Petition to Make Special

The table below presents the data as entered.

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MARK SECTION	
MARK	https://tmng-al.uspto.gov/resting2/api/img/97689924/large
LITERAL ELEMENT	FEIZDU
STANDARD CHARACTERS	YES
USPTO-GENERATED IMAGE	YES
MARK STATEMENT	The mark consists of standard characters, without claim to any particular font style, size or color.
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OWNER SECTION (Current)	
NAME	Astellas US LLC
MAILING ADDRESS	1 Astellas Way
CITY	Northbrook
STATE	Illinois
COUNTRY/REGION/JURISDICTION/U.S. TERRITORY	United States
ZIP/POSTAL CODE	60062
EMAIL	XXXX
OWNER SECTION (Proposed)	
NAME	Astellas US LLC
MAILING ADDRESS	1 Astellas Way
CITY	Northbrook
STATE	Illinois
COUNTRY/REGION/JURISDICTION/U.S. TERRITORY	United States
ZIP/POSTAL CODE	60062
EMAIL	XXXX
ATTORNEY INFORMATION (current)	
NAME	Keith Toms, Esq.

ATTORNEY BAR MEMBERSHIP NUMBER	XXX
YEAR OF ADMISSION	XXXX
U.S. STATE/ COMMONWEALTH/ TERRITORY	XX
FIRM NAME	McCarter & English, LLP
STREET	265 Franklin Street
CITY	Boston
STATE	Massachusetts
POSTAL CODE	02110-3113
COUNTRY/REGION/JURISDICTION/U.S. TERRITORY	United States
PHONE	617-449-6500
EMAIL	ktoms@mccarter.com
DOCKET/REFERENCE NUMBER	127206-10200
ATTORNEY INFORMATION (proposed)	
NAME	Keith Toms, Esq.
ATTORNEY BAR MEMBERSHIP NUMBER	XXX
YEAR OF ADMISSION	XXXX
U.S. STATE/ COMMONWEALTH/ TERRITORY	XX
FIRM NAME	McCarter & English, LLP
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PHONE	617-449-6500
EMAIL	ktoms@mccarter.com
DOCKET/REFERENCE NUMBER	127206-10200
CORRESPONDENCE INFORMATION (current)	
NAME	Keith Toms, Esq.
PRIMARY EMAIL ADDRESS FOR CORRESPONDENCE	ktoms@mccarter.com
SECONDARY EMAIL ADDRESS(ES) (COURTESY COPIES)	bostontrademarks@mccarter.com; mandrews@mccarter.com
DOCKET/REFERENCE NUMBER	127206-10200
CORRESPONDENCE INFORMATION (proposed)	
NAME	Keith Toms, Esq.
PRIMARY EMAIL ADDRESS FOR CORRESPONDENCE	ktoms@mccarter.com
SECONDARY EMAIL ADDRESS(ES) (COURTESY COPIES)	bostontrademarks@mccarter.com; mandrews@mccarter.com
DOCKET/REFERENCE NUMBER	127206-10200
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NUMBER OF CLASSES	1

PETITION TO DIRECTOR FEE	250
TOTAL FEES DUE	250
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SIGNATORY'S NAME	Christopher Bolinger
SIGNATORY'S POSITION	Sr. Director, IP Development & Commercial, Trademarks
SIGNATORY'S PHONE NUMBER	000-000-0000
SIGNATURE METHOD	Handwritten
SUBMISSION SIGNATURE	/Keith Toms/
SIGNATORY'S NAME	Keith Toms
SIGNATORY'S POSITION	Attorney of record, MA Bar Member
SIGNATORY'S PHONE NUMBER	617-449-6500
DATE SIGNED	12/05/2022
ROLE OF AUTHORIZED SIGNATORY	Authorized U.S.-Licensed Attorney
SIGNATURE METHOD	Sent to third party for signature
FILING INFORMATION SECTION	
SUBMIT DATE	Mon Dec 05 21:31:48 EST 2022
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Petition to Make Special

To the Commissioner for Trademarks:

The following is submitted for application serial number: **97689924**

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Attachments-92
Attachments-93

The owner proposes to amend the following:

Current: Astellas US LLC, having an address of
1 Astellas Way
Northbrook, Illinois 60062
United States
Email Address: XXXX

Proposed: Astellas US LLC, having an address of
1 Astellas Way
Northbrook, Illinois 60062
United States
Email Address: XXXX
The owner's/holder's current attorney information: Keith Toms, Esq.. Keith Toms, Esq. of McCarter & English, LLP, is a member of the XX bar, admitted to the bar in XXXX, bar membership no. XXX, is located at

265 Franklin Street
Boston, Massachusetts 02110-3113
United States
The docket/reference number is 127206-10200.

The phone number is 617-449-6500.

The email address is ktoms@mccarter.com

The owner's/holder's proposed attorney information: Keith Toms, Esq.. Keith Toms, Esq. of McCarter & English, LLP, is a member of the XX bar, admitted to the bar in XXXX, bar membership no. XXX, is located at

265 Franklin Street
Boston, Massachusetts 02110-3113
United States
The docket/reference number is 127206-10200.

The phone number is 617-449-6500.

The email address is ktoms@mccarter.com

Correspondence Information (current):
Keith Toms, Esq.
PRIMARY EMAIL FOR CORRESPONDENCE: ktoms@mccarter.com
SECONDARY EMAIL ADDRESS(ES) (COURTESY COPIES): bostontrademarks@mccarter.com; mandrews@mccarter.com

The docket/reference number is 127206-10200.

Correspondence Information (proposed):
Keith Toms, Esq.
PRIMARY EMAIL FOR CORRESPONDENCE: ktoms@mccarter.com
SECONDARY EMAIL ADDRESS(ES) (COURTESY COPIES): bostontrademarks@mccarter.com; mandrews@mccarter.com

The docket/reference number is 127206-10200.

Requirement for Email and Electronic Filing: I understand that a valid email address must be maintained by the applicant owner/holder and the applicant owner's/holder's attorney, if appointed, and that all official trademark correspondence must be submitted via the Trademark Electronic Application System (TEAS).

FEE(S)
Fee(s) in the amount of $250 is being submitted.

SIGNATURE(S)
Declaration Signature
Original PDF file:
Signed_Declaration_-_Petition_to_Make_Special_202211573918881.pdf
Converted PDF file(s) (1 page)

Signature File1
Signatory's Name: Christopher Bolinger
Signatory's Position: Sr. Director, IP Development & Commercial, Trademarks
Signatory's Phone Number: 000-000-0000
Signature method: Handwritten

Submission Signature
Signature: /Keith Toms/ Date: 12/05/2022
Signatory's Name: Keith Toms
Signatory's Position: Attorney of record, MA Bar Member
Signatory's Phone Number: 617-449-6500
Signature method: Sent to third party for signature

The signatory has confirmed that he/she is a U.S.-licensed attorney who is an active member in good standing of the bar of the highest court of a U.S. state (including the District of Columbia and any U.S. Commonwealth or territory); and he/she is currently the petitioner's attorney or an associate thereof; and to the best of his/her knowledge, if prior to his/her appointment another U.S.-licensed attorney not currently associated with his/her company/firm previously represented the petitioner in this matter: the petitioner has revoked their power of attorney by a signed revocation or substitute power of attorney with the USPTO; the USPTO has granted that attorney's withdrawal; the petitioner has filed a power of attorney appointing him/her in this matter; or the petitioner's appointed U.S.-licensed attorney has filed a power of attorney appointing him/her as an associate attorney in this matter.

Mailing Address: Keith Toms, Esq.
McCarter & English, LLP

265 Franklin Street
Boston, Massachusetts 02110-3113
Mailing Address: Keith Toms, Esq.
McCarter & English, LLP

265 Franklin Street
Boston, Massachusetts 02110-3113

PAYMENT: 31492498
PAYMENT DATE: 12/05/2022

Serial Number: 97689924
Internet Transmission Date: Mon Dec 05 21:31:48 EST 2022
TEAS Stamp: USPTO/PMS-XX.XXX.X.XXX-20221205213148000
633-97689924-20221205193704660072-DA-314
92498-20221205193704660072

Mark: FEIZDU
Application No.: 97/689,924
Application Date: November 23, 2022
Owner: Astellas US LLC

PETITION TO MAKE SPECIAL

Petitioner Astellas US LLC ("Astellas") respectfully requests that its U.S. Application Serial No. 97/689,924 for FEIZDU be made the subject of a special action pursuant to 37 C.F.R. § 2.146 and be examined without delay.[1] In particular, Astellas requests this extraordinary remedy to avoid the demonstrable loss of substantial rights that may arise if it is unable to coordinate the timing of the present application with the timeline for the approval of proposed proprietary names to the Food and Drug Administration ("FDA").

Astellas recognizes that petitions to make special must meet an extraordinary bar and believes, as discussed below, that the circumstances surrounding its application warrant the granting of this Petition. The Declaration of Christopher Bolinger, Sr. Director, IP Development

[1] Through separate filings, Astellas is requesting that ten applications be made special so that it may adapt its FDA submission if the proprietary name currently under review is not accepted. Given the proximity of the PDUFA Action Date, Astellas will need to work closely with the FDA to identify a proprietary name that can quickly and successfully pass Agency review. Astellas believes it can minimize the risk of a substantial loss of rights by presenting a diverse slate of candidate marks to the FDA for initial feedback, and thus respectfully seeks to have examination expedited for the full slate of marks so it can exclude any marks with trademark registrability issues.

37 C.F.R. § 2.146 does not place any numeric limits on the number of applications that can be made special, and Astellas believes that it has good cause for each of the applications to be made special given the challenging FDA review of the fezolinetant proprietary name. The slate of marks includes both a diversity of marks, in case the FDA identifies a fundamental obstacle with a particular mark, and spelling variations, in case the FDA's concerns can be mitigated by modifying a mark. Given the late stage of the FDA review process, Astellas believes that having this diversity of name candidates is essential to minimizing the risk of a substantial loss of rights.

Should the USPTO, however, determine only to grant a subset of the Petitions, Astellas respectfully requests that the applications for VEYJAH (SN 97689948), FEIZDU (SN 97689924), CEVMIHO (SN 97657239), and FEZKAYO (SN 97689932) be prioritized.

& Commercial, Trademarks, verifying this petition attests that Astellas believes it will suffer a loss of substantial rights if the Petition to Make Special is not granted.

STATEMENT OF FACTS

In August 2022, Astellas' New Drug Application ("NDA") for a drug generically named fezolinetant was accepted by the U.S. Food and Drug Administration ("FDA") for Priority Review. The fezolinetant drug product is a first-in-class nonhormonal treatment option for moderate to severe vasomotor symptoms (VMS) associated with menopause. Per the guidelines specified in the Prescription Drug User Fee Act ("PDUFA"), FDA priority review of Astellas' NDAs will be complete by February 22, 2022 (the "PDUFA Action Date"). *See* Ex. 1, Fezolinetant Press Release.

In early 2020, long before the submission of its NDA, Astellas had begun the process of securing trademark protection and regulatory approval for a proprietary brand name for fezolinetant. Its diligence culminated in selecting a primary mark, which was submitted to the FDA in February 2021. Unfortunately, in August 2021 the FDA's review determined that Astellas' first-choice proprietary name did not satisfy all the rigorous requirements for FDA approval due a conflict with another undisclosed product under FDA review.

Astellas then submitted a second mark VEOZA (U.S. Serial No. 97/070,486) in December 2021. While Astellas was supposed to receive preliminary feedback on this proprietary name by June 2022, the FDA did not complete its review until September 2022, where the VEOZA mark was found unacceptable due to an orthographic handwriting conflict with a prior drug product.

The FDA refusal of the backup mark has necessitated efforts by Astellas to develop and seek protection for new proprietary names that will satisfy the rigorous requirements of both the

FDA and the USPTO. After consultation with the FDA, Astellas determined that its previously filed back-up applications, that had already been prosecuted at the USPTO, would not be suitable. Instead, Astellas developed a new mark that it has instead submitted for FDA approval in October 2022.

Review of this FDA submission is pending, with a decision expected in January 2023. Given the nature of the FDA review, however, there remains a significant risk that the name under current consideration will not be approved, which leads little time before the PDUFA Action Date to submit an alternative. The application for the FEIZDU mark is part of a slate of backup marks specifically developed to maximize the speed of FDA review and approval in advance of the PDUFA Action Date or as soon thereafter as possible.

Due to the FDA's rejection of its first and second choice proprietary names, the uncertainty regarding its current pending candidate name, Astellas now faces a significant issue of timing that could lead to a demonstrable possibility of a substantial loss of rights. Should the current name under consideration not be accepted, Astellas will need to work closely with the FDA and move quickly to submit a name to the FDA for hope of approval in advance of the February 2023 PDUFA Action Date. Under standard USPTO examination timelines, however, the earliest Astellas can expect the present application to be examined would be August 2023. *See* Ex. 2 (indicating average first action in 8.2 months). As such, Astellas would not have time to submit an alternative name for FDA approval if, for example, the Examining Attorney finds the proposed proprietary name to be unregisterable.

Failure to have a proprietary name that is both registerable at the USPTO and acceptable to the FDA by the PDUFA Action Date would lead to a demonstrable loss of substantive rights for Astellas under any scenario. If the lack of a proprietary name were to delay launch, then

Astellas is losing part of its substantial rights to limited market exclusivity and data exclusivity, which are granted to Astellas pursuant to the patent statute and the Hatch-Waxman act. *See* 21 C.F.R. § 314.108 (providing right to 5 years exclusivity for new molecular entities like fezolinetant). A delayed launch would also deprive patients of a beneficial drug treatment. Alternatively, if Astellas accepts an FDA-approved proprietary name that ultimately cannot be registered at the USPTO, then Astellas would be losing the substantive rights associated with a federally registered trademark. Finally, proceeding to market with its new drug under the generic name fezolinetant would also lead to a loss of substantial rights, namely the ability to use a trademark to capture the goodwill generated by a successful product launch of an exciting new drug.

The circumstances giving rise to Astellas' present issue are rare and will not be encountered by a substantial number of other companies, as new drugs are one of the few products or services that require regulatory approval of trademarks before their use. Indeed, even in the pharmaceutical industry, only a small number of drug products received Priority Review status. *See* Ex. 3 at 5, FDA FY2021 Performance Report to Congress (noting five-year average of fifty-six Original Priority NDA and BLA filings per year for new molecular entities ("NMEs") and non-NME products). While Astellas is not aware of statistics, presumably only a small subset thereof encounters similar challenges in selecting a proprietary name.

I. THE APPLICATION FOR FEIZDU SHOULD BE EXAMINED ON AN EXPEDITED BASIS

Astellas respectfully requests that its application be examined out of order to avoid a demonstrable loss of substantive rights that could arise if it cannot appropriately coordinate the timing of USPTO and FDA review procedures. *See* TMEP § 1710.01 (an application may be made special on the finding of "a *demonstrable* possibility of the loss of a substantial right.").

First, given the situation outlined above, there is a demonstrable risk that Astellas will suffer a loss of substantive rights if the present application is not examined in time to submit an alternative name to the FDA should trademark registration not be available. Indeed, as shown above, Astellas would be put in the unenviable situation of choosing between (1) losing a portion of its substantial right to time-limited market exclusivity with a delayed launch, (2) foregoing the substantial rights granted by federal trademark protection, or (3) foregoing the substantial rights inherent in using a trademark altogether. Expedited review of Astellas' trademark application would materially improve its chances of securing a brand name acceptable both to the USPTO and FDA by the PDUFA Action Date or as quickly thereafter as possible, thereby avoiding this harm.[2]

Moreover, the present issue has arisen despite Astellas' diligence in taking all reasonable steps available in selecting a proprietary name for fezolinetant. Astellas not only started the proprietary name selection process in early 2020, but it had also prosecuted its first and second choice trademarks to USPTO Allowance well in advance of the PDUFA Action Date. Given the FDA review timelines, the fact that the FDA will only review one mark at a time, and the FDA's delay in reviewing Astellas' second choice mark, there is nothing further that Astellas could have done to avoid the present situation.

Astellas does not believe the present situation would apply equally to a large number of applicants, and thus there is no reason to deny the reasonable relief that Astellas is seeking. First, new drugs are one of the very few types of products that require regulatory approval of brand names before their use, so this rules out applicants operating in virtually all other industries.

[2] Even if the USPTO is not able to act on the Petition by the deadline to submit an alternative mark to the FDA, expedited review of this application will still alleviate the harm to Astellas by minimizing any delay in market entry.

Even among pharmaceutical applicants, Astellas' present timing challenges are the result of an exceedingly rare combination of (1) the six-month time frame of FDA Priority review of an NDA, and (2) the FDA's rejection of Astellas' primary name, the delayed rejection of its backup name and guidance on name modifications, and the FDA review timeline for additional submissions. Given the small number of NDAs to be granted Priority Review each year, few applicants are likely to encounter the challenges that Astellas has encountered.

The TMEP recognizes that a requirement for government approval of a brand name may commonly warrant special examination. *See* TMEP § 1710.01 ("Commonly accepted types of evidence for granting Petition to Make Special . . . or copies of government regulations showing that a trademark registration is required to secure government approval for the goods or services."). While trademark registration is not formally required for FDA approval, Astellas has amply demonstrated that the absence of a USPTO registerable and FDA approved proprietary name by the PDUFA Action Date will cause significant, demonstrable harm that can be alleviated with expedited examination. Moreover, rare is the case where a difficult FDA examination necessitates late-game adjustments to a company's trademark filings, despite years of diligence and its best efforts to the contrary.

Further, granting this Petition to Make Special will also create appropriate incentives for companies navigating the complexities of FDA and USPTO review of drug brand names. Expedited trademark examination is an important safety net in the rare case where, despite a company's extensive diligence, FDA requirements necessitate last minute changes to the brand selected. In contrast, the denial of this Petition would create further incentives for companies to file on and maintain even more backup marks and mark variations, which will further aggravate the crowding of Class 5.

Finally, this application has been prepared to facilitate fast and streamlined examination, thereby minimizing the Office's resources required should the Petition be granted. The FEIZDU mark is a fanciful coined term with no meaning in industry, and the goods identification is short and well within the specificity guidance for pharmaceutical preparations.

CONCLUSION

For the foregoing reasons, the FEIZDU application meets all requirements for special handling pursuant to 37 C.F.R. § 2.146 and TMEP § 1710, and thus Astellas respectfully requests that this petition be granted and the application be examined without delay. Should the Commissioner require any other information in order to make a determination on this Petition to Make Special, please telephone Astellas' undersigned attorney.

Astellas US, LLC

By Its Attorneys,

/Keith Toms/_____

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Exhibit 1

U.S. FDA Accepts Astellas' New Drug Application for Fezolinetant

If approved by the FDA, fezolinetant would be a nonhormonal treatment for moderate to severe vasomotor symptoms associated with menopause

TOKYO, Aug. 18, 2022 /PRNewswire/ -- Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's New Drug Application (NDA) for fezolinetant, an investigational oral, nonhormonal compound seeking approval for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause. VMS, characterized by hot flashes and/or night sweats, are common symptoms of menopause.[1,2]

The PDUFA target action date is February 22, 2023, following use of a priority review voucher (PRV). Astellas booked ¥13.1 billion of amortization of the intangible asset relating to PRV as R&D expense in the first quarter of fiscal year 2022.

"The FDA's acceptance of our NDA for fezolinetant brings us one step closer to advancing care for women in the U.S. who experience VMS," said Ahsan Arozullah, M.D., M.P.H., Senior Vice President and Head of Development Therapeutic Areas, Astellas. "We look forward to the FDA's review of our application, and the potential to offer a first-in-class nonhormonal treatment option to reduce the frequency and severity of moderate to severe VMS associated with menopause."

The NDA is supported by results from the BRIGHT SKY™ program, which included three Phase 3 clinical trials that collectively enrolled over 2,800 women with VMS across the U.S., Canada and Europe. Results from the SKYLIGHT 1™ and SKYLIGHT 2™ pivotal trials characterize the efficacy and safety of fezolinetant for the treatment of moderate to severe VMS associated with menopause. Data from the SKYLIGHT 4™ safety study further characterizes the long-term safety profile of fezolinetant. Within the NDA, Astellas proposes a 45 mg daily dose, which is subject to the FDA's review.

Fezolinetant is an investigational nonhormonal selective neurokinin 3 (NK3) receptor antagonist. The safety and efficacy of fezolinetant are under investigation and have not been established.

The impact of this acceptance on Astellas' financial results of the current fiscal year ending March 31, 2023, is expected to be minor.

About the BRIGHT SKY™ Phase 3 Program

The BRIGHT SKY pivotal trials, SKYLIGHT 1™ (NCT04003155) and SKYLIGHT 2™ (NCT04003142), enrolled over 1,000 women with moderate to severe VMS. The trials are double-blinded, placebo-controlled for the first 12 weeks followed by a 40-week treatment extension period. Women were enrolled at over 180 sites within the U.S., Canada and Europe. SKYLIGHT 4™ (NCT04003389) is a 52-week double-blinded, placebo-controlled study designed to investigate the long-term safety of fezolinetant. For SKYLIGHT 4, over 1,800 women with VMS were enrolled at over 180 sites within the U.S., Canada and Europe.

