
# FY 2021

## *Real Time Report*

*pursuant to the*

## *Generic Drug User Fee Amendments*

*as amended by the FDA Reauthorization Act of 2017*

# *Acronyms*

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

**FDA** – Food and Drug Administration

**FDARA** – FDA Reauthorization Act of 2017

**FY** – Fiscal Year (October 1 to September 30)

**GDUFA** – Generic Drug User Fee Amendments

**Q1** – Quarter 1 (October 1 to December 31)

**Q2** – Quarter 2 (January 1 to March 31)

**Q3** – Quarter 3 (April 1 to June 30)

**Q4** – Quarter 4 (July 1 to September 30)

# Background

On August 18, 2017, the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52) was signed into law. FDARA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to revise and extend the user fee programs for human drugs, biologics, generic drugs, medical devices, and biosimilar biological products.

Section 744C(a)(2) of the FD&C Act, as added by section 903 of FDARA, requires the Food and Drug Administration (FDA) to provide "Real Time" reporting, posted on a quarterly basis, of guidance documents and public meetings related to human generic drug activities.[1]

**Real Time Reporting Under Section 744C(a)(2) of the FD&C Act**

This report is being issued pursuant to the requirement of Section 744C(a)(2) of the FD&C Act, which states:

> "Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary [of Health and Human Services] shall post…on the internet website of the Food and Drug Administration…
>
> - "The number and titles of draft and final guidance on topics related to human generic drug activities and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017."
> - "The number and titles of public meetings held on topics related to human generic drug activities and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017."

[1] This report provides information related to human generic drug activities, which are defined by section 744A(9) of the FD&C Act as 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 Biosimilars User Fee Act.

# *Human Generic Drugs*

## Guidance Documents

Pursuant to Section 744C(a)(2) of the FD&C Act, the table below lists the number and titles of draft and final guidances on topics related to human generic drug activities and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017. Guidances are listed by the quarter in which they were issued and are provided in a cumulative format for Fiscal Year (FY) 2021.

**Table 1: Draft and Final Guidance Documents Related to the Human Generic Drug Activities for FY 2021**

| 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 | The Use of Physiologically Based Pharmacokinetic Analyses — Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls www.fda.gov/media/142500/download | 10/1/2020 | Other | NA |
| 2 | Q1 | Referencing Approved Drug Products in ANDA Submissions; Final Guidance for Industry www.fda.gov/media/102360/download | 10/27/2020 | None | N/A |
| 3 | Q1 | Tiotropium Bromide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021936.pdf | 11/18/2020 | Other | N/A |
| 4 | Q1 | Azelaic Acid; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207071.pdf | 11/19/2020 | Other | N/A |
| 5 | Q1 | Budesonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205613.pdf | 11/19/2020 | Other | N/A |
| 6 | Q1 | Bupropion Hydrochloride; Naltrexone Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200063.pdf | 11/19/2020 | Other | N/A |
| 7 | Q1 | Calcipotriene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022563.pdf | 11/19/2020 | Other | N/A |
| 8 | Q1 | Ceritinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211225.pdf | 11/19/2020 | Other | N/A |
| 9 | Q1 | Clobazam; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210833.pdf | 11/19/2020 | 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) |
|---|---|---|---|---|---|
| 10 | Q1 | Clobetasol Propionate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022013.pdf | 11/19/2020 | Other | N/A |
| 11 | Q1 | Crofelemer; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202292.pdf | 11/19/2020 | Other | N/A |
| 12 | Q1 | Desonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021978.pdf | 11/19/2020 | Other | N/A |
| 13 | Q1 | Diazepam; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211635.pdf | 11/19/2020 | Other | N/A |
| 14 | Q1 | Epinephrine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205920.pdf | 11/19/2020 | Other | N/A |
| 15 | Q1 | Erythromycin Ethylsuccinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_061904.pdf | 11/19/2020 | Other | N/A |
| 16 | Q1 | Erythromycin Ethylsuccinate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050207.pdf | 11/19/2020 | Other | N/A |
| 17 | Q1 | Erythromycin Ethylsuccinate; Sulfisoxazole Acetyl; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050529.pdf | 11/19/2020 | Other | N/A |
| 18 | Q1 | Fluorodopa F-18; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_200655.pdf | 11/19/2020 | Other | N/A |
| 19 | Q1 | Fluphenazine Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_011751.pdf | 11/19/2020 | Other | N/A |
| 20 | Q1 | Hydrocortisone Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017351.pdf | 11/19/2020 | Other | N/A |
| 21 | Q1 | Isotretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021951.pdf | 11/19/2020 | 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) |
|---|---|---|---|---|---|
| 22 | Q1 | Isotretinoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018662.pdf | 11/19/2020 | Other | N/A |
| 23 | Q1 | Lefamulin Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211672.pdf | 11/19/2020 | Other | N/A |
| 24 | Q1 | Levorphanol Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_008720.pdf | 11/19/2020 | Other | N/A |
| 25 | Q1 | Lomitapide Mesylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203858.pdf | 11/19/2020 | Other | N/A |
| 26 | Q1 | Methylphenidate Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207960.pdf | 11/19/2020 | Other | N/A |
| 27 | Q1 | Naloxone Hydrochloride; Oxycodone Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205777.pdf | 11/19/2020 | Other | N/A |
| 28 | Q1 | Pimavanserin Tartrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207318.pdf | 11/19/2020 | Other | N/A |
| 29 | Q1 | Pretomanid; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212862.pdf | 11/19/2020 | Other | N/A |
| 30 | Q1 | Prochlorperazine Maleate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_010571.pdf | 11/19/2020 | Other | N/A |
| 31 | Q1 | Propranolol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016418.pdf | 11/19/2020 | Other | N/A |
| 32 | Q1 | Propranolol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021438.pdf | 11/19/2020 | Other | N/A |

