



FDA U.S. FOOD & DRUG
ADMINISTRATION

FY 2024

Real Time Report

pursuant to the

Federal Food, Drug, and Cosmetic Act

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

Acronyms

BLA – Biologics License Application

CBER – Center for Biologics Evaluation and Research

CDER – Center for Drug Evaluation and Research

FDA – Food and Drug Administration

FDAUFRA 2022 – **FDA User Fee Reauthorization Act of 2022**

FY – Fiscal Year (October 1 to September 30)

NDA – New Drug Application

PDUFA – Prescription Drug User Fee Act

Q1 – Quarter 1 (October 1 to December 31)

Q2 – Quarter 2 (January 1 to March 31)

Q3 – Quarter 3 (April 1 to June 30)

Q4 – Quarter 4 (July 1 to September 30)

Background

On September 30, 2022, the FDA User Fee Reauthorization Act of 2022 (FDAUFRA) (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 drugs, biologics, generic drugs, medical devices, and biosimilar biological products.

Section 736B(a)(3) of the FD&C Act, as amended by Section 903 of the FDA Reauthorization Act (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 the process for the review of human drugs and biologics, and the number of new drug and biologics license applications filed, and the number of approvals.

Real Time Reporting Under Section 736B(a)(3) of the FD&C Act

This report provides the PDUFA real time reporting metrics, required under Section 736B(a)(3) of the FD&C Act as in effect on September 30, 2022¹:

Not later than 30 calendar days after the end of the second quarter of fiscal year 2023, 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:

- 1) The number and titles of draft and final guidance on topics related to the process for the review of human drug applications and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2022.
- 2) The number and titles of public meetings held on topics related to the process for the review of human drug applications, and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2022.
- 3) The number of new drug applications and biological licensing applications approved.
- 4) The number of new drug applications and biological licensing applications filed.
- 5) For fiscal years 2023 and 2024, of the meeting requests from sponsors for which the Secretary has determined that a face-to-face meeting is appropriate, the number of face-to-face meetings requested by sponsors to be conducted in person (in such manner as the Secretary shall prescribe on the website of the Food and Drug Administration), and the number of such in-person meetings granted by the Secretary, with both such numbers disaggregated by the relevant agency center.

¹ Effective October 1, 2022, section 736B(a)(3) of the FD&C Act was slightly amended by the Prescription Drug User Fee Amendments of 2022, as enacted under title I of Division F (FDA User Fee Reauthorization Act of 2022) of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Public Law 117-180).

Human Drugs and Biologics

Guidance Documents

Pursuant to Section 736B(a)(3) of the FD&C Act, the table below lists the number and titles of draft and final guidance on topics related to the process for the review of human drug and biologics license applications and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2022. Guidance documents are listed by the quarter in which they were issued and are provided in a cumulative format for fiscal year 2024.

Table 1: Draft and Final Guidance Documents Related to the Process for the Review of Human Drug and Biologics License Applications 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	Human Prescription Drug and Biological Products — Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers — “Dose Banding” Guidance for Industry www.fda.gov/media/172571/download	10/2/2023	No	N/A
2	Q1	Stimulant Use Disorders: Developing Drugs for Treatment; Draft Guidance for Industry www.fda.gov/media/172703/download	10/5/2023	No	N/A
3	Q1	Diabetic Foot Infections: Developing Drugs for Treatment; Draft Guidance for Industry www.fda.gov/media/173006/download	10/17/2023	No	N/A
4	Q1	Benefit-Risk Assessment for New Drug and Biological Products; Final Guidance for Industry www.fda.gov/media/152544/download	10/17/2023	No	N/A
5	Q1	Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products Questions and Answers; Draft Guidance for Industry www.fda.gov/media/173172/download	10/24/2023	No	N/A
6	Q1	Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities; Draft Guidance for Industry www.fda.gov/media/173286/download	10/26/2023	No	N/A
7	Q1	Submitting Patient-Reported Outcome Data in Cancer Clinical Trials; Final Guidance for Industry www.fda.gov/media/173581/download	11/06/2023	No	N/A
8	Q1	Submitting Clinical Trial Datasets and Documentation for Clinical Outcome Assessments Using Item Response Theory; Final Guidance for Industry www.fda.gov/media/173587/download	11/06/2023	No	N/A