About VMS Associated with Menopause

VMS, characterized by hot flashes (also called hot flushes) and/or night sweats, are common symptoms of menopause.[1,2] In the U.S., about 60% to 80% of women experience these symptoms during or after the menopausal transition and, worldwide, more than half of women 40 to 64 years of age experience VMS.[3,4,5,6] VMS can have a disruptive impact on women's daily activities and overall quality of life.[1]

About Fezolinetant

Fezolinetant is an investigational oral, nonhormonal therapy in clinical development for the treatment of moderate to severe VMS associated with menopause. Fezolinetant works by blocking neurokinin B (NKB) binding on the kisspeptin/neurokinin/dynorphin (KNDy) neuron to moderate neuronal activity in the thermoregulatory center of the brain (the hypothalamus) to reduce the frequency and severity of moderate to severe VMS associated with menopause.[7,8,9] The safety and efficacy of fezolinetant are under investigation and have not been established. There is no guarantee the agent will receive regulatory approval or become commercially available for the uses being investigated.

About Astellas

Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are

Cautionary Notes

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties. Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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SOURCE Astellas Pharma Inc.

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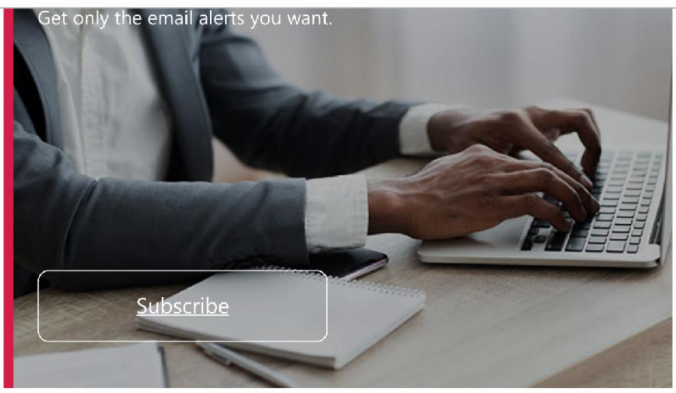

Research and clinical trials are innovative avenues needed to advance the #GastricCancer treatment landscape.

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Exhibit 2

UNITED STATES PATENT AND TRADEMARK OFFICE

Current trademark processing wait times

If you have an application, response, or other filing that hasn't been assigned or reviewed yet, we understand your frustration.

Customers filed new applications and trademark registration maintenance documents in record numbers in 2021. As we work through this surge of filings, you may experience longer than normal wait times in the following circumstances:

- **New application in the Trademark Status & Document Retrieval (https://tsdr.uspto.gov/) (TSDR) system and Trademark Electronic Search System (https://tess2.uspto.gov/) (TESS) system**
  Initial applications generally appear on the TSDR documents tab in about a week. However, if you're filing an application under Madrid Protocol and your trademark has a design or stylization, such as stylized wording or an image, your application may take a little longer.

- **New application assigned to attorney**
  With the huge surge in filings, our unexamined application inventory is much larger, and it is taking longer than usual to examine new applications. See the current **first action pendency information** in the chart below.

- **Post Registration**
  Processing post-registration maintenance filings may take longer than usual.

We're taking action to shorten average wait times and will update wait time information to reflect any changes. Since it takes time to track new wait time data, you may see that our information is generally one month behind. The published data below is the most current data available.

Sometimes your wait time will be less than the average, and sometimes it will be longer than the average. You can help shorten your wait time by following these tips to **avoiding processing delays (https://www.uspto.gov/trademarks/apply/avoid-processing-delays)**. Filing a complete and accurate initial application, response form, and post registration form can help speed up the process.

We appreciate your patience with us as we address the surge in filings, and apologize for any inconvenience these delays may cause.

Customers with a specific technical question about their TEAS application can contact our TEAS team directly at **TEAS@uspto.gov (mailto:TEAS@uspto.gov)**.

Customers with an urgent question about a filing or the status of their application or registration may contact the Trademark Assistance Center at 1-800-786-9199 (select option 1).

Trademark New Applications average processing wait times		
Trademark New Applications	**As of July 2022**	**Target**
First Action	8.2 months	2.5-7.5 months
Disposal	13.4 months	13.5 months

Current Trademark average processing wait times		
Trademark Processing Times	**As of July 2022**	**Target**
Pre-Examination Unit		
TEAS	14 days	10 days
MADRID	1 day	10 days
Examination Support Unit (ESU)		
Amendments/Corrections	22 days	14 days
Intent to use		
Extension requests	11 days	15 days
Statement of use	17 days	15 days
Divisional requests	12 days	15 days
Petitions Office		
Letters of protest	54 days	60 days
Post Registration		
Affidavits of Use/Incontestability	110 days	30 days
Renewals	112 days	30 days
Amendments/Corrections	100 days	30 days
Assignment		
ETAS	15 days	2 days
Fax	0 day	10 days
Paper	14 days	14 days

See the **Trademarks dashboard (/dashboards/trademarks)** for more data.

For more information visit the USPTO Performance and Accountability Report (https://www.uspto.gov/sites/default/files/documents/USPTOFY20PAR.pdf)
Email TMDashboard@uspto.gov with comments and suggestions (mailto:TMDashboard@uspto.gov)
Open the Excel datasheet (/dashboard/data/trademarks/tm_dashboard_data.xlsx)

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Exhibit 3

FY 2021

PERFORMANCE REPORT TO CONGRESS

for the

Prescription Drug User Fee Act

Commissioner's Report

I am pleased to present to Congress the Food and Drug Administration's (FDA's or Agency's) fiscal year (FY) 2021 Prescription Drug User Fee Act (PDUFA) performance report. This report marks the 29th year of PDUFA and the fourth year of PDUFA VI (which covers FY 2018 through FY 2022).

This report presents updated data on FDA's progress in meeting FY 2020 performance goals, preliminary data on FDA's progress in meeting FY 2021 review performance goals, and data on other commitments under PDUFA VI as of September 30, 2021.

FY 2021 turned out to be another unique year, with additional unforeseen challenges and obstacles due to the continuing COVID-19 pandemic. In FY 2021, despite the sustained high workload, the increased use of expedited programs, the development and review of new therapeutics and vaccines to address the public health emergency, and the challenges of managing a remote workforce, FDA rose to the challenge and maintained its high level of performance in meeting PDUFA goals and initiatives.

FDA continues its longstanding commitment to meeting all PDUFA performance goals related to human drug review. In FY 2021, the Agency continued to engage in increased efforts to recruit and hire new talent for the human drug review program to better enable FDA to meet increasing demands on the program. Moving forward into FY 2022, FDA will continue to enhance the program's staffing and strengthen efforts to improve the program's performance while maintaining a focus on ensuring that safe, effective, and high-quality new drugs and biological products are reviewed in an efficient and predictable time frame.

Janet Woodcock, M.D.
Acting Commissioner of Food and Drugs

Acronyms

ADaM – Analysis Data Model
ARIA – Active Risk Identification and Analysis
BEST – Biologics Effectiveness and Safety Initiative
BLA – Biologics License Application
BQP – Biomarkers Qualification Program
BT – Breakthrough Therapy
CBER – Center for Biologics Evaluation and Research
CDER – Center for Drug Evaluation and Research
CDISC – Clinical Data Interchange Standards Consortium
CDRH – Center for Devices and Radiological Health
CID – Complex Innovative Design
COA – Clinical Outcome Assessment
DDT – Drug Development Tool
EHR – Electronic Health Record
EOP – End of Phase
ESG – Electronic Submissions Gateway
ETASU – Elements to Assure Safe Use
FDA – Food and Drug Administration
FD&C Act – Federal Food, Drug, and Cosmetic Act
FDARA – FDA Reauthorization Act of 2017
FTE – Full-Time Equivalent
FY – Fiscal Year (October 1 to September 30)
IMEDS – Innovation in Medical Evidence Development and Surveillance
IND – Investigational New Drug
ISTAND - Innovative Science and Technology Approaches for New Drugs
IT – Information Technology
LIST – Lifecycle Safety Tool
MAPP – Manual of Policies and Procedures
MIDD – Model-Informed Drug Development
NDA – New Drug Application
NISS – Newly Identified Safety Signal

NME – New Molecular Entity

OC – Office of the Commissioner

OND – Office of New Drugs

ORA – Office of Regulatory Affairs

PDUFA – Prescription Drug User Fee Act

PFDD – Patient-focused Drug Development

RDT – Rare Diseases Team

REMS – Risk Evaluation and Mitigation Strategy

RMAT – Regenerative Medicine Advanced Therapies

RWD – Real-World Data

RWE – Real-World Evidence

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Executive Summary

The Prescription Drug User Fee Act (PDUFA) was enacted in 1992 and authorized the Food and Drug Administration (FDA or Agency) to collect user fees from pharmaceutical and biotechnology companies for the review of certain human drug and biological products. In return, FDA committed to certain review performance goals, procedural and processing goals, and other commitments that are part of the Agency's agreement with the regulated industry.

PDUFA has been reauthorized by Congress every 5 years. The fifth reauthorization (known as PDUFA VI) occurred on August 18, 2017, when the President signed into law the FDA Reauthorization Act of 2017. As directed by Congress, FDA developed proposed enhancements for PDUFA VI in consultation with drug industry representatives, patient and consumer advocates, health care professionals, and other public stakeholders. These discussions led to the current set of performance goals for the fiscal year (FY) 2018 to FY 2022 period, detailed in a document commonly known as the PDUFA VI Commitment Letter.[1]

This report summarizes FDA's performance results in meeting PDUFA goals and commitments for FY 2020 and FY 2021. Specifically, this report updates performance data for submissions received in FY 2020 (initially reported in the FY 2020 PDUFA Performance Report)[2] and presents preliminary data on FDA's progress in meeting FY 2021 goals. Updates on FDA's accomplishments related to additional PDUFA VI commitments for FY 2021 and historical review trend data are also included. Appendices include details of review cycle data on all original new drug applications and biologics license applications (BLAs) approved during FY 2021, the number and characteristics of applications filed by review division, and definitions of key terms used in this report. In addition, descriptions of the various submission types are included on page 4 of this report.

The estimated[3] median approval times for priority NDAs and BLAs received in FY 2020 remained the same compared to the estimated median approval times for priority NDAs and BLAs received in FY 2019. The preliminary data show that the percentage of priority and standard applications filed in FY 2020 and approved during the first review cycle were 81 percent and 53 percent, respectively.

Achievements in FY 2021

In March 2020, FDA experienced the unexpected onset of a public health emergency, the impact of which continued throughout the following fiscal year. The COVID-19 pandemic resulted in a shift to 100 percent virtual work for the majority of the Agency's staff, and this shift continued throughout FY 2021.

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[1] www.fda.gov/media/99140/download.
[2] www.fda.gov/about-fda/user-fee-performance-reports/pdufa-performance-reports.
[3] The median approval time is estimated because an application can receive an approval after multiple review cycles, thus impacting the median approval time for all applications in a given receipt cohort. Some applications may be approved several years after their original receipt.

In FY 2021, the Agency continued to appropriately shift its limited resources to prioritize work focused on addressing the pandemic. In fact, the increased workload the Agency experienced in FY 2020 was sustained throughout FY 2021. However, in FY 2021, FDA not only met most of the review performance goals but also exceeded some goals. For example, 100 percent of current performance goals were achieved for Original Priority new medical entities (NMEs) and BLAs and Original Standard NMEs and BLAs.

Review Performance Results

The FY 2020 cohort had a workload of 3,429 goal closing actions. FDA met or exceeded the 90 percent performance level for 10 of the 12 review performance goals for FY 2020.

For the FY 2021 cohort, FDA had completed 2,055 actions as of September 30, 2021. FDA is currently meeting or exceeding 9 of the 12 review performance goals for FY 2021. With 1,466 submissions under review and still within the PDUFA goal date, FDA has the potential to meet or exceed 10 of the 12 review performance goals for FY 2021.

Procedural and Processing Performance Results

For the FY 2020 cohort, FDA's workload for activities related to procedural and processing goals and commitments (i.e., meeting management, procedural responses, and procedural notifications) totaled 11,920 actions. FDA met or exceeded the performance level for 8 of the 20 procedural and processing goals for FY 2020.

For the FY 2021 cohort, FDA is currently meeting or exceeding 9 of the 20 procedural and processing goals. With 1,269 submissions under review and still within the PDUFA goal date, FDA has the potential to meet or exceed 9 of the 20 procedural and processing goal commitments for FY 2021.

Additional PDUFA VI Commitments

During FY 2021, FDA made significant progress implementing other important PDUFA VI commitments, including enhancing patient input and benefit-risk assessments in regulatory decision-making, enhancing regulatory science, exploring the use of real-world evidence, enhancing regulatory decision tools to support drug development and review, enhancing and modernizing FDA's drug safety system, and improving the efficiency of human drug review through the required electronic submission and standardization of electronic drug application data. These achievements, as well as information about FDA's information technology accomplishments, are included in this report.

To highlight just a few of these achievements, there were a number of important PDUFA commitments completed in FY 2021, including the following:

- The PDUFA VI IND Communications Assessment and its associated public workshop were completed, and best practices identified by the assessment were applied as relevant.
- FDA's rare disease programs engaged in numerous internal and external educational and collaborative activities to advance the development of medical products for rare diseases.
- Guidance documents were published on the use of real-world data and benefit-risk assessments for new drug review.
- Workshops or public meetings were held on Model Informed Drug Development, the use of Sentinel (FDA's medical product safety surveillance system), and financial transparency and efficiency.

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Introduction

On August 18, 2017, the President signed the FDA Reauthorization Act of 2017 (FDARA) into law, which included the fifth reauthorization of the Prescription Drug User Fee Act (PDUFA) for fiscal year (FY) 2018 through FY 2022, known as PDUFA VI. PDUFA VI continues to provide the Food and Drug Administration (FDA or Agency) with a consistent source of funding to help maintain a predictable and efficient review process for human drugs and biological products. In commitments tied to this funding, FDA agreed to certain review performance goals, such as reviewing and acting on new drug application (NDA) and biologics license application (BLA) submissions within predictable time frames.

Since the enactment of PDUFA I in 1992, FDA has used PDUFA resources to significantly reduce the time needed to evaluate new drugs and biological products without compromising its rigorous standards for a demonstration of safety, efficacy, and quality of these products before approval. The efficiency gains under PDUFA have revolutionized the drug review process in the United States and enabled FDA to ensure more timely access to innovative and important new therapies for patients.

More information on the history of PDUFA is available on FDA's website.[4]

Information Presented in This Report

This report presents PDUFA performance and workload information for two different types of goals: (1) the review of applications and other submissions pertaining to human drugs and biological products and (2) meeting management and other procedural goals related to responses and notifications in the human drug review process. PDUFA workload information for these goals is included in the tables that follow. Significant components of the PDUFA workload (such as reviews of investigational new drug (IND) applications, labeling supplements, and annual reports, as well as the ongoing monitoring of drug safety in the postmarket setting) are not captured by PDUFA goals and are therefore not presented in this report.

PDUFA performance information related to achieving these two types of goals includes reviews of submissions pending from the previous fiscal year as well as reviews of submissions received during the current fiscal year. This report presents the final performance results for the FY 2020 cohort of submissions based on actions completed in FY 2020 and FY 2021. In addition, this report includes the preliminary performance results for the FY 2021 cohort of submissions that had actions completed or due for completion in FY 2021. Final performance for the FY 2021 cohort will be presented in the FY 2022 PDUFA Performance Report and will include actions for submissions still pending within the PDUFA goal date as of September 30, 2021.

The following information refers to FDA's performance presented in this report.

[4] www.fda.gov/about-fda/user-fee-performance-reports/pdufa-performance-reports.

- The following terminology is used throughout this document:

    - *Application* means a new, original marketing application.
    - *Supplement* means a request to approve a change in an application that has been approved.
    - *Resubmission* means a resubmitted application or supplement in response to a complete response, approvable, not approvable, or tentative approval letter.
    - *New molecular entities (NMEs)* refer only to NMEs that are submitted for approval under NDAs (not BLAs).
    - *Submission* applies to all of the above.
    - *Action* refers to an FDA decision on any of the above, including an approval, a tentative approval, a complete response, or withdrawal of the submission by the sponsor.

- Under PDUFA VI, the preliminary counts of NMEs in workload tables for the current fiscal year may not reflect the final determination of NME status for that fiscal year. FDA often receives multiple submissions for the same NME (e.g., different dosage forms). All such submissions are initially designated as NMEs, and once FDA approves the first of the multiple submissions, the other submissions will be designated as non-NMEs, and workload numbers will be appropriately updated in later years.

- The data presented in this report do not include biosimilar INDs or biosimilar BLAs. These data are presented in the annual Biosimilar User Fee Act (BsUFA) Performance Reports located on FDA's website.[5]

- FDA files applications only that are sufficiently complete to permit a substantive review. The Agency makes a filing decision within 60 days of an original application's receipt by FDA. FDA's review of an application begins once the application is received. For NME NDAs and original BLAs reviewed under the program (see the PDUFA VI Commitment Letter[6] for more information), the PDUFA clock begins after the conclusion of the 60-day filing period. For all other submissions, the PDUFA clock begins upon FDA's receipt of the application.

- FDA annually reports PDUFA performance data for each fiscal year receipt cohort (defined as submissions filed from October 1 to September 30 of the following year). In each fiscal year, FDA receives submissions that will have associated goals due in the following fiscal year. For these submissions, FDA's performance data will be reported in subsequent fiscal years, either after the Agency takes an action or when the goal becomes overdue, whichever comes first.

- Submission types (e.g., responses to clinical holds) with shorter (e.g., 30-day) review time goals tend to have a larger percentage of reviews completed by the end of the fiscal

[5] www.fda.gov/about-fda/user-fee-performance-reports/bsufa-performance-reports.
[6] www.fda.gov/media/99140/download.

year, and these submission types' preliminary performance data are a more reliable indicator of their final performance results. However, submission types (e.g., standard NME NDA/BLA) with longer (e.g., within 10 months of the 60-day filing date) review time goals tend to have a smaller percentage of reviews completed within the reporting period, and these submission types' preliminary performance data are a less reliable indicator of their final performance results.

- Final performance results for FY 2020 submissions are shown as the percentage of submissions that were reviewed within the specified goal timeline. Submission types with 90 percent or more submissions reviewed by the goal date are shown as having met the goal.

- Preliminary performance results for FY 2021 submissions are shown as the percentage of submissions reviewed on time as of September 30, 2021, excluding actions pending within the PDUFA goal date. Submission types with a current performance result of 90 percent or more reviewed by the goal date are shown as currently meeting the goal. The highest possible percent of reviews that may be completed on time (i.e., the highest possible performance results) if all non-overdue pending reviews are completed within the goal is also shown.

- Filed applications and supplements include submissions that have been filed or are in pending filing status. Data do not include submissions that are unacceptable for filing because of nonpayment of user fees, have been withdrawn within 60 days of receipt, or have been refused to file.

- FY 2021 workload and performance figures include applications that are identified as *undesignated*, which means they are still within the 60-day filing date and have not yet had a review designation, standard or priority, made.

- For resubmitted applications, the applicable performance goal is determined by the fiscal year in which the resubmission is received, rather than the year in which the original application was submitted.

- Unless otherwise noted, all performance data are as of September 30, 2021.

- Definitions of key terms used throughout this report can be found in Appendix E.

Submission Types Included in This Report

- **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 sponsor submits to FDA an NDA. The application must contain data from specific technical viewpoints for review, including chemical, pharmacological, medical, biopharmaceutical, and statistical. If the NDA is approved, the product may be marketed in the United States.
- **NME** – An NME is an active ingredient that contains no active moiety that has been previously approved by FDA in an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or has been previously marketed as a drug in the United States.
- **BLA** – A BLA is a submission that contains specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology, and the clinical effects of a biological product. If the information provided meets FDA requirements, the application is approved and a license is issued allowing the firm to market the product.
- **Resubmission** – A resubmitted original application or supplement is a complete response to an FDA action letter that addresses all identified deficiencies.
- **Supplement** – A supplement is an application to allow a company to make changes in a product that already has an approved NDA or to seek FDA approval for new uses of an approved drug. The Center for Drug Evaluation and Research (CDER) must approve all major NDA changes (in packaging or ingredients, for instance) to ensure the conditions originally set for the product are still being met.
- **Source:** www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms

PDUFA Review Goals

Review Workload: FY 2016 to FY 2021

In the table below, preliminary workload numbers from FY 2021 are compared to the previous 5-year averages for original NDAs and BLAs, resubmissions, and supplements, and the workload numbers for the previous 5 years are presented. FDA saw an increase between FY 2020 and FY 2021 in the number of original priority NMEs and BLAs, original priority non-NME NDA submissions, original standard non-NME NDAs, and NDA and BLA manufacturing supplements requiring prior approval.

Definitions of Class 1 and Class 2 resubmissions and other terms are found in Appendix E. The data presented in this section represent receipts by FDA of the submission types listed in the table.

Workload for Applications and Submissions

Submission Type	FY 16	FY 17	FY 18	FY 19	FY 20*	FY 21	FY 16 to FY 20 5-Year Average	FY 21 Compared to 5-Year Average
Original Priority NMEs and BLAs	23	31	48	44	54	55**	40	38%
Original Standard NMEs and BLAs	24	22	22	35	29	28	26	8%
Original Priority Non-NME NDAs	12	24	16	16	14	25**	16	56%
Original Standard Non-NME NDAs	72	81	69	68	59	68	70	-3%
Class 1 Resubmitted NDAs and BLAs	5	8	9	8	5	5	7	-29%
Class 2 Resubmitted NDAs and BLAs	31	49	50	41	57	53	46	15%
Priority NDA and BLA Efficacy Supplements	54	78	97	81	112	100**	84	19%
Standard NDA and BLA Efficacy Supplements	145	173	177	197	195	158	177	-11%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	3	3	3	4	3	3	3	0%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	11	11	11	2	20	10	11	-9%
NDA and BLA Manufacturing Supplements Requiring Prior Approval	842	968	992	973	1,168	1,319	989	33%
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	1,475	1,540	1,610	1,450	1,717	1,697	1,558	9%

* FY 2020 numbers were changed to reflect updates to the data presented in the FY 2020 PDUFA Performance Report.

