Letter
232	Q4	Tramadol Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021692.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021692.pdf</a>	8/22/2024	Other	N/A
233	Q4	Trofinetide; Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217026.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_217026.pdf</a>	8/22/2024	Yes	Section III.C.2.c of GDUFA III Commitment Letter

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
234	Q4	Trospium Chloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022103.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022103.pdf</a>	8/22/2024	Other	N/A
235	Q4	Venlafaxine Hydrochloride; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022104.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022104.pdf</a>	8/22/2024	Other	N/A
236	Q4	Verteporfin; Revised Draft Guidance for Industry <a href="http://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021119.pdf">www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021119.pdf</a>	8/22/2024	Other	N/A
237	Q4	Control of Nitrosamine Impurities in Human Drugs; Final Guidance for Industry <a href="http://www.fda.gov/media/141720/download">www.fda.gov/media/141720/download</a>	9/5/2024	No	N/A
238	Q4	ANDA Submissions – Amendments to Abbreviated New Drug Applications under GDUFA; Final Guidance for Industry <a href="http://www.fda.gov/media/89258/download">www.fda.gov/media/89258/download</a>	9/11/24	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 2024.

**Table 2: Public Meetings Held on Topics Related to Human Generic Drug Activities for FY 2024**

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	2023 NanoDay Symposium: Continuous Manufacturing of Nanomaterials <a href="http://www.fda.gov/drugs/news-events-human-drugs/2023-nanoday-symposium-continuous-manufacturing-nanomaterials-10112023">www.fda.gov/drugs/news-events-human-drugs/2023-nanoday-symposium-continuous-manufacturing-nanomaterials-10112023</a>	10/11/2023	No
2	Q1	FDA and Center for Research on Complex Generics Co-Hosted Workshop: Advances in PBPK Modeling and its Regulatory Utility for Oral Drug Product Development <a href="http://www.fda.gov/news-events/advances-pbpbk-modeling-and-its-regulatory-utility-oral-drug-product-development-10122023">www.fda.gov/news-events/advances-pbpbk-modeling-and-its-regulatory-utility-oral-drug-product-development-10122023</a>	10/12/2023	No