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
9	Q1	Translation of Good Laboratory Practice Study Reports: Questions and Answers; Draft Guidance for Industry www.fda.gov/media/173989/download	11/22/2023	No	N/A
10	Q1	COVID-19: Developing Drugs and Biological Products for Treatment or Prevention; Final Guidance for Industry www.fda.gov/media/167274/download	11/24/2023	No	N/A
11	Q1	Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional Labeling and Advertisements; Final Guidance for Industry www.fda.gov/media/169803/download	12/12/2023	No	N/A
12	Q1	Advanced Manufacturing Technologies Designation Program; Draft Guidance for Industry www.fda.gov/media/174651/download	12/13/2023	No	N/A
13	Q1	Clinical Pharmacology Considerations for Peptide Drug Products; Draft Guidance for Industry www.fda.gov/media/171901/download	12/14/2023	No	N/A
14	Q1	Development of Monoclonal Antibody Products Targeting SARS-CoV-2 for Emergency Use Authorization; Final Guidance for Industry www.fda.gov/media/146173/download	12/21/2023	No	N/A
15	Q1	Master Protocols for Drug and Biological Product Development; Draft Guidance for Industry www.fda.gov/media/174976/download	12/21/2023	No	N/A
16	Q1	Data Standards for Drug and Biological Product Submissions Containing Real-World Data; Final Guidance for Industry www.fda.gov/media/153341/download	12/22/2023	No	N/A
17	Q1	Real-World Data: Assessing Registries To Support Regulatory Decision-Making for Drug and Biological Products; Final Guidance for Industry www.fda.gov/media/154449/download	12/22/2023	No	N/A
18	Q1	Digital Health Technologies for Remote Data Acquisition in Clinical Investigations; Final Guidance for Industry www.fda.gov/media/155022/download	12/22/2023	Yes	FDORA 3607(a)
19	Q1	Rare Diseases: Considerations for the Development of Drugs and Biological Products; Final Guidance for Industry www.fda.gov/media/119757/download	12/26/2023	No	N/A
20	Q1	Quality Considerations for Topical Ophthalmic Drug Products; Draft Guidance for Industry www.fda.gov/media/172937/download	12/27/2023	No	N/A
21	Q1	Reformulating Drug Products That Contain Carbomers Manufactured With Benzene; Final Guidance for Industry www.fda.gov/media/175083/download	12/28/2023	No	N/A

Public Meetings

Pursuant to Section 736B(a)(3) of the FD&C Act, the table below lists the number and titles of public meetings held on topics related to the process for the review of human drug and biologics license applications and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 101(b) of the Prescription 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 fiscal year 2024.

Table 2: Public Meetings Held Related to the Process for the Review of Human Drug and Biologics License Applications for FY 2024