** Some applications have not yet received a review priority designation. There were four undesignated NMEs and BLAs counted as Priority NMEs and BLAs, six undesignated non-NME NDAs counted as Priority non-NME NDAs, and 17 undesignated efficacy supplements counted as Priority NDA and BLA Efficacy Supplements in the table above. Performance results in all categories may

change once designations are made for these applications, and the table will then be updated accordingly, as appropriate, in the FY 2022 PDUFA Performance Report.

Final FY 2020 Review Goal Performance Results

The final FY 2020 review goal performance results are presented in the table below. The final performance results for submission types that met or exceeded the goal (i.e., 90 percent or more actions were completed by the goal date) are shown in bold text. FDA met or exceeded the 90 percent performance level for 10 of the 12 review performance goals in FY 2020.

Submission Type	Goal: Act on 90 Percent Within	Total	FY 2020 Performance
Original Priority NMEs and BLAs	6 months of filing date	49 of 53 on time	**92%**
Original Standard NMEs and BLAs	10 months of filing date	23 of 27 on time	85%
Original Priority Non-NME NDAs	6 months	14 of 14 on time	**100%**
Original Standard Non-NME NDAs	10 months	55 of 58 on time	**95%**
Class 1 Resubmitted NDAs and BLAs	2 months	5 of 5 on time	**100%**
Class 2 Resubmitted NDAs and BLAs	6 months	51 of 57 on time	89%
Priority NDA and BLA Efficacy Supplements	6 months	111 of 112 on time	**99%**
Standard NDA and BLA Efficacy Supplements	10 months	181 of 195 on time	**93%**
Class 1 Resubmitted NDA and BLA Efficacy Supplements	2 months	3 of 3 on time	**100%**
Class 2 Resubmitted NDA and BLA Efficacy Supplements	6 months	19 of 20 on time	**95%**
NDA and BLA Manufacturing Supplements Requiring Prior Approval	4 months	1,133 of 1,168 on time	**97%**
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	6 months	1,686 of 1,717 on time	**98%**

Final FY 2020 Review Goal Performance Details

The following tables detail the final performance data for the FY 2020 cohort of submissions. These data include the number of submissions reviewed *on time* (i.e., acted on by the PDUFA goal date) or *overdue* (i.e., acted on past the goal date or pending past the goal date) and the final *percent on time* (i.e., final performance with no actions pending within the PDUFA goal date). The performance data presented here have been updated from the preliminary performance information reported in the FY 2020 PDUFA Performance Report.

Original Applications

Original Application Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent on Time
Priority NMEs & BLAs	6 months of filing date	54	49	4	92%*
Standard NMEs & BLAs	10 months of filing date	29	23	4	85%†
Priority Non-NME NDAs	6 months	14	14	0	100%
Standard Non-NME NDAs	10 months	59	55	3	95%**

* One priority NME is pending within goal as of September 30, 2021. Regardless of the action, the final performance result will remain above 90 percent.

† Two standard NMEs and BLAs are pending within goal as of September 30, 2021. Regardless of the action, the final performance result will remain below 90 percent.

** One standard non-NME NDA is pending within goal as of September 30, 2021. Regardless of the action, the final performance result will remain above 90 percent.

Resubmitted Original Applications

Resubmitted Application Type	Goal: Act on 90 Percent Within	Received	On Time	Overdue	Percent on Time
Class 1	2 months	5	5	0	100%
Class 2	6 months	57	51	6	89%

Efficacy Supplements

Efficacy Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent on Time
Priority	6 months	112	111	1	99%
Standard	10 months	195	181	14	93%

Resubmitted Efficacy Supplements

Resubmitted Efficacy Supplement Type	Goal: Act on 90 Percent Within	Received	On Time	Overdue	Percent on Time
Class 1	2 months	3	3	0	100%
Class 2	6 months	20	19	1	95%

Manufacturing Supplements

Manufacturing Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent on Time
Prior Approval Required	4 months	1,168	1,133	35	97%
Prior Approval Not Required	6 months	1,717	1,686	31	98%

Preliminary FY 2021 Review Goal Performance Results

The preliminary FY 2021 review goal performance results are presented in the table below.

- The *progress* (i.e., the number of reviews completed) and the total number of submissions received for each submission type are shown in the second column. *Current performance* includes submissions reviewed *on time* (i.e., acted on by the PDUFA goal date) or *overdue* (i.e., acted on past the goal date or pending past the goal date). The current performance results for submission types with a greater proportion of reviews completed will be more representative of the final performance results. The *highest possible final performance* is the best potential final performance result, which accounts for actions pending within the PDUFA goal date.

- The current performance results for submission types that are meeting the performance goal (i.e., 90 percent or more reviews were completed by the goal date) as of September 30, 2021, are shown in bold text. FDA is currently meeting or exceeding the 90 percent performance level for 9 of the 12 performance goals.

- If all non-overdue pending submissions are reviewed on time, FDA will achieve the performance results presented in the Highest Possible Final Performance column. FDA has the potential to meet or exceed the 90 percent performance level for 10 of the 12 review performance goals.

Submission Type	Progress*	Goal: Act on 90 Percent Within	FY 2021 Current Performance	Highest Possible Final Performance
Original Priority NMEs and BLAs	21 of 51 complete	6 months of filing date	**100%**	100%
Original Standard NMEs and BLAs	1 of 28 complete	10 months of filing date	**100%**	100%
Original Priority Non-NME NDAs	9 of 19 complete	6 months	78%	89%
Original Standard Non-NME NDAs	13 of 68 complete	10 months	**92%**	99%
Class 1 Resubmitted NDAs and BLAs	5 of 5 complete	2 months	80%	80%
Class 2 Resubmitted NDAs and BLAs	19 of 53 complete	6 months	**95%**	98%
Priority NDA and BLA Efficacy Supplements	61 of 83 complete	6 months	87%	90%
Standard NDA and BLA Efficacy Supplements	41 of 158 complete	10 months	**100%**	100%

Submission Type	Progress*	Goal: Act on 90 Percent Within	FY 2021 Current Performance	Highest Possible Final Performance
Class 1 Resubmitted NDA and BLA Efficacy Supplements	3 of 3 complete	2 months	**100%**	100%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	8 of 10 complete	6 months	**100%**	100%
NDA and BLA Manufacturing Supplements Requiring Prior Approval	830 of 1,319 complete	4 months	**97%**	98%
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	1,044 of 1,697 complete	6 months	**98%**	99%

* This column does not include undesignated applications in the total. Undesignated applications have only pending status.

Preliminary FY 2021 Review Goal Performance Details

The following detailed performance information for the FY 2021 cohort submissions includes the number of submissions *filed*, reviewed *on time* (i.e., acted on by the PDUFA goal date), and *overdue* (i.e., acted on past the goal date or pending past the goal date). The number of submissions not yet acted on but still pending within the PDUFA goal date (*pending within goal*) is also provided, along with the highest possible percent of reviews that may be completed on time (*highest possible percent on time*).

Original Applications

Original Application Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Priority NMEs & BLAs	6 months of filing date	51	21	0	30	100%	100%
Standard NMEs & BLAs	10 months of filing date	28	1	0	27	100%	100%
Priority Non-NME NDAs	6 months	19	7	2	10	78%	89%
Standard Non-NME NDAs	10 months	68	12	1	55	92%	99%
Review Priority Undesignated*	N/A	10	--	--	10	--	--
Total		176	41	3	132	--	--

* These applications have not yet received a review priority designation. There were four undesignated NMEs and BLAs and six undesignated non-NME NDAs.

Resubmitted Original Applications

Resubmitted Application Type	Goal: Act on 90 Percent Within	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Class 1	2 months	5	4	1	0	80%	80%
Class 2	6 months	53	18	1	34	95%	98%

Efficacy Supplements

Efficacy Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Priority	6 months	83	53	8	22	87%	90%
Standard	10 months	158	41	0	117	100%	100%
Review Priority Undesignated*	N/A	17	--	--	17	--	--

* These applications have not yet received a review priority designation.

Resubmitted Efficacy Supplements

Resubmitted Efficacy Supplement Type	Goal: Act on 90 Percent Within	Received	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Class 1	2 months	3	3	0	0	100%	100%
Class 2	6 months	10	8	0	2	100%	100%

Manufacturing Supplements

Manufacturing Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Prior Approval Required	4 months	1,319	809	21	489	97%	98%
Prior Approval Not Required	6 months	1,697	1,023	21	653	98%	99%
Review Priority Undesignated*	N/A	0	--	--	0	--	--

* These applications have not yet received a review priority designation.

PDUFA Procedural and Processing Goals and Commitments

Procedural and Processing Workload: FY 2016 to FY 2021

The FY 2021 procedural and processing workload, which includes activities related to meeting management, procedural responses, and procedural notifications, is compared to the previous 5-year averages in the table below. The upward trend of meeting management workload continued into FY 2021.

A new category of Type B meeting, Type B End of Phase (EOP), was created under PDUFA VI; therefore, when comparing PDUFA VI (i.e., FY 2020 and FY 2021) data to previous years' data, it is important to combine both Type B meeting categories. This new category also included a new meeting metric, Preliminary Response for Type B(EOP) Meetings. Meeting type definitions and other terms can be found in Appendix E. The table shows updated final FY 2020 performance and presents new reporting required under PDUFA VI.

Beginning in FY 2020, FDA committed to establish timelines for the review and comment on protocols for Human Factors studies of combination drug-device and biologic-device products. This additional goal is reflected in the number of procedural and processing goals reported.

Meeting Management, Procedural Responses, and Procedural Notifications Workload

Submission/Request Type	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020*	FY 2021	FY 2016 to FY 2020 5-Year Average	FY 2021 Compared to 5-Year Average
Type A Meeting Requests	135	175	146	153	182	255**	158	61%
Type B Meeting Requests	1,738	1,850	1,609	1,725	2,438	2,290	1,872	22%
Type B(EOP) Meeting Requests	--	--	343	343	350	339	--†	--†
Type C Meeting Requests	1,372	1,391	1,403	1,550	1,716	1,674	1,486	13%
Type A Meetings Scheduled	123	159	127	130	147	222**	137	62%
Type B Meetings Scheduled	1,183	1,293	945	936	869	785	1,045	-25%
Type B(EOP) Meetings Scheduled	--	--	324	325	322	285	--†	--†
Type C Meetings Scheduled	596	660	640	732	699	653	665	-2%
Type A Written Response	--	--	6	6	13	13	--†	--†
Type B Written Response	469	482	578	719	1,430	1,382	736	88%
Type B(EOP) Written Response	--	--	14	11	23	42	--†	--†
Type C Written Response	658	652	686	728	905	891	726	23%
Preliminary Response for Type B(EOP) Meetings	--	--	303	305	309	271	--†	--†

Submission/Request Type	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020*	FY 2021	FY 2016 to FY 2020 5-Year Average	FY 2021 Compared to 5-Year Average
Meeting Minutes	1,500	1,679	1,541	1,638	1,515	1,383	1,575	-12%
Responses to Clinical Holds	232	193	199	197	261	274	216	27%
Major Dispute Resolutions	17	20	23	28	35	13	25	-48%
Special Protocol Assessments	215	173	160	158	148	152	171	-11%
Review of Proprietary Names Submitted During IND Phase	158	176	159	212	224	214	186	15%
Review of Proprietary Names Submitted During NDA/BLA Phase	202	255	228	230	255	226	234	-3%
Human Factors Protocol Submissions	--	--	--	70	79	76	--†	--†

* FY 2020 numbers were changed to reflect updates to the data presented in the FY 2020 PDUFA Performance Report.

** Some meeting requests and the subsequent scheduling of meetings are for requests where the type cannot be initially determined. There were 80 undesignated meetings counted as Type A meeting *requests* and *scheduled* in the table above. Performance in all categories will change once designations are made for these requests and scheduling and will be updated in the FY 2022 PDUFA Performance Report.

† Because of changing reporting requirements, no past average is presented for this area.

Final FY 2020 Procedural and Processing Performance Results

The table below presents the final performance results for FY 2020 submissions in meeting goals related to meeting management, procedural responses, and procedural notifications. The final performance results for submission types that met or exceeded the goal (e.g., 90 percent or more reviews were completed by the goal date) are shown in bold text. FDA exceeded the performance level for 8 of the 20 procedural and processing goals in FY 2020.

Submission/Request Type	Goal: 90 Percent	Total	FY 2020 Performance
Type A Meeting Requests	Respond within 14 days	166 of 182 on time	**91%**
Type B Meeting Requests	Respond within 21 days	2,237 of 2,438 on time	**92%**
Type B(EOP) Meeting Requests	Respond within 14 days	289 of 350 on time	83%
Type C Meeting Requests	Respond within 21 days	1,519 of 1,716 on time	89%
Type A Meetings Scheduled	Schedule within 30 days	111 of 147 on time	76%
Type B Meetings Scheduled	Schedule within 60 days	652 of 869 on time	75%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	258 of 322 on time	80%
Type C Meetings Scheduled	Schedule within 75 days	542 of 699 on time	78%
Type A Written Response	Respond within 30 days	10 of 13 on time	77%

Submission/Request Type	Goal: 90 Percent	Total	FY 2020 Performance
Type B Written Response	Respond within 60 days	1,173 of 1,430 on time	82%
Type B(EOP) Written Response	Respond within 70 days	19 of 23 on time	83%
Type C Written Response	Respond within 75 days	715 of 905 on time	79%
Preliminary Response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	252 of 309 on time	82%
Meeting Minutes	Issue within 30 days after meeting date	1,408 of 1,515 on time	**93%**
Responses to Clinical Holds	Respond within 30 days	248 of 261 on time	**95%**
Major Dispute Resolutions	Respond within 30 days	31 of 35 on time	89%
Special Protocol Assessments	Respond within 45 days	143 of 148 on time	**97%**
Proprietary Name Submitted During IND Phase	Review and respond within 180 days	216 of 224 on time	**96%**
Proprietary Name Submitted During NDA/BLA Phase	Review and respond within 90 days	249 of 255 on time	**98%**

Submission/Request Type	Goal: 70 Percent	Total	FY 2020 Performance
Human Factors Protocol Submissions	Respond within 60 days	68 of 79 on time	**86%**

Final FY 2020 Procedural and Processing Goal Performance Details

The following tables detail the final performance data for the FY 2020 cohort of submissions. These data include the number of submissions reviewed *on time* (i.e., acted on by the PDUFA goal date) or *overdue* (i.e., acted on past the goal date or pending past the goal date) and the final *percent on time* (i.e., final performance with no actions pending within the PDUFA goal date). The performance data presented here have been updated from the preliminary performance information reported in the FY 2020 PDUFA Performance Report.

Meeting Management

Type	Goal: 90 Percent	Received*	On Time	Overdue	Percent on Time
Type A Meeting Requests	Respond within 14 days	182	166	16	91%
Type B Meeting Requests	Respond within 21 days	2,438	2,237	201	92%
Type B(EOP) Meeting Requests	Respond within 14 days	350	289	61	83%
Type C Meeting Requests	Respond within 21 days	1,716	1,519	197	89%
Type A Meetings Scheduled	Schedule within 30 days	147	111	36	76%
Type B Meetings Scheduled	Schedule within 60 days	869	652	217	75%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	322	258	64	80%
Type C Meetings Scheduled	Schedule within 75 days	699	542	157	78%
Type A Written Response	Respond within 30 days	13	10	3	77%
Type B Written Response	Respond within 60 days	1,430	1,173	257	82%
Type B(EOP) Written Response	Respond within 70 days	23	19	4	83%
Type C Written Response	Respond within 75 days	905	715	190	79%
Preliminary Response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	309	252	57	82%
Meeting Minutes	Issue within 30 days after meeting date	1,515	1,408	107	93%

* Not all meeting requests are granted; therefore, the number of meetings scheduled may differ from the number of meeting requests received. Not all scheduled meetings are held; therefore, the number of meeting minutes may differ from the number of meetings scheduled.

Responses to Clinical Holds

Goal	Received	On Time	Overdue	Percent on Time
Respond to 90 percent within 30 days	261	248	13	95%

Major Dispute Resolutions

Goal	Responses*	On Time	Overdue	Percent on Time
Respond to 90 percent within 30 days	35	31	4	89%

* This figure represents the number of FDA-generated 30-day responses to requests for review that have been received. This figure is not representative of the number of unique appeals received that have been reviewed as there may be more than one response to an original appeal.

Special Protocol Assessments

Goal	Received	On Time	Overdue	Percent on Time
Respond to 90 percent within 45 days	148	143	5	97%

Special Protocol Assessment Resubmissions

SPAs with Resubmissions	Applications with 1 Resubmission	Applications with 2 Resubmissions	Applications with 3 Resubmissions	Applications with 4 Resubmissions	Total Resubmissions
16	15	1	0	0	17

Drug/Biological Product Proprietary Names

Submission Type	Goal: 90 Percent	Received	On Time	Overdue	Percent on Time
Proprietary Name Submitted During IND Phase	Review and respond within 180 days	224	216	8	96%
Proprietary Name Submitted During NDA/BLA Phase	Review and respond within 90 days	255	249	6	98%

Human Factors Protocol Submissions

Submission Type	Goal: 70 Percent	Received	On Time	Overdue	Percent on Time
Human Factors Protocol Submissions	Respond within 60 days	79	68	11	86%

Preliminary FY 2021 Procedural and Processing Performance Results

The table below presents preliminary performance results for FY 2021 submissions in achieving goals related to meeting management, procedural responses, and procedural notifications as outlined under PDUFA VI.

- The *progress* (i.e., the number of review activities completed or pending overdue) and the total number of submissions received for each submission type are shown in the second column. *Current performance* includes the number of submissions reviewed *on time* (i.e., acted on by the PDUFA goal date) or *overdue* (i.e., acted on past the goal date or pending past the goal date). *Highest possible final performance* is the best potential final performance result, which accounts for actions pending within the PDUFA goal date.
- The current performance results for submission types that are meeting the performance goal as of September 30, 2021, are shown in bold text. FDA is currently meeting or exceeding the performance level for 9 of the 20 procedural and processing goals. If all pending submissions are reviewed on time, FDA has the potential to meet 9 of the 20 goals, as seen in the Highest Possible Final Performance column.

Submission/Request Type	Progress	Goal: 90 Percent	FY 2021 Current Performance	Highest Possible Final Performance
Type A Meeting Requests	179 of 255 complete	Respond within 14 days	**91%**	94%
Type B Meeting Requests	2,245 of 2,290 complete	Respond within 21 days	**90%**	90%
Type B(EOP) Meeting Requests	331 of 339 complete	Respond within 14 days	85%	86%
Type C Meeting Requests	1,649 of 1,674 complete	Respond within 21 days	**91%**	91%
Type A Meetings Scheduled	141 of 222 complete	Schedule within 30 days	77%	86%
Type B Meetings Scheduled	734 of 785 complete	Schedule within 60 days	77%	79%
Type B(EOP) Meetings Scheduled	275 of 285 complete	Schedule within 70 days	81%	82%
Type C Meetings Scheduled	632 of 653 complete	Schedule within 75 days	81%	82%
Type A Written Response	12 of 13 complete	Respond within 30 days	83%	85%
Type B Written Response	1,206 of 1,382 complete	Respond within 60 days	71%	75%
Type B(EOP) Written Response	35 of 42 complete	Respond within 70 days	49%	57%
Type C Written Response	737 of 891 complete	Respond within 75 days	76%	80%
Preliminary Response for Type B(EOP) Meetings	221 of 271 complete	Issue no later than 5 days prior to meeting date	82%	85%

Submission/Request Type	Progress	Goal: 90 Percent	FY 2021 Current Performance	Highest Possible Final Performance
Meeting Minutes	1,012 of 1,383 complete	Issue within 30 days after meeting date	**93%**	95%
Responses to Clinical Holds	253 of 274 complete	Respond within 30 days	**93%**	93%
Major Dispute Resolutions	12 of 13 complete	Respond within 30 days	**92%**	92%
Special Protocol Assessments	133 of 152 complete	Respond within 45 days	**95%**	95%
Proprietary Name Submitted During IND Phase	129 of 214 complete	Review and respond within 180 days	**95%**	97%
Proprietary Name Submitted During NDA/BLA Phase	170 of 226 complete	Review and respond within 90 days	**96%**	97%
Human Factors Protocol Submissions	65 of 76 complete	Respond within 60 days	32%	42%

Preliminary FY 2021 Procedural and Processing Goal Performance Details

The following detailed performance information for FY 2021 cohort submissions includes the number of submissions *received*, reviewed *on time* (i.e., acted on by the PDUFA goal date), and *overdue* (i.e., acted on past the goal date or pending past the goal date). The number of submissions not yet acted on but still pending within the PDUFA goal date (*Pending Within Goal*) is also provided, along with the highest possible percent of reviews that may be completed on time (*Highest Possible Percent On Time*).

