

FY 2026

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, 2026.

Category	Total
Guidance Documents	48
Public Meetings	25
NDAs & BLAs Filed *	172
NDAs & BLAs Approved **	132

* 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.

** Data includes all tentative approval and full approval actions issued within the reported fiscal year. Therefore, an NDA application can be counted multiple times if it receives multiple approval actions within the reported fiscal year.

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 2026.

Table 1: Draft and Final Guidance Documents Related to the Process for the Review of Human Drug and Biologics License Applications for FY 2026

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	Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers www.fda.gov/media/162793/download	10/22/2025	No	N/A
2	Q1	Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments www.fda.gov/media/159500/download	10/23/2025	Yes	PFDD efforts in accordance with 21st Century Cures Act and The Food and Drug Administration

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)
					Reauthorization Act of 2017 Title I and PDUFA VI commitment under section I.J.1
3	Q1	Q3E Guideline for Extractables and Leachables: Supporting Documentation: Class 3 Leachable Monographs; Draft Guidance for Industry www.fda.gov/media/189891/download	11/28/2025	No	N/A
4	Q1	Q3E Guideline for Extractables and Leachables; Draft Guidance for Industry www.fda.gov/media/189890/download	11/28/2025	No	N/A
5	Q1	Medical Gases — Current Good Manufacturing Practice: Draft Guidance for Industry; Draft Guidance for Industry www.fda.gov/media/70973/download	11/28/2025	No	N/A
6	Q1	Monoclonal Antibodies: Streamlined Nonclinical Safety Studies: Draft Guidance for Industry; Draft Guidance for Industry www.fda.gov/media/189920/download	12/2/2025	No	N/A
7	Q1	QTc Information in Human Prescription Drug and Biological Product Labeling: Guidance for Industry Final Guidance for Industry www.fda.gov/media/170814/download	12/3/2025	No	N/A
8	Q1	Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers; Final Guidance for Industry www.fda.gov/media/134862/download	12/9/2025	Yes	Section II.D.2.c of BSUFA III Commitment Letter
9	Q1	ICH E22 General considerations for patient preference studies - Scientific guideline www.ema.europa.eu/en/ich-e22-general-considerations-patient-preference-studies-scientific-guideline	12/12/2025	No	N/A
10	Q1	Study of Sex Differences in the Clinical Evaluation of Medical Products; Draft Guidance for Industry www.fda.gov/media/184907/download	12/15/2025	No	N/A
11	Q1	Enhancing Participation in Clinical Trials – Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance www.fda.gov/media/190162/download	12/15/2025	Yes	Section 610(a)(3) of the FDA Reauthorization Act of 2017 (FDARA) (21 U.S.C. 360bbb note)

