FY 2023

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 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

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 2023.

Table 1: Draft and Final Guidance Documents Related to the Process for the Review of Human Drug and Biologics License Applications for FY 2023

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	Comparability Protocols for Postapproval Changes to the Chemistry, Manufacturing, and Controls Information in an NDA, ANDA, or BLA; Final Guidance for Industry www.fda.gov/media/162263/download	10/14/2022	No	N/A
2	Q1	Human Gene Therapy for Neurodegenerative Diseases; Final Guidance for Industry www.fda.gov/media/144886/download	10/25/2022	No	N/A
3	Q1	*Clostridioides difficile* Infection: Developing Drugs for Treatment, Reduction of Recurrence, and Prevention; Draft Guidance for Industry www.fda.gov/media/162692/download	10/28/2022	Yes	FDASIA section 812
4	Q1	Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) - Small Entity Compliance Guide; Final Guidance for Industry www.fda.gov/media/70689/download	11/1/2022	No	N/A
5	Q1	Measuring Growth and Evaluating Pubertal Development in Pediatric Clinical Trials; Draft Guidance for Industry www.fda.gov/media/162725/download	11/1/2022	No	N/A
6	Q1	Expanded Access to Investigational Drugs for Treatment Use - Questions and Answers; Draft Guidance for Industry www.fda.gov/media/162793/download	11/2/2022	Yes	FDARA 2017 Section 610
7	Q1	S1B(R1) Addendum to S1B Testing for Carcinogenicity of Pharmaceuticals; Final Guidance for Industry www.fda.gov/media/152777/download	11/2/2022	No	N/A
8	Q1	Cross Labeling Oncology Drugs in Combination Regimens; Final Guidance for Industry www.fda.gov/media/162806/download	11/3/2022	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	Pharmacokinetic-Based Criteria for Supporting Alternative Dosing Regimens of Programmed Cell Death Receptor-1 (PD-1) or Programmed Cell Death-Ligand 1 (PD-L1) Blocking Antibodies for Treatment of Patients with Cancer; Final Guidance for Industry www.fda.gov/media/151745/download	12/6/2022	No	N/A
10	Q1	Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations; Draft Guidance for Industry www.fda.gov/media/163799/download	12/7/2022	No	N/A
11	Q1	Pulmonary Tuberculosis: Developing Drugs for Treatment; Draft Guidance for Industry www.fda.gov/media/87194/download	12/15/2022	Yes	FDASIA section 812

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 2023.

Table 2: Public Meetings Held Related to the Process for the Review of Human Drug and Biologics License Applications for FY 2023

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	An In-Depth Look at the Final FDA Guidance: Bioavailability Studies Submitted in NDAs or INDs – General Considerations; Webcast www.fda.gov/drugs/news-events-human-drugs/depth-look-final-fda-guidance-bioavailability-studies-submitted-ndas-or-inds-general-considerations	10/26/2022	No
2	Q1	FDA/IMS Joint Workshop: Future of Drug Development in Multiple Myeloma; Workshop www.fda.gov/drugs/news-events-human-drugs/fdaims-joint-workshop-future-drug-development-multiple-myeloma-11082022	11/8/2022 – 11/9/2022	No
3	Q1	Bridging Efficacy and Safety to the Obese: Considerations and Scientific Approaches; Workshop www.fda.gov/drugs/news-events-human-drugs/bridging-efficacy-and-safety-obese-considerations-and-scientific-approaches-11092022	11/9/2022	No
4	Q1	FDA CBER OTAT Patient-Focused Drug Development Listening Meeting — Patient Perspectives on Gene Therapy Products; Webcast www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fda-cber-otat-patient-focused-drug-development-listening-meeting-patient-perspectives-gene-therapy	11/15/2022	Yes
5	Q1	FDA-CDER-CDRH, SNMMI, and MITA Workshop: Quantitative Brain Amyloid PET Imaging-Technical Considerations; Workshop www.fda.gov/drugs/news-events-human-drugs/fda-cder-cdrh-snmmi-and-mita-workshop-quantitative-brain-amyloid-pet-imaging-technical	11/17/2022	No
6	Q1	Assessing Genetic Heterogeneity in the Context of Genome Editing Off-Targets in Gene Therapy Products; Workshop www.fda.gov/vaccines-blood-biologics/workshops-meetings-conferences-biologics/assessing-genetic-heterogeneity-context-genome-editing-targets-gene-therapy-products-12162022	12/16/2022	No

7	Q1	OTAT Town Hall: Cell Therapy Chemistry, Manufacturing, and Controls; Town Hall https://www.fda.gov/news-events/otat-town-hall-cell-therapy-chemistry-manufacturing-and-controls-12072022	12/7/2022	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 2023. 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 December 31, 2022.

Quarterly filed figures are preliminary.

Table 3: The number of NDAs and BLAs filed* in FY 2023 (as of December 31, 2022)

Application Type	Q1	Q2	Q3	Q4	Cumulative
NDAs	33				33
BLAs	12				12
Total	**45**				**45**

* 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 2023 (as of December 31, 2022)

Application Type	Q1	Q2	Q3	Q4	Cumulative
NDAs	20				20
BLAs	10				10
Total	**30**				**30**

[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.