Meeting Management

Type	Goal: 90 Percent	Received*	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Type A Meeting Requests†	Respond within 14 days	255	163	16	76	91%	94%
Type B Meeting Requests	Respond within 21 days	2,290	2,011	234	45	90%	90%
Type B(EOP) Meeting Requests	Respond within 14 days	339	282	49	8	85%	86%
Type C Meeting Requests	Respond within 21 days	1,674	1,499	150	25	91%	91%
Type A Meetings Scheduled†	Schedule within 30 days	222	109	32	81	77%	86%
Type B Meetings Scheduled	Schedule within 60 days	785	566	168	51	77%	79%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	285	223	52	10	81%	82%
Type C Meetings Scheduled	Schedule within 75 days	653	515	117	21	81%	82%
Type A Written Response	Respond within 30 days	13	10	2	1	83%	85%
Type B Written Response	Respond within 60 days	1,382	858	348	176	71%	75%
Type B(EOP) Written Response	Respond within 70 days	42	17	18	7	49%	57%
Type C Written Response	Respond within 75 days	891	557	180	154	76%	80%
Preliminary Response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	271	181	40	50	82%	85%
Meeting Minutes	Issue within 30 days after meeting date	1,383	942	70	371	93%	95%

* Not all meeting requests are granted; therefore, the number of meetings scheduled may differ from the number of meeting requests received. Not all scheduled meetings are held; therefore, the number of meeting minutes may differ from the number of meetings scheduled.

† Some meeting requests and subsequent scheduling of meetings are for requests where the type cannot be initially determined. There were 80 undesignated meetings counted as Type A meeting *requests* and *scheduled* in the table above. Performance in

all categories will change once designations are made for these requests and scheduling and will be updated in the FY 2022 PDUFA Performance Report.

Responses to Clinical Holds

Goal	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Respond to 90 percent within 30 days	274	235	18	21	93%	93%

Major Dispute Resolutions

Goal	Responses*	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Respond to 90 percent within 30 days	13	11	1	1	92%	92%

* This figure represents the number of FDA-generated 30-day responses to requests for review that have been received. This figure is not representative of the number of unique appeals received that have been reviewed as there may be more than one response to an original appeal.

Special Protocol Assessments

Goal	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Respond to 90 percent within 45 days	152	126	7	19	95%	95%

Special Protocol Assessment Resubmissions

SPAs with Resubmissions	Applications with 1 Resubmission	Applications with 2 Resubmissions	Applications with 3 Resubmissions	Applications with 4 Resubmissions	Total Resubmissions
19	16	2	1	0	23

Drug/Biological Product Proprietary Names

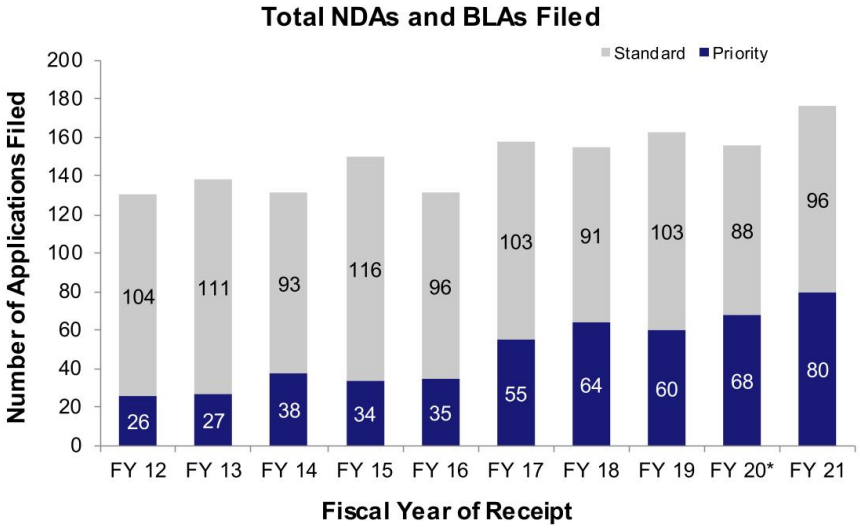
Submission Type	Goal: 90 Percent	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Proprietary Name Submitted During IND Phase	Review and respond within 180 days	214	123	6	85	95%	97%
Proprietary Name Submitted During NDA/BLA Phase	Review and respond within 90 days	226	163	7	56	96%	97%

Human Factors Protocol Submissions

Submission Type	Goal: 90 Percent	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Human Factors Protocol Submissions	Respond within 60 days	76	21	44	11	32%	42%

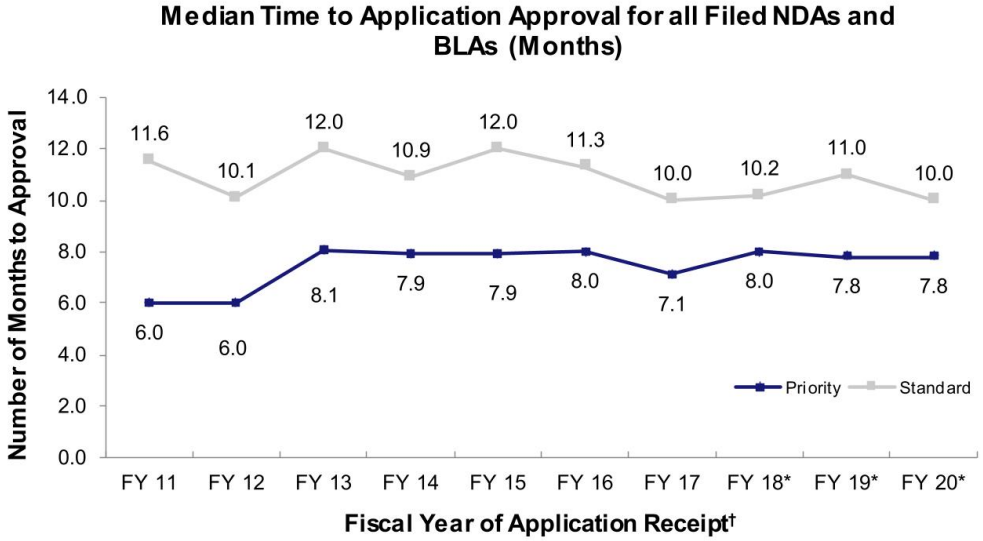
PDUFA Trend Graphs

The number of NDAs and BLAs filed from FY 2012 to FY 2021 is presented in the graph below. The total number of all original applications (NDAs and BLAs) filed in FY 2021 increased from the number filed in FY 2020, and the total number of priority applications filed reached a new high in FY 2021.



* FY 2020 numbers were changed to reflect updates to the data presented in the FY 2020 PDUFA Performance Report.

The median total times to approval for priority and standard applications received from FY 2011 through FY 2020 are presented in the graph below.[7] The data represented in the graph are updated based on the approvals reported in Appendix A. FY 2021 data are too preliminary to estimate the median approval time.

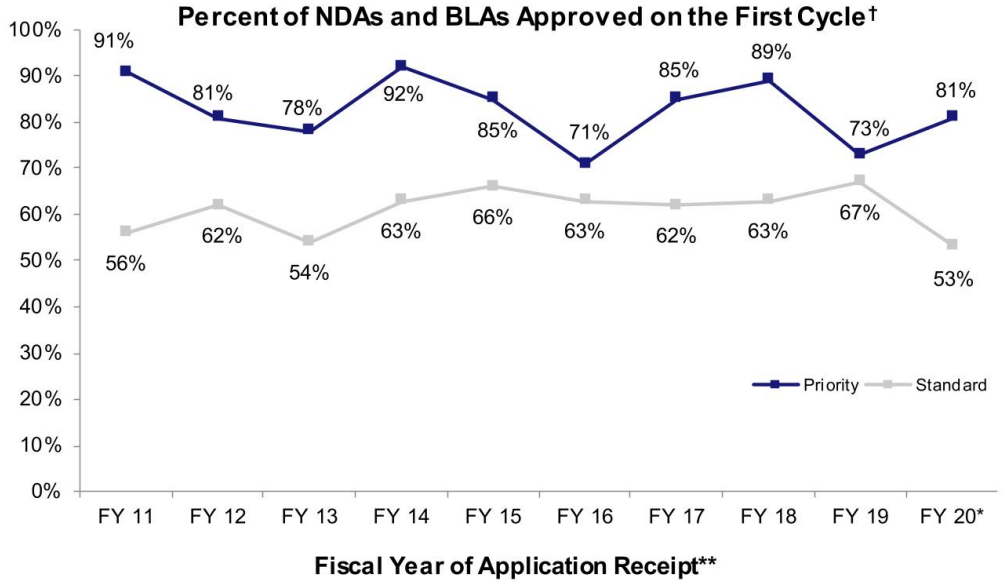


* The median approval times for the 3 most recent years are estimated.

† The data represented in this graph are based on the approvals reported in Appendix A.

[7] The total time for applications that are approved in the first cycle includes only FDA's response times. Applications approved after multiple review cycles include both FDA's and sponsor's response times. The *median total approval time* is the median of all application times for a given cohort, including applications with multiple review cycles.

The graph below depicts the percentages of priority and standard NDAs and BLAs approved in the first review cycle for the receipt cohorts from FY 2011 to FY 2020. These percentages are based on the approvals reported in Appendix A. The percentage of standard applications in first-cycle approvals decreased in FY 2020. For the FY 2020 cohort, which is still preliminary, 53 percent of standard applications were approved on the first cycle. First-cycle approvals for approved priority applications increased in FY 2020, with 81 percent of approved priority applications being approved on the first cycle. The FY 2021 data are too preliminary to estimate the percent of first-cycle approvals.



* First-cycle approvals are still possible for FY 2020 standard applications, so the data are preliminary.
† The data were changed to reflect updates to the data presented in the FY 2020 PDUFA Performance Report.
** The data represented in this graph are based on the approvals reported in Appendix A.

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Additional PDUFA VI Commitments

Under Section VI of the PDUFA VI Commitment Letter, FDA committed to report its progress on the specific commitments identified in the following sections of the Commitment Letter:[8]

- Section I.I: Enhancing Regulatory Science and Expediting Drug Development,
- Section I.J: Enhancing Regulatory Decision Tools to Support Drug Development and Review,
- Section I.K: Enhancement and Modernization of the FDA Drug Safety System,
- Section II: Enhancing Management of User Fee Resources,
- Section III: Improving FDA Hiring and Retention of Review Staff, and
- Section IV: Information Technology Goals

Further, section 736B(a) of the FD&C Act, as amended by section 103 of FDARA, requires FDA to report on the Agency's performance under PDUFA VI.

FDA and industry designed these enhancements to improve the efficiency of drug development and the human drug review process. The progress reports in this section detail the work FDA performed in FY 2021 on commitments in Sections I.I-K of the Commitment Letter. In addition, this report includes updates on FDA's accomplishments under Section II: Enhancing Management of User Fee Resources, Section III: Improving FDA Hiring and Retention of Review Staff, and Section IV: Information Technology Goals. The Section II progress reports are duplicated in the FY 2021 PDUFA VI Financial Report. Each accomplishment includes a reference to a specific section of the Commitment Letter. External references are also provided to published guidances, meeting summaries, and other pertinent public information.

FDA is dedicated to the goals outlined in these sections of the Commitment Letter. When applicable, for each section, additional information is included on other activities FDA has conducted that are not specifically required but further the goals outlined in the Commitment Letter.

[8] www.fda.gov/media/99140/download.

Section I.I: Enhancing Regulatory Science and Expediting Drug Development

Commitment Title	FY 2021 Accomplishments
I.I.1 Promoting Innovation Through Enhanced Communication Between FDA and Sponsors During Drug Development	• The PDUFA VI IND Communications Assessment (www.fda.gov/media/138379/download) and associated public workshop were completed in FY 2020. Best practices identified by the assessment are applied as relevant (I.I.1a and I.I.1b).
I.I.2 Ensuring Sustained Success of Breakthrough Therapy Program	• Under the Breakthrough Therapy (BT) Program,[9] FDA: o Received 112 BT Designation Requests (CDER: 103 and the Center for Biologics Evaluation and Research (CBER): 9), o Granted 52 BT Designation Requests (CDER: 48 and CBER: 4), o Approved 22 original (CDER: 18, CBER: 4) and 14 supplemental (CDER: 14) marketing applications for BT-Designated products.[10] • Under the Regenerative Medicine Advanced Therapies (RMAT) Program,[11] CBER: o Received 24 RMAT Designation Requests, o Granted 6 RMAT Designation Requests, o Granted 2 Original approvals for RMAT-Designated products.
I.I.3 Early Consultation on the Use of New Surrogate Endpoints	• For PDUFA VI Type C surrogate endpoint meetings, FDA: o Received 10 requests o Completed 7 meetings o Cancelled 1 meeting that was determined not to be a Type C surrogate endpoint meeting o Denied 2 meeting requests (i.e., for 1 meeting that was deemed premature but an Advisory Committee was held on the topic and for 1 meeting in which the sponsor didn't address previous recommendations)
I.I.4 Advancing Drug Development of Drugs for Rare Diseases	• In FY 2021, FDA's Rare Diseases Team (RDT) continued to consult on or contribute to the approval of rare disease drug applications across the review divisions in FDA's Office of New Drugs (OND) regarding issues and workshops related to the trial design, endpoint selection, and labeling of rare disease products. As part of this effort, the RDT worked closely with other FDA offices within CDER to provide expertise for the rare disease pediatric voucher program. • The RDT continued to meet with offices within CBER to coordinate their efforts in documenting FDA's progress in advancing the development of drug and biologics treatments for rare diseases through application review, training, and stakeholder engagement.

[9] www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FDASIA/ucm329491.htm.

[10] BT-Designated product approvals are tracked and posted on FDA's website (www.fda.gov) by calendar year. However, the BT approval numbers included in this PDUFA report are reflective of FY 2021.

[11] The RMAT Program expedites the development and review of designated regenerative medicine PDUFA products and is often used in lieu of requesting BT Designation in CBER's Office of Tissues and Advanced Therapies.

	• The RDT continued to collaborate with FDA's Office of Orphan Products Development in activities to advance the development of drugs and biological products for rare diseases, such as contributing to FDA Rare Disease Day 2021, a public meeting held on March 5, 2021. • As part of the RDT's training efforts, in September 2021, RDT held a 2-day annual training event titled "Partnering to Make a Difference in Rare Diseases." This training focused on collaborations across FDA's Centers and Offices (i.e., the Office of the Commissioner (OC), CDER, CBER, and the Center for Devices and Radiological Health (CDRH)), which have impacted the development of medical products for rare diseases. There were 351 attendees on the first day of the training, and 404 attendees on the second day. • As part of furthering collaboration (specifically with other regulatory agencies), the RDT continued to lead the International Rare Diseases Cluster for FDA. In addition to FDA, this cluster included the European Medicines Agency and Health Canada. • The RDT collaborated with external stakeholders—including the National Organization for Rare Disorders, the National Institutes of Health, the National Center for Advancing Translational Sciences, and the Office of Rare Diseases Research—to advance rare disease drug development. • In 2021, FDA's Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine, in conjunction with RDT, launched the Rare Disease Drug Development Council, which is an internal FDA council composed of rare disease experts, to provide a forum for OND divisions to discuss cross-cutting issues and applications pertinent to their rare disease drug development programs and review. • FDA's Rare Disease Program, as a Rare Disease Coordinating Committee meeting activity, continued the series of case study presentations on flexibility in the review of biological products. • FDA continued to track rare disease-related stakeholder engagement activities. In FY 2021, FDA staff participated in a minimum of 166 outreach activities intended to support the development of biological products for rare diseases. These activities included presentations (51%), publications (38%), and posters/abstracts (11%). • FDA's Centers continued to collaborate in activities to advance the development of drugs and biological products for rare diseases, such as by contributing to the annual rare disease training held in September 2021; by contributing to the quarterly rare disease seminar series for FDA review staff; by planning and contributing to FDA Rare Disease Day 2021; by holding a public meeting on March 5, 2021; and by composing and distributing an internal newsletter for FDA staff on rare disease activities. Also, in FY 2021, FDA review staff prepared and gave presentations at six of the eight International Rare Diseases Cluster meetings held with the European Medicines Agency and Health Canada.
I.I.5 Advancing Development of Drug-Device and Biologic-Device Combination Products Regulated by CBER and CDER	• In FY 2021, there were no commitments due and no new activities to report.
I.I.6 Enhancing Use of Real World Evidence for Use in Regulatory Decision-Making	• FDA satisfied the commitment to complete a public workshop in September 2017 and continued to engage key stakeholders annually. For example, in FY 2021 (from February 16-17,

	2021), FDA hosted a 2-day meeting titled "Evaluating RWE from Observational studies in Regulatory Decision-Making: Lessons Learned from Trial Replication Analyses" (see healthpolicy.duke.edu/events/evaluating-rwe-observational-studies-regulatory-decision-making-lessons-learned-trial) (PI.I.6.a). • FDA satisfied the commitment to initiate real-world evidence (RWE) activities in FY 2017 and continued to oversee ongoing CBER- and CDER-supported demonstration projects. Activities in FY 2021 included utilization of FDA CBER's Biologics Effectiveness and Safety (BEST) System to generate RWE that informs regulatory decision-making for COVID-19 vaccines and continuation of an inter-Agency agreement with the Centers for Medicare & Medicaid Services that uses real-world data (RWD) to investigate the safety and effectiveness of vaccines as well as the natural history of COVID-19 disease. Also in FY 2021, and to further address evolving considerations for the use of RWE in regulatory decision-making, CDER established an inter-Agency agreement with the U.S. Department of Veterans Affairs both to support RWD/RWE investigations that are relevant to the safety and effectiveness of FDA-regulated medical products and to promote a learning health care system and improve public health (PI.I.6.b). • FDA satisfied the commitment to publish a draft guidance on how RWE can contribute to the assessment of safety and effectiveness in regulatory submissions by publishing, in September 2021, the draft guidance for industry "Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products" (see www.fda.gov/regulatory-information/search-fda-guidance-documents/real-world-data-assessing-electronic-health-records-and-medical-claims-data-support-regulatory?utm_medium=email&utm_source=govdelivery). For further related RWE guidances, please see www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence (PI.I.6.c).

Section I.J: Enhancing Regulatory Decision Tools to Support Drug Development and Review

Commitment Title	FY 2021 Accomplishments
I.J.1 Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making	• FDA continued to strengthen staff capacity to facilitate the development and use of patient-focused methods to inform drug development and regulatory decisions. These staff, who are integrated across review divisions, increasingly interacted with patient stakeholders and provided consultations to sponsors developing clinical outcome assessments (COAs) that will be used to collect patient and caregiver input. These interactions included conducting three FDA-led patient-focused drug development meetings, over 15 patient listening sessions, and multiple informal meetings between patient groups and review divisions, as well as participating in 14 externally-led patient-focused drug development (PFDD) meetings (I.J.1.a). • FDA continued the Standard Core Clinical Outcomes and Endpoints Grant Program that (1) funds the development of core outcome sets in a variety of clinical divisions, including funding an additional two grants in FY 2021 and (2) increases the familiarity and understanding of the development of COAs within review divisions and other areas (I.J.1.a). • FDA continued to progress towards completion of the PFDD guidance document series. Though the commitment due date for the Guidance 4 document (titled "Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments into Endpoints for Regulatory Decision Making") was missed in FY 2021 due largely to a shift in priorities created by the Agency's COVID-19 response, the Agency is actively working on and remaining committed to issuing the Guidance 4 document as soon as possible (I.J.1.b.v). • FDA maintained and enhanced its repository of publicly available tools and resources for stakeholders (I.J.1.c). • FDA continued to hold held monthly cross-disciplinary meetings to discuss reviews, guidance documents, and process changes. Also, staff provided presentations at several internal meetings and public meetings with a high attendance by FDA staff. Further, FDA offered a semester-long course to increase reviewer proficiency with psychometric techniques used to analyze the properties and data from COAs. In addition, FDA staff and reviewers participated in multiple internal trainings to increase their familiarity and understanding of the role of patient preference studies in drug development (I.J.1.d). • FDA finalized a guidance document on enhancing the diversity of clinical trial populations, which included a section on considerations to make trial participation less burdensome for participants and a section on enhancing enrollment and retention practices fo foster inclusiveness (see www.fda.gov/media/127712/download). This guidance document was informed by the public workshop on patient engagement in clinical trials (I.J.1.e).
I.J.2 Enhancing the Benefit-Risk Assessment in Regulatory Decision-Making	• FDA published a draft guidance entitled "Benefit-Risk Assessment for New Drug Review" (see www.fda.gov/regulatory-information/search-fda-guidance-

	documents/benefit-risk-assessment-new-drug-and-biological-products) and opened a *Federal Register* public comment period. Also, FDA developed a Guidance Snapshot Pilot to supplement the dissemination of important guidance topics (see www.fda.gov/drugs/guidances-drugs/guidance-snapshot-pilot) (I.J.2.c). • FDA continued in its work with a third-party contractor to conduct an evaluation of the implementation of the Benefit-Risk Framework into new drug review processes. Work in FY 2021 focused on evaluation design and the initiation of internal data collection (I.J.2.d). • FDA continued to implement the Benefit-Risk Framework into review processes, templates, and trainings as part of the phased rollout of the new Integrated Assessment process and Integrated Review document. Also, FDA initiated an overview training, which was available to all CDER staff, on the benefit-risk assessment and decision science. Further, FDA continued to provide benefit-risk training to reviewers (I.J.2.e). • FDA staff presented at conferences on relevant topics regarding benefit-risk assessments in regulatory decision-making and continued their participation in multi-stakeholder workgroups, such as the Council for International Organizations of Medical Sciences, that seek to leverage the Benefit-Risk Framework and International Council for Harmonisation guidelines ME4(R2). FDA conducted quantitative benefit-risk assessments to inform some of its complex regulatory decisions, such as regarding BLAs and emergency use authorizations of COVID-19 vaccines.
I.J.3 Advancing Model-Informed Drug Development	• The Office of Biostatistics and Epidemiology in CBER invited representatives from Certara, a biotech software company, to provide staff with a foundational understanding of the model-informed drug development (MIDD) approaches developed by the company (I.J.3.a). • The Office of Clinical Pharmacology in CDER hosted an MIDD education series seminar titled "Decision Making in Drug Development: An Opportunity for Model-based Knowledge Integration and Scenario Evaluation" by Dr. Marc Gastonguay, Metrum Research Group, on April 26, 2021, which had 150 attendees (I.J.3.a). • FDA staff organized the MCBIOS 2021 Breakout Session: Model-Informed Drug Discovery and Development: Opportunities and Challenges Workshop (April 26, 2021) (I.J.3.b). • FDA held the Model-Informed Drug Development Approaches for Immunogenicity Assessment Public Workshop on June 9, 2021, which had 520 attendees (I.J.3.b.4). • The Office of Clinical Pharmacology planned for the Model Informed Drug Development: Best Practices for Development and Applications of Disease Progression Models Workshop held on November 19, 2021. A meeting proceedings will be developed post workshop (I.J.3.b.3). • FDA selected proposals on a quarterly basis for which MIDD would be needed to assess uncertainties regarding dosing, duration, and patient selection to help inform decision-making. The Office of Clinical Pharmacology granted 10 MIDD requests. The Office of Biostatistics and Epidemiology in CBER granted one MIDD request of two CBER-specific sponsor submissions (I.J.3.c).