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|---|---|---|---|---|---|
| 33 | Q1 | Propranolol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018553.pdf | 11/19/2020 | Other | N/A |
| 34 | Q1 | Tafamidis Meglumine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211996.pdf | 11/19/2020 | Other | N/A |
| 35 | Q1 | Tiotropium Bromide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021936.pdf | 11/19/2020 | Other | N/A |
| 36 | Q1 | Tofacitinib Citrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208246.pdf | 11/19/2020 | Other | N/A |
| 37 | Q1 | Vancomycin Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208910.pdf | 11/19/2020 | Other | N/A |
| 38 | Q1 | Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA; Final Guidance for Industry www.fda.gov/media/107626/download | 11/24/2020 | Yes | GDUFA Commitment Letter Section III (Pre-ANDA Program) |
| 39 | Q1 | Controlled Correspondence Related to Generic Drug Development; Final Guidance for Industry www.fda.gov/media/109232/download | 12/16/2020 | Other | N/A |
| 40 | Q1 | Review Timelines for Applicant Responses to Complete Response Letters When a Facility Assessment Is Needed During the COVID-19 Public Health Emergency Guidance for Industry www.fda.gov/media/144690/download | 12/21/2020 | Other | N/A |
| 41 | Q2 | Protecting Participants in Bioequivalence Studies for Abbreviated New Drug Applications During the COVID-19 Public Health Emergency; Final Guidance for Industry www.fda.gov/media/145162/download | 01/15/2021 | None | N/A |
| 42 | Q2 | Bremelanotide Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210557.pdf | 3/25/2021 | Other | N/A |
| 43 | Q2 | Calcifediol; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208010.pdf | 3/25/2021 | Other | N/A |
| 44 | Q2 | Cannabidiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210365.pdf | 3/25/2021 | Other | N/A |
| 45 | Q2 | Ciclesonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021658.pdf | 3/25/2021 | 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) |
|---|---|---|---|---|---|
| 46 | Q2 | Cysteamine Bitartrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213491.pdf | 3/25/2021 | Other | N/A |
| 47 | Q2 | Degarelix Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022201.pdf | 3/25/2021 | Other | N/A |
| 48 | Q2 | Doxycycline Hyclate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050533.pdf | 3/25/2021 | Other | N/A |
| 49 | Q2 | Elexacaftor, Ivacaftor, Tezacaftor; Ivacaftor; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212273.pdf | 3/25/2021 | Other | N/A |
| 50 | Q2 | Entrectinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212725.pdf | 3/25/2021 | Other | N/A |
| 51 | Q2 | Ethinyl Estradiol; Levonorgestrel; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208612.pdf | 3/25/2021 | Other | N/A |
| 52 | Q2 | Ethinyl Estradiol; Levonorgestrel; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209405.pdf | 3/25/2021 | Other | N/A |
| 53 | Q2 | Fedratinib Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212327.pdf | 3/25/2021 | Other | N/A |
| 54 | Q2 | Fenoprofen Calcium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017604.pdf | 3/25/2021 | Other | N/A |
| 55 | Q2 | Ferric Maltol; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212320.pdf | 3/25/2021 | Other | N/A |
| 56 | Q2 | Guanfacine Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019032.pdf | 3/25/2021 | Other | N/A |
| 57 | Q2 | Ipratropium Bromide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021527.pdf | 3/25/2021 | Other | N/A |
| 58 | Q2 | Istradefylline; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022075.pdf | 3/25/2021 | Other | N/A |
| 59 | Q2 | Ivacaftor; Ivacaftor, Tezacaftor; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210491.pdf | 3/25/2021 | Other | N/A |
| 60 | Q2 | Labetalol Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_018687.pdf | 3/25/2021 | Other | N/A |

