The Food and Drug Administration

Report on the Performance of Drugs and Biologics Firms in Conducting Postmarketing Requirements and Commitments

Fiscal Year 2023

I. Background

A. Postmarketing Requirements and Commitments

A postmarketing requirement (PMR) is a study or clinical trial that an applicant is required by statute or regulation to conduct after the approval of a drug or biological product, or postapproval. A postmarketing commitment (PMC) is a study or clinical trial that an applicant agrees in writing to conduct postapproval, but that is not required by statute or regulation. PMRs and PMCs can be issued upon approval of a drug[1] or postapproval, if warranted.[2]

The Food and Drug Administration (FDA or Agency) can require application holders to conduct postmarketing studies and clinical trials:

- To assess a known serious risk, assess signals of serious risk, or identify an unexpected serious risk related to the use of a drug product (section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(o)(3)), as added by the Food and Drug Administration Amendments Act of 2007 (FDAAA)) and

[1] For the purposes of this report, references to "drugs" or "drug products" include drugs approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and biological products licensed under the Public Health Service Act other than biological products that also meet the definition of a device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)).

[2] The number of PMRs and PMCs issued varies from fiscal year to fiscal year due to a variety of factors, including but not necessarily limited to: (1) The number of applications approved in that year; (2) whether additional efficacy or clinical benefit issues needed to be evaluated postapproval; (3) if any drug-associated serious risk(s) were identified; and (4) whether or not FDA determined that a postmarketing study or clinical trial was necessary to further assess risk(s) or efficacy issues.

amended by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (SUPPORT Act).

- Under the Pediatric Research Equity Act (PREA), to study certain new drugs for pediatric populations, when these drugs are not adequately labeled for children. Under section 505B(a)(3) of the FD&C Act (21 U.S.C. 355c), the initiation of these studies may be deferred until required safety information from other studies in adults has first been submitted and reviewed.
- To verify and describe the predicted effect or other clinical benefit for drugs approved in accordance with the accelerated approval provisions in section 506(c)(2)(A) of the FD&C Act (21 U.S.C. 356(c)(2)(A)) (21 CFR 314.510 and 21 CFR 601.41).
- For a drug that was approved on the basis of animal efficacy data because human efficacy trials are not ethical or feasible (21 CFR 314.610(b)(1) and 21 CFR 601.91(b)(1)). PMRs for drug products approved under the animal efficacy rule[3] can be conducted only when the drug product is used for its indication and when an exigency (or event or need) arises. In the absence of a public health emergency, these studies or clinical trials will remain pending indefinitely.

B. Reporting Requirements

Under the regulations (21 CFR 314.81(b)(2)(vii) and 21 CFR 601.70), applicants of approved drugs and licensed biological products are required to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study or clinical trial either required by FDA or that they have committed to conduct, either at the time of approval or after approval of their new drug application (NDA), abbreviated new

[3] 21 CFR 314.600 for drugs; 21 CFR 601.90 for biological products.

drug application (ANDA), or biologics license application (BLA). Applicants are required to report to FDA on these requirements and commitments made for NDAs and ANDAs under 21 CFR § 314.81(b)(2)(viii). The status of PMCs concerning chemistry, manufacturing, and production controls and the status of other studies or clinical trials conducted on an applicant's own initiative are not required to be reported under 21 CFR §§ 314.81(b)(2)(vii) and 601.70 and are not addressed in this report.

Section 505(o)(3)(E)(ii) of the FD&C Act requires an applicant to periodically report on the status of each PMR required under this authority. FDA considers the submission of the annual report required under section 506B of the FD&C Act and 21 CFR 314.81(b)(2)(vii) or 21 CFR 601.70, as applicable, as satisfying this periodic reporting requirement, if the elements listed in 505(o)(3)(E)(ii) and 21 CFR 314.81(b)(2)(vii) or 21 CFR 601.70, as applicable, are included in the annual report. Section 505(o)(3)(E)(ii) also requires that applicants report periodically on the status of any other study or clinical trial undertaken to investigate a safety issue, and FDA considers the submission of the annual report to satisfy this periodic reporting requirement.