	• The Office of Clinical Pharmacology conducted nine industry meetings from October 2020 to September 2021 related to nine applications (I.J.3.c.ii). • The Office of Clinical Pharmacology developed a Population Pharmacokinetics Standard Operating Procedure that was implemented into the review process of MIDD applications (I.J.3.e).

I.J.4 Enhancing Capacity to Review Complex Innovative Designs	• In FY 2021, FDA continued to develop staff capacity to enable processes to facilitate the appropriate use of complex adaptive, Bayesian, and other novel clinical trial designs (I.J.4.a) through the following activities:
	  ○ FDA's Office of Biostatistics in CDER initiated a Bayesian training series and conducted seven Bayesian lectures.
	  ○ FDA's Office of Biostatistics conducted two lectures under the continuing education-accredited Complex Innovative Design (CID) seminar series
	  ○ Staff participated in internal and external trainings on simulations.
	• Under the CID Pilot Meeting Program (I.J.4.b),
	  ○ FDA completed a paired meeting series for one proposed CID.
	  ○ FDA denied two CID meeting requests due to the inappropriateness of the proposed designs for the CID Pilot Meeting Program.
	  ○ Under the disclosure agreement, FDA presented trial designs developed as part of the program as case studies at five professional meetings.
	  ○ FDA staff collaborated with the University of Maryland Center for Excellence in Regulatory Science and Innovation on a public workshop entitled "Advancing the Development of Pediatric Therapeutics Complex Innovative Designs" in September 2021 (see www.fda.gov/drugs/news-events-human-drugs/fda-m-cersi-advancing-development-pediatric-therapeutics-complex-innovative-trial-design-public).
	• FDA published the final guidance for industry entitled "Interacting with the FDA on Complex Innovative Trial Designs for Drugs and Biological Products" (see www.fda.gov/media/130897/download).

I.J.5 Enhancing Capacity to Support Analysis Data Standards for Product Development and Review	• Completed the Clinical Data Interchange Standards Consortium (CDISC) Analysis Data Model (ADaM) training video series and posted the training on FDA's internal website (I.J.5.a). • Drafted the Technical Specifications for Clinical Outcomes Assessments (COAs) Utilizing Item Response Theory (IRT) document, which, once finalized, will provide specifications for the submission of CDISC SDTM and ADaM data sets in COAs that implement IRT (I.J.5.B). • The Office of Biostatistics collaborated with external stakeholders/groups on projects intended to support not only the collaborative development and application of data standards but also a shared understanding of statistical reviews. Also, the Office of Biostatistics staff helped plan for and presented at various external conferences related to analysis data standards (I.J.5.d).
I.J.6 Enhancing Drug Development Tools Qualification Pathway for Biomarkers	• FDA administered three qualification programs (i.e., the biomarkers qualification program (BQP), COAs, and animal

	models for use under the animal rule) and one pilot program (i.e., the Innovative Science and Technology Approaches for New Drugs (ISTAND) pilot). These four programs work together in the development of inter-related process, communications, and policy. • The BQP experienced continued interest and growth, with 87 projects under development. In FY 2021, the program reviewed 12 submissions (six Letters of Intent and six Qualification Plans). • Overall, the Drug Development Tool (DDT) qualification program had over 147 projects under development. In the first half of FY 2021, the program reviewed 19 submissions (14 Letters of Intent, four Qualification Plans, and one final qualification package). • The BQP continued its extensive public engagement with key stakeholder groups (i.e., the FNIH Biomarkers Consortium, the Critical Path Institute, and the Innovative Medicines Initiative). FDA staff were invited to speak at over 15 scientific conferences (I.J.6.a). • FDA's ISTAND Pilot Program, which is designed to expand DDT types by encouraging the development of potentially beneficial DDTs that are out of scope for existing DDT qualification programs, received 14 submissions in FY 2021. These DDT submissions included tools proposed to enable remote or decentralized trials, advance FDA's understanding of drug safety and metabolism using in vitro systems, and utilize digital health technologies (I.J.6.a). • FDA's Biomarker Working Group planned to sponsor a virtual public workshop titled "Multi-component Biomarkers Workshop" on March 23-24, 2022. • FDA worked to develop an evidentiary framework guidance document and a biomarker qualification analytics guidance document (I.J.6.d), both of which will continue to undergo clearance in FY 2022. FDA also worked to develop the draft guidance for industry titled "Considerations for Surrogate Endpoints Intended as Primary Efficacy Endpoints for Drugs and Biologics Approvals." • FDA renewed the DDT RO1 grant program to assist DDT programs that had already been accepted into the FDA DDT qualification program at the LOI stage. FDA reviewed 10 grant requests and awarded 6 projects with an FDA DDT grant. • FDA carried out a public posting of a Comprehensive Surrogate Endpoint Table for CDER- and CBER-regulated products.

Section I.K: Enhancement and Modernization of FDA's Drug Safety System

Commitment Title	FY 2021 Accomplishments
I.K.1 Advancing Postmarketing Drug Safety Evaluation Through Expansion of the Sentinel System, and Integration into FDA Pharmacovigilance Activities	• Expanded sources of data and enhanced core capabilities (I.K.1.a). FDA completed the following actions: o FDA updated the Sentinel Common Data Model to version 8.0.0. This update allowed for increased data capture, improved data precision, and the opening of

	this model to broader use (even internationally) of RWD. ○ FDA developed new analytic capabilities in the Active Risk Identification and Anaysis (ARIA) system, distributed tools to conduct descriptive analyses on drug dosage, and expanded cohort attrition table information. Also, FDA implemented made major enhancements to the ARIA local reporting tools to consolidate disparate local reporting tools, enhance visualization capabilities, and develop comprehensive documentation for public use. ○ FDA conducted analyses in new electronic health record (EHR)-based data sources, including the National Patient-Centered Clinical Research Network (PCORnet) and TriNetX, to improve understanding of these resources. ○ The Innovation Center initiated seven projects and continued two projects to advance a strategic goal of developing a new EHR-based distributed data network. • CBER's component of the Sentinel Initiative is called the BEST Initiative. The BEST Initiative has access to the following data sources: administrative claims data of the four largest health insurance companies in the United States covering over 200 million patients; U.S. Medicare administrative claims data covering over 100 million patients; partial Medicaid administrative claims data covering over 54 million patients; EHR data covering approximately 120 million patients; and three linked claims-EHR data sources covering over 30 million patients. • FDA enhanced communication with sponsors and the public on methodologies for Sentinel queries (I.K.1.b). FDA completed the following actions: ○ Continued to post all analytic packages and query results on the Sentinel website. ○ Continued notification of sponsors of Sentinel analyses and results according to the policies and processes outlined in the Manual of Policies and Procedures (MAPP) 6701.4 (see www.fda.gov/media/141216/download) (I.K.1.e). ○ Made publicly available on the Sentinel website upgrades to distributed and local reporting tools used for ARIA analyses, including analytic programming code and comprehensive documentation. ○ Conducted a public training on November 2, 2020, on maternal health and pregnancy. The training covered how Sentinel tools are used to assess medical product use during pregnancy and to conduct pregnancy-related safety analyses using linked mother and infant data. • FDA facilitated public and sponsor access to Sentinel (I.K.1.c). FDA completed the following actions: ○ The Innovation in Medical Evidence Development and Surveillance (IMEDS) is a program run by the Reagan-Udall Foundation for the FDA that provides the private sector with access to a subset of FDA's Sentinel Network to conduct assessments of medical product safety and effectiveness. IMEDS benefits from Sentinel's curated data and routine analytic toolset. In FY 2021, the Sentinel Operations Center supported five IMEDS queries.

	○ Redesigned the Sentinel website, which serves as a central hub for communications related to Sentinel. The new website provides for better navigation and improved searching capabilities (see www.sentinelinitiative.org). ○ Initiated a public quarterly newsletter to inform the Sentinel community of the work being done by Sentinel, upcoming events, and new publications. • FDA analyzed and reported on its use of Sentinel for regulatory purposes (I.K.1.h). FDA completed the following actions: ○ As part of the Sentinel website redesign, FDA created a downloadable table of drug assessments that provides a single view of analytic packages, results, and regulatory impacts of Sentinel analyses (see sentinelinitiative.org/assessments/drugs). ○ Made updates to eight drug assessments pages on the Sentinel website, describing ongoing queries, completed queries, and regulatory impacts. ○ Made ongoing updates to the "Assessing ARIA's Ability to Evaluate a Safety Concern" web page containing ARIA sufficiency memos (see sentinelinitiative.org/assessments/drugs/assessing-arias-ability-evaluate-safety-concern). ○ Published a summary of how FDA's Sentinel System has contributed to FDA's COVID-19 pandemic response, including lessons learned about the use of RWD to address urgent public health questions. This summer is titled "A COVID-19-ready Public Health Surveillance System: *The Food and Drug Administration's Sentinel System"* (see onlinelibrary.wiley.com/doi/10.1002/pds.5240). • The BEST Initiative has set up an on-demand ad-hoc computer programming capability for interrogating all data sources; therefore, the system can run a variety of studies in a timely manner to answer different regulatory questions. A cadre of multi-disciplinary scientists and clinicians from CBER, academia, and other organizations worked together to perform studies and evaluate regulatory questions. • CBER used the BEST program, which is fully integrated into the life cycle of biologics (including pre-market reviews and evaluations and post-market active surveillances and pharmacovigilance activities), to monitor and evaluate the safety of different biologics. BEST conducted multiple studies to evaluate the safety of all COVID-19 vaccines that have received Emergency Use Authorization or approval from FDA.

I.K.2 Timely and Effective Evaluation and Communication of Postmarketing Safety Findings Related to Human Drugs	• Based on ongoing user feedback, FDA continued to improve the Lifecycle Safety Tool (LiST) in CDER's Nexus (powered by Appian) through quarterly enhancements (I.K.2.a). • FDA continued to engage with its internal stakeholders to address questions and concerns, and the Newly Identified Safety Signal Implementation Team worked to operationalize MAPP 4121.3 (titled "Collaborative Identification, Evaluation, and Resolution of a Newly Identified Safety Signal (NISS)") and the LiST within the team members' offices (I.K.2.a). • FDA developed and implemented new data fields in its electronic system for managing regulatory reviews, known as the Regulatory Management System – Biologics Licensed Applications. The new fields track review memorandums on postmarket safety issues, allowing staff to more easily locate and access post-market safety related information (I.K.2.a). • FDA contracted with a third party to assess how "data systems and processes, as described in MAPPs and [Standard Operating Policies and Procedures], support review, oversight, and communication of postmarketing drug safety issues" in CDER and CBER. This assessment will be completed by September 2022 and produce an internal report and public summary outlining results (I.K.2.c).

Section II: Enhancing the Management of User Fee Resources

Commitment Title	FY 2021 Accomplishments
II.A Resource Capacity Planning and Modernized Time Reporting	• In FY 2021, there were no commitments due and no new activities to report.
II.B Financial Transparency and Efficiency	• FDA published the FY 2021 PDUFA Five-Year Financial Plan Update in March 2021 (see www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans) (II.B.2). • FDA held a public meeting on June 28, 2021, regarding this plan (see FDA's "Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments" web page at www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and) (II.B.3).

Section III: Improving FDA's Hiring and Retention of Review Staff

Commitment Title	FY 2021 Accomplishments
III.A Completion of Modernization of the Hiring System Infrastructure and Augmentation of System Capacity	• FDA has entered over 11,000 position descriptions within the classification tool that allows standardized position descriptions to be used and provides easy access to position descriptions to reduce the administrative burden. • The Applicant Tracking Lifecycle Analysis System was deployed as a pilot in 2018 to track each step in the hiring process of FDA's nine hiring authorities. In FY 2021, FDA made enhancements to the system, and the system will be fully deployed in FY 2022. This system provides real-time tracking of hiring actions and has increased transparency, performance, and accountability.
III.B Augmentation of Hiring Staff Capacity and Capability	• In FY 2021, there were no commitments due and no new activities to report.
III.C Complete Establishment of a Dedicated Function to Ensure Needed Scientific Staffing for Human Drug Review Program	• The Scientific Staffing Office has established over 30 new strategic partnerships to promote careers at FDA with academic, government, or professional associations in order to increase scientific staffing outreach.
III.D Set Clear Goals for Human Drug Review Program Hiring	• FDA's FY 2021 hiring goal was for 18 full-time equivalents (FTEs), and 15 FTEs were onboarded (which was 83 percent of the FY 2021 hiring goal) (III.D.2). • FDA's hiring progress against this goal and the goals from previous years were posted on FDA's website (see www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data) (III.D.2).
III.E Comprehensive and Continuous Assessment of Hiring and Retention	• FDA published a human resources interim report on June 5, 2020, and held a public meeting on July 30, 2020 (see www.fda.gov/industry/prescription-drug-user-fee-amendments/fda-interim-hiring-and-retention-assessment-report) (III.E.2). • FDA engaged an independent contractor to perform the final human resources assessment, which will be published by December 31, 2021, and a public meeting held by March 30, 2022.

Section IV: Information Technology Goals

Goal	FY 2021 Accomplishments
IV.B Improve the Predictability and Consistency of PDUFA Electronic Submission Processes	• The Electronic Submissions Gateway's (ESG's) operational status, along with submission target time frames, continued to be published on FDA's public website. • The rejection process for electronic submissions was published and updated periodically (see www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vi-information-technology-goals-and-progress). • The software versions of eCTD validation tools were posted. • Industry was involved, as needed, to provide feedback or participate in user acceptance testing.
IV.C Enhance Transparency and Accountability of FDA Electronic Submission and Data Standards Activities	• Quarterly meetings with industry were conducted with a focus on ESG; the identification of medicinal products standards; technical rejections; pharmaceutical quality/chemistry, manufacturing, and controls data standards; and IND safety reporting systems and processes. • A collaboration meeting was held in June 2021, which focused on implementation of the identification of medicinal products. • CDER's and CBER's Data Standards Action Plan continued to be updated quarterly and posted on FDA's public website. • The FDA Data Standards Catalog was updated, as needed, and posted on FDA's public website (see www.fda.gov/industry/fda-resources-data-standards).

Additional PDUFA VI Review Program Reporting

Hiring and Placement of New PDUFA VI Staff at FDA

The hiring and placement of new staff at FDA under PDUFA VI are reported on a quarterly basis and posted on the FDARA hiring performance web page.[12] FDA reports its progress in hiring new staff to support new initiatives in the annual PDUFA Financial Report, as per the PDUFA VI Commitment Letter.

Rationale for PDUFA Program Changes

FDARA amended the FD&C Act to require the reporting of certain information relating to PDUFA program changes in the annual performance report starting with FY 2020.

Specifically, section 903(a) of FDARA added section 736(b)(4) to the FD&C Act, which requires the annual PDUFA performance report to include the following:

[12] www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm604305.htm.

(A) data, analysis, and discussion of the changes in the number of FTEs hired as agreed upon in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017 and the number of FTEs funded by budget authority at FDA by each division within CDER, CBER, the Office of Regulatory Affairs (ORA), and OC;

(B) data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of human drugs, including identifying drivers of such changes; and

(C) for each of the CDER, CBER, ORA, and OC, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required.

The information below fulfills these reporting requirements.

A. Changes in the number of FTEs hired as agreed in the PDUFA VI Commitment Letter and the number of FTEs funded by budget authority at FDA by division within CDER, CBER, ORA, and OC

This section addresses the requirement to provide data, an analysis, and a discussion of the changes in the number of FTEs hired as agreed upon in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017 and the number of FTEs funded by budget authority at the FDA by each division within CDER, CBER, ORA, and OC.

Changes in the number of FTEs hired as agreed upon in the PDUFA VI Commitment Letter

FDA is committed to hiring 230 FTEs from FY 2018 to FY 2022 as agreed upon in the PDUFA VI Commitment Letter. FDA has successfully hired 212 FTEs of the 230 FTEs (92 percent) as of September 30, 2021. The data in the following table show the total number of FTEs hired towards the FY 2020 and FY 2021 hiring targets as agreed upon in the PDUFA VI Commitment Letter and the change in the number of FTE hires from FY 2020 to FY 2021.

The hiring of FTEs decreased from FY 2020 to FY 2021 due to the hiring goal targets decreasing from 58 FTEs in FY 2020 to 18 FTEs in FY 2021. FDA has successfully fulfilled 93 percent of its hiring target for FY 2020 and 83 percent of its hiring target for FY 2021 as of September 30, 2021. With a total of 18 FTEs remaining to hire through FY 2022, FDA will continue hiring new FTEs to meet its commitments as agreed upon in the PDUFA VI Commitment Letter.

Number of FTEs Hired as Agreed in the PDUFA VI Commitment Letter

Center	FY 2020 Hires*	FY 2021 Hires*	Change in Number of FTE Hires
CDER	41	14	-27
CBER	7	1	-6
ORA	0	0	0
OC/Other	6	0	-6

* A *hire* is defined as someone who has been confirmed as on board by the date indicated in a full-time position at the noted Center. Although some hires are recruited from outside the Center/FDA, a hire can also be a current Center/FDA employee who is changing positions within the Agency.

Number of FTEs funded by budget authority at FDA by division within CDER, CDRH, CBER, ORA, and OC

The data in the table below show the change from FY 2020 to FY 2021 in the number of FTEs funded by budget authority at FDA by each division within CDER, CDRH, CBER, ORA, and OC. This table reflects the number of FTEs funded by budget authority for the PDUFA VI program. For this table, *budget authority* refers to FDA's non-user fee annual appropriations. To address the requirement that information on the number of FTEs funded by budget authority be presented "by each division," the information in this table is broken down to the office level for the Centers, ORA, and OC. FDA uses a 2080-hour workload to equate to one FTE, and this calculation is reflected in the table below. Data for FY 2021 and the previous year, FY 2020, are presented and compared to show the change in the number of FTEs over the last 2 fiscal years committed to PDUFA work. The number of FTEs funded by budget authority for FY 2020 are those FTEs as of September 30, 2020. The number of FTEs funded by budget authority for FY 2021 are those FTEs as of September 30, 2021.

FDA reported a decrease in budget authority-funded FTEs in FY 2021 compared to FY 2020. The decrease in reported FTEs was attributable to the impacts of COVID-19-related efforts.

Center and Office	Number of PDUFA Program FTEs Funded by Budget Authority*		Change in Number of PDUFA Program FTEs Funded by Budget Authority
	FY 2020	FY 2021	
CDER			
Office of Communications	0.4	3.1	2.7
Office of Compliance	28.5	21.3	-7.2
Office of the Center Director	0.8	0.8	0.0
Office of Executive Programs	0.4	7.5	7.1
Office of Generic Drugs	3.3	4.5	1.2
Office of Medical Policy	10.1	5.1	-5.0

Office of Management	1.3	1.6	0.3
Office of New Drugs	157.3	137.6	-19.7
Office of Pharmaceutical Quality	68.2	73.4	5.2
Office of Regulatory Policy	6.5	9.5	3.0
Office of Surveillance and Epidemiology	5.0	20.9	15.9
Office of Strategic Planning	4.4	4.8	0.4
Office of Information Management and Technology	0.1	0.1	0.0
Office of Translational Sciences	55.4	33.7	-21.7
Other Offices	2.7	3.4	0.7
Working Capital Fund (WCF)	43.2	55.5	12.3
CDRH			
Office of Product Evaluation and Quality	1.6	7.1	5.5
Office of Management	0.1	1.2	1.1
Office of Science and Engineering Laboratories	0.3	0.6	0.3
WCF	0.8	0.9	0.1
CBER			
Office of Biostatistics and Epidemiology	17.9	13.7	-4.2
Office of Blood Research and Review	4.6	4.9	0.3
Office of Compliance and Biologics Quality	19.4	22.8	3.4
Office of Tissues and Advanced Therapies	57.1	59.5	2.4
Office of Vaccines Research and Review	84.8	96.4	11.6
Office of Communication Outreach and Development	11.1	11.9	0.8
Office of the Center Director	17.3	20.3	3.0
Office of Management	19.2	17.5	-1.7
Other Offices	1.8	2.0	0.2
WCF	33.1	34.0	0.9
OC			

OC Immediate Office	4.4	2.3	-2.1
Office of the Chief Counsel	14.9	6.4	-8.5
Office of the Chief Scientist	9.9	4.6	-5.3
Office of Clinical Policy and Programs	22.0	9.9	-12.1
Office of External Affairs	5.0	2.6	-2.4
Office of Health Informatics	1.7	0.6	-1.1
Office of International Programs	0.1	0.0	-0.1
Office of Operations	8.8	8.7	-0.1
Office of Policy Legislation and International Affairs	11.5	4.6	-6.9
Office of Special Medical Programs	0.2	0.0	-0.2
WCF	17.1	13.0	-4.1
ORA			
Office of Pharmaceutical Quality Operations	89.9	91.0	1.1
WCF	8.6	8.4	-0.2

* This table includes PDUFA program FTE calculated through WCF assessments for certain centrally administered services provided to CDER, CDRH, CBER, ORA, and OC. Because many employees under OC and WCF do not report time, an average cost per OC and WCF FTE was applied to derive the number of PDUFA program FTEs funded by budget authority.