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|---|---|---|---|---|---|
| 61 | Q2 | Ledipasvir; Sofosbuvir; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212477.pdf | 3/25/2021 | Other | N/A |
| 62 | Q2 | Monomethyl Fumarate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210296.pdf | 3/25/2021 | Other | N/A |
| 63 | Q2 | Nitazoxanide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021497.pdf | 3/25/2021 | Other | N/A |
| 64 | Q2 | Nitazoxanide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021498.pdf | 3/25/2021 | Other | N/A |
| 65 | Q2 | Octreotide Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208232.pdf | 3/25/2021 | Other | N/A |
| 66 | Q2 | Octreotide Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213224.pdf | 3/25/2021 | Other | N/A |
| 67 | Q2 | Pazopanib Hydrochloride; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022465.pdf | 3/25/2021 | Other | N/A |
| 68 | Q2 | Penicillin G Benzathine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050141.pdf | 3/25/2021 | Other | N/A |
| 69 | Q2 | Regorafenib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203085.pdf | 3/25/2021 | Other | N/A |
| 70 | Q2 | Rucaparib Camsylate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209115.pdf | 3/25/2021 | Other | N/A |
| 71 | Q2 | Selinexor; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212306.pdf | 3/25/2021 | Other | N/A |
| 72 | Q2 | Siponimod Fumaric Acid; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209884.pdf | 3/25/2021 | Other | N/A |
| 73 | Q2 | Sofosbuvir; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212480.pdf | 3/25/2021 | Other | N/A |
| 74 | Q2 | Solriamfetol Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211230.pdf | 3/25/2021 | Other | N/A |
| 75 | Q2 | Testosterone Undecanoate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206089.pdf | 3/25/2021 | Other | N/A |
| 76 | Q2 | Ursodiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019594.pdf | 3/25/2021 | Other | N/A |
| 77 | Q2 | Ursodiol; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020675.pdf | 3/25/2021 | 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) |
|---|---|---|---|---|---|
| 78 | Q3 | Development of Abbreviated New Drug Applications During the COVID-19 Pandemic – Questions and Answers, Final Guidance for Industry www.fda.gov/media/147355/download | 04/05/2021 | Other | N/A |
| 79 | Q3 | Remote Interactive Evaluations of Drug manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Health Emergency Guidance for Industry www.fda.gov/media/147582/download | 4/14/21 | Other | N/A |
| 80 | Q3 | M9 Biopharmaceutics Classification System-Based Biowaivers, Final Guidance for Industry www.fda.gov/media/148472/download | 05/11/2021 | Other | N/A |
| 81 | Q3 | Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers www.fda.gov/media/141312/download | 5/17/21 | Other | N/A |
| 82 | Q3 | ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin, Final Guidance for Industry www.fda.gov/media/107622/download | 05/19/2021 | Other | N/A |
| 83 | Q3 | Amlodipine Besylate; Celecoxib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210045.pdf | 5/19/2021 | Other | N/A |
| 84 | Q3 | Azacitidine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_050794.pdf | 5/19/2021 | Other | N/A |
| 85 | Q3 | Dasatinib; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021986.pdf | 5/19/2021 | Other | N/A |
| 86 | Q3 | Fluticasone Furoate; Umeclidinium Bromide; Vilanterol Trifenatate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209482.pdf | 5/19/2021 | Other | N/A |
| 87 | Q3 | Fluticasone Propionate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205434.pdf | 5/19/2021 | Other | N/A |
| 88 | Q3 | Ledipasvir; Sofosbuvir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205834.pdf | 5/19/2021 | Other | N/A |
| 89 | Q3 | Lumateperone Tosylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209500.pdf | 5/19/2021 | Other | N/A |
| 90 | Q3 | Meloxicam; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_210583.pdf | 5/19/2021 | Other | N/A |
| 91 | Q3 | Metoclopramide Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209388.pdf | 5/19/2021 | Other | N/A |

