FY 2022

Real Time Report

pursuant to the

Prescription Drug User Fee Act

as amended by the FDA Reauthorization Act of 2017

Acronyms

BLA – Biologics License Application

CBER – Center for Biologics Evaluation and Research

CDER – Center for Drug Evaluation and Research

FDA – Food and Drug Administration

FDARA – FDA Reauthorization Act of 2017

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 August 18, 2017, the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52) was signed into law. FDARA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to revise and extend 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:

> Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, 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 2017.
> 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 2017.
> 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, which is defined by section 735(1) of the FD&C Act as 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 Biosimilars User Fee Act.

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 2017. Guidance documents are listed by the quarter in which they were issued and are provided in a cumulative format for fiscal year 2022.

Table 1: Draft and Final Guidance Documents Related to the Process for the Review of Human Drug and Biologics License Applications for FY 2022

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	S1B(R1) Addendum to S1B Testing for Carcinogenecity of Pharmaceuticals www.fda.gov/media/152777/download	10/5/2021	N/A	N/A
2	Q1	Q13 Continuous Manufacturing of Drug Substances and Drug Products www.fda.gov/media/153044/download	10/13/2021	N/A	N/A
3	Q1	Data Standards for Drug and Biological Product Submissions Containing Real-World Data www.fda.gov/media/153341/download	10/22/21	Yes	PDUFA VI Commitment Letter Section I.6.c
4	Q1	Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act Guidance for Industry www.fda.gov/media/153665/downloadw	10/29/2021	Yes	Section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act, as added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).
5	Q1	Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products www.fda.gov/media/154449/download	11/30/21	Yes	PDUFA VI Commitment Letter Section I.6.c
6	Q1	IND Submissions for Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases: Chemistry, Manufacturing, and Controls Recommendations Guidance for Sponsor-Investigators www.fda.gov/media/154664/download	12/8/2021	N/A	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)
7	Q1	Investigational New Drug Application Submissions for Individualized Antisense Oligonucleotide Drug Products Severely Debilitating or Life-Threatening Diseases: Clinical Recommendations www.fda.gov/media/154663/download	12/8/2021	N/A	N/A
8	Q1	CMC Postapproval Manufacturing Changes for Specified Biological Products To Be Documented in Annual Reports Guidance for Industry www.fda.gov/media/106935/download	12/9/2021	N/A	N/A
9	Q1	Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products www.fda.gov/media/154714/download	12/9/21	Yes	PDUFA VI Commitment Letter Section I.6.c
10	Q1	Development of Anti-Infective Drug Products for the Pediatric Population www.fda.gov/media/139586/download	12/10/21	N/A	FDASIA Section 804
11	Q1	Chronic Rhinosinusitis with Nasal Polyps: Developing Drugs for Treatment www.fda.gov/media/154724/download	12/10/21	N/A	N/A
12	Q1	Bowel Cleansing for Colonoscopy: Efficacy and Safety Considerations for Developing New Products www.fda.gov/media/154760/download	12/10/21	N/A	N/A
13	Q1	Inspection of Injectable Products for Visible Particulates www.fda.gov/media/154868/download	12/16/2021	N/A	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 2022.

Table 2: Public Meetings Held Related to the Process for the Review of Human Drug and Biologics License Applications for FY 2022

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	Best Practices for Development and Application of Disease Progression Models www.fda.gov/drugs/news-events-human-drugs/best-practices-development-and-application-disease-progression-models-11192021-11192021	11/19/21	PDUFA VI Commitment Letter Section J.3.b
2	Q1	Regenerative Medicine 101 Webinar: Information for Patients, Caregivers & Advocates	11/16/21	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 2022. Figures are calculated based on the same criteria used in the annual PDUFA Report to Congress. The filed figures are based on when the application was received and include applications that are still within the 60-day filing date and have not yet been filed.[2] The approved figures include applications that have received an approval or tentative approval action. All data is as of December 31, 2021.

Quarterly filed figures are preliminary.

Table 3: The number of NDAs and BLAs filed* in FY 2022 (as of December 31, 2021)

Application Type	Q1	Q2	Q3	Q4	Cumulative
NDAs	24				24
BLAs	7				7
Total	**31**				**31**

* 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 2022 (as of December 31, 2021)

Application Type	Q1	Q2	Q3	Q4	Cumulative
NDAs	33				33
BLAs	7				7
Total	**40**				**40**

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

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.