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	Menopause: Potential Impact on Clinical Pharmacology and Opportunities for Future Research www.fda.gov/consumers/womens-health-events/menopause-potential-impact-clinical-pharmacology-and-opportunities-future-research-10112023	10/11/2023	No
2	Q1	2023 NanoDay Symposium: Continuous Manufacturing of Nanomaterials www.fda.gov/drugs/news-events-human-drugs/2023-nanoday-symposium-continuous-manufacturing-nanomaterials-10112023	10/11/2023	No
3	Q1	Advances in PBPK Modeling and its Regulatory Utility for Oral Drug Product Development www.fda.gov/news-events/advances-pbpbk-modeling-and-its-regulatory-utility-oral-drug-product-development-10122023	10/12/2023	No
4	Q1	FDA/CDER Office of Clinical Pharmacology and International Society of Pharmacometrics (ISoP) Public Workshop: Using Modeling and Simulation to Evaluate the Effects of Intrinsic and Extrinsic Factors www.fda.gov/news-events/fdacder-office-clinical-pharmacology-and-international-society-pharmacometrics-isop-public-workshop	10/16/2023	No
5	Q1	FDA CTTI Meeting on 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	10/18/2023-10/19/2023	FDORA 3605
6	Q1	Defining 'Candy-Like' Nonprescription Drug Products www.fda.gov/drugs/news-events-human-drugs/defining-candy-nonprescription-drug-products-10302023#:~:text=Currently%2C%20no%20clear%20definition%20of,consumer%20understanding%20of%20these%20products	10/30/2023	No
7	Q1	Pharmaceutical Quality Symposium 2023: Quality, Supply Chain & Advanced Manufacturing www.fda.gov/drugs/news-events-human-drugs/pharmaceutical-quality-symposium-2023-quality-supply-chain-advanced-manufacturing-10312023	10/31/2023-11/1/2023	No

8	Q1	Endpoints and Trial Designs to Advance Drug Development in Kidney Transplantation www.fda.gov/drugs/news-events-human-drugs/endpoints-and-trial-designs-advance-drug-development-kidney-transplantation-11092023	11/9/2023	No
9	Q1	FDA Office of Clinical Pharmacology and International Society of Pharmacometrics (ISoP) Public Workshop: Using Modeling and Simulation to Select Dosages for Combination Therapies and New Indications www.fda.gov/news-events/fda-office-clinical-pharmacology-and-international-society-pharmacometrics-isop-public-workshop	11/9/2023	No
10	Q1	Positron Emission Tomography: Product Quality Regulatory Submissions, Facility Inspections, and Benefit-Risk Considerations www.fda.gov/drugs/news-events-human-drugs/positron-emission-tomography-product-quality-regulatory-submissions-facility-inspections-and-benefit	11/13/2023- 11/14/2023	No
11	Q1	Common Issues with SEND Data Submitted for Safety Pharmacology Studies www.fda.gov/drugs/news-events-human-drugs/common-issues-send-data-submitted-safety-pharmacology-studies-11162023	11/16/2023	No
12	Q1	Toward Global IDMP Implementation: A Focus on Global Use Cases www.fda.gov/drugs/news-events-human-drugs/toward-global-idmp-implementation-focus-global-use-cases-11282023	11/28/2023	No
13	Q1	FDA CTTI Public Workshop to Enhance Clinical Study Diversity www.fda.gov/drugs/news-events-human-drugs/discussing-approaches-enhance-clinical-study-diversity-public-workshop-11292023	11/29/2023- 11/30/2023	FDORA 3603
14	Q1	Advancing the Development of Pediatric Therapeutics (ADEPT) 8 Workshop on Drug Dosing in Pediatric Patients with Renal Impairment www.fda.gov/drugs/news-events-human-drugs/advancing-development-pediatric-therapeutics-adept-8-workshop-drug-dosing-pediatric-patients-renal	11/30/2023- 12/1/2023	No
15	Q1	FDA Clinical Investigator Training Course (CITC) 2023 www.fda.gov/drugs/news-events-human-drugs/fda-clinical-investigator-training-course-citc-2023-12062023	12/6/2023- 12/7/2023	No
16	Q1	Navigating Complex Waters: A Deep Dive into FDA Drug Interactions Guidances and Resources www.fda.gov/drugs/news-events-human-drugs/navigating-complex-waters-deep-dive-fda-drug-interactions-guidances-and-resources-12122023	12/12/2023- 12/13/2023	No
17	Q1	Adult Attention-Deficit/Hyperactivity Disorder: Diagnosis, Treatment, and Implications for Drug Development Workshop www.fda.gov/drugs/adult-attention-deficithyperactivity-disorder-diagnosis-treatment-and-implications-drug-development	12/12/2023- 12/13/2023	No
18	Q1	Public Meeting on Advancing the Development of Therapeutics Through Rare Disease Patient Community Engagement www.fda.gov/drugs/news-events-human-drugs/public-meeting-advancing-development-therapeutics-through-rare-disease-patient-community-engagement	12/14/2023	No