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|---|---|---|---|---|---|
| 92 | Q3 | Midazolam; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211321.pdf | 5/19/2021 | Other | N/A |
| 93 | Q3 | Nitrofurantoin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_009175.pdf | 5/19/2021 | Other | N/A |
| 94 | Q3 | Pentosan Polysulfate Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020193.pdf | 5/19/2021 | Other | N/A |
| 95 | Q3 | Pexidartinib Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211810.pdf | 5/19/2021 | Other | N/A |
| 96 | Q3 | Pitolisant Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211150.pdf | 5/19/2021 | Other | N/A |
| 97 | Q3 | Quinidine Gluconate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_016647.pdf | 5/19/2021 | Other | N/A |
| 98 | Q3 | Sofosbuvir; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204671.pdf | 5/19/2021 | Other | N/A |
| 99 | Q3 | Tofacitinib Citrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208246.pdf | 5/19/2021 | Other | N/A |
| 100 | Q3 | Trifarotene; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211527.pdf | 5/19/2021 | Other | N/A |
| 101 | Q3 | Ubrogepant; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211765.pdf | 5/19/2021 | Other | N/A |
| 102 | Q3 | Voxelotor; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213137.pdf | 5/19/2021 | Other | N/A |
| 103 | Q3 | Zanubrutinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213217.pdf | 5/19/2021 | Other | N/A |
| 104 | Q3 | ICH Q12: Implementation considerations for FDA-Regulated Products Draft Guidance for Industry www.fda.gov/media/148947/download | 5/20/21 | Other | N/A |
| 105 | Q3 | GUI DRAFT – Oral Drug products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations Draft Guidance for Industry www.fda.gov/media/149688/download | 6/3/21 | Other | N/A |
| 106 | Q4 | Cilastatin Sodium; Imipenem; Relebactam; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212819.pdf | 7/19/2021 | Other | N/A |