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)
12	Q1	Sponsor Responsibilities – Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies; Final Guidance for Industry www.fda.gov/media/150356/download	12/16/2025	No	N/A
13	Q1	Investigator Responsibilities – Safety Reporting for Investigational Drugs and Devices; Final Guidance for Investigators, Industry, and Institutional Review Boards www.fda.gov/media/152530/download	12/16/2025	No	N/A
14	Q1	Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act www.fda.gov/media/169628/download	12/23/2025	No	N/A
15	Q2	Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products www.fda.gov/media/190505/download	1/12/2026	Yes	Section I.J.4.d of PDUFA VI Commitment Letter
16	Q2	E22 General Considerations for Patient Preference Studies; ICH www.fda.gov/media/190946/download	2/6/2026	No	N/A
17	Q2	M14 General Principles on Planning, OSDesigning, Analyzing and Reporting of Noninterventional Studies That Utilize Real-World Data for Safety Assessment of Medicines	3/4/2026	No	N/A
18	Q2	E2D(R1) Postapproval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports www.fda.gov/media/176977/download	3/4/2026	No	N/A
19	Q2	Study Data Technical Conformance Guide - Technical Specifications Document; Final Guidance for Industry https://www.fda.gov/media/153632/download	03/31/2026	No	N/A
20	Q2	Pyrogen and Endotoxins Testing: Questions and Answers: Final Guidance for Industry www.fda.gov/media/83477/download	03/18/2026	No	N/A
21	Q2	General Considerations for the Use of New Approach Methodologies in Drug Development: Draft Guidance for Industry www.fda.gov/media/191589/download	03/18/2026	No	N/A
22	Q2	Physicochemical and Structural (Q3) Characterization of Topical Drug Products Submitted in ANDAs; Final Guidance for Industry www.fda.gov/media/162471/download	03/17/2026	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	Questions and Answers on Biosimilar Development and the BPCI Act: Final Guidance for Industry www.fda.gov/media/119258/download	03/09/2026	No	N/A
24	Q2	New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 4): Draft Guidance for Industry www.fda.gov/media/119278/download	03/09/2026	No	N/A
25	Q2	Responding to FDA Form 483 Observations at the Conclusion of a Drug CGMP Inspection; Draft Guidance for Industry www.fda.gov/media/191427/download	03/06/2026	No	N/A
26	Q2	E2D(R1) Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports; Final Guidance for Industry www.fda.gov/media/176977/download	03/03/2026	No	N/A
27	Q2	M14 General Principles on Planning, Designing, Analyzing, and Reporting of Non-interventional Studies That Utilize Real-World Data for Safety Assessment of Medicines; Final Guidance for Industry www.fda.gov/media/179795/download	03/03/2026	No	N/A
28	Q2	New Clinical Investigation Exclusivity (3-Year Exclusivity) for Drug Products: Questions and Answers; Draft Guidance for Industry www.fda.gov/media/191368/download	03/03/2026	No	N/A
29	Q2	Certification Process for Designated Medical Gases www.fda.gov/media/191040/download	02/11/2026	No	N/A
30	Q3	Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers www.fda.gov/media/162793/download	4/17/2026	No	N/A
31	Q3	Submitting Continuous Glucose Monitoring Data in Clinical Trials Guidance for Industry Technical Specifications Document www.fda.gov/media/192367/download	5/7/2026	Yes	PDUFA VII IV.C.5.a.
32	Q3	Pulmonary Tuberculosis: Developing Drugs for Treatment www.fda.gov/media/87194/download	5/11/2026	No	N/A
33	Q3	Clostridioides difficile Infection: Developing Drugs for Treatment, Reduction or Recurrence, or Prevention www.fda.gov/media/162692/download	5/11/2026	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)
34	Q3	Master Protocols for Drug and Biological Product Development www.fda.gov/media/174976/download	6/24/2026	Yes	N/A
35	Q3	Quantitative Systems Pharmacology (QSP) – Based Dose Selection for Minimum Anticipated Biological Effect Level (MABEL) in First-in-Humans (FIH) Trials www.fda.gov/media/193230/download	6/24/2026	No	Section 3607(b)(2)(C-F) of FDORA
36	Q3	Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products www.fda.gov/media/133660/download	6/24/2026	No	N/A
37	Q3	Safety Assessment of Genome Editing in Human Gene Therapy Products Using Next-Generation Sequencing Draft Guidance for Industry https://www.fda.gov/media/191966/download	04/14/2026	No	N/A
38	Q3	Establishing Impurity Specifications for Antibiotics www.fda.gov/media/192017/download	04/20/2026	No	N/A
39	Q4	Formal Meetings Between FDA and Sponsors or Applicants of PDUFA Products www.fda.gov/media/172311/download	8/12/2026	Yes	Section I.K.1.b of the PDUFAVII Commitment Letter
40	Q4	Container Closure Systems for Human Drugs and Biological Products www.fda.gov/media/194220/download	08/13/2026	No	N/A
41	Q3	Chemistry, Manufacturing, and Controls Flexibilities for Developing Human Cellular and Gene Therapy Products for a Biologics License Application; Guidance for Industry https://www.fda.gov/media/192321/download	05/05/2026	NO	N/A
42	Q3	Leveraging Prior Knowledge in the Development of Human Gene Therapy Products Incorporating Genome Editing; Draft Guidance for Industry https://www.fda.gov/media/192810/download	06/03/2026	Yes	Section I.O.4.b of the PDUFA VII Commitment Letter
43	Q3	M15 General Principles for Model-Informed Drug Development https://www.fda.gov/media/184747/download	06/03/2026	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)
44	Q3	Submitting Clinical Trial Datasets to Evaluate the Impact of Immunogenicity on the Pharmacokinetics of a Drug https: https://www.fda.gov/media/193208/download	6/17/26	Np	NA
45	Q4	Psychedelic Drugs: Considerations for Clinical Investigations www.fda.gov/media/169694/download	7/13/2026	No	N/A
46	Q4	Formal Meetings Between FDA and Sponsors or Applicants of PDUFA Products www.fda.gov/media/172311/download	8/12/2026	Yes	Section I.K.1.b of the PDUFAVII Commitment Letter
47	Q4	Frequently Asked Questions — Developing Potential Cellular and Gene Therapy Products; Guidance for Industry https://www.fda.gov/media/183631/download	8/19/2026	Yes	Section I.O.4 of the PDUFAVII Commitment Letter
48	Q4	Pharmacokinetics in Patients with Impaired Hepatic Function - Study Design, Data Analysis, and Impact on Dosage https://www.fda.gov/media/71311/download	09/02/2026	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 2026.

