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.[1]

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, 2022[2]:

> 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

[1] This report provides information related to human drug applications. The term "human drug application" is defined for purposes of PDUFA by section 735(1) of the FD&C Act to mean an application for approval of a new drug submitted under section 505(b) of the FD&C Act or licensure of a biological product under section 351(a) of the Public Health Service (PHS) Act, with certain exceptions including supplemental applications and applications for certain types of drugs and biologics. 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.

[2] 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).

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.

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	Yes	FDASIA/GAIN Section 804/U.S.C 306a-1
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	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
6	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
7	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
8	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

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	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
10	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
11	Q1	Advanced Manufacturing Technologies Designation Program; Draft Guidance for Industry www.fda.gov/media/174651/download	12/13/2023	No	N/A
12	Q1	Clinical Pharmacology Considerations for Peptide Drug Products; Draft Guidance for Industry www.fda.gov/media/171901/download	12/14/2023	No	N/A
13	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
14	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
15	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
16	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
17	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) and PDUFA VI.C.5.b.
18	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	Yes	FDORA 3202(b)
19	Q1	Quality Considerations for Topical Ophthalmic Drug Products; Draft Guidance for Industry www.fda.gov/media/172937/download	12/27/2023	No	N/A
20	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
22	Q2	Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products; Draft Guidance for Industry www.fda.gov/media/175746/download	1/30/2024	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)
23	Q2	Use of Data Monitoring Committees in Clinical Trials; Draft Guidance for Industry www.fda.gov/media/176107/download	2/13/2024	No	N/A
24	Q2	Charging for Investigational Drugs Under an IND: Questions and Answers; Final Guidance for Industry www.fda.gov/media/176308/download	2/14/2024	No	N/A
25	Q2	Assessing COVID-19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID-19 Prevention or Treatment; Final Guidance for Industry www.fda.gov/media/167275/download	2/22/2024	No	N/A
26	Q2	Clinical Pharmacology Considerations for Antibody-Drug Conjugates; Final Guidance for Industry www.fda.gov/media/155997/download	3/1/2024	No	N/A
27	Q2	Key Information and Facilitating Understanding in Informed Consent Guidance for Sponsors, Investigators, and Institutional Review Boards; Draft Guidance for Industry www.fda.gov/media/176663/download	3/1/2024	No	N/A
28	Q2	Q2(R2) Validation of Analytical Procedures; Final Guidance for Industry www.fda.gov/media/161201/download	3/6/2024	No	N/A
29	Q2	Q14 Analytical Procedure Development; Final Guidance for Industry www.fda.gov/media/161202/download	3/7/2024	No	N/A
30	Q2	Early Alzheimer's Disease: Developing Drugs for Treatment; Draft Guidance for Industry www.fda.gov/media/110903/download	3/12/2024	No	N/A
31	Q2	Annual Reportable Labeling Changes for New Drug Applications and Abbreviated New Drug Applications for Nonprescription Drug Products www.fda.gov/media/176915/download	3/13/2024	No	N/A
32	Q2	E2D(R1) Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports; Draft Guidance for Industry www.fda.gov/media/176977/download	3/13/2024	No	N/A
33	Q2	Pharmacokinetics in Patients with Impaired Renal Function — Study Design, Data Analysis, and Impact on Dosing; Final Guidance for Industry www.fda.gov/media/78573/download	3/15/2024	No	N/A
34	Q2	Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products; Draft Guidance for Industry www.fda.gov/media/177128/download	3/21/2024	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)
35	Q2	Handling and Retention of Bioavailability BA and Bioequivalence BE Testing Samples; Draft Guidance for Industry www.fda.gov/media/71393/download	3/27/2024	No	N/A
36	Q3	Providing Regulatory Submissions in Electronic Format: Investigational New Drug Application Safety Reports; Final Guidance for Industry www.fda.gov/media/132079/download	4/1/2024	No	N/A
37	Q3	Content and Format of Composition Statement and Corresponding Statement of Ingredients in Labeling in NDAs and ANDAs; Draft Guidance for Industry www.fda.gov/media/178099/download	4/29/2024	No	N/A
38	Q3	REMS Logic Model: A Framework to Link Program Design With Assessment; Draft Guidance for Industry www.fda.gov/media/178291/download	5/7/2024	Yes	PDUFA VII M.1.a.
39	Q3	Q&A Manufacturing and Testing Controls for Ophthalmic Sterility www.fda.gov/drugs/guidances-drugs/questions-and-answers-current-good-manufacturing-practice-regulations-production-and-process#23	5/24/2024	No	N/A
40	Q3	Platform Technology Designation Program for Drug Development; Draft Guidance for Industry www.fda.gov/media/178938/download	5/28/2024	Yes	Section 506K FD&C Act/ 21 U.S.C. 356k
41	Q3	Processes and Practices Applicable to Bioresearch Monitoring Inspections; Draft Guidance for Industry www.fda.gov/media/179027/download	6/5/2024	No	N/A
42	Q3	Clinical Pharmacology Considerations for the Development of Oligonucleotide Therapeutics; Final Guidance for Industry www.fda.gov/media/159414/download	6/14/2024	No	N/A
43	Q3	Diabetic Foot Infections: Developing Drugs for Treatment; Final Guidance for Industry www.fda.gov/media/173006/download	6/17/2024	Yes	FDASIA/GAIN Section 804/U.S.C 306a-1
44	Q3	Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection; Final Guidance for Industry www.fda.gov/media/86328/download	6/20/2024	No	N/A
45	Q3	Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies; Draft Guidance for Industry www.fda.gov/media/179593/download	6/26/2024	Yes	FDORA Section 3604
46	Q3	Essential Drug Delivery Outputs for Devices Intended to Deliver Drugs and Biological Products; Draft Guidance for Industry www.fda.gov/media/179545/download	6/28/2024	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-pbpk-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

