FY 2025

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.

[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).

Human Drugs and Biologics

Summary

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

Table 1: Total Number of FY 2025 Guidance Documents and Public Meetings as of September 30, 2025

Category	Total
Guidance Documents	40
Public Meetings	32
NDAs & BLAs Filed	157
NDAs & BLAs Approved	143

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 FY 2025.

Table 2: Draft and Final Guidance Documents Related to the Process for the Review of Human Drug and Biologics License Applications for FY 2025

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
1	Q1	Core Patient-Reported Outcomes in Cancer Clinical Trials; Final Guidance for Industry www.fda.gov/media/149994/download	10/17/2024	No	N/A
2	Q1	Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Final Guidance for Industry www.fda.gov/media/165239/download	10/17/2024	No	N/A
3	Q1	Postoperative Nausea and Vomiting: Developing Drugs for Prevention; Draft Guidance for Industry www.fda.gov/media/182757/download	10/17/2024	No	N/A
4	Q1	Drug Interaction Information in Human Prescription Drug and Biological Product Labeling; Draft Guidance for Industry www.fda.gov/media/182893/download	10/21/2024	No	N/A
5	Q1	M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms; Final Guidance for Industry www.fda.gov/media/165049/download	10/30/2024	No	N/A
6	Q1	Nonclinical Safety Assessment of Oligonucleotide-Based Therapeutics; Draft Guidance for Industry www.fda.gov/media/183496/download	11/15/2024	No	N/A
7	Q1	Frequently Asked Questions — Developing Potential Cellular and Gene Therapy Products; Draft Guidance for Industry www.fda.gov/media/183631/download	11/18/2024	Pursuant to Commitment Letter	PDUFA VII Section I.O.2.c
8	Q1	Assessment of Ovarian Toxicity in Premenopausal Adults During Drug Development for Oncologic Products; Draft Guidance for Industry www.fda.gov/media/183839/download	11/26/2024	No	N/A
9	Q1	Recommended Follow-up Testing for an Ames-Positive Drug (Active Ingredient) or Metabolite To Support First-in-Human Clinical Trials With Healthy Subjects; Draft Guidance for Industry www.fda.gov/media/183844/download	11/27/2024	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)
10	Q1	Expedited Program for Serious Conditions – Accelerated Approval of Drugs and Biologics; Draft Guidance for Industry www.fda.gov/media/184120/download	12/5/2024	Yes	Consolidated Appropriations Act, 2023 Section 3210
11	Q1	Technical Specifications for Submitting Clinical Trial Data Sets for Treatment of Noncirrhotic Nonalcoholic Steatohepatitis (NASH); Guidance for Industry Technical Specifications Document (Level 2) www.fda.gov/media/151870/download	12/13/2024	No	N/A
12	Q1	Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices; Draft Guidance for Industry www.fda.gov/media/184745/download	12/30/2024	No	N/A
13	Q1	M15 General Principles for Model-Informed Drug Development; Draft Guidance for Industry www.fda.gov/media/184747/download	12/30/2024	No	N/A
14	Q1	E6(R3) Good Clinical Practice: Annex 2; Draft Guidance for Industry www.fda.gov/media/184746/download	12/30/2024	No	N/A
15	Q1	E11A Pediatric Extrapolation; Final Guidance for Industry www.fda.gov/media/161190/download	12/30/2024	No	N/A
16	Q1	Advanced Manufacturing Technologies Designation Program; Final Guidance for Industry www.fda.gov/media/174651/download	12/31/2024	Yes	FD&C Act section 506L
17	Q2	Considerations for Complying with 21 CFR 211.110; Draft Guidance for Industry www.fda.gov/media/184825/download	1/6/2025	No	N/A
18	Q2	Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products https://www.fda.gov/media/184830/download	1/6/2025	No	N/A
19	Q2	Study of Sex Differences in the Clinical Evaluation of Medical Products; Draft Guidance for Industry www.govinfo.gov/content/pkg/FR-2025-01-07/pdf/2024-31537.pdf	1/6/2025	No	N/A
20	Q2	Obesity and Overweight: Developing Drugs and Biological Products for Weight Reduction; Draft Guidance for Industry www.fda.gov/media/71252/download	1/7/2025	No	N/A
21	Q2	Developing Drugs for Optical Imaging; Draft Guidance for Industry www.fda.gov/media/184943/download	1/7/2025	No	N/A
22	Q3	Replacing Color Additives in Approved or Marketed Drug Products; Draft Guidance for Industry www.fda.gov/media/186692/download	5/29/2025	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	Q3	M13B Bioequivalence for Immediate-Release Solid Oral Dosage Forms: Additional Strengths Biowaiver; Draft Guidance for Industry www.fda.gov/media/186703/download	5/30/2025	No	N/A
24	Q3	Recommendations for Complying With Over-the-Counter Monograph Procedure for Minor Changes C001: Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs	6/5/2025	Yes	FD&C Act Section 505G/ OMUFA Section 2.B.2
25	Q3	Q1 Stability Testing of Drug Substances and Drug Products; Draft Guidance for Industry www.fda.gov/media/187161/download	6/23/2025	No	N/A
26	Q3	Conducting Remote Regulatory Assessments Questions and Answers; Final Guidance for Industry www.fda.gov/media/160173/download	6/24/2025	No	N/A
27	Q3	Unique Device Identifier Requirements for Combination Products; Draft Guidance for Industry www.fda.gov/media/187245/download	6/25/2025	No	N/A
28	Q3	Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases – Questions and Answers; Final Guidance for Industry www.fda.gov/media/158589/download	6/26/2025	Yes	FDASIA Title VIII Section 804
29	Q3	Early Lyme Disease as Manifested by Erythema Migrans: Developing Drugs for Treatment; Final Guidance for Industry www.fda.gov/media/164949/download	6/26/2025	Yes	FDASIA Title VIII Section 804
30	Q4	Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations www.fda.gov/media/163799/download	7/3/2025	No	N/A
31	Q4	E21 Inclusion of Pregnant and Breastfeeding Women in Clinical Trials; Draft Guidance for Industry www.fda.gov/media/187755/download	7/21/2025	No	N/A
32	Q4	E6(R3) Good Clinical Practice: Final Guidance for Industry www.fda.gov/media/169090/download	9/9/2025	No	N/A
33	Q4	Development of Non-Opioid Analgesics for Chronic Pain; Draft Guidance for Industry www.fda.gov/media/188612/download	9/10/2025	Yes	Section 3001(b) of the SUPPORT Act.
34	Q4	Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications; Final Guidance for Industry www.fda.gov/media/172290/download	9/11/2025	Yes	PDUFA VII Section I.N.3
35	Q4	Disseminated Coccidioidomycosis: Developing Drugs for Treatment; Draft Guidance for Industry www.fda.gov/media/188759/download	9/17/2025	Yes	FDORA Act 2022 Section 3211