New Drug and Biologics License Applications

The figures in the tables below represent filed and approved New Drug Applications (NDAs) and Biologics License Applications (BLAs) during FY 2024. Figures are calculated based on the same criteria used in the annual PDUFA Report to Congress. The filed figures are based on when the application was received and include applications that are still within the 60-day filing date and have not yet been filed.² The approved figures include applications that have received an approval or tentative approval action. All data is as of December 31, 2023.

Quarterly filed figures are preliminary.

Table 3: The number of NDAs and BLAs filed* in FY 2024 (as of December 31, 2023)

Application Type	Q1	Q2	Q3	Q4	Cumulative
NDAs	23				23
BLAs	16				16
Total	39				39

* Data excludes applications that are unacceptable for filing due to nonpayment of user fees, have been withdrawn within 60 days of receipt, or have been refused to file.

Table 4: The number of NDAs and BLAs approved in FY 2024 (as of December 31, 2023)

Application Type	Q1	Q2	Q3	Q4	Cumulative
NDAs	30				30
BLAs	12				12
Total	42				42

Number of In-Person/Face-to-Face Meetings Requested/Granted

The tables below represent the number of in-person meetings that were requested by Sponsors and granted by FDA as face-to-face (in-person or virtual) and the number of in-person meetings requested by Sponsors that FDA granted as in-person during FY 2024. The data are reported for each applicable Center.

Table 5: The number of Sponsor requested in-person meetings that FDA granted as face-to-face meetings (In-Person or Virtual)[†] in FY 2024 (as of December 31, 2023)

² FDA only files applications that are sufficiently complete to permit a substantive review. The Agency makes a filing decision within 60 days of an original application's receipt.

FDA Center	Q1	Q2	Q3	Q4	Cumulative
CBER	21				21
CDER	54				54
Total	75				75

† Includes meetings granted but later canceled. In-person meetings may also include a hybrid component.

Table 6: The number of Sponsor requested in-person meetings that FDA granted as in-person meetings[†] in FY 2024 (as of December 31, 2023)

FDA Center	Q1	Q2	Q3	Q4	Cumulative
CBER	1				1
CDER	22				22
Total	23				23

Includes meetings granted but later canceled. In-person meetings may also include a hybrid component.

Glossary of Terms Included in This Report

Approval – An official action by FDA, communicated via letter to a NDA or BLA applicant, that the applicant has satisfied the requirements of the statute for approval and allows the commercial marketing of the product.

BLA – The BLA must contain specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology, and the clinical effects of a biologic product. If the information provided meets FDA requirements, the application is approved, and a license is issued allowing the firm to market the product.

Face-to-Face – As defined in footnote 9 in [PDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2023 THROUGH 2027](#), a face-to-face meeting includes both in-person meetings and virtual meetings on IT platforms that allow for both audio and visual communication.

NDA – When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet FDA's requirements for marketing approval, the applicant submits to FDA a new drug application. The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. If the NDA is approved, the product may be marketed in the United States.

Refuse to File – An official action from FDA, communicated via letter to a NDA or BLA applicant, stating that the FDA has made a threshold determination that the application is not sufficiently complete to permit a substantive review

Tentative Approval – An official action by FDA, communicated via letter to a NDA applicant, stating that the NDA otherwise meets the requirements for approval, but that it may not be legally marketed in the U.S. until the market exclusivity and/or patent term of the listed drug upon which the application relies has expired.

Unacceptable for Filing – An official action by FDA, communicated via letter to a NDA applicant, stating that the application is not accepted by the FDA for review. Note: PDUFA requires this action when the applicant has not submitted payment for the application, or when the applicant is determined to be in arrears for non-payment of annual program fees.