19	Q2	Advancing Drug Development for the Prevention of Spontaneous Preterm Birth www.fda.gov/drugs/news-events-human-drugs/advancing-drug-development-prevention-spontaneous-preterm-birth-01232024	1/23/2024-1/24/2024	No
20	Q2	Public Workshop: Advancing Psychedelic Clinical Study Design www.fda.gov/news-events/fda-meetings-conferences-and-workshops/public-workshop-advancing-psychedelic-clinical-study-design-01312024	1/31/2024-2/1/2024	No
21	Q2	Building Quality into the Design and Conduct of Clinical Studies: Integrating Quality by Design (QbD) and Risk-Based Monitoring (RBM) Approaches www.fda.gov/drugs/news-events-human-drugs/building-quality-design-and-conduct-clinical-studies-integrating-quality-design-qbd-and-risk-based	1/31/2024	No
22	Q2	A Joint US-FDA | MHRA-UK | Health Canada Good Clinical Practice & Pharmacovigilance Compliance Symposium www.fda.gov/drugs/news-events-human-drugs/joint-us-fda-mhra-uk-health-canada-good-clinical-practice-pharmacovigilance-compliance-symposium	2/13/2024-2/15/2024	No
23	Q2	FDA/CDER Office of Clinical Pharmacology and American Association for Cancer Research Public Workshop www.fda.gov/drugs/news-events-human-drugs/fdacder-office-clinical-pharmacology-and-american-association-cancer-research-public-workshop	2/15/2024-2/16/2024	No
24	Q2	Joint US FDA – Health Canada ICH Public Meeting www.fda.gov/drugs/news-events-human-drugs/joint-us-fda-health-canada-ich-public-meeting-02222024	2/22/2024	No
25	Q2	Biomarker-driven Drug Development for Allergic Diseases and Asthma; Public Workshop www.fda.gov/news-events/fda-meetings-conferences-and-workshops/biomarker-driven-drug-development-allergic-diseases-and-asthma-public-workshop-02222024	2/22/2024	No
26	Q2	FDA/CDER and American Association of Pharmaceutical Scientists (AAPS) Hybrid Public Workshop www.fda.gov/drugs/news-events-human-drugs/fdacder-and-american-association-pharmaceutical-scientists-aaps-hybrid-public-workshop-02262024	2/26/2024	No
27	Q2	Product Quality Research Institute (PQRI) Workshop: MIDD Approaches in Pediatric Formulation Development www.fda.gov/drugs/news-events-human-drugs/product-quality-research-institute-pqri-workshop-midd-approaches-pediatric-formulation-development	2/28/2024-2/29/2024	No
28	Q2	Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice www.fda.gov/news-events/advancing-use-complex-innovative-designs-clinical-trials-pilot-practice-03052024	3/5/2024	PDUFA VII.I.L.4
29	Q2	Integrated Safety Analyses in Drug Marketing Applications: Avoiding Common Mistakes www.fda.gov/drugs/news-events-human-drugs/integrated-safety-analyses-drug-marketing-applications-avoiding-common-mistakes-03072024	3/7/2024	No