B. Changes in the fee revenue amounts and costs for the review process

Section 903(a) of FDARA amended the FD&C Act to require FDA to provide data, an analysis, and a discussion of the changes in the fee revenue amounts and costs for the process for the review of human drugs, including identifying drivers of such changes. Accordingly, the table below provides data for the PDUFA fee revenue amounts and process costs for FY 2020 and FY 2021, as well as the changes in these amounts from FY 2020 to FY 2021. Relevant information about the data provided is as follows:

- *Fee Revenue Amounts* represent FDA's net collection of human drug user fees.
- *Review Process Costs* represent FDA's total expenditure of the PDUFA program.
- Numbers are provided for both the most recent fiscal year (FY 2021) and the prior fiscal year (FY 2020). Although FDARA does not explicitly require this data, they do provide relevant context necessary to interpret the required information.

In FY 2021, FDA had net collections of $1.153 billion in prescription drug user fees, spent $1.109 billion in user fees for the human drug review process, and carried a cumulative balance of $245 million forward for future fiscal years. Detailed financial information for the PDUFA user fee program can be found in the FY 2021 PDUFA Financial Report.

The process for setting the annual target revenue is set forth in the statute. For FY 2021, the base revenue amount is $1,065,707,676. The FY 2021 base revenue amount is adjusted for inflation and for the resource capacity needs for the process for the review of human drug applications (the capacity planning adjustment). An additional dollar amount specified in the statute (see section 736(b)(1)(F) of the FD&C Act) is then added to provide for additional FTE positions to support PDUFA VI initiatives. The FY 2021 revenue amount may be adjusted further, if necessary, to provide for sufficient operating reserves of carryover user fees. Finally, the amount is adjusted to provide for additional direct costs yielding a total adjusted fee revenue amount of $1,107,199,000 (rounded to the nearest thousand dollars), which funds PDUFA VI initiatives.

In FY 2021, PDUFA costs increased just under two percent above the prior fiscal year, an amount close to the inflationary pressures on the program.

Changes in the Fee Revenue Amounts and Review Process Costs

Fiscal Year	FY 2020	FY 2021	Change from FY 2020 to FY 2021
Net Fiscal Year Collections	$1,020,229,037	$1,152,538,861	13%
Review Process Costs	$1,471,144,928	$1,499,064,056	2%

C. Number of Employees for Whom Time Reporting Is Required

Section 903(a) of FDARA amended the FD&C Act to require FDA to provide—for CDER, CBER, ORA, and OC—the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required. Accordingly, the table below provides the number of employees within CDER, CBER, ORA, and OC who are required to report their time and those who are not required to report their time as of September 30, 2021.

These data reflect time reporting across all employees in each entity, rather than only those engaged in PDUFA program activities.

Time Reporting Requirements for FY 2021

Center	FTEs for Whom Time Reporting Is Required	FTEs for Whom Time Reporting Is Not Required
CDER	5,315	45
CBER	1,194	18
ORA	3,111	1,804
OC	41	2,609

Appendices

Appendix A: List of Approved Applications

This appendix includes detailed review histories of the NDA and BLA submissions approved under PDUFA VI in FY 2021. Approvals are grouped by priority designation and submission year and listed in order of total approval time. *Approval time* is presented in months and includes each review cycle's time with FDA, time with the sponsor, and the total time on that application.

Review histories of the NDA and BLA submissions approved prior to FY 2021 can be found in the appendices of the earlier PDUFA performance reports.[13]

When determining total time, FDA calculates the number of months and rounds to the nearest tenth. Therefore, when cycle times are added, rounding discrepancies may occur.

Because months consist of varying numbers of days, FDA uses the average number of days in a month to calculate review time in months. Therefore, a submission may appear overdue even though it was approved on the goal date. For example, the submission ZOKINVY on page A-4 was received on March 20, 2020, and had an 8-month review goal date of November 20, 2020, as it was reviewed under the program and had priority review. FDA approved the submission on the goal date, but because FDA uses the average number of days in a month to calculate months, the time taken to review the submission is reported as 8.1 months, and the review appears overdue.

Terms and Coding Used in Tables in This Appendix

Action Codes:
AE = Approvable
AP = Approved
CR = Complete Response
NA = Not Approvable
TA = Tentative Approval
WD = Withdrawn

▲ Denotes Class 1 Resubmission (2-month review-time goal)

△ Denotes Class 2 Resubmission (6-month review-time goal)

◊ Expedited review and TA of an NDA by FDA for fixed dose combinations and co-packaged antiretroviral medications as part of the President's Emergency Plan for AIDS Relief

♦ Application reviewed under the program with review goals starting from the 60-day filing date, rather than the submission date

[13] www.fda.gov/about-fda/user-fee-performance-reports/pdufa-performance-reports.

♯ Major amendment was received, which extended the action goal date by 3 months[14]

FY 2021 Priority NDA and BLA Approvals (by Fiscal Year of Receipt)

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
Submitted in FY 2021							
COMIRNATY (COVID-19 Vaccine, mRNA)	BioNTech Manufacturing GmbH	Y	First	3.2	AP	3.2	Y♦
LUMAKRAS (sotorasib)	Amgen Inc.	Y	First	5.4	AP	5.4	Y♦
EPCLUSA (sofosbuvir and velpatisvir)	Gilead Sciences Inc.	N	First	5.8	AP	5.8	Y
RYBREVANT (amivantamab-vmjw)	Janssen Biotech Inc.	Y	First	5.9	AP	5.9	Y♦
MAVYRET (glecaprevir and pibrentasvir)	Abbvie Inc.	N	First	6.0	AP	6.0	Y
WEGOVY (semaglutide)	Novo Nordisk Inc.	N	First	6.0	AP	6.0	Y
EXKIVITY (mobocertinib)	Takeda Pharmaceuticals USA Inc.	Y	First	6.6	AP	6.6	Y♦
WELIREG (belzutifan)	Merck Sharp and Dohme Corp. a Sub of Merck and Co. Inc.	Y	First	6.9	AP	6.9	Y♦
TIVDAK (tisotumab vedotin-tftv)	Seagen Inc.	Y	First	7.3	AP	7.3	Y♦
TEMBEXA (brincidofovir)	Chimerix Inc.	N	First	7.9	AP	7.9	Y♯
TEMBEXA (brincidofovir)	Chimerix Inc.	N	First	7.9	AP	7.9	Y♯
TICOVAC (Tick-Borne Encephalitis Vaccine)	Pfizer Ireland Pharmaceuticals	Y	First	7.9	AP	7.9	Y♦
BREXAFEMME (ibrexafungerp)	Scynexis Inc.	Y	First	8.0	AP	8.0	Y♦
BYLVAY (odevixibat)	Albireo AB	Y	First	8.0	AP	8.0	Y♦
JEMPERLI (dostarlimab-gxly)	Glaxosmithkline LLC (GSK)	N[15]	First	8.0	AP	8.0	Y♦
KORSUVA (difelikefalin)	Cara Therapeutics Inc.	Y	First	8.0	AP	8.0	Y♦
KERENDIA (finerenone)	Bayer Healthcare Pharamceuticals Inc.	Y	First	8.0	AP	8.0	Y♦
LIVMARLI (maralixibat)	Mirum Pharamceuticals Inc.	Y	First	8.0	AP	8.0	Y♦

[14] Under PDUFA VI, a major amendment can be received any time during the review cycle and extend the goal date by 3 months. If the review cycle occurred prior to FY 2013, the major amendment must have been received within 3 months of the action due date to extend the action goal date by 3 months.

[15] This non-NME NDA was reviewed under the PDUFA NME Program. At the time of receipt, the active ingredient (dostarlimab-gxly) had never been approved in the United States, which allowed for an NME designation; however, at the time of approval, (dostarlimab-gxly) had already been approved for marketing in another application, causing this application to lose its NME designation.

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
PREVNAR 20 (20-valent Pneumococcal Conjugate Vaccine)	Wyeth Pharmaceuticals LLC	Y	First	8.0	AP	8.0	Y♦
QULIPTA (atogepant)	Abbvie Inc.	Y	First	8.0	AP	8.0	Y♦
VAXNEUVANCE (Pneumococcal 15-valent Conjugate Vaccine)	Merck Sharp and Dohme Corp.	Y	First	8.0	AP	8.0	Y♦
OPZELURA (ruxolitinib)	Incyte Corp.	N	First	9.0	AP	9.0	Y♯
Submitted in FY 2020							
VEKLURY (remdesivir)	Gilead Sciences Inc.	Y	First	2.5	AP	2.5	Y♦
MYRBETRIQ GRANULES (mirabegron)	Astellas Pharma Global Development Inc.	N	First	5.9	AP	5.9	Y
dolutegravir	Mylan Laboratories Ltd.	N	First	6.0	TA	6.0	Y◊
HETLIOZ LQ (tasimelteon)	Vanda Pharmaceuticals Inc.	N	First	6.0	AP	6.0	Y
EBANGA (ansuvimab-zykl)	Ridgeback Biotherapeutics LP.	Y	First	6.8	AP	6.8	Y♦
ZYNLONTA (loncastuximab tesirine-lpyl)	ADC Therapeutics SA	Y	First	7.0	AP	7.0	Y♦
TEPMETKO (tepotinib)	EMD Serono Inc.	Y	First	7.2	AP	7.2	Y♦
INMAZEB (atoltivimab, maftivimab, and odesivimab-ebgn)	Regeneron Pharmaceuticals Inc.	Y	First	7.6	AP	7.6	Y♦
OXLUMO (lumasiran)	Alnylam Pharmaceuticals Inc.	Y	First	7.7	AP	7.7	Y♦
UKONIQ (umbralisib)	TG Therapeutics Inc.	Y	First	7.7	AP	7.7	Y♦
DANYELZA (naxitamab-gqgk)	Y-Mabs Therapeutics Inc.	Y	First	7.9	AP	7.9	Y♦
PEPAXTO (melphalan flufenamide)	Oncopeptides AB	Y	First	7.9	AP	7.9	Y♦
PYLARIFY (piflufolastat f-18)	Progenics Pharmaceuticals Inc.	Y	First	7.9	AP	7.9	Y♦
TRUSELTIQ (infigratinib)	QED Therapeutics Inc.	Y	First	7.9	AP	7.9	Y♦
ABECMA (idecabtagene vicleucel)	Celgene Corporation, a Bristol-Myers Squibb Company	Y	First	8.0	AP	8.0	Y♦
COSELA (trilaciclib)	G1 Therapeutics Inc.	Y	First	8.0	AP	8.0	Y♦
EMPAVELI (pegcetacoplan)	Apellis Pharmaceuticals Inc.	Y	First	8.0	AP	8.0	Y♦
IMCIVREE (setmelanotide)	Rhythm Pharmaceuticals Inc.	Y	First	8.0	AP	8.0	Y♦
NULIBRY (fosdenopterin)	Origin Biosciences Inc.	Y	First	8.0	AP	8.0	Y♦
ORGOVYX (relugolix)	Myovant Sciences GmbH	Y	First	8.0	AP	8.0	Y♦

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
VERQUVO (vericiguat)	Merck Sharp and Dohme Corp.	Y	First	8.0	AP	8.0	Y♦
AMONDYS 45 (casimersen)	Sarepta Therapeutics Inc.	Y	First	8.1	AP	8.1	Y♦
EVKEEZA (evinacumab-dgnb)	Regeneron Pharmaceuticals Inc.	Y	First	8.1	AP	8.1	Y♦
LUPKYNIS (voclosporin)	Aurinia Pharmaceuticals Inc.	Y	First	8.1	AP	8.1	Y♦
ZOKINVY (lonafarnib)	Eiger Biopharmaceuticals Inc.	Y	First	8.1	AP	8.1	Y♦
dolutegravir	Macleods Pharmaceuticals Ltd.	N	First	9.0	TA	9.0	Y♯◊
PRADAXA (dabigatran etexilate mesylate)	Boehringer Ingelheim Pharmaceuticals Inc.	N	First	9.0	AP	9.0	Y♯
REZUROCK (belumosudil)	Kadmon Pharmaceuticals LLC	Y	First	9.5	AP	9.5	Y♯♦
NEXVIAZYME (avalglucosidase alfa-ngpt)	Genzyme Corp.	Y	First	10.6	AP	10.6	Y♯♦
ADUHELM (aducanumab-avwa)	Biogen Inc.	Y	First	11.0	AP	11.0	Y♯♦
STRATAGRAFT (Allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen - dsat)	Stratatech Corporation	Y	First	12.3	AP	12.3	N♦
BREYANZI (lisocabtagene maraleucel)	Juno Therapeutics, Inc. a Bristol-Myers Squibb Company	Y	First	13.6	AP	13.6	N♦
JEMPERLI (dostarlimab-gxly)	Glaxosmithkline LLC (GSK)	Y	First	16.1	AP	16.1	N♦
fexinidazole	Sanofi Aventis US LLC	Y	First	8.1	CR	8.1	Y♦
			Sponsor	6.1		14.2	
			Second	1.9	AP	16.1	Y▲
Submitted in FY 2019							
CABENUVA (cabotegravir extended release injectable suspension; rilpivirine extended release injectable suspension)	Viiv Healthcare Co.	Y	First	7.7	CR	7.7	Y♦
			Sponsor	7.3		15.0	
			Second	5.8	AP	20.8	Y△
VOCABRIA (cabotegravir)	Viiv Healthcare Co.	N[16]	First	7.7	CR	7.7	Y♦
			Sponsor	7.3		15.0	
			Second	5.8	AP	20.8	Y△
vancomycin	Xellia Pharmaceuticals APS	N	First	6.0	CR	6.0	Y
			Sponsor	11.3		17.3	

[16] The applicant submitted two NDAs for the same new moiety (cabotegravir), but one of the NDAs is in combination with a currently marketed drug (rilpivirine). Only one NDA retains the NME designation upon approval; in this case, the NDA for cabotegravir and rilpivirine retained the NME designation.

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
			Second	6.0	AP	23.3	Y△
ZYNRELEF (bupivacaine and meloxicam)	Heron Therapeutics Inc.	N	First	6.0	CR	6.0	Y
			Sponsor	4.9		10.9	
			Second	9.0	CR	19.9	Y♯△
			Sponsor	4.6		24.5	
			Third	6.0	AP	30.5	Y△
Submitted in FY 2017							
RYPLAZIM (plasminogen, human-tvmh)	ProMetic BioTherapeutics, Inc.	Y	First	7.8	CR	7.8	Y♦
			Sponsor	28.8		36.6	
			Second	9.0	AP	45.6	Y♯△

FY 2021 Standard NDA and BLA Approvals (by Fiscal Year of Receipt)

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
Submitted in FY 2021							
RYLAZE (asparaginase erwinia chrysanthemi (recombinant)-rywn)	Jazz Pharmaceuticals Ireland Ltd.	Y	First	2.0	AP	2.0	Y♦
bortezomib	Intas Pharmaceuticals Ltd.	N	First	9.7	TA	9.7	Y
TWYNEO (tretinoin and benzoyl peroxide)	Sol-Gel Technologies Ltd.	N	First	9.8	AP	9.8	Y
LOREEV XR (lorazepam)	Almatica Pharma LLC	N	First	9.9	AP	9.9	Y
TRUDHESA (dihydroergotamine mesylate)	Impel Neuropharma	N	First	9.9	AP	9.9	Y
Sitagliptin	Zydus Worldwide DMCC	N	First	10.0	TA	10.0	Y
succinylcholine chloride	Hikma Pharmaceuticals USA Inc.	N	First	10.0	AP	10.0	Y
Submitted in FY 2020							
sodium phenylacetate and sodium benzoate	Maia Pharmaceuticals Inc.	N	First	9.6	AP	9.6	Y
ASTEPRO ALLERGY AND CHILDREN'S ASTEPRO ALLERGY (azelastine hcl)	Bayer Healthcare LLC	N	First	9.9	AP	9.9	Y
CAMCEVI (leuprolide)	Foresee Pharmaceuticals Co. Ltd.	N	First	9.9	AP	9.9	Y
REZIPRES (ephedrine hydrochloride)	Eton Pharmaceuticals Inc.	N	First	9.9	AP	9.9	Y
VERKAZIA (cyclosporine)	Santen Inc.	N	First	9.9	AP	9.9	Y
dolutegravir, emtricitabine, and tenofovir alafenamide	Laurus Labs Ltd.	N	First	10.0	TA	10.0	Y◊

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
dolutegravir, lamivudine, and tenofovir disoproxil fumarate	Shanghai Desano Bio-Pharmaceuticals Co. Ltd.	N	First	10.0	TA	10.0	Y◊
ephedrine sulfate	Endo Ventures Ltd.	N	First	10.0	AP	10.0	Y
esomeprazole	Dexcel Pharma Technologies Ltd.	N	First	10.0	AP	10.0	Y
KIMYRSA (oritavancin)	Melinta Therapeutics LLC	N	First	10.0	AP	10.0	Y
labetalol hydrochloride in dextrose	Hikma Pharmaceuticals International Ltd.	N	First	10.0	AP	10.0	Y
levothyroxine	Custopharm Inc.	N	First	10.0	AP	10.0	Y
norepinephrine bitartrate in 5% dextrose	Baxter Healthcare Corp.	N	First	10.0	AP	10.0	Y
NOXAFIL (posaconazole)	Merck Sharp and Dohme Corp. a Sub of Merck and Co. Inc.	N	First	10.0	AP	10.0	Y
pemetrexed	Sandoz Inc.	N	First	10.0	TA	10.0	Y
THYQUIDITY (levothyroxine sodium)	Vistapharm Inc.	N	First	10.0	AP	10.0	Y
UPTRAVI (selexipag)	Actelion Pharmaceuticals US Inc.	N	First	10.0	AP	10.0	Y
XOFLUZA (baloxavir marboxil)	Genentech Inc.	N	First	10.0	AP	10.0	Y
pemetrexed	Hospira Inc.	N	First	10.1	TA	10.1	Y
FOTIVDA (tivozanib)	Aveo Pharmaceuticals Inc.	Y	First	11.3	AP	11.3	Y♦
KLISYRI (tirbanibulin)	Almirall LLC	Y	First	11.5	AP	11.5	Y♦
MYFEMBREE (relugolix, estradiol, norethindrone acetate)	Myovant Sciences GmbH	N	First	11.8	AP	11.8	Y
ZEGALOGUE (dasiglucagon)	Zealand Pharma US Inc.	Y	First	11.8	AP	11.8	Y♦
GEMTESA (vibegron)	Urovant Sciences GmbH	Y	First	11.9	AP	11.9	Y♦
AZSTARYS (serdexmethylphenidate chloride and dexmethylphenidate hydrochloride)	Commave Therapeutics SA	Y	First	12.0	AP	12.0	Y♦
MARGENZA (margetuximab-cmkb)	MacroGenics, Inc.	Y	First	12.0	AP	12.0	Y♦
NEXTSTELLIS (drospirenone and estetrol)	Mayne Pharma LLC	Y	First	12.0	AP	12.0	Y♦
ORLADEYO (berotralstat)	Biocryst Pharmaceuticals Inc.	Y	First	12.0	AP	12.0	Y♦
PONVORY (ponesimod)	Janssen Pharmaceuticals Inc.	Y	First	12.0	AP	12.0	Y♦
SAPHNELO (anifrolumab-fnia)	Astrazeneca AB	Y	First	12.0	AP	12.0	Y♦
midazolam	Inforlife SA	N	First	12.8	AP	12.8	Y♯
SKYTROFA (lonapegsomatropin-tcgd)	Ascendis Pharma Endocrinology Division A/S	Y	First	14.0	AP	14.0	Y♯♦
QELBREE (viloxazine)	Supernus Pharmaceuticals Inc.	Y	First	12.0	CR	12.0	Y♦
			Sponsor	2.9		14.9	

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
			Second	1.9	AP	16.8	Y▲
LYBALVI (olanzapine and samidorphan)	Alkermes Inc.	Y	First	12.0	CR	12.0	Y♦
			Sponsor	0.6		12.6	
			Second	5.9	AP	18.5	YΔ
Submitted in FY 2019							
PSMA-11 GA 68	University of California Los Angeles	Y	First	14.9	AP	14.9	Y♯♦
PSMA-11 GA 68	University of California San Francisco	N[17]	First	14.9	AP	14.9	Y♯♦
SUTAB (sodium sulafate, magnesium sulfate, potassium chloride)	Braintree Laboratories Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	2.0		12.0	
			Second	6.0	AP	18.0	YΔ
ROSZET (rosuvastatin and ezetimibe)	Althera Pharmaceuticals LLC	N	First	9.9	CR	9.9	Y
			Sponsor	3.9		13.8	
			Second	6.0	AP	19.8	YΔ
micafungin	Par Sterile Products LLC	N	First	10.0	CR	10.0	Y
			Sponsor	7.1		17.1	
			Second	5.8	AP	22.9	YΔ
KLOXXADO (naloxone hcl)	Hikma Pharmaceuticals USA Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	8.0		18.0	
			Second	6.0	AP	24.0	YΔ
EYSUVIS (loteprednol etabonate)	Kala Pharmaceuticals Inc.	N	First	9.7	CR	9.7	Y
			Sponsor	8.8		18.5	
			Second	5.9	AP	24.4	YΔ
SOAANZ (torsemide)	Sarfez Pharmaceuticals Inc.	N	First	9.9	CR	9.9	Y
			Sponsor	11.2		21.1	
			Second	6.0	AP	27.1	YΔ
micafungin sodium	Teva Pharmaceuticals USA Inc.	N	First	9.2	CR	9.2	Y
			Sponsor	7.0		16.2	
			Second	5.9	TA	22.1	YΔ
			Sponsor	6.3		28.4	
			Third	1.8	AP	30.2	Y▲
dolutegravir, lamivudine and tenofovir disoproxil fumarate	Lupin Ltd.	N	First	10.0	CR	10.0	Y◊
			Sponsor	15.4		25.4	
			Second	5.8	TA	31.2	YΔ

[17] This non-NME NDA was reviewed under the PDUFA NME Program. At the time of receipt, the active ingredient (PSMA-11 GA 68) had never been approved in the United States, which allowed for NME designation; however, at the time of approval, (PSMA-11 GA 68) had already been approved for marketing in another application, causing this application to lose its NME designation.