An applicant must report on the progress of the PMR/PMC on the anniversary of the drug product's approval[4] until the PMR/PMC is completed or terminated and FDA determines that the PMR/PMC has been fulfilled or that the PMR/PMC is either no longer feasible or would no longer provide useful information. The annual status report (ASR) must include a description of the PMR/PMC, a schedule for completing the PMR/PMC, and a characterization of the current status of the PMR/PMC. The report must also provide an explanation of the PMR/PMC status

[4] An applicant must submit an annual status report on the progress of each open PMR/PMC within 60 days of the anniversary date of U.S. approval of the original application or on an alternate reporting date that was granted by FDA in writing. Some applicants have requested and been granted by FDA alternate annual reporting dates to facilitate harmonized reporting across multiple applications.

by briefly describing the progress of the PMR/PMC. A PMR/PMC schedule is expected to include the actual or projected dates for the following: (1) Submission of the final protocol to FDA; (2) completion of the study or clinical trial; and (3) submission of the final report to FDA.

Section 506B(a)(2) of the FD&C Act requires an applicant with an open study or clinical trial required under 506(c) of the FD&C Act and 21 CFR 314.510 and 601.41 to submit reports on the progress of each open confirmatory study or clinical trial to the NDA or BLA 180 days after the date of approval of the NDA or BLA and approximately every 180 days thereafter. [5]

C. PMR/PMC Status Categories

The status of the PMR/PMC must be described in the ASR according to the terms and definitions provided in 21 CFR §§ 314.81 and 601.70. For its own reporting purposes, FDA has also established terms to describe when the conditions of the PMR/PMC have been met, and when it has been determined that a PMR/PMC is no longer necessary.[6] The PMR/PMC status categories are summarized in the following list. As reflected in the definitions, the status of a PMR/PMC is generally determined based on the original schedule.[7]

Pending: The study or clinical trial has not been initiated (i.e., no subjects have been enrolled or animals dosed), but does not meet the criteria for delayed (i.e., the original

[5] Section 506(c)(2)(A) applies to accelerated approval provisions. Under section 506B(a)(2) of the FD&C Act, an applicant must submit the initial report 180 days after the date of approval (with a 60-day grace period) and the subsequent 180-day report must be submitted with the ASR required under section 506B(a)(1) of the FDCA and 21 CFR 314.81(b)(2) for NDAs and 21 CFR 601.70(b) for BLAs. The applicant must submit both 180-day reports each year until the final report for the corresponding study or clinical trial is submitted.

[6] See the guidance for industry entitled "Reports on the Status of Postmarketing Study Commitments — Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997" available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM080569.pdf.

[7] The definitions for the terms "pending", "ongoing", "delayed", "terminated", and "submitted" are adapted from 21 CFR §§ 314.81 and 601.70; the definitions for the terms "fulfilled" and "released" are described in the guidance for industry entitled "Reports on the Status of Postmarketing Study Commitments — Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997."

projected date for initiation of subject accrual or initiation of animal dosing has not passed).[8]

Ongoing: The study or clinical trial is proceeding according to or ahead of the original schedule.

Delayed: The study or clinical trial is behind the original schedule.[9]

Terminated: The study or clinical trial was ended before completion, but a final report has not been submitted to FDA.

Submitted: The study or clinical trial has been completed or terminated, and a final report has been submitted to FDA.

Fulfilled: The final report for the study or clinical trial was submitted to FDA and FDA notified the applicant that the requirement or commitment was fulfilled through written correspondence.

Released: FDA has informed the applicant in writing that it is released from its obligation to conduct the study or clinical trial because the study or clinical trial is no longer feasible, would no longer provide useful information, or the underlying application has been formally withdrawn.