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)
36	Q4	Symptomatic Nonerosive Gastroesophageal Reflux Disease: Developing Drugs for Treatment; Draft Guidance for Industry www.fda.gov/media/188760/download	9/17/2025	No	N/A
37	Q4	Erosive Esophagitis: Developing Drugs for Treatment; Draft Guidance for Industry www.fda.gov/media/188761/download	9/17/2025	No	N/A
38	Q4	Safety Labeling Changes—Implementation of Section 505(o)(4) of the FD&C Act; Draft Guidance for Industry www.fda.gov/media/188793/download	9/18/2025	No	N/A
39	Q4	Malaria: Developing Drugs for Treatment; Draft Guidance for Industry www.fda.gov/media/188817/download	9/23/2025	No	N/A
40	Q4	E20 Adaptive Designs for Clinical Trials; Draft Guidance for Industry www.fda.gov/media/188961/download	9/30/2025	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 2025.

Table 3: Public Meetings Held Related to the Process for the Review of Human Drug and Biologics License Applications for FY 2025

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	Proteinuria and GFR as Clinical Trial Endpoints in Focal Segmental Glomerulosclerosis: A Scientific Workshop www.fda.gov/drugs/proteinuria-and-gfr-clinical-trial-endpoints-focal-segmental-glomerulosclerosis-scientific-workshop	10/7/2024-10/8/2024	No
2	Q1	ICH M12 Drug-Drug Interaction Studies Final Guidance www.fda.gov/drugs/news-events-human-drugs/ich-m12-drug-drug-interaction-studies-final-guidance-10092024	10/9/2024	No

