



FDA U.S. FOOD & DRUG
ADMINISTRATION

FY 2021

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 2021.

Table 1: Draft and Final Guidance Documents Related to the Process for the Review of Human Drug and Biologics License Applications for FY 2021

| 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 | Emergency Use Authorization for Vaccines to Prevent COVID-19 www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19 | 10/1/2020 | Other | N/A |
| 2 | Q1 | The Use of Physiologically Based Pharmacokinetic Analyses — Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls www.fda.gov/media/142500/download | 10/1/2020 | Other | N/A |
| 3 | Q1 | Opioid Use Disorder: Endpoints for Demonstrating Effectiveness of Drugs for Treatment www.fda.gov/regulatory-information/search-fda-guidance-documents/opioid-use-disorder-endpoints-demonstrating-effectiveness-drugs-treatment-guidance-industry | 10/2/2020 | Other | N/A |
| 4 | Q1 | Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989 www.fda.gov/regulatory-information/search-fda-guidance-documents/annual-status-report-information-and-other-submissions-postmarketing-requirements-and-commitments | 10/21/2020 | Other | N/A |
| 5 | Q1 | Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products www.fda.gov/regulatory-information/search-fda-guidance-documents/nonclinical-testing-orally-inhaled-nicotine-containing-drug-products-guidance-industry | 10/29/2020 | 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) |
|--------|----------------|--|-------------|--|---|
| 6 | Q1 | Cross Labeling Oncology Drugs in Combination Drug Regimens www.fda.gov/regulatory-information/search-fda-guidance-documents/cross-labeling-oncology-drugs-combination-regimens-guidance-industry | 11/20/2020 | Other | N/A |
| 7 | Q1 | Interacting with the FDA on Complex Innovative Trial Designs for Drugs and Biological Products www.fda.gov/regulatory-information/search-fda-guidance-documents/interacting-fda-complex-innovative-trial-designs-drugs-and-biological-products | 12/1/2020 | Required by Statute | Section 3021 of the 21st Century Cures Act (Cures Act) |
| 8 | Q1 | Dry Eye: Development Drugs for Treatment www.fda.gov/regulatory-information/search-fda-guidance-documents/dry-eye-developing-drugs-treatment-guidance-industry | 12/17/2020 | Other | N/A |
| 9 | Q1 | Review Timelines for Applicant Responses to Complete Response Letters When a Facility Assessment Is Needed During the COVID-19 Public Health Emergency Guidance for Industry www.fda.gov/media/144690/download | 12/21/2020 | Other | N/A |
| 10 | Q2 | Human Gene Therapy for Neurodegenerative Diseases; Draft Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/human-gene-therapy-neurodegenerative-diseases | 1/5/2021 | Other | N/A |
| 11 | Q2 | Investigational New Drug Submissions for Individualized Antisense Oligonucleotide Drug Products: Administrative and Procedural Recommendations www.fda.gov/media/144872/download | 1/5/2021 | Other | N/A |
| 12 | Q2 | COVID-19: Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting SARS-CoV-2 Infectivity www.fda.gov/regulatory-information/search-fda-guidance-documents/covid-19-potency-assay-considerations-mono-clonal-antibodies-and-other-therapeutic-proteins-targeting | 1/13/2021 | Other | N/A |
| 13 | Q2 | Manufacturing Considerations for Licensed and Investigational Cellular and Gene Therapy Products During COVID-19 Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/manufacturing-considerations-licensed-and-investigational-cellular-and-gene-therapy-products-during | 1/19/2021 | Other | N/A |
| 14 | Q2 | COVID-19: Developing Drugs and Biological Products for Treatment or Prevention www.fda.gov/media/137926/download | 2/22/2021 | 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) |
|--------|----------------|---|-------------|--|---|
| 15 | Q2 | Emergency Use Authorization for Vaccines to Prevent COVID-19 www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19 | 2/22/2021 | Other | N/A |
| 16 | Q2 | COVID-19 Container Closure System and Component Changes: Glass Vials and Stoppers www.fda.gov/regulatory-information/search-fda-guidance-documents/covid-19-container-closure-system-and-component-changes-glass-vials-and-stoppers-guidance-industry | 3/4/2021 | Other | N/A |
| 17 | Q3 | Remote Interactive Evaluations of Drug manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Health Emergency Guidance for Industry www.fda.gov/media/147582/download | 4/14/21 | Other | N/A |
| 18 | Q3 | Nonclinical Testing of Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases www.fda.gov/media/147876/download | 4/27/21 | Other | N/A |
| 19 | Q3 | Qualified Infectious Disease Product Designation Questions and Answers www.fda.gov/media/148480/download | 5/12/21 | Other | N/A |
| 20 | Q3 | COVID-19 Master Protocols for Drugs and Biological Products for Treatment or Prevention www.fda.gov/media/148739/download | 5/17/21 | Other | N/A |
| 21 | Q3 | Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers www.fda.gov/media/141312/download | 5/17/21 | Other | N/A |
| 22 | Q3 | Chemotherapy-Induced Nausea and Vomiting: Developing Drugs for Prevention www.fda.gov/media/148829/download | 5/19/21 | Other | N/A |
| 23 | Q3 | ICH Q12: Implementation considerations for FDA-Regulated Products Draft Guidance for Industry www.fda.gov/media/148947/download | 5/20/21 | Other | N/A |
| 24 | Q3 | GUI DRAFT – Oral Drug products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations Draft Guidance for Industry www.fda.gov/media/149688/download | 6/3/21 | Other | N/A |
| 25 | Q3 | MAPP New – Evaluating Color Additives and Flavors Intended for Oral Drug Products Submitted or Referenced in INDs and NDAs www.fda.gov/media/149813/download | 6/3/21 | Other | N/A |
| 26 | Q3 | Providing Regulatory Submissions in Electronic Format – Standardized Study Data (Revision 2) www.fda.gov/media/82716/download | 6/22/21 | 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) |
|--------|----------------|---|-------------|--|---|
| 27 | Q3 | Emergency Use Authorization for Vaccines to Prevent COVID-19; Guidance for Industry www.fda.gov/media/142749/download | 5/25/21 | Other | N/A |
| 28 | Q3 | Chemistry, Manufacturing, and Controls Changes to an Approved Application; Certain Biological Products; Guidance for Industry www.fda.gov/media/109615/download | 6/21 | 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 2021.