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
Submitted in FY 2018							
SESQUIENT (fosphenytoin sodium)	Sedor Pharmaceuticals LLC	N	First	10.0	CR	10.0	Y
			Sponsor	3.2		13.2	
			Second	5.8	CR	19.0	Y△
			Sponsor	4.6		23.6	
			Third	6.0	AP	29.6	Y△
paclitaxel	HBT Labs Inc.	N	First	9.5	CR	9.5	Y
			Sponsor	10.4		19.9	
			Second	14.2	TA	34.1	N△
argatroban	Accord Healthcare Inc.	N	First	10.0	TA	10.0	Y
			Sponsor	25.3		35.3	
			Second	2.0	AP	37.3	Y▲
Submitted in FY 2017							
acetaminophen in the pab container	B Braun Medical Inc.	N	First	9.5	CR	9.5	Y
			Sponsor	12.0		21.5	
			Second	6.0	CR	27.5	Y△
			Sponsor	6.9		34.4	
			Third	6.0	CR	40.4	Y△
			Sponsor	4.1		44.5	
			Fourth	5.8	AP	46.2	Y△
daptomycin	Hospira Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	33.1		43.1	
			Second	6.0	AP	49.1	Y△
cyclophosphamide	Auromedics Pharma LLC	N	First	9.9	CR	9.9	Y
			Sponsor	2.9		12.8	
			Second	5.8	CR	18.6	Y△
			Sponsor	2.6		21.2	
			Third	6.0	CR	27.2	Y△
			Sponsor	17.3		44.5	
			Fourth	5.5	AP	50.0	Y△
Submitted in FY 2016							
pemetrexed	Hospira Inc.	N	First	9.8	CR	9.8	Y
			Sponsor	36.0		45.8	
			Second	6.0	TA	51.8	Y△
Submitted in FY 2015							
TLANDO (testosterone undecanoate)	Lipocine Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	13.3		23.3	
			Second	9.0	CR	32.3	Y♯△

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
			Sponsor	12.0		44.3	
			Third	6.0	CR	50.3	YΔ
			Sponsor	3.7		54.0	
			Fourth	9.3	TA	63.3	NΔ
Submitted in FY 2014							
acetaminophen	Mylan Laboratories Ltd.	N	First	9.8	CR	9.8	Y
			Sponsor	6.4		16.2	
			Second	6.0	CR	22.2	YΔ
			Sponsor	4.8		27.0	
			Third	6.0	CR	33.0	YΔ
			Sponsor	4.1		37.1	
			Fourth	6.0	CR	43.1	YΔ
			Sponsor	12.0		55.1	
			Fifth	6.0	CR	61.1	YΔ
			Sponsor	1.1		62.2	
			Sixth	18.2	AP	80.4	NΔ
Submitted in FY 2013							
POSIMIR (bupivacaine)	Durect Corp.	N	First	10.1	CR	10.1	Y
			Sponsor	64.5		74.6	
			Second	19.2	AP	93.8	NΔ
Submitted in FY 2012							
BRONCHITOL (mannitol)	Chiesi USA Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	69.1		79.1	
			Second	6.0	CR	85.1	YΔ
			Sponsor	10.4		95.5	
			Third	6.0	AP	101.5	YΔ

Appendix B: Filed Application Numbers by Review Division

The tables below and on the pages that follow show the number of applications filed in FY 2021 for various application types and review designations broken out by review division. This reporting for PDUFA VI is required under section 736B(a) of the FD&C Act.

Original Applications Filed in FY 2021 by Review Division/Office

Review Division/Office	Priority NDAs	Standard NDAs	Priority BLAs	Standard BLAs	Undesignated Original Applications
CDER Review Divisions					
Division of Anesthesiology, Addiction Medicine, and Pain Medicine	1	3	0	0	1
Division of Anti-Infectives	7	1	0	0	0
Division of Antivirals	8	4	1	0	1
Division of Cardiology and Nephrology	4	8	0	0	1
Division of Dermatology and Dentistry	3	2	0	1	2
Division of Diabetes, Lipid Disorders, and Obesity	2	1	1	0	0
Division of Gastroenterology	1	2	0	0	1
Division of General Endocrinology	1	4	0	1	0
Division of Hematologic Malignancies I	1	1	0	2	0
Division of Hematologic Malignancies II	3	7	0	1	0
Division of Hepatology and Nutrition	2	2	0	0	0
Division of Imaging and Radiation Medicine	2	3	0	0	0
Division of Neurology I	0	5	0	1	0
Division of Neurology II	2	5	0	0	1
Division of Non-Malignant Hematology	5	1	1	1	0
Division of Non-Prescription Drugs I	0	2	0	0	0
Division of Non-Prescription Drugs II	0	0	0	0	0
Division of Oncology I	2	0	4	0	1

Review Division/Office	Priority NDAs	Standard NDAs	Priority BLAs	Standard BLAs	Undesignated Original Applications
Division of Oncology II	3	2	1	3	0
Division of Oncology III	0	0	3	1	1
Division of Ophthalmology	0	6	2	0	0
Division of Psychiatry	2	12	0	0	0
Division of Pulmonology, Allergy, and Critical Care	0	1	1	0	0
Division of Rare Diseases and Medical Genetics	0	3	0	1	0
Division of Rheumatology and Transplant Medicine	0	1	0	0	0
Division of Urology, Obstetrics, and Gynecology	0	5	0	0	1
CDER Totals	*49*	*81*	*14*	*12*	*10*
CBER Review Offices					
Office of Blood Research and Review	0	0	0	0	0
Office of Tissues and Advanced Therapies	0	0	2	1	0
Office of Vaccines Research and Review	0	0	5	2	0
CBER Totals	*0*	*0*	*7*	*3*	*0*
FDA Totals	**49**	**81**	**21**	**15**	**10**

Efficacy Supplements Filed in FY 2021 by Review Division/Office

Review Division/Office	Priority Efficacy Supplements	Standard Efficacy Supplements	Undesignated Efficacy Supplements
CDER Review Divisions			
Division of Anesthesiology, Addiction Medicine, and Pain Medicine	0	2	2
Division of Anti-Infectives	0	4	0
Division of Antivirals	8	15	3
Division of Cardiology and Nephrology	1	3	1
Division of Dermatology and Dentistry	1	7	0
Division of Diabetes, Lipid Disorders, and Obesity	3	15	0
Division of Gastroenterology	1	2	2

Review Division/Office	Priority Efficacy Supplements	Standard Efficacy Supplements	Undesignated Efficacy Supplements
Division of General Endocrinology	0	8	0
Division of Hematologic Malignancies I	9	1	0
Division of Hematologic Malignancies II	2	16	0
Division of Hepatology and Nutrition	1	0	0
Division of Imaging and Radiation Medicine	0	0	0
Division of Neurology I	1	2	0
Division of Neurology II	1	15	1
Division of Non-Malignant Hematology	3	3	1
Division of Non-Prescription Drugs I	0	0	0
Division of Non-Prescription Drugs II	0	1	0
Division of Oncology I	23	17	1
Division of Oncology II	4	11	0
Division of Oncology III	6	8	2
Division of Ophthalmology	1	3	0
Division of Psychiatry	4	6	0
Division of Pulmonology, Allergy, and Critical Care	5	6	0
Division of Rare Diseases and Medical Genetics	0	0	0
Division of Rheumatology and Transplant Medicine	6	2	4
Division of Urology, Obstetrics, and Gynecology	1	3	0
CDER Totals	*81*	*150*	*17*
CBER Review Offices			
Office of Blood Research and Review	0	0	0
Office of Tissues and Advanced Therapies	1	4	0
Office of Vaccines Research and Review	1	4	0
CBER Totals	*2*	*8*	*0*
FDA Totals	**83**	**158**	**17**

Submissions with Special Designations Filed in FY 2021 by Review Division/Office

Review Division/Office	Accelerated Approval	Fast Track Products	Orphan Designations	Breakthrough Designations*
CDER Review Divisions				
Division of Anesthesiology, Addiction Medicine, and Pain Medicine	0	1	0	0
Division of Anti-Infectives	0	6	0	2
Division of Antivirals	0	7	6	1
Division of Cardiology and Nephrology	0	2	6	1
Division of Dermatology and Dentistry	0	1	1	2
Division of Diabetes, Lipid Disorders, and Obesity	0	0	0	2
Division of Gastroenterology	0	0	2	0
Division of General Endocrinology	0	1	3	0
Division of Hematologic Malignancies I	0	2	2	3
Division of Hematologic Malignancies II	3	4	4	3
Division of Hepatology and Nutrition	0	1	3	2
Division of Imaging and Radiation Medicine	0	1	2	1
Division of Neurology I	0	2	3	2
Division of Neurology II	0	0	1	0
Division of Non-Malignant Hematology	0	2	4	3
Division of Non-Prescription Drugs I	0	0	0	0
Division of Non-Prescription Drugs II	0	0	0	0
Division of Oncology I	2	2	1	4
Division of Oncology II	4	4	6	9
Division of Oncology III	0	3	4	5
Division of Ophthalmology	0	0	0	2
Division of Psychiatry	0	2	1	4
Division of Pulmonology, Allergy, and Critical Care	0	0	0	1

Review Division/Office	Accelerated Approval	Fast Track Products	Orphan Designations	Breakthrough Designations*
Division of Rare Diseases and Medical Genetics	0	0	3	1
Division of Rheumatology and Transplant Medicine	0	0	0	0
Division of Urology, Obstetrics, and Gynecology	0	0	0	0
CDER Totals	*9*	*41*	*52*	*48*
CBER Review Offices				
Office of Blood Research and Review	0	0	0	0
Office of Tissues and Advanced Therapies	0	1	2	2
Office of Vaccines Research and Review	0	2	0	2
CBER Totals	*0*	*3*	*2*	*4*
FDA Totals	**9**	**44**	**54**	**52**

* This column does not represent filed figures; rather it shows the number of BT designations granted on INDs, NDAs, and BLAs during FY 2021. BT designation is granted based on indication, and therefore, one submission may have more than one BT designation granted.

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Appendix C: Analysis of Use of Funds

On August 18, 2017, FDARA was signed into law. FDARA amended the FD&C Act to revise and extend the user fee programs for human drugs, biologics, generic drugs, medical devices, and biosimilar biological products.

FDARA requires, in the annual performance reports of each of the human medical product user fee programs, specified analyses of the use of funds to include information such as the differences between aggregate numbers of applications and approvals, an analysis of performance enhancement goals, and the most common causes and trends affecting the ability to meet goals. In addition, FDARA (specifically, section 904) requires the issuance of corrective action reports.

A. Original Application Approval Cycle Summary

The following table addresses section 904(a)(1) of FDARA (section 736B(a)(5)(A) of the FD&C Act), pertaining to PDUFA, which requires FDA to include data showing the aggregate number of approvals that occurred during FY 2021. Data represent all the original NDA and BLA approvals that occurred during FY 2021, regardless of when the application was received. Data are presented by the type of application and performance goal, as well as whether the approval occurred on time or was overdue on the performance goal.

This table captures not only first cycle approvals, but also multiple cycle approvals. For applications that were approved after multiple cycles, the performance metric is counted for the last cycle when the approval was given. Approval counts also include applications that were given a tentative approval.

Figures provided in the table below are indicated in detail in Appendix A of this report, which provides a detailed review history of the NDAs and BLAs approved under PDUFA during FY 2021.[18]

[18] Performance is calculated only on the first cycle in which the application received an approval or tentative approval. Any subsequent tentative or full approvals, after the first tentative approval action, will not affect the performance metric regardless of the fiscal year of the first tentative approval.

Approval Cycle Type	Performance Goal: Act on 90 Percent Within	Approval Count	On Time	Overdue	Percent On Time
First Cycle Priority NMEs & BLAs	6 months of filing date	44	41	3	**93%**
First Cycle Standard NMEs & BLAs	10 months of filing date	13	13	0	**100%**
First Cycle Priority Non-NME NDAs	6 months	11	11	0	**100%**
First Cycle Standard Non-NME NDAs	10 months	29	29	0	**100%**
Class 1 Resubmissions	2 months	2	2	0	**100%**
Class 2 Resubmissions	6 months	24	20	4	**83%**
Total		**123**	**116**	**7**	**--***

* Performance is not calculated on combined goals.

B. Performance Enhancement Goals

The following table addresses section 904(a)(1) of FDARA (section 736B(a)(5)(B) of the FD&C Act), pertaining to PDUFA, which requires FDA to include relevant data to determine whether CDER and CBER have met performance enhancement goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017 for the applicable fiscal year. A link to each performance enhancement goal completed under PDUFA VI can be found on FDA's website.[19]

For purposes of this report, *performance enhancement goals* are defined as any non-review performance goal described in PDUFA with a specified goal date that falls within the applicable fiscal year.

[19] www.fda.gov/industry/prescription-drug-user-fee-amendments/completed-pdufa-vi-deliverables.

The table below represents FDA's FY 2020 updated performance.

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
PDUFA FY 2020 Hiring Web Posting – Quarter 4	10/15/2020	Y	10/8/2020	FDARA Hiring Data (see www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data).

The table below represents FDA's FY 2021 performance.

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
CY 2020 FDA Data Standards Action Plan – Quarter 4	12/31/2020	Y	10/21/2020	Data Standards Program Action Plan, Version 4.3 (see www.fda.gov/media/143280/download)
PDUFA FY 2021 Hiring Web Posting – Quarter 1	1/15/2021	Y	1/14/2021	FDARA hiring data (see www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data).
CY 2021 FDA Data Standards Action Plan – Quarter 1	3/30/2021	Y	1/29/2021	Data Standards Program Action Plan, Version 5.0 (see www.fda.gov/media/145851/download).
Public Workshop on IND Communications	3/31/2021	Y	8/11/2020	Public meeting: Independent Third-Party Assessment of IND FDA-Sponsor Communication Practices in PDUFA VI (see www.fda.gov/drugs/news-events-human-drugs/public-meeting-independent-third-party-assessment-ind-fda-sponsor-communication-practices-pdufa-vi).
2021 Annual Update to the 5-Year Plan	3/31/2021	Y	3/30/2021	Five-Year Financial Plan Fiscal Years 2018-2019-2020-2021-2022, 2021 Update for the Prescription Drug User Fee Act Program (see www.fda.gov/media/147061/download).
PDUFA FY 2021 Hiring Web Posting – Quarter 2	4/15/2021	Y	4/15/2021	FDARA hiring data (see www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data).
FY 2021 Financial Public Meetings	6/30/2021	Y	6/28/2021	Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments (see www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and).
CY 2021 FDA Data Standards Action Plan – Quarter 2	6/30/2021	Y	5/25/2021	Data Standards Program Action Plan, Version 5.1 (see www.fda.gov/media/149624/download).
PDUFA FY 2021 Hiring Web Posting – Quarter 3	7/15/2021	Y	7/8/2021	FDARA hiring data (see www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data).
FY 2021 MIDD Quarterly Selections and Meetings – Quarter 1	9/30/2021	Y	10/5/2020	
FY 2021 MIDD Quarterly Selections and Meetings – Quarter 2	9/30/2021	Y	1/8/2021	
FY 2021 MIDD Quarterly Selections and Meetings – Quarter 3	9/30/2021	Y	4/7/2021	
FY 2021 MIDD Quarterly Selections and Meetings – Quarter 4	9/30/2021	Y	7/9/2021	
Draft Guidance on Real World Evidence	9/30/2021	Y	9/29/2021	Draft guidance for industry "Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products (see www.fda.gov/regulatory-

				information/search-fda-guidance-documents/real-world-data-assessing-electronic-health-records-and-medical-claims-data-support-regulatory
Draft Guidance Document on PFDD: Incorporating Clinical Outcome Assessments into Endpoints for Regulatory Decision Making (Guidance 4)	9/30/2021	N	N/A	On December 6, 2019, FDA held a public workshop to support guidance development (see www.fda.gov/drugs/development-approval-process-drugs/public-workshop-patient-focused-drug-development-guidance-4-incorporating-clinical-outcome).
CY 2021 FDA Data Standards Action Plan – Quarter 3	9/30/2021	Y	8/27/2021	Data Standards Program Action Plan, Version: 5.2 (see www.fda.gov/media/151833/download).
Electronic Submissions and Data Standards FY2021 Meetings – Quarter 1	9/30/2021	Y	11/10/2020	
Electronic Submissions and Data Standards FY2021 Meetings – Quarter 2	9/30/2021	Y	2/23/2021	
Electronic Submissions and Data Standards FY2021 Meetings – Quarter 3	9/30/2021	Y	6/8/2021	
Electronic Submissions and Data Standards FY2021 Meetings – Quarter 4	9/30/2021	Y	9/14/2021	
Developing and Revising MIDD MAPPs and Trainings	9/30/2021	Y	3/30/2021	
Innovative Trial Design Pilot Program FY 2021 Meetings – Quarter 1	9/30/2021	Y	12/17/2020	
Innovative Trial Design Pilot Program FY 2021 Meetings – Quarter 2	9/30/2021	Y	2/12/2021	
Innovative Trial Design Pilot Program FY 2021 Meetings – Quarter 3	9/30/2021	Y	5/5/2021	
Innovative Trial Design Pilot Program FY 2021 Meetings – Quarter 4	9/30/2021	Y	9/30/2021	No meeting was held this quarter because there were no requests.
Annual ESG and Standard Metrics - Submission Statistics FY 2021	9/30/2021	Y	11/10/2020	ESG metrics: Submission Statistics (see http://www.fda.gov/industry/about-esg/submission-statistics). Standards adoption and conformance: Study Data Standards Resource (see www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources).
FY 2021 Annual Discussion of IT Strategic Plan	9/30/2021	Y	2/23/2021	
Annual Public Meeting FY 2021 for IT Strategic Plan	9/30/2021	Y	4/7/2021	PDUFA VI information technology (IT) public meeting – FY 2021 (see www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vi-information-technology-goals-and-progress).
PDUFA FY 2021 Hiring Goals	9/30/2021	N	N/A	FDA's FY 2021 hiring goal was for 18 FTEs, and 15 FTEs were onboarded (83 percent of the FY 2021 hiring goal). FDARA hiring data (see www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data).

C. Common Causes and Trends Impacting Ability to Meet Goals

The following table addresses section 904(a)(1) of FDARA (section 736B(a)(5)(C) of the FD&C Act), pertaining to PDUFA, which requires FDA to identify the most common causes and trends of external or other circumstances affecting the ability of FDA, including CDER, CBER, and ORA, to meet the review time and performance enhancement goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017.

Cause or Trend	Impact on FDA's Ability to Meet Goals
COVID-19 health pandemic	• The continuing COVID-19 health pandemic required FDA to shift resources towards addressing the health emergency, which impacted the goals that were eventually missed. The volume of COVID-19-related workload, including Emergency Use Authorizations and meeting requests, continued to impact FDA's meeting-related workload.* • The need for experts to prioritize COVID-19-related issues also caused a delay in the publication of a patient input guidance and in meeting other review goals, such as Human Factors protocol submissions. • Furthermore, due to restrictions in place to protect the safety and well-being of staff, or restrictions set forth by other national entities, otherwise required pre-approval, in-person inspections may not have been able to be conducted within normal time frames.
Increase in Human Factors protocol submissions and decrease in staff	• In FY 2021, staffing levels for this work were reduced for extensive periods of time due to the loss of experienced employees who left the Agency or took on different roles and continued prioritization of work related to the COVID-19 pandemic. Due to the highly specialized nature of the work involved, staff could not be easily reassigned and there were challenges in finding suitable replacements in a timely fashion. Furthermore, there has been an increasing trend in Human Factor protocol workload. Between FY 2018 and FY 2021, the Agency has seen a 30 percent increase in submissions of Human Factor protocols without a correlating number of new resources to address this significant increase. This, in conjunction with the prioritization of staff to work on COVID-19-related issues, led to a shortage in the number of staff available to review these submissions.
Delayed start dates for new candidates	• The federal hiring process (e.g., security and ethics clearances) delayed the onboarding process. Additionally, several candidates either delayed their start dates until FY 2022 or declined offers.
High Volume of Meeting Requests	• In FY 2021, FDA continued to receive a high volume of meeting requests as compared to the pre-pandemic number of meeting requests. Meeting requests increased in part due to COVID-19-related drug development activities. Unfortunately, the Agency did not receive a correlating number of new resources to address this significant increase in meeting volume.

* Additional information on FDA's COVID-19 pandemic-related activities may be found on the Coronavirus Treatment Acceleration Program (CTAP) website (see www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap) and the Coronavirus Disease 2019 Emergency Use Authorization web page (see www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization).