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
3	Q1	FDA-CDER and HESI | Nitrosamine Ames Data Review and Method Development Workshop www.fda.gov/drugs/fda-cder-and-hesi-nitrosamine-ames-data-review-and-method-development-workshop-10152024	10/15/2024-10/16/2024	No
4	Q1	Global IDMP Implementation - Getting Closer to the Goal www.fda.gov/drugs/news-events-human-drugs/global-idmp-implementation-getting-closer-goal-10162024	10/16/2024	No
5	Q1	Advancing Rare Disease Therapies Through an FDA Rare Disease Innovation Hub www.fda.gov/drugs/news-events-human-drugs/advancing-rare-disease-therapies-through-fda-rare-disease-innovation-hub-10162024	10/16/2024	No
6	Q1	Advancing Smoking Cessation: FDA and NIH Priorities www.fda.gov/tobacco-products/ctp-newsroom/fda-and-nih-joint-public-meeting-advancing-smoking-cessation-priorities-registration-open	10/21/2024	No
7	Q1	2024 DIA/FDA Oligonucleotide-Based Therapeutics Conference www.fda.gov/drugs/2024-diafda-oligonucleotide-based-therapeutics-conference-10282024	10/28/2024-10/30/2024	No
8	Q1	Opportunities to Improve Dose-Finding and Optimization for Rare Disease Drug Development www.fda.gov/drugs/news-events-human-drugs/opportunities-improve-dose-finding-and-optimization-rare-disease-drug-development-10292024	10/29/2024	No
9	Q1	Updates on Approaches to Acceptable Intakes of Nitrosamine Drug Substance Related Impurities and Bioequivalence Assessment for Reformulated Drug Products www.fda.gov/drugs/news-events-human-drugs/updates-approaches-acceptable-intakes-nitrosamine-drug-substance-related-impurities-and	11/6/2024-11/7/2024	No
10	Q1	Putting the Pieces Together: REMS Logic Model in REMS Design, Implementation, and Evaluation www.fda.gov/drugs/news-events-human-drugs/putting-pieces-together-rems-logic-model-rems-design-implementation-and-evaluation-11072024	11/7/2024	No
11	Q1	16th Annual Sentinel Initiative Public Workshop https://www.fda.gov/drugs/news-events-human-drugs/16th-annual-sentinel-initiative-public-workshop-11072024	11/7/2024	No
12	Q1	Clinical Pharmacology Considerations for Radiolabeled Mass Balance Studies www.fda.gov/drugs/news-events-human-drugs/clinical-pharmacology-considerations-radiolabeled-mass-balance-studies-11122024	11/12/2024	No
13	Q1	Workshop on Integration Site Analysis During Long Term Follow-Up for Gene Therapies with Integrating Viral Vectors www.fda.gov/news-events/otp-events-meetings-and-workshops/workshop-integration-site-analysis-during-long-term-follow-gene-therapies-integrating-viral-vectors	11/14/2024	No

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
14	Q1	Nonprescription Analgesic/Antipyretic Drug Development in Children 2 to Less Than 12 Years of Age www.fda.gov/drugs/news-events-human-drugs/nonprescription-analgesicantipyretic-drug-development-children-2-less-12-years-age-11152024	11/15/2024	No
15	Q1	M13A: Bioequivalence for Immediate-Release Solid Oral Dosage Forms - Implementing the Final Guidance www.fda.gov/drugs/news-events-human-drugs/m13a-bioequivalence-immediate-release-solid-oral-dosage-forms-implementing-final-guidance-11212024	11/21/2024	No
16	Q1	Clinical Pharmacology Considerations for Novel Therapeutic Modalities www.fda.gov/drugs/news-events-human-drugs/clinical-pharmacology-considerations-novel-therapeutic-modalities-12042024	12/4/2024	No
17	Q1	Patient and Care Partner Perspectives on Early Enrollment into Gene Therapy Clinical Trials for Rare Diseases www.fda.gov/news-events/meeting-2-patient-and-care-partner-perspectives-early-enrollment-gene-therapy-clinical-trials-rare	12/4/2024	No
18	Q1	FDA Clinical Investigator Training Course (CITC) 2024 www.fda.gov/drugs/news-events-human-drugs/fda-clinical-investigator-training-course-citc-2024-12102024	12/10/2024-12/12/2024	No
19	Q1	Optimizing the Use of Real-World Evidence in Regulatory Decision-Making for Drugs and Biological Products www.fda.gov/drugs/optimizing-use-real-world-evidence-regulatory-decision-making-drugs-and-biological-products-12122024	12/12/2024	No
20	Q1	OTP Town Hall: Best Practices for Regulatory Interactions with OTP www.fda.gov/news-events/otp-events-meetings-and-workshops/otp-town-hall-best-practices-regulatory-interactions-otp-12122024	12/12/2024	No
21	Q1	Patient-Focused Drug Development: Workshop to Discuss Methodologic and Other Challenges Related to Patient Experience Data www.fda.gov/drugs/news-events-human-drugs/patient-focused-drug-development-workshop-discuss-methodologic-and-other-challenges-related-patient	12/13/2024	No
22	Q2	Cell Therapies and Tissue-Based Products: A Public Workshop on Generating Scientific Evidence to Facilitate Development www.fda.gov/news-events/otp-events-meetings-and-workshops/cell-therapies-and-tissue-based-products-public-workshop-generating-scientific-evidence-facilitate	2/25/2025	Required by FDORA
23	Q3	Primary Mitochondrial Diseases Virtual Public Workshop www.fda.gov/drugs/news-events-human-drugs/primary-mitochondrial-diseases-virtual-public-workshop-05222025	5/22/2025	No