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|---|---|---|---|---|---|
| 107 | Q4 | Field Alert Report Submission: Questions and Answers Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/field-alert-report-submission-questions-and-answers-guidance-industry | 7/23/21 | Other | N/A |
| 108 | Q4 | Olodaterol Hydrochloride; Tiotropium Bromide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_206756.pdf | 7/28/2021 | Other | N/A |
| 109 | Q4 | Development and Submission of Near Infrared Analytical Procedures www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-submission-near-infrared-analytical-procedures | 8/9/21 | Other | N/A |
| 110 | Q4 | Acyclovir; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_202408.pdf | 8/20/2021 | Other | N/A |
| 111 | Q4 | Albuterol Sulfate; Ipratropium Bromide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021747.pdf | 8/20/2021 | Other | N/A |
| 112 | Q4 | Amisulpride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209510.pdf | 8/20/2021 | Other | N/A |
| 113 | Q4 | Avapritinib; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212608.pdf | 8/20/2021 | Other | N/A |
| 114 | Q4 | Bexarotene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021055.pdf | 8/20/2021 | Other | N/A |
| 115 | Q4 | Budesonide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021324.pdf | 8/20/2021 | Other | N/A |
| 116 | Q4 | Carbinoxamine Maleate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_008915.pdf | 8/20/2021 | Other | N/A |
| 117 | Q4 | Cefiderocol Sulfate Tosylate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209445.pdf | 8/20/2021 | Other | N/A |
| 118 | Q4 | Copper Dotatate Cu-64; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213227.pdf | 8/20/2021 | Other | N/A |
| 119 | Q4 | Eltrombopag Olamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_022291.pdf | 8/20/2021 | Other | N/A |
| 120 | Q4 | Eltrombopag Olamine; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207027.pdf | 8/20/2021 | Other | N/A |
| 121 | Q4 | Esomeprazole Magnesium; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_214278.pdf | 8/20/2021 | 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) |
|---|---|---|---|---|---|
| 122 | Q4 | Estradiol; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021166.pdf | 8/20/2021 | Other | N/A |
| 123 | Q4 | Ethinyl Estradiol; Levonorgestrel; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_204017.pdf | 8/20/2021 | Other | N/A |
| 124 | Q4 | Ferric Citrate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205874.pdf | 8/20/2021 | Other | N/A |
| 125 | Q4 | Fostemsavir Tromethamine; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212950.pdf | 8/20/2021 | Other | N/A |
| 126 | Q4 | Indomethacin; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_017814.pdf | 8/20/2021 | Other | N/A |
| 127 | Q4 | Ipratropium Bromide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020393.pdf | 8/20/2021 | Other | N/A |
| 128 | Q4 | Lasmiditan Succinate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211280.pdf | 8/20/2021 | Other | N/A |
| 129 | Q4 | Letrozole; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020726.pdf | 8/20/2021 | Other | N/A |
| 130 | Q4 | Leuprolide Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_019732.pdf | 8/20/2021 | Other | N/A |
| 131 | Q4 | Leuprolide Acetate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020517.pdf | 8/20/2021 | Other | N/A |
| 132 | Q4 | Leuprolide Acetate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021343.pdf | 8/20/2021 | Other | N/A |
| 133 | Q4 | Liothyronine Sodium; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_010379.pdf | 8/20/2021 | Other | N/A |
| 134 | Q4 | Loteprednol Etabonate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020583.pdf | 8/20/2021 | Other | N/A |
| 135 | Q4 | Loteprednol Etabonate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_208219.pdf | 8/20/2021 | Other | N/A |
| 136 | Q4 | Nystatin; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_060578.pdf | 8/20/2021 | Other | N/A |
| 137 | Q4 | Olodaterol Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203108.pdf | 8/20/2021 | Other | N/A |

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|---|---|---|---|---|---|
| 138 | Q4 | Orlistat; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020766.pdf | 8/20/2021 | Other | N/A |
| 139 | Q4 | Osilodrostat Phosphate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_212801.pdf | 8/20/2021 | Other | N/A |
| 140 | Q4 | Ozanimod Hydrochloride; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209899.pdf | 8/20/2021 | Other | N/A |
| 141 | Q4 | Paclitaxel; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021660.pdf | 8/20/2021 | Other | N/A |
| 142 | Q4 | Paliperidone Palmitate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207946.pdf | 8/20/2021 | Other | N/A |
| 143 | Q4 | Podofilox; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_020529.pdf | 8/20/2021 | Other | N/A |
| 144 | Q4 | Semaglutide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213051.pdf | 8/20/2021 | Other | N/A |
| 145 | Q4 | Sodium Zirconium Cyclosilicate; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_207078.pdf | 8/20/2021 | Other | N/A |
| 146 | Q4 | Sufentanil Citrate; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_209128.pdf | 8/20/2021 | Other | N/A |
| 147 | Q4 | Tazarotene; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021184-Cre-0.05P.pdf | 8/20/2021 | Other | N/A |
| 148 | Q4 | Tazemetostat Hydrobromide; Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_211723.pdf | 8/20/2021 | Other | N/A |
| 149 | Q4 | Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application; Revised Draft Guidance for Industry Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application \| FDA | 8/20/21 | Other | N/A |
| 150 | Q4 | Development of Abbreviated New Drug Applications During the COVID-19 Pandemic – Questions and Answers; Guidance for Industry Development of Abbreviated New Drug Applications During the COVID-19 Pandemic – Questions and Answers Guidance for Industry \| FDA | 9/8/21 | Other | N/A |
| 151 | Q4 | Ferric Oxyhydroxide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_205109.pdf | 9/16/2021 | Other | N/A |
| 152 | Q4 | Ferric Oxyhydroxide; Revised Draft Guidance for Industry www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_021135.pdf | 9/16/2021 | 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) |
|---|---|---|---|---|---|
| 153 | Q4 | Microbiological Quality Considerations in Non-Sterile Drug Manufacturing www.fda.gov/regulatory-information/search-fda-guidance-documents/microbiological-quality-considerations-non-sterile-drug-manufacturing | 9/30/21 | Other | N/A |