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
3	Q1	FDA   CTTI Meeting on Mitigating Clinical Study Disruptions During Disasters and Public Health Emergencies <a href="http://www.fda.gov/drugs/news-events-human-drugs/fdactti-meeting-mitigating-clinical-study-disruptions-during-disasters-and-public-health-emergencies">www.fda.gov/drugs/news-events-human-drugs/fdactti-meeting-mitigating-clinical-study-disruptions-during-disasters-and-public-health-emergencies</a>	10/18/2023-10/19/2023	FDORA 3605
4	Q1	Pharmaceutical Quality Symposium 2023: Quality, Supply Chain & Advanced Manufacturing <a href="http://www.fda.gov/drugs/news-events-human-drugs/pharmaceutical-quality-symposium-2023-quality-supply-chain-advanced-manufacturing-10312023">www.fda.gov/drugs/news-events-human-drugs/pharmaceutical-quality-symposium-2023-quality-supply-chain-advanced-manufacturing-10312023</a>	10/31/2023-11/1/2023	No
5	Q1	Positron Emission Tomography: Product Quality Regulatory Submissions, Facility Inspections, and Benefit-Risk Considerations <a href="http://www.fda.gov/drugs/news-events-human-drugs/positron-emission-tomography-product-quality-regulatory-submissions-facility-inspections-and-benefit">www.fda.gov/drugs/news-events-human-drugs/positron-emission-tomography-product-quality-regulatory-submissions-facility-inspections-and-benefit</a>	11/13/2023-11/14/2023	No
6	Q1	FDA   CTTI Public Workshop to Enhance Clinical Study Diversity <a href="http://www.fda.gov/drugs/news-events-human-drugs/discussing-approaches-enhance-clinical-study-diversity-public-workshop-11292023">www.fda.gov/drugs/news-events-human-drugs/discussing-approaches-enhance-clinical-study-diversity-public-workshop-11292023</a>	11/29/2023-11/30/2023	FDORA 3603
7	Q1	FDA and Center for Research on Complex Generics Co-Hosted Workshop: Characterization of Complex Excipients and Formulations <a href="http://www.complexgenerics.org/education-training/characterization-of-complex-excipients-formulations/">www.complexgenerics.org/education-training/characterization-of-complex-excipients-formulations/</a>	12/07/2023	No
8	Q2	A Deep Dive: FDA's Model-Integrated Evidence (MIE) Industry Meeting Pilot Program for Generic Drugs <a href="http://www.fda.gov/drugs/news-events-human-drugs/deep-dive-fdas-model-integrated-evidence-mie-industry-meeting-pilot-program-generic-drugs-01182024">www.fda.gov/drugs/news-events-human-drugs/deep-dive-fdas-model-integrated-evidence-mie-industry-meeting-pilot-program-generic-drugs-01182024</a>	1/18/2024	No
9	Q2	Expanding Generic Drug Access Through International Engagements <a href="http://www.fda.gov/drugs/news-events-human-drugs/expanding-generic-drug-access-through-international-engagements-02282024">www.fda.gov/drugs/news-events-human-drugs/expanding-generic-drug-access-through-international-engagements-02282024</a>	2/28/2024	No
10	Q2	Product Quality Research Institute (PQRI) Workshop: MIDD Approaches in Pediatric Formulation Development <a href="http://www.fda.gov/drugs/news-events-human-drugs/product-quality-research-institute-pqri-workshop-midd-approaches-pediatric-formulation-development">www.fda.gov/drugs/news-events-human-drugs/product-quality-research-institute-pqri-workshop-midd-approaches-pediatric-formulation-development</a>	2/28/2024-2/29/2024	No
11	Q2	FDA and Center for Research on Complex Generics Co-Hosted Workshop: Drug-Device Combination Products: Updates and Challenges with Demonstrating Generic Substitutability <a href="http://www.complexgenerics.org/education-training/drug-device-combination-products-updates-and-challenges-with-demonstrating-generic-substitutability/">www.complexgenerics.org/education-training/drug-device-combination-products-updates-and-challenges-with-demonstrating-generic-substitutability/</a>	3/14/2024-3/15/2024	No
12	Q3	Generic Drugs Forum (GDF) 2024: Regulatory Considerations to Enhance Generic Drug Access <a href="http://www.fda.gov/drugs/news-events-human-drugs/generic-drugs-forum-gdf-2024-regulatory-considerations-enhance-generic-drug-access-04102024">www.fda.gov/drugs/news-events-human-drugs/generic-drugs-forum-gdf-2024-regulatory-considerations-enhance-generic-drug-access-04102024</a>	4/10/2024-4/11/2024	No

