



FDA U.S. FOOD & DRUG
ADMINISTRATION

FY 2020

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 2020.

Table 1: Draft and Final Guidance Documents Related to the Process for the Review of Human Drug and Biologics License Applications for FY 2020

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	Patient Focused Drug Development: Methods to Identify What is Important to Patients www.fda.gov/media/131230/download	10/1/2019	Pursuant to Commitment Letter	I.J.1.b.iii
2	Q1	Investigational Enzyme Replacement Therapy Products: Nonclinical Assessment www.fda.gov/media/131295/download	10/3/2019	Other	N/A
3	Q1	Investigational In Vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination www.fda.gov/media/112605/download	10/10/2019	Other	N/A
4	Q1	Prescription Drug User Fee Act Waivers, Reductions and Refunds for Drug and Biological Products www.fda.gov/media/131797/download	10/17/2019	Other	N/A
5	Q1	Drug Master File Guidance for Industry www.fda.gov/media/131861/download	10/18/2019	Other	N/A
6	Q1	Level 2 guidance - Identification of Manufacturing Establishments in Applications Submitted to CBER and CDER Questions and Answers www.fda.gov/media/131911/download	10/22/2019	Other	N/A
7	Q1	Postmarketing Studies and Clinical Trials - Implementation of Section 505(o)(3) of the Federal Food, Drug and Cosmetic Act www.fda.gov/media/131980/download	10/25/2019	Other	N/A
8	Q1	Electronic Submission of IND Safety Reports Technical Conformance Guide www.fda.gov/media/132078/download	10/29/2019	Other	N/A
9	Q1	Type V DMFs for CDER-Led Combination Products Using Device Constituent Parts with Electronics or Software www.fda.gov/media/132043/download	10/30/2019	Other	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	Providing Regulatory Submissions in Electronic Format: Investigational New Drug Application Safety Reports www.fda.gov/media/132079/download	10/30/2019	Other	N/A
11	Q1	Chronic Hepatitis D Virus Infection: Developing Drugs for Treatment www.fda.gov/media/132137/download	11/1/2019	Other	N/A
12	Q1	Smallpox (Variola Virus) Infection: Developing Drugs for Treatment www.fda.gov/media/132623/download	11/18/2019	Other	N/A
13	Q1	Adaptive Designs for Clinical Trials of Drugs and Biologics www.fda.gov/media/78495/download	12/2/2019	Other	N/A
14	Q1	Interstitial Cystitis/Bladder Pain Syndrome: Establishing Effectiveness of Drugs for Treatment www.fda.gov/media/133190/download	12/5/2019	Other	N/A
15	Q1	Development of Locally Applied Corticosteroid Products for the Short-Term Treatment of Symptoms Associated with Internal or External Hemorrhoids www.fda.gov/media/133256/download	12/9/2019	Other	N/A
16	Q1	Qualification Process for Drug Development Tools www.fda.gov/media/133511/download	12/16/2019	Pursuant to Commitment Letter	I.J.6.d
17	Q1	Bridging for Drug-Device and Biologic-Device Combination Products www.fda.gov/media/133676/download	12/19/2019	Pursuant to Commitment Letter	I.I.5.h.i.
18	Q1	Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review; Guidance for Industry; Technical Specifications Document www.fda.gov/media/112581/download	12/21/2019	Other	N/A
19	Q2	Hematologic Malignancies: Regulatory Considerations for Use of Minimal Residual Disease in Development of Drug and Biological Products for Treatment www.fda.gov/media/134605/download	1/27/2020	Other	N/A
20	Q2	Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations; Draft Guidance for Industry www.fda.gov/media/134731/download	1/30/2020	Other	N/A
21	Q2	Chemistry, Manufacturing, and Control Information for Human Gene Therapy Investigational New Drug Applications; Guidance for Industry www.fda.gov/media/113760/download	1/30/2020	Other	N/A
22	Q2	Human Gene Therapy for Retinal Disorders; Guidance for Industry www.fda.gov/media/124641/download	1/30/2020	Other	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	Human Gene Therapy for Hemophilia; Guidance for Industry www.fda.gov/media/113799/download	1/30/2020	Other	N/A
24	Q2	Long Term Follow-up After Administration of Human Gene Therapy Products; Guidance for Industry www.fda.gov/media/113768/download	1/30/2020	Other	N/A
25	Q2	Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up; Guidance for Industry www.fda.gov/media/113790/download	1/30/2020	Other	N/A
26	Q2	Human Gene Therapy for Rare Diseases; Guidance for Industry www.fda.gov/media/113807/download	1/30/2020	Other	N/A
27	Q2	Mucopolysaccharidosis Type III (Sanfillippo Syndrome): Developing Drugs for Treatment www.fda.gov/media/134893/download	2/5/2020	Other	N/A
28	Q2	Nonclinical Safety Evaluation of the Immunotoxic Potential of Drugs and Biologics www.fda.gov/media/135312/download	2/20/2020	Other	N/A
29	Q2	Providing Regulatory Submissions in Electronic Format - Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (Revision7) www.fda.gov/media/135373/download	2/24/2020	Other	N/A
30	Q2	Safety Testing of Drug Metabolites www.fda.gov/media/72279/download	3/5/2020	Other	N/A
31	Q2	The "Deemed to be a License" Provision of the Biologics Price Competition and Innovation Act: Questions and Answers www.fda.gov/media/135838/download	3/5/2020	Other	N/A
32	Q2	Contact Dermatitis From Tropical Products for Cutaneous Application: Human Safety Assessment www.fda.gov/media/135888/download	3/9/2020	Other	N/A
33	Q2	Type 2 Diabetes Mellitus: Evaluating the Safety of New Drugs for Improving Glycemic Control www.fda.gov/media/135936/download	3/10/2020	Other	N/A
34	Q2	Slowly Progressive, Low-Prevalence Rare Diseases With Substrate Deposition That Results From Single Enzyme Defects: Providing Evidence of Effectiveness for Replacement or Corrective Therapies www.fda.gov/media/136058/download	3/16/2020	Other	N/A
35	Q3	Cytomegalovirus in Transplantation: Developing Drugs to Treat or Prevent Disease www.fda.gov/media/112942/download	5/8/2020	Other	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)
36	Q3	COVID-19: Developing Drugs and Biological Products for Treatment or Prevention www.fda.gov/media/137926/download	5/11/2020	Other	N/A
37	Q3	Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment www.fda.gov/media/75149/download	6/25/2020	Other	N/A
38	Q3	Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment www.fda.gov/media/79516/download	6/25/2020	Other	N/A
39	Q3	Development and Licensure of Vaccines to Prevent COVID-19 www.fda.gov/media/139638/download	6/30/2020	Other	N/A
40	Q3	Development of Anti-Infective Drug Products for the Pediatric Population www.fda.gov/media/139586/download	6/30/2020	Other	N/A
41	Q4	Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research, draft Guidance for Industry www.fda.gov/media/140319/download	7/21/2020	Other	N/A
42	Q4	Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use www.fda.gov/media/109176/download	7/21/2020	Other	N/A
43	Q4	Expiration Dating of Unit-Dose Repackaged Solid Oral Dosage Form Drug Products, Final Guidance for Industry www.fda.gov/media/70985/download	7/29/2020	Other	N/A
44	Q4	Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biological Products www.fda.gov/media/140410/download	7/29/2020	Other	N/A
45	Q4	Pregnancy, Lactation and Reproductive Potential: Labeling for Human Prescription and Drug and Biological Products www.fda.gov/media/90160/download	7/30/2020	Other	N/A
46	Q4	Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Initial Pediatric Study Plans www.fda.gov/media/86340/download	8/3/2020	Other	N/A
47	Q4	Control of Nitrosamine Impurities in Human Drugs, Final Guidance for Industry www.fda.gov/media/141720/download	9/1/2020	Other	N/A
48	Q4	Eosinophilic Esophagitis: Developing Drugs for Treatment www.fda.gov/media/120089/download	9/16/2020	Other	N/A
49	Q4	Geriatric Information in Human Prescription Drug and Biological Product Labeling www.fda.gov/media/142162/download	9/16/2020	Other	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)
50	Q4	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 www.fda.gov/media/142143/download	9/29/2020	Other	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 2020.