## Public Meetings

Pursuant to Section 744C(a)(2) of the FD&C Act, the table below lists the number and titles of public meetings held on topics related to human generic drug activities and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017. Public meetings are listed by the quarter in which they were held and are provided in a cumulative format for FY 2021.

**Table 2: Public Meetings Held on Topics Related to Human Generic Drug Activities for FY 2021**

| Number | Quarter Held | Title | Date Held | Held as Required by Statute or Pursuant to Commitment Letter |
|---|---|---|---|---|
| 1 | Q1 | The FDA/DIA Complex Generic Drug-Device Combination Products Conference 2020 www.fda.gov/drugs/news-events-human-drugs/fdadia-complex-generic-drug-device-combination-products-conference-2020-10192020-10202020 | October 19-20, 2020 | No |
| 2 | Q1 | Regulatory Education for Industry: Celebrating 40 Years: An In-Depth Examination of the FDA Orange Book www.fda.gov/drugs/news-events-human-drugs/regulatory-education-industry-celebrating-40-years-depth-examination-fda-orange-book-10272020 | October 27-28, 2020 | No |
| 3 | Q2 | Non-clinical Immunogenicity Assessment of Generic Peptide Products: Development, Validation, and Sampling Workshop www.fda.gov/drugs/news-events-human-drugs/non-clinical-immunogenicity-assessment-generic-peptide-products-development-validation-and-sampling | January 26, 2021 | No |
| 4 | Q3 | Generic Drugs Forum 2021: Lifecycle of a Generic Drug www.fda.gov/drugs/news-events-human-drugs/generic-drugs-forum-2021-lifecycle-generic-drug-04282021-04292021 | April 28-29, 2021 | No |
| 5 | Q3 | FDA Product-Specific Guidances: Lighting the Development Pathway for Generic Drugs www.fda.gov/drugs/fda-product-specific-guidances-lighting-development-pathway-generic-drugs-05052021-05052021 | May 5, 2021 | No |
| 6 | Q3 | Common Labeling Deficiencies and Tips for Generic Drug Applications www.fda.gov/drugs/news-events-human-drugs/common-labeling-deficiencies-and-tips-generic-drug-applications-05072021-05072021 | May 7, 2021 | No |

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|---|---|---|---|---|
| 7 | Q3 | FY 2021 Generic Drug Science and Research Initiatives Public Workshop www.fda.gov/drugs/news-events-human-drugs/fy-2021-generic-drug-science-and-research-initiatives-public-workshop-06232021-06232021 | June 23, 2021 | Yes |
| 8 | Q3 | Food and Drug Administration Public Meeting on Financial Efficiency of Human Drug User Fee Program www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and | June 28, 2021 | Yes |
| 9 | Q4 | FDA and Center for Research on Complex Generics Co-Hosted Workshop: In Vitro Release Test (IVRT) and In Vitro Permeation Test (IVPT) Methods: Best Practices and Scientific Considerations for ANDA Submissions www.fda.gov/drugs/news-events-human-drugs/fda-and-center-research-complex-generics-co-hosted-workshop-in-vitro-release-test-ivrt-and-vitro | August 18-20, 2021 | No |
| 10 | Q4 | SBIA Workshop: Advancing Generic Drug Development: Translating Science to Approval www.fda.gov/drugs/news-events-human-drugs/advancing-generic-drug-development-translating-science-approval-09212021-09222021 | September 21-22, 2021 | No |
| 11 | Q4 | FDA and Center for Research on Complex Generics Co-Hosted Workshop: Regulatory Utility of Mechanistic Modeling to Support Alternative Bioequivalence Approaches www.fda.gov/drugs/news-events-human-drugs/fda-and-center-research-complex-generics-co-hosted-workshop-regulatory-utility-mechanistic-modeling | September 30-October 1, 2021 | No |