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
13	Q3	PQRI/EUFEPS Global Bioequivalence Harmonisation Initiative (GBHI): 6th International Workshop <a href="http://www.fda.gov/drugs/news-events-human-drugs/pqrieufeps-global-bioequivalence-harmonisation-initiative-gbhi-6th-international-workshop-04162024">www.fda.gov/drugs/news-events-human-drugs/pqrieufeps-global-bioequivalence-harmonisation-initiative-gbhi-6th-international-workshop-04162024</a>	4/16/2024-4/17/2024	No
14	Q3	PQRI Workshop: Challenges and Opportunities for Modified Release Oral Drug Product Development <a href="http://www.fda.gov/drugs/news-events-human-drugs/pqri-workshop-challenges-and-opportunities-modified-release-oral-drug-product-development-04182024">www.fda.gov/drugs/news-events-human-drugs/pqri-workshop-challenges-and-opportunities-modified-release-oral-drug-product-development-04182024</a>	4/18/2024	No
15	Q3	Streamlining Drug Development and Improving Public Health through Quantitative Medicine: An Introduction to the CDER Quantitative Medicine Center of Excellence <a href="http://www.fda.gov/drugs/news-events-human-drugs/streamlining-drug-development-and-improving-public-health-through-quantitative-medicine-introduction">www.fda.gov/drugs/news-events-human-drugs/streamlining-drug-development-and-improving-public-health-through-quantitative-medicine-introduction</a>	4/25/2024	No
16	Q3	Facilitating Generic Drug Product Development through Product-Specific Guidances <a href="http://www.fda.gov/drugs/news-events-human-drugs/facilitating-generic-drug-product-development-through-product-specific-guidances-04252024">www.fda.gov/drugs/news-events-human-drugs/facilitating-generic-drug-product-development-through-product-specific-guidances-04252024</a>	4/25/2024	No
17	Q3	FDA and Center for Research on Complex Generics Co-Hosted Workshop: Considerations and Potential Regulatory Applications for a Model Master File <a href="http://www.complexgenerics.org/education-training/considerations-and-potential-regulatory-applications-for-a-model-master-file/">www.complexgenerics.org/education-training/considerations-and-potential-regulatory-applications-for-a-model-master-file/</a>	5/2/2024-5/3/2024	No
18	Q3	Redesigned Pre-Submission Meetings in GDUFA III: Benefits for ANDA Submission and Approval <a href="http://www.fda.gov/drugs/news-events-human-drugs/redesigned-pre-submission-meetings-gdufa-iii-benefits-anda-submission-and-approval-05092024">www.fda.gov/drugs/news-events-human-drugs/redesigned-pre-submission-meetings-gdufa-iii-benefits-anda-submission-and-approval-05092024</a>	5/9/2024	No
19	Q3	Fiscal Year 2024 Generic Drug Science and Research Initiatives Public Workshop <a href="http://www.fda.gov/drugs/news-events-human-drugs/fiscal-year-2024-generic-drug-science-and-research-initiatives-public-workshop-05202024">www.fda.gov/drugs/news-events-human-drugs/fiscal-year-2024-generic-drug-science-and-research-initiatives-public-workshop-05202024</a>	5/20/2024-5/21/2024	Yes
20	Q3	2024 Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments <a href="http://www.fda.gov/drugs/news-events-human-drugs/2024-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act">www.fda.gov/drugs/news-events-human-drugs/2024-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act</a>	6/6/2024	Yes
21	Q3	OSIS Workshop: CDER Bioavailability/Bioequivalence Study Sites and Inspections of Good Laboratory Practice <a href="http://www.fda.gov/drugs/news-events-human-drugs/osis-workshop-cder-bioavailabilitybioequivalence-study-sites-and-inspections-good-laboratory">www.fda.gov/drugs/news-events-human-drugs/osis-workshop-cder-bioavailabilitybioequivalence-study-sites-and-inspections-good-laboratory</a>	6/13/2024	No
25	Q4	Evaluating Excipient Safety in Pediatric Populations: Current Thinking from a Bioequivalence Perspective <a href="http://www.fda.gov/drugs/news-events-human-drugs/evaluating-excipient-safety-pediatric-populations-current-thinking-bioequivalence-perspective">www.fda.gov/drugs/news-events-human-drugs/evaluating-excipient-safety-pediatric-populations-current-thinking-bioequivalence-perspective</a>	8/8/2024	No
28	Q4	2024 PDA/ FDA Joint Regulatory Conference <a href="http://www.fda.gov/news-events/2024-pda-fda-joint-regulatory-conference-09092024">www.fda.gov/news-events/2024-pda-fda-joint-regulatory-conference-09092024</a>	9/9/2024-9/11/2024	No

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
29	Q4	ANDA Submissions – Amendments to Abbreviated New Drug Applications under GDUFA <a href="http://www.fda.gov/drugs/news-events-human-drugs/anda-submissions-amendments-abbreviated-new-drug-applications-under-gdufa-09102024">www.fda.gov/drugs/news-events-human-drugs/anda-submissions-amendments-abbreviated-new-drug-applications-under-gdufa-09102024</a>	9/10/2024	No
30	Q4	Advancing Generic Drug Development: Translating Science to Approval 2024 <a href="http://www.fda.gov/drugs/news-events-human-drugs/advancing-generic-drug-development-translating-science-approval-2024-09242024">www.fda.gov/drugs/news-events-human-drugs/advancing-generic-drug-development-translating-science-approval-2024-09242024</a>	9/24/2024-9/25/2024	No