Appendix D: FY 2021 Corrective Action Report

On August 18, 2017, FDARA (Public Law 115-52) was signed into law. FDARA amended the FD&C Act to revise and extend the user fee programs for drugs, biologics, medical devices, and biosimilar biological products, as well as to perform other purposes. Among the provisions of Title IX, section 904 of FDARA, FDA is required to publicly issue an analysis of its use of funds, which includes a corrective action report that details FDA's progress in meeting the review and performance enhancement goals identified in PDUFA VI for the applicable fiscal year.

If each of the review and performance enhancement goals for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the human drug application process.

For any of the review and performance enhancement goals during the applicable fiscal year that were not met, the corrective action report shall include a justification, as applicable, for the types of circumstances and trends that contributed to missed review goal times; and with respect to performance enhancement goals that were not met, a description of the efforts that FDA has put in place to improve the ability of the Agency to meet each goal in the coming fiscal year. Such a description of corrective efforts is not required by statute for review time goals, but FDA is providing this information regardless in an effort to be complete.

This report satisfies this reporting requirement.

Executive Summary

FY 2020 Review Goal Performance (Updated)

Goal Type	Circumstances and Trends Impacting FDA's Ability to Meet Goal Dates	Corrective Action Plan
Review Goals	• Original Standard NMEs and BLAs: ○ 29 submissions were received in FY 2020, a seven percent increase over the 5-year average despite the increased workload due to the COVID-19 pandemic ○ An inability to conduct foreign inspections due to the COVID-19 pandemic resulted in two missed review goals. Had these two applications not been delayed due to inspection issues, the overall performance goal would have been achieved successfully. ○ Staff resources were limited due to increased workload associated with the review of EUAs for therapeutics for COVID-19 • Class 2 Resubmitted NDAs and BLAs: ○ 57 submissions were received in FY 2020, a 36 percent increase over the 5-year despite the increased workload due to the COVID-19 pandemic ○ Staff resources were limited due to increased workload associated with the review of EUAs for therapeutics for COVID-19.	• FDA anticipates that when the COVID workload decreases and limitations related to the Agency's ability to conduct pre-approval inspections abate, FDA's ability to meet the user fee review goals will return. Notwithstanding, FDA continues to assess ways to more effectively and efficiently review marketing applications received each year, including exploring alternative methods for satisfying inspection requirements.

FY 2021 Review Goal Performance

Goal Type	Circumstances and Trends Impacting FDA's Ability to Meet Goal Dates	Corrective Action Plan
Review Goals	• Original Priority non-NME NDAs: ○ 25 submissions were received in FY 2021, represents a 79 percent increase over FY 2020, and a 56 percent increase over the 5-year average for this type of submission. ○ Staff resources were limited due to increased workload associated with the review of EUAs for therapeutics for COVID-19. • Class 1 Resubmitted NDAs and BLAs: ○ Due to the small number of submissions (i.e., five) in FY 2021, missing a single goal date resulted in missing the overall 90 percent performance goal. • Priority NDA and BLA Efficacy Supplements: ○ In FY 2021, there was a 19 percent increase in these submissions over the 5-year average. ○ If the remaining reviews are completed within the goal date, FDA will achieve its performance goal. ○ There was a sustained increased workload due to the COVID-19 pandemic in addition to the regular workload. ○ Staff resources were limited due to increased workload associated with the review of EUAs for therapeutics for COVID-19.	• FDA anticipates that when the COVID workload decreases, the Agency's ability to meet the user fee review goals will return. Notwithstanding, FDA continues to assess ways to more effectively and efficiently review marketing applications received each year.

Goal Type	Circumstances and Trends Impacting FDA's Ability to Meet Goal Dates	Corrective Action Plan
Procedural and Processing Goals	• Meeting Management Goals: o There were 4,558 meeting requests in FY 2021. o There was a continued COVID-19-related increase in workload in addition to the regular workload. o Staff resources were limited due to increased workload associated with the review of EUAs for therapeutics for COVID-19. • Human Factors Protocol Submissions: o In FY 2021, FDA received 70 Human Factors Protocol Submissions that were subject to PDUFA goal dates. This number represents a 30 percent increase in submissions from FY 2018 since the reauthorization covering FY 2018 through FY2022, without a corresponding number of new staffing resources to address this significant increase. o Staffing levels for this work were temporarily reduced for extensive periods of time in FY 2021 because some experienced employees left the Agency or took on different roles and because of the continued prioritization of work related to the COVID-19 pandemic. Because of the highly specialized nature of the work involved, staff could not be temporarily reassigned from other areas, and there were challenges in finding suitable replacements in a timely fashion. o Staffing levels were also reduced for intermittent, limited periods of time as employees were deployed to support HHS COVID-19 and Unaccompanied Children Program missions. Due to the technical and specialized nature of the work, staff with appropriate training and background are needed both for short-term and long-term replacements, and the use of non-specialized staff to support the work requires a larger learning curve before such staff can achieve the same capacity and efficiency as a departing experienced employee. o In addition, the continuation of the COVID-19 pandemic required the Agency to prioritize submissions related to COVID-19, utilizing its limited resources to appropriately address the public health emergency.	Meeting Management Goals: • FDA continues to assess ways to more effectively handle the large volume of formal meeting requests received each year in addition to completing other regulatory and review work. Human Factors Protocol Submissions Goals: • FDA will re-evaluate its resource allocation to ensure that adequate resources are allotted to support the increasing workload in the Human Factors program. • FDA will continue to use the hiring authority granted under the 21st Century Cures Act to advance hiring. Hiring managers will continue to increase their use of innovative recruitment tools to identify candidates with the specialized training and background needed for the technical work. • FDA anticipates that as the response activities for the COVID-19 pandemic normalize, some of its limited resources will be able return to the review of protocols in a more timely manner.

FY 2021 Performance Enhancement Goal Performance

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Guidances	• One guidance document goal date was missed in FY 2021 due to the COVID-19 health pandemic. The resources needed to expedite the development and clearance of this guidance document were instead directed to the pandemic and to earlier guidance documents in the series that were also delayed by the pandemic.	• The draft guidance document will be published when complete.
Human Capital/Hiring	• The federal hiring process (e.g., security and ethics clearances) delayed the onboarding process. Additionally, several candidates either delayed their start dates until FY 2022 or declined offers.	• By integrating recruitment strategies linked to specific hiring goals, FDA should be able to source potential candidates more quickly and reduce time frames on the front end of the hiring process. This should leave more time to manage federal pre-employment clearances and to reinitiate vacancies after declinations.

PDUFA Review Goals

The following section addresses section 904(a)(2)(B) of FDARA (section 736B(c)(2)(A) of the FD&C Act), which requires FDA to provide a justification for the determination of review goals missed during FY 2021, and a description of the circumstances and any trends related to missed review goals.

This section presents PDUFA performance and workload information for two different types of goals: (1) review of applications and other submissions pertaining to human drugs and biologics and (2) meeting management and other procedural goals related to responses and notifications in the human drug review process.

This section includes all PDUFA VI goals as they pertain to receipts/filed submissions in FY 2021.

I. FY 2020 Review Performance

A. *Summary of Performance*

FDA missed the following review goals:

- Original Standard NMEs and BLAs
- Class 2 Resubmitted NDAs and BLAs

B. *Justification*

Review Goals

In FY 2020, FDA received an increased number of regulatory submissions, in part due to the COVID-19 pandemic. The Agency appropriately prioritized COVID-19-related work, utilizing its limited resources to address the public health emergency. The increased workload, pandemic focus, and pandemic restrictions impacting FDA's ability to conduct pre-approval inspections resulted in difficulty achieving a small subset of review performance goals (2 of 12).

C. *FY 2022 Corrective Actions*

FDA continues to assess ways to more effectively handle the large volume of regulatory submissions received each year, including exploring alternative methods for satisfying inspection requirements. FDA continues to appropriately prioritize and address the COVID-19 pandemic; however, the Agency anticipates that as the response activities for the pandemic normalize, its regulatory submission volume will return to pre-COVID-19 levels, restrictions impacting inspections will abate, and FDA's limited resources will be able to address application review in a timely manner.

II. 2021 Review and Procedural and Processing Performance

A. *Summary of Performance*

FDA missed the following review goals:

- Original Priority non-NME NDAs
- Class 1 Resubmitted NDAs and BLAs
- Priority NDA and BLA Efficacy Supplements

FDA missed the following procedural goals:

- Meeting request response for Type B(EOP)
- Meeting scheduling for Type A, B, B(EOP), and C
- Final written response for Type A, B, B(EOP), and C
- Meeting preliminary response for Type B(EOP)

B. *Justification*

Review Goals

In FY 2021, FDA continued to receive an increased number of regulatory submissions, in part due to the ongoing COVID-19 pandemic. The Agency continues to appropriately prioritize COVID-19-related work, utilizing its limited resources to address the public health emergency. The increased workload, ongoing pandemic focus, and limited staff resources resulted in difficulty achieving a small subset of FDA's review performance goals (3 of 12).

Meeting Management Goals

In FY 2021, FDA received 4,558 formal PDUFA meeting requests. This continued high volume of meeting requests reflects a 21 percent increase over meeting requests received in FY 2019, which was pre-COVID-19. Unfortunately, the Agency did not receive a correlating number of new staff to address this significant increase in meeting volume. In addition, the continuation of the COVID-19 pandemic (which contributed to the increase in workload), required the Agency to continue to prioritize COVID-19-related submissions, utilizing FDA's limited resources to appropriately address the public health emergency. The increased workload, pandemic focus, and limited staff resources resulted in difficulty achieving the meeting management goals.

Human Factors Protocol Submissions

In FY 2021, FDA received 70 Human Factors Protocol Submissions that were subject to PDUFA goal dates. This figure represents a 30 percent increase in submissions since the reauthorization of PDUFA covering FY 2018 through FY 2022, without a corresponding number of new staffing resources to address this significant increase. Staffing levels for this work were temporarily reduced for extensive periods of time in FY 2021 because some experienced employees left the Agency or took on different roles

within the Agency. Because of the highly specialized nature of the work involved, staff could not be temporarily reassigned from other areas and there were challenges in finding suitable replacements in a timely fashion. Staffing levels were also reduced for intermittent, limited periods of time as employees were deployed to support HHS COVID-19 and Unaccompanied Children Program missions. Due to the technical and specialized nature of the work, staff with appropriate training and background are needed both for short-term and long-term replacements, and the use of non-specialized staff to support the work requires a larger learning curve before such staff can achieve the same capacity and efficiency as a departing experienced employee. In addition, the continuation of the COVID-19 pandemic required the Agency to prioritize submissions related to COVID-19, utilizing FDA's limited resources to appropriately address the public health emergency.

C. *FY 2022 Corrective Actions*

Review and Meeting Management Goals

FDA continues to assess ways to more effectively handle the marketing applications, meeting requests, and other regulatory submissions received each year.

As the Agency continues to appropriately prioritize and address the COVID-19 pandemic, FDA anticipates that as the response activities for the pandemic normalize, the Agency's regulatory submission and formal PDUFA meeting volume will return to pre-COVID levels and its limited resources will be able to address application review and meeting requests in a more timely manner.

Human Factors Protocol Submissions

FDA anticipates that as the response activities for the COVID-19 pandemic normalize, some of its limited resources will be able to return to the review of protocols in a more timely manner. FDA will re-evaluate its resource allocation to ensure that adequate resources are allotted to support the increasing workload in the Human Factors program. FDA will continue to use the hiring authority granted under the 21st Century Cures Act to advance hiring. Hiring managers will continue to increase their use of innovative recruitment tools to identify candidates with the specialized training and background needed for the technical work.

PDUFA Performance Enhancement Goals

The following section addresses section 904(a)(2) of FDARA (section 736B(c)(2) of the FD&C Act), which requires FDA to provide a justification for missed performance enhancement goals and a description of the efforts FDA has put in place to improve the ability of the Agency to meet each goal in the coming fiscal year (included here under the heading "FY 2022 Corrective Actions").

This section presents non-review performance goals cited in the PDUFA VI Commitment Letter with required completion dates in FY 2021. For the purposes of this report, *performance enhancement goals* are defined as any non-review performance goal with a specified deadline as named in the PDUFA Commitment Letter. Performance enhancement goals with specified completion dates in FY 2022 will be covered in subsequent corrective action reports.

I. Guidances

A. *Summary of Performance*

The PDUFA goal date for the following guidance document was missed:

- Draft patient-focused drug development guidance on incorporating clinical outcome assessments into endpoints for regulatory decision making.

B. *Justification*

The PFDD Guidance 4 document, which will be titled "Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments into Endpoints for Regulatory Decision Making" will address methodologies, standards, and technologies that may be used for the collection, capture, storage, and analysis of COA data. The pandemic utilized the reviewers working on the Guidance 4 document to consult on trial changes, to review submissions, and to help draft COVID-19 specific guidance documents. This impacted several guidance documents in the PFDD guidance series. The earlier documents in the series are being finalized for issuance, and work on the PFDD Guidance 4 document continues

C. *FY 2022 Corrective Actions*

The PFDD Guidance 4 document, which will be titled, "Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments into Endpoints for Regulatory Decision Making," will be published as soon as it is complete.

II. Human Capital/Hiring

A. *Summary of Performance*

FDA missed the PDUFA goal for hiring in FY 2021. Specifically, 15 out of 18 employees (83 percent) were hired.

B. *Justification*

FDA's FY 2021 PDUFA hiring goals were not met; however, candidates were identified and selected for all positions, and hiring managers were on track to meet the hiring goal. The federal hiring process (e.g., security and ethics clearances) continued to delay the onboarding process. To address this, hiring managers focused on making selections by the end of the third quarter of FY 2021. However, hiring managers had to consider the candidate's onboarding preferences during the negotiation process and/or restart the process when candidates declined the job offer. Candidates for two of the remaining vacancies are set to onboard in FY 2022. The third remaining vacancy was reinitiated three times due to candidate declinations late in the hiring process.

C. *FY 2022 Corrective Actions*

As FDA continues to use the hiring authority granted under the 21st Century Cures Act, the Agency will continue to focus on building strategic partnerships to strengthen its scientific talent pipeline. This focus will include exploring the integration of recruitment strategies linked to specific PDUFA hiring goals. By doing so, FDA will be able to connect potential candidates to the hiring managers more quickly, thereby reducing time frames on the front end of the hiring process and providing additional time in the process to manage federal pre-pemployment clearances and declinations.

Appendix E: Definitions of Key Terms

A. The phrase *review and act on* means the issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

B. Review Performance Goal Extensions

1. Major Amendments

   a. A major amendment to an original application, efficacy supplement, or Class 2 resubmission of any of these applications, submitted at any time during the review cycle, may extend the goal date by 3 months. [Note: If the review cycle occurred prior to FY 2013, the major amendment must have been received within 3 months of the action due date to extend the action goal date by 3 months.]

   b. A major amendment may include, for example, a major new clinical safety/efficacy study report; major re-analysis of previously submitted study (studies); submission of a Risk Evaluation and Mitigation Strategy (REMS) with Elements to Assure Safe Use (ETASU) not included in the original application; or significant amendment to a previously submitted REMS with ETASU. Generally, changes to REMS that do not include ETASU and minor changes to REMS with ETASU will not be considered major amendments.

   c. A major amendment to a manufacturing supplement submitted at any time during the review cycle may extend the goal date by 2 months. [Note: If the review cycle occurred prior to FY 2013, the major amendment must have been received within 2 months of the action due date to extend the action goal date by 2 months.]

   d. Only one extension can be given per review cycle.

   e. Consistent with the underlying principles articulated in the Good Review Management Principles and Practices for PDUFA Products guidance,[20] FDA's decision to extend the review clock should, except in rare circumstances, be limited to occasions where review of the new information could address outstanding deficiencies in the application and lead to approval in the current review cycle.

2. Inspection of Facilities Not Adequately Identified in an Original Application or Supplement

   a. All original applications, including those in the "Program," and supplements are expected to include a comprehensive and readily located list of all manufacturing facilities included or referenced in the application or supplement. This list provides FDA with information needed to schedule inspections of manufacturing facilities that may be necessary before approval of the original application or supplement.

[20] www.fda.gov/media/99140/download

b. If, during FDA's review of an original application or supplement, the Agency identifies a manufacturing facility that was not included in the comprehensive and readily located list, the goal date may be extended.

   i. If FDA identifies the need to inspect a manufacturing facility that is not included as part of the comprehensive and readily located list in an original application or efficacy supplement, the goal date may be extended by 3 months.
   ii. If FDA identifies the need to inspect a manufacturing facility that is not included as part of the comprehensive and readily located list in a manufacturing supplement, the goal date may be extended by 2 months.

C. A *resubmitted original application* is an applicant's complete response to an action letter addressing all identified deficiencies.

D. *Class 1 resubmitted applications* are applications resubmitted after a complete response letter (or a not approvable or approvable letter) that include the following items only (or combinations of these items):

1. Final printed labeling
2. Draft labeling
3. Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information, including important new adverse experiences not previously reported with the product, are presented in the resubmission)
4. Stability updates to support provisional or final dating periods
5. Commitments to perform postmarketing studies, including proposals for such studies
6. Assay validation data
7. Final release testing on the last 1-2 lots used to support approval
8. A minor reanalysis of data previously submitted to the application (determined by the Agency as fitting the Class 1 category)
9. Other minor clarifying information (determined by the Agency as fitting the Class 1 category)
10. Other specific items may be added later as the Agency gains experience with the scheme and will be communicated via guidance documents to industry

E. *Class 2 resubmissions* are resubmissions that include any other items, including any item that would require presentation to an advisory committee.

F. Meeting requests commit FDA to notify the requestor of a formal meeting in writing within 14 days of request for Type A and Type B(EOP) meetings or within 21 days of request for Type B and Type C meetings.

G. Scheduled meetings should be made within 30 days of receipt of request for Type A meetings, 60 days for Type B meetings, 70 days for Type B(EOP) meetings, and 75 days for Type C meetings. If the requested date for any of these types of meetings is greater than

30, 60, 70, or 75 days, as appropriate, from the date the request is received by FDA, the meeting date should be within 14 days of the requested date.

H. Preliminary responses to sponsor questions contained in the background package for Type B(EOP) meetings should be sent to the sponsor no later than 5 calendar days prior to the meeting date.

I. Meeting minutes are to be prepared by FDA clearly outlining agreements, disagreements, issues for further discussion, and action items. They will be available to the sponsor within 30 days of the meeting.

J. A Type A Meeting is a meeting that is necessary for an otherwise stalled drug development program to proceed (a "critical path" meeting) or to address an important safety issue.

K. A Type B meeting includes pre-IND meetings and pre-NDA/BLA meetings, while Type B(EOP) meetings are reserved for certain End-of-Phase 1 meetings (i.e., for 21 CFR part 312 subpart E or 21 CFR part 314 subpart H or similar products) and End-of-Phase 2/pre-Phase 3 meetings. Meetings regarding REMS or postmarketing requirements that occur outside the context of the review of a marketing application will also generally be considered Type B meetings.

L. A Type C Meeting is any other type of meeting.

M. The performance goals and procedures also apply to original applications and supplements for human drugs initially marketed on an over-the-counter (OTC) basis through an NDA or switched from prescription to OTC status through an NDA or supplement.

N. IT-specific definitions:

1. *Program* refers to the organizational resources, procedures, and activities assigned to conduct "the process for the review of human drug applications," as defined in PDUFA.
2. *Standards-base* means compliant with published specifications that address terminology or information exchange between FDA and regulated parties or external stakeholders, as adopted by FDA or other agencies of the federal government, and often based on the publications of national or international Standards Development Organizations.
3. *FDA Standards* means technical specifications that have been adopted and published by FDA through the appropriate governance process. FDA standards may apply to terminology, information exchange, engineering or technology specifications, or other technical matters related to information systems. FDA standards often are based on the publications of other federal agencies or the publications of national or international Standards Development Organizations.
4. *Product life cycle* means the sequential stages of human drug development, regulatory review and approval, postmarket surveillance and risk management, and where applicable, withdrawal of an approved drug from the market. In the context of the process for the review of human drug applications, the product life cycle begins with the earliest regulatory submissions in the IND phase, continues through the NDA or BLA review phase, and includes postmarket surveillance and risk management activities as covered under the process for the review of human drug applications.

O. Special Protocol Assessments: Upon specific request by a sponsor, FDA will evaluate certain protocols and issues to assess whether the design is adequate to meet scientific and regulatory requirements identified by the sponsor.

P. The Application Integrity Policy focuses on the integrity of data and information in applications submitted to FDA for review and approval. It describes FDA's approach regarding the review of applications that may be affected by wrongful acts that raise significant questions regarding data reliability. More information on the policy is available at www.fda.gov/media/71236/download.

This report was prepared by FDA's Office of Planning in collaboration with FDA's Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research. For information on obtaining additional copies, contact:

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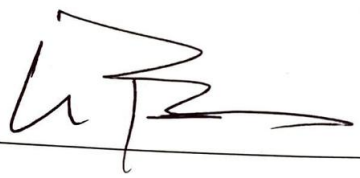
This report is available on the FDA home page at www.fda.gov.

Declaration Signature

The signatory being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements and the like may jeopardize the validity of the application, submission, or any registration resulting therefrom, declares that the facts set forth above are true; all statements made of his/her own knowledge are true; and all statements made on information and belief are believed to be true.

Signature Section:

Signature: 

Date Signed: 12/1/2022

Signatory's Name: Christopher Bolinger

Signatory's Position: Sr. Director, IP Development & Commercial, Trademarks

Signatory's Phone Number: 000-000-0000