Table 2: Public Meetings Held Related to the Process for the Review of Human Drug and Biologics License Applications for FY 2020

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	Use of Fecal Microbiota for Transplantation (FMT) to Treat Clostridium difficile Infection Not Responsive to Standard Therapies	11/4/2019	Other
2	Q1	Development of Best Practices in Physiologically Based Pharmacokinetic Modeling to Support Clinical Pharmacology Regulatory Decision Making	11/18/2019	Pursuant to Commitment Letter
3	Q1	Patient-Focused Drug Development Guidance: Incorporating Clinical Outcome Assessments into Endpoints for Regulatory Decision Making	12/6/2019	Pursuant to Commitment Letter
4	Q2	Facilitating End-to-End Development of Individualized Therapeutics	3/3/2020	Other
5	Q2	Advancing Animal Models for Antibacterial Drug Development	3/5/2020	Other
6	Q2	Summary of FDA & EMA Global Regulators Meeting on Data Requirements Supporting First-in-Human Clinical Trials with SARS-CoV-2 Vaccines	3/18/2020	Other
7	Q3	Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments	6/10/2020	Pursuant to Commitment Letter
8	Q4	Reauthorization of the Prescription Drug User Fee Act; Public Meeting	7/23/2020	Required by Statute
9	Q4	Independent Third-Party Assessment of Investigational New Drug Food and Drug Administration-Sponsor Communication Practices in Prescription Drug User Fee Act VI	8/11/2020	Pursuant to Commitment Letter
10	Q4	Considerations for the Use of Real-World Evidence to Assess the Effectiveness of Preventive Vaccines	9/17-18/2020	Required by Statute

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 2020. 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 September 30, 2020.

Quarterly filed figures are preliminary.

Table 3: The number of NDAs and BLAs filed* in FY 2020 (as of September 30, 2020)

Application Type	Q1	Q2	Q3	Q4	Cumulative
NDAs	33	31	29 ^a	32	125
BLAs	11	5	8 ^b	9	33
Total	44	36	37	41	158

* 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 quarter 3 decreased by three after the June 30, 2020 report due to three refuse to file actions.

^b The BLA filed count for quarter 3 decreased by one after the June 30, 2020 report due to a refuse to file action.

Table 4: The number of NDAs and BLAs approved in FY 2020 (as of September 30, 2020)

Application Type	Q1	Q2	Q3	Q4	Cumulative
NDAs	38	26	32	29	125
BLAs	6	5	8	6	25
Total	44	31	40	35	150

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.