FY 2018

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 – Food and Drug Administration 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 Food and Drug Administration Reauthorization Act (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 2018.

Table 1: Draft and Final Guidance Documents Related to the Process for the Review of Human Drug and Biologics License Applications for FY 2018

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	Assessing User Fees Under the Prescription Drug User Fee Amendments; Draft www.federalregister.gov/documents/2017/10/13/2017-22192/assessing-user-fees-under-the-prescription-drug-user-fee-amendments-of-2017-draft-guidance-for	10/13/2017	Other	N/A
2	Q1	Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Draft Guidance for Industry www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM585414.pdf	11/1/2017	Other	N/A
3	Q1	Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM585403.pdf	11/1/2017	Other	N/A
4	Q1	Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception; Guidance for Industry www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM419926.pdf	11/1/2017	Other	N/A
5	Q1	Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products; Draft Guidance for Industry www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/UCM590118.pdf	12/1/2017	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	Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research; Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/UCM589416.pdf	12/1/2017	Other	N/A
7	Q1	Drug Products, Including Biological Products, that Contain Nanomaterials - Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM588857.pdf	12/15/2017	Other	N/A
8	Q1	Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System. Guidance for Industry www.fda.gov/downloads/Drugs/Guidances/ucm070246.pdf	12/22/2017	Other	N/A
9	Q1	Best Practices for Communication Between Investigational New Drug Application Sponsors and the Food and Drug Administration; Final www.federalregister.gov/documents/2017/12/29/2017-28139/best-practices-for-communication-between-investigational-new-drug-application-sponsors-and-the-food	12/29/2017	Pursuant to Commitment Letter	I.I.1.c
10	Q1	Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Prescription Drug User Fee Act; Draft www.federalregister.gov/documents/2017/12/29/2017-28140/formal-meetings-between-the-food-and-drug-administration-and-sponsors-or-applicants-of-prescription	12/29/2017	Pursuant to Commitment Letter	I.H.8
11	Q2	Regulatory Classification of Pharmaceutical Co-Crystals www.fda.gov/downloads/Drugs/Guidances/UCM281764.pdf	2/14/2018	Other	N/A
12	Q2	Q11 Development and Manufacture of Drug Substances--Questions and Answers (Chemical Entities and Biotechnological/Biological Entities) www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM542176.pdf	2/23/2018	Other	N/A
13	Q3	Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation www.fda.gov/downloads/drugs/guidances/ucm070570.pdf	4/4/2018	Other	N/A
14	Q3	Pilot Meetings Program for Model-Informed Drug Development Approaches www.gpo.gov/fdsys/pkg/FR-2018-04-17/pdf/2018-08010.pdf	4/17/2018	Pursuant to Commitment Letter	I.J.3.c.i