30	Q2	Enhancing Adoption of Innovative Clinical Trial Approaches www.fda.gov/drugs/news-events-human-drugs/enhancing-adoption-innovative-clinical-trial-approaches-03192024	3/19/2024-3/20/2024	No
31	Q3	PQRI/EUFEPS Global Bioequivalence Harmonisation Initiative (GBHI): 6th International Workshop www.fda.gov/drugs/news-events-human-drugs/pqrieufeps-global-bioequivalence-harmonisation-initiative-gbhi-6th-international-workshop-04162024	4/16/2024-4/17/2024	No
32	Q3	PQRI Workshop: Challenges and Opportunities for Modified Release Oral Drug Product Development www.fda.gov/drugs/news-events-human-drugs/pqri-workshop-challenges-and-opportunities-modified-release-oral-drug-product-development-04182024	4/18/2024	No
33	Q3	Drug Development Considerations for Empiric Antibacterial Therapy in Febrile Neutropenic Patients www.fda.gov/drugs/news-events-human-drugs/drug-development-considerations-empiric-antibacterial-therapy-febrile-neutropenic-patients-04232024	4/23/2024	No
34	Q3	Streamlining Drug Development and Improving Public Health through Quantitative Medicine: An Introduction to the CDER Quantitative Medicine Center of Excellence www.fda.gov/drugs/news-events-human-drugs/streamlining-drug-development-and-improving-public-health-through-quantitative-medicine-introduction	4/25/2024	No
35	Q3	FDA/CRCG Workshop: Considerations and Potential Regulatory Applications for a Model Master File www.fda.gov/drugs/news-events-human-drugs/fdacrcg-workshop-considerations-and-potential-regulatory-applications-model-master-file-05022024#event-information	5/2/2024-5/3/2024	No
36	Q3	Drug Development Considerations for the Treatment of Neonatal Enterovirus Infection and Congenital Cytomegalovirus Infection--Virtual Public Workshop www.fda.gov/drugs/news-events-human-drugs/drug-development-considerations-treatment-neonatal-enterovirus-infection-and-congenital	5/7/2024-5/8/2024	No
37	Q3	Clinical Pharmacology Guidances Advancing Drug Development and Regulatory Assessment | Role and Opportunities www.fda.gov/drugs/news-events-human-drugs/clinical-pharmacology-guidances-advancing-drug-development-and-regulatory-assessment-role-and	5/8/2024-5/9/2024	No
38	Q3	Natural History Studies and Registries in the Development of Rare Disease Treatments www.fda.gov/drugs/news-events-human-drugs/natural-history-studies-and-registries-development-rare-disease-treatments-05132024	5/13/2024	No
39	Q3	Statistical Considerations for Premarketing Risk Assessment www.fda.gov/drugs/news-events-human-drugs/statistical-considerations-premarketing-risk-assessment-05162024	5/16/2024	No
40	Q3	Regulatory Education for Industry (REdI) Annual Conference 2024: Innovation in Medical Product Development www.fda.gov/drugs/news-events-human-drugs/regulatory-education-industry-redi-annual-conference-2024-innovation-medical-product-development	5/29/2024-5/30/2024	No

41	Q3	FDA/PHUSE Computational Science Symposium www.fda.gov/drugs/news-events-human-drugs/fdaphuse-computational-science-symposium-06032024	6/3/2024-6/5/2024	No
42	Q3	2024 Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments www.fda.gov/drugs/news-events-human-drugs/2024-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act	6/6/2024	No
43	Q3	OSIS Workshop: CDER Bioavailability/Bioequivalence Study Sites and Inspections of Good Laboratory Practice www.fda.gov/drugs/news-events-human-drugs/osis-workshop-cder-bioavailabilitybioequivalence-study-sites-and-inspections-good-laboratory	6/13/2024	No
44	Q3	Rx Drug Promotion and the Clear, Conspicuous, and Neutral Final Rule www.fda.gov/drugs/news-events-human-drugs/rx-drug-promotion-and-clear-conspicuous-and-neutral-final-rule-06262024#:~:text=FDA%27s%20Office%20of%20Prescription%20Drug,Major%20Statement%20in%20a%20Clear%2C	6/26/2024	No
45	Q3	Understanding Current Use of Ketamine for Emerging Areas of Therapeutic Interest www.fda.gov/drugs/news-events-human-drugs/understanding-current-use-ketamine-emerging-areas-therapeutic-interest-06272024	6/27/2024	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.[3] The approved figures include applications that have received an approval or tentative approval action. All data is as of June 30, 2024.

Quarterly filed figures are preliminary.

Table 3: The number of NDAs and BLAs filed* in FY 2024 (as of June 30, 2024)

Application Type	Q1	Q2	Q3	Q4	Cumulative
NDAs	21	22 [a]	22		65
BLAs	15	7 [b]	7		29
Total	**36**	**29**	29		**94**

[3] 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.

* 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.

[a] The NDA filed count for Q2 decreased by three since the March 31, 2024 report due to two applications receiving a refuse to file action and one application receiving an unacceptable for filing action.

[b] The BLA filed count for Q2 decreased by one since the March 31, 2024 report due to the application being reclassified as to an efficacy supplement.

Table 4: The number of NDAs and BLAs approved in FY 2024 (as of June 30, 2024)

Application Type	Q1	Q2	Q3	Q4	Cumulative
NDAs	30	20	28		78
BLAs	12	5	8		25
Total	**42**	**25**	36		**103**

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 June 30, 2024)

FDA Center	Q1	Q2	Q3	Q4	Cumulative
CBER	22 [a]	57 [b]	80		159
CDER	62	70 [c]	62		194
Total	**84**	**127**	142		**353**

† Includes meetings granted but later canceled. In-person meetings may also include a hybrid component.
[a] The CBER Q1 count for Table 5 decreased by one due to meeting record changes and updates throughout the meeting lifecycle.
[b] The CBER Q2 count for Table 5 increased by 12 due to meeting record changes and updates throughout the meeting lifecycle.
[c] The CDER Q2 count for Table 5 increased by ten due to meeting record changes and updates throughout the meeting lifecycle.

Table 6: The number of Sponsor requested in-person meetings that FDA granted as in-person meetings† in FY 2024 (as of June 30, 2024)

FDA Center	Q1	Q2	Q3	Q4	Cumulative
CBER	4 [a]	6 [b]	10		20
CDER	25	56 [c]	53		134
Total	**29**	**62**	63		**154**

Includes meetings granted but later canceled. In-person meetings may also include a hybrid component.
[a] The CBER Q1 count for Table 6 increased by three due to meeting record changes and updates throughout the meeting lifecycle.
[b] The CBER Q2 count for Table 6 increased by two due to meeting record changes and updates throughout the meeting lifecycle.

[c] The CDER Q2 count for Table 6 increased by ten due to meeting record changes and updates throughout the meeting lifecycle.

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.