Table 2: Public Meetings Held Related to the Process for the Review of Human Drug and Biologics License Applications for FY 2026

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	Pediatric Developmental Safety Assessment: New Approach Methods www.fda.gov/drugs/news-events-human-drugs/pediatric-developmental-safety-assessment-new-approach-methods-12052025	12/5/2025	No

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
2	Q1	Quality and Regulatory Predictability: Shaping USP Standards www.fda.gov/drugs/news-events-human-drugs/quality-and-regulatory-predictability-shaping-usp-standards-12112025	12/11/2025	No
3	Q1	Improving Anaphylaxis Outcomes: Approaches for Enhancing Access to Epinephrine www.fda.gov/drugs/news-events-human-drugs/improving-anaphylaxis-outcomes-approaches-enhancing-access-epinephrine-12162025	12/16/2025	No
4	Q1	OTP Town Hall: Gene Therapy Manufacturing CMC and Facility Readiness for BLAs and Post-licensure Changes OTP Town Hall: Gene Therapy Manufacturing CMC and Facility Readiness for BLAs and Post-licensure Changes - 10/22/2025 | FDA	10/22/2025	No
5	Q1	Approval of New Patch Tests for the Diagnosis of Allergic Contact Dermatitis; Public Workshop Approval of New Patch Tests for the Diagnosis of Allergic Contact Dermatitis; Public Workshop - 10/23/2025 | FDA	10/23/2025	No
6	Q2	Eco-NAMs Webinar Series | Gill Cell-Line Assay for Acute Fish Toxicity Prediction www.fda.gov/news-events/fda-meetings-conferences-and-workshops/eco-nams-webinar-series-gill-cell-line-assay-acute-fish-toxicity-prediction-01282026	01/28/2026	No
7	Q3	Expanded Access to Investigational Drugs for Treatment Use – Questions and Answers www.fda.gov/drugs/news-events-human-drugs/expanded-access-investigational-drugs-treatment-use-questions-and-answers-04152026	4/15/2026	No
8	Q3	Advancing Novel Surrogate Endpoints for Rare Disease Drug Development Workshop www.fda.gov/drugs/news-events-human-drugs/advancing-novel-surrogate-endpoints-rare-disease-drug-development-workshop-05182026	5/18/2026	No
9	Q3	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/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and-1	6/23/2026	Yes

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
10	Q4	Development of Antihypertensive Therapies for Use in Pediatric Patients www.fda.gov/drugs/news-events-human-drugs/development-antihypertensive-therapies-use-pediatric-patients-07152026	7/15-16/2026	No
11	Q4	FDA/Health and Environmental Sciences Institute/Safety Pharmacology Society Hybrid Workshop: ICH S7A and New Approach Methodology (NAMS) in Safety Pharmacology www.fda.gov/drugs/news-events-human-drugs/fdahealth-and-environmental-sciences-institutesafety-pharmacology-society-hybrid-workshop-ich-s7a	7/28/2026	No
12	Q4	Accelerating Product Development for Pediatric Systemic Lupus Erythematosus (SLE) www.fda.gov/drugs/news-events-human-drugs/accelerating-product-development-pediatric-systemic-lupus-erythematosus-sle-07302026	7/30-31/2026	No
13	Q4	Drug Repurposing: Considerations for Selection Criteria and Prioritization www.fda.gov/drugs/news-events-human-drugs/drug-repurposing-considerations-selection-criteria-and-prioritization-08052026	8/5/2026	No
14	Q4	FDA Public Meeting: FDA-Led Patient-Focused Drug Development Meeting for Nonhealing Chronic Wounds	8/25/2026	No
15	Q4	FDA Virtual Workshop on Digital Health Technologies and Statistical Considerations for Digitally-Derived Endpoints in Clinical Trials www.fda.gov/drugs/news-events-human-drugs/fda-virtual-workshop-digital-health-technologies-and-statistical-considerations-digitally-derived	8/27/2026	Yes
16	Q4	FDA/Duke Margolis Institute for Health Policy Virtual Public Meeting: Innovation in Quantitative Medicine Summit www.fda.gov/drugs/news-events-human-drugs/fdaduke-margolis-institute-health-policy-virtual-public-meeting-innovation-quantitative-medicine	9/1/2026	No
17	Q4	Addressing the Public Health Effects of Opioid Medications www.fda.gov/drugs/news-events-human-drugs/addressing-public-health-effects-opioid-medications-09092026	9/9/2026	No