Table 2: Public Meetings Held Related to the Process for the Review of Human Drug and Biologics License Applications for FY 2021

| Number | Quarter Held | Title | Date Held | Held as Required by Statute or Pursuant to Commitment Letter |
|--------|--------------|--|-----------|--|
| 1 | Q1 | Patient-Focused Drug Development for Stimulant Use Disorder | 10/3/2020 | Pursuant to Commitment Letter |
| 2 | Q2 | Patient-Focused Drug Development for Vitiligo | 3/8/2021 | Pursuant to, Commitment Letter |
| 3 | Q3 | Food and Drug Administration Public Meeting on Financial Efficiency of Human Drug User Fee Program | 6/28/21 | Pursuant to Commitment Letter |
| 4 | Q3 | Patient Engagement & Regenerative Medicine: An FDA CBER Workshop for Patient Advocates www.fda.gov/vaccines-blood-biologics/workshops-meetings-conferences-biologics/patient-engagement-regenerative-medicine-fda-cber-workshop-patient-advocates-05062021-05062021 | 5/6/21 | N/A |
| 5 | Q3 | Model Informed Drug Development Approaches for Immunogenicity Assessments | 6/9/21 | n/a |

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 2021. 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 June 30, 2021.

Quarterly filed figures are preliminary.

Table 3: The number of NDAs and BLAs filed* in FY 2021 (as of June 30, 2021)

| Application Type | Q1 | Q2 | Q3 | Q4 | Cumulative |
|------------------|-----------|-----------------|-----------|----|------------|
| NDAs | 44 | 30 ^a | 30 | | 104 |
| BLAs | 12 | 8 | 9 | | 29 |
| Total | 56 | 38 | 39 | | 133 |

* 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 Q2 had a net increase of one since the March 31, 2020 report due to the addition of a late data entry.

Table 4: The number of NDAs and BLAs approved in FY 2021 (as of June 30, 2021)

| Application Type | Q1 | Q2 | Q3 | Q4 | Cumulative |
|------------------|-----------|-----------|-----------|----|------------|
| NDAs | 25 | 25 | 31 | | 81 |
| BLAs | 4 | 3 | 8 | | 15 |
| Total | 29 | 28 | 39 | | 96 |

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.