In addition to the above statuses, PMRs/PMCs may also be characterized as open or closed. Open PMRs/PMCs comprise those that are pending, ongoing, delayed, submitted, or terminated; whereas closed[10] PMRs/PMCs are either fulfilled or released. Open PMRs/PMCs are also described by whether they are on- or off-schedule. On-schedule PMRs/PMCs are those

[8] It is important to note that PMRs/PMCs that are in pending status are not yet delayed; that is, per the milestones, the studies or clinical trials are indeed on schedule and are not expected to be underway yet.
[9] In some instances, an applicant may have justifiable reasons for delay of its PMR/PMC (see section I.D.).
[10] Previous FDA reports on the status of PMRs/PMCs used the term "completed" to refer to PMRs/PMCs that are closed.

that are pending, ongoing, or submitted. Off-schedule PMRs/PMCs are those that have missed one of the milestone dates in the original schedule and are categorized as either delayed or terminated.

D. Additional Requirements

If an applicant fails to comply with the original schedule for completion of postmarketing studies or clinical trials required under section 505(o)(3) of the FD&C Act (i.e., under the FDAAA authorities), or fails to submit periodic reports on the status of the studies or clinical trials, the applicant is considered to be in violation of section 505(o)(3), unless it has demonstrated good cause for its noncompliance or other violation. Failure to meet an original milestone and, as a result, falling behind the original schedule is one type of noncompliance with a PMR issued under section 505(o)(3) of the FD&C Act. In these circumstances, the 505(o)(3) PMR is considered delayed, with or without good cause.[11]

Section 505B(a)(3)(B) of the FD&C Act, as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to grant an extension of the deferred pediatric assessments that are required under PREA.[12] On its own initiative or upon request, FDA may grant an extension of a pediatric assessment deferral, provided that certain applicable PREA criteria for deferral are still met and the applicant submits certain materials in support of the extension.[13] Applicants must submit requests for deferral extensions to FDA not less than 90 days before the date the deferral would otherwise expire. If FDA grants the extension of a pediatric assessment deferral, this new deferral date is considered the original due

[11] See the guidance for industry entitled: Postmarketing Studies and Clinical Trials: Determining Good Cause for Noncompliance with Section 505(o)(3)(E)(ii) of the Federal Good, Drug, and Cosmetic Act (July 2023) available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-studies-and-clinical-trials-determining-good-cause-noncompliance-section-505o3eii

[12] This provision does not apply to PMRs required under other provisions, or to PMCs.

[13] See section 505B(a)(3)(B) of the FD&C Act.

date of the PMR. Consequently, the status of PREA PMRs would be determined based on the new deferral date (and not the original PREA PMR schedule).

FDA may take enforcement action against applicants who are noncompliant with or otherwise fail to conduct studies and clinical trials required under FDA statutes and regulations (see, for example, sections 505(o)(1), 502(z), and 303(f)(4) of the FD&C Act (21 U.S.C. 355(o)(1), 352(z), and 333(f)(4))).

II. Understanding FDA's Data on Postmarketing Studies and Clinical Trials

A. FDA's Internal PMR/PMC Databases

Databases containing information on PMRs/PMCs are maintained at the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The information in these databases is periodically updated as new PMRs/PMCs are issued, upon FDA review of PMR/PMC ASRs or other PMR/PMC correspondence, upon receipt of final reports from completed studies and clinical trials, after the final reports are reviewed and FDA determines that the PMR/PMC has been fulfilled, or when FDA determines that the PMR/PMC is either no longer feasible or would no longer provide useful information. Because applicants typically report on the status of their PMRs/PMCs annually, and because updating the status of PMRs/PMCs in FDA's databases involves FDA review of received information, there is an inherent lag in updating the data (that is, the data are not real time).

Both CDER and CBER have established policies and procedures to help ensure that FDA