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
18	Q4	Considerations for Potential Future Therapeutic Use of Psychedelic Drugs Public Hearing www.fda.gov/news-events/fda-meetings-conferences-and-workshops/considerations-potential-future-therapeutic-use-psychedelic-drugs-public-hearing-09142026	9/14/2026	No
19	Q4	Public Meeting on the Recommendations for Reauthorization of the Prescription Drug User Fee Act (PDUFA) www.fda.gov/drugs/news-events-human-drugs/public-meeting-recommendations-reauthorization-prescription-drug-user-fee-act-pdufa-09162026	9/16/2026	Yes
20	Q4	Eco-NAMs Webinar Series QSARs to Predict Aquatic Toxicity	9/17/2026	No
21	Q4	Communicating Drug Interaction and QTc Information in the U.S. Prescribing Information www.fda.gov/drugs/news-events-human-drugs/communicating-drug-interaction-and-qtc-information-us-prescribing-information-09232026	9/23/2026	No
22	Q4	2026 DIA/FDA Oligonucleotide-Based Therapeutics Conference	9/23-25/2026	No
23	Q4	Regulatory Perspectives on Herbal Medicinal/Botanical Drug Product Development www.fda.gov/drugs/news-events-human-drugs/regulatory-perspectives-herbal-medicinalbotanical-drug-product-development-joint-fdaema-workshop	9/25/2026	No
24	Q4	RISE to the Challenge: Statistical Considerations for Rare Disease Clinical Investigations www.fda.gov/news-events/fda-meetings-conferences-and-workshops/rise-challenge-statistical-considerations-rare-disease-clinical-investigations-09292026	9/29/2026	No
25	Q4	FDA's Drug Registration and Listing Workshop: Compliance, Regulatory and Submission Updates www.fda.gov/drugs/news-events-human-drugs/fdas-drug-registration-and-listing-workshop-compliance-regulatory-and-submission-updates-09292026	9/29/2026	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 2026. The filed figures are based on when the application was received. This includes applications that are still within the 60-day filing date and have not yet been filed[3], which is the same criteria used in the annual PDUFA Report to Congress. The approved figures include applications that have received an approval or tentative approval action. All data is as of September 30, 2026.

Quarterly filed figures are preliminary.

Table 3: The number of NDAs and BLAs filed* in FY 2026 (As of September 30, 2026)

Application Type	Q1	Q2	Q3	Q4	Cumulative
NDAs	34	38	38 [b]	28	138
BLAs	14 [a]	3	6 [c]	11	34
Total	**48**	**41**	**44**	**39**	**172**

* 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 BLA filed count for Q1 decreased by one since the June 30, 2026 report due to the application receiving a refuse to file action.

[b] The NDA filed count for Q3 decreased by one since the June 30, 2026 report due to the application being reclassified to an efficacy supplement.

[c] The BLA filed count for Q3 decreased by one since the June 30, 2026 report due to the application being reclassified to a BsUFA application.

Table 4: The number of NDAs* and BLAs approved in FY 2026 (As of September 30, 2026)

Application Type	Q1	Q2	Q3	Q4	Cumulative
NDAs	24	20	20	38	102
BLAs	10	4 [a]	6	10	30
Total	**34**	**24**	**26**	**48**	**132**

* Data includes all tentative approval and full approval actions issued within the reported fiscal year. Therefore, an NDA application can be counted multiple times if it receives multiple approval actions within the reported fiscal year.

[a] The BLA approval count for Q2 decreased by one since the June 30, 2026 report due to the application being reclassified to an efficacy supplement.

[3] FDA files only 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.