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	Q3	Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products--Quality Considerations www.federalregister.gov/documents/2018/04/19/2018-08200/metered-dose-inhaler-and-dry-powder-inhaler-drug-products-quality-considerations-draft-guidance-for	4/18/2018	Other	N/A
16	Q3	Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review; Guidance for Industry; Technical Specifications Document www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/UCM605147.pdf	4/19/2018	Other	N/A
17	Q3	Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients: Questions and Answers www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM605076.pdf	4/19/2018	Other	N/A
18	Q3	Assessing User Fees Under the Prescription Drug User Fee Amendments; Final www.gpo.gov/fdsys/pkg/FR-2018-05-03/pdf/2018-09366.pdf	5/3/2018	Other	N/A
19	Q3	Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management Core Guideline Guidance for Industry www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609205.pdf	5/30/2018	Other	N/A
20	Q3	Prescription Drug User Fee Act Waivers for Fixed-Combination Antiretroviral Drugs for President's Emergency Plan for AIDS Relief www.gpo.gov/fdsys/pkg/FR-2018-06-07/pdf/2018-12217.pdf	6/7/2018	Other	N/A
21	Q3	Patient-Focused Drug Development: Collecting Comprehensive and Representative Input www.gpo.gov/fdsys/pkg/FR-2018-06-13/pdf/2018-12636.pdf	6/13/2018	Pursuant to Commitment Letter	I.J.1.b.i
22	Q3	Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products www.gpo.gov/fdsys/pkg/FR-2018-06-21/pdf/2018-13295.pdf	6/21/2018	Other	N/A
23	Q4	Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs); Draft Guidance for Industry www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM610795.pdf	7/12/2018	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)
24	Q4	Long Term Follow-up After Administration of Human Gene Therapy Products; Draft Guidance for Industry www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM610797.pdf	7/12/2018	Other	N/A
25	Q4	Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up; Draft Guidance for Industry www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM610800.pdf	7/12/2018	Other	N/A
26	Q4	Human Gene Therapy for Hemophilia; Draft Guidance for Industry www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM610801.pdf	7/12/2018	Other	N/A
27	Q4	Human Gene Therapy for Rare Diseases; Draft Guidance for Industry www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM610802.pdf	7/12/2018	Other	N/A
28	Q4	Human Gene Therapy for Retinal Disorders; Draft Guidance for Industry www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM610803.pdf	7/12/2018	Other	N/A
29	Q4	Field Alert Report Submission: Questions and Answers www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM613753.pdf	7/18/2018	Other	N/A
30	Q4	Use of Liquids and/or Soft Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for Product Quality Assessments www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM614401.pdf	7/24/2018	Other	N/A
31	Q4	Elemental Impurities in Drug Products www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM509432.pdf	8/7/2018	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)
32	Q4	Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM456594.pdf	8/8/2018	Other	N/A
33	Q4	Quality Attribute Considerations for Chewable Tablets www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM507098.pdf	8/20/2018	Other	N/A
34	Q4	Good Review Management Principles and Practices for New Drug Applications and Biologics Licensed www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm079748.pdf20789/good-review-management-principles-and-practices-for-new-drug-applications-and-biologics-license	9/25/2018	Pursuant to Commitment Letter	I.C
35	Q4	Adaptive Designs for Clinical Trials of Drugs and Biologics www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm201790.pdf	9/28/2018	Pursuant to Commitment Letter	I.J.4.d

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 2018.

Table 2: Public Meetings Held Related to the Process for the Review of Human Drug and Biologics License Applications for FY 2018

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	Patient-Focused Drug Development: Guidance 1 - Collecting Comprehensive and Representative Input	12/18/2017	Commitment letter, I.J.1.b
2	Q2	Best Practices in Modeling and Simulation for Oncology Products	2/1/2018	Commitment letter, I.J.3.b
3	Q2	Biologics Effectiveness and Safety (BEST) Sentinel Initiative Industry Day	2/12/2018	N/A
4	Q2	21st US-Japan Cellular and Gene Therapy Conference	3/1/2018	N/A
5	Q2	Promoting the Use of Complex Innovative Designs in Clinical Trials	3/20/2018	Commitment letter, I.J.4.c
6	Q2	Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards; Public Meeting	3/21/2018	Commitment letter, IV.C.2
7	Q4	Science and Regulation of Live Microbiome-Based Products Used to Prevent, Treat, or Cure Diseases in Humans; Public Workshop	8/17/2018	N/A
8	Q4	Evidence-Based Treatment Decision in Transplantation: Patient Individualized Treatment; Choosing the Right Regimen for the Right Patient; Public Workshop	9/27/2018	Commitment letter, I.I.6.a

New Drug and Biologics License Applications

The figures in the tables below represent filed and approved NDAs and BLAs during FY 2018. 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, 2018, including data previously provided.

Quarterly filed figures are preliminary.

Table 3: The number of NDAs and BLAs filed* in FY 2018 (as of September 30, 2018)

Application Type	Q1	Q2	Q3	Q4	Cumulative
NDAs	46[a]	33	31[b]	27	137
BLAs	7	4	7	3	21
Total	**53**	**37**	**38**	**30**	**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 1 decreased by one after the June 30, 2018 report as a result of one application that had been administratively split into two separate applications, upon approval, had one of the split applications converted to an efficacy supplement.

[b] The NDA filed count for quarter 3 decreased by four after the June 30, 2018 report as a result of three applications receiving refuse to file actions, and one application that had been incorrectly coded as received in quarter 3, was corrected to accurately show receipt in quarter 4.

Table 4: The number of NDAs and BLAs approved in FY 2018 (as of September 30, 2018)

Application Type	Q1	Q2	Q3	Q4	Cumulative
NDAs	43	26	28	46	143
BLAs	8	2	5	9	24
Total	**51**	**28**	**33**	**55**	**167**

[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 approved, and thus 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.