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
24	Q4	Public Meeting on the Reauthorization of the Prescription Drug User Fee Act (PDUFA) www.fda.gov/industry/public-meeting-reauthorization-prescription-drug-user-fee-act-pdufa-07142025	7/14/2025	No
25	Q4	Lessons Learned From the Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot (CDRP) Program www.fda.gov/drugs/news-events-human-drugs/lessons-learned-chemistry-manufacturing-and-controls-cmc-development-and-readiness-pilot-cdrp	9/10/2025	Yes
26	Q4	ICH M13B Webinar: Navigating the Draft ICH M13B Additional Strengths Biowaiver Guideline www.fda.gov/drugs/news-events-human-drugs/ich-m13b-webinar-navigating-draft-ich-m13b-additional-strengths-biowaiver-guideline-09112025	9/11/2025	No
27	Q4	Assessing Novel Efficacy Endpoints in Ophthalmologic Rare Disease Drug and Biologics Development www.fda.gov/drugs/news-events-human-drugs/assessing-novel-efficacy-endpoints-ophthalmologic-rare-disease-drug-and-biologics-development	9/17/2025	No
28	Q4	Patient-Focused Drug Development: Workshop #2 to Discuss Methodologic and Other Challenges Related to Patient Experience Data www.fda.gov/drugs/news-events-human-drugs/patient-focused-drug-development-workshop-2-discuss-methodologic-and-other-challenges-related	9/18/2025-9/19/2025	Yes
29	Q4	Regulatory Submissions with Real-World Evidence: Successes, Challenges, and Lessons Learned Public Workshop healthpolicy.duke.edu/events/regulatory-submissions-real-world-evidence-successes-challenges-and-lessons-learned	9/23/2025	Yes
30	Q4	Prescription Drug User Fee Act and Biosimilar User Fee Amendments Hiring and Retention Assessment Public Meeting www.fda.gov/drugs/news-events-human-drugs/prescription-drug-user-fee-act-and-biosimilar-user-fee-amendments-hiring-and-retention-assessment	9/24/2025	Yes
31	Q4	Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments www.federalregister.gov/documents/2025/08/21/2025-15936/financial-transparency-and-efficiency-of-the-prescription-drug-user-fee-act-biosimilar-user-fee-act	9/30/2025	Yes
32	Q4	FDA Public Meeting: Onshoring Manufacturing of Drugs and Biological Products www.fda.gov/drugs/news-events-human-drugs/fda-public-meeting-onshoring-manufacturing-drugs-and-biological-products-09302025	9/30/2025	EO 14293

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 2025. 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 **September** 30, 2025.

Quarterly filed figures are preliminary.

Table 4: The number of NDAs and BLAs filed* in FY 2025 (As of September 30, 2025)

Application Type	Q1	Q2	Q3	Q4	Cumulative
NDAs	41	23	25 [a]	35	124
BLAs	13	7	7	6	33
Total	**54**	**30**	**32**	**41**	**157**

* 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 Q3 decreased by three since the June 30, 2025 report due to one application being withdrawn within 60 days of receipt and two applications receiving a refuse to file action.

Table 5: The number of NDAs and BLAs approved in FY 2025 (As of September 30, 2025)

Application Type	Q1	Q2	Q3	Q4	Cumulative
NDAs	24 [a]	25	27	37	113
BLAs	12	4	9	5	30
Total	**36**	**29**	**36**	**42**	**143**

[a] The NDA approval count for Q1 decreased by one since the June 30, 2025 report due to an administratively split application becoming an efficacy supplement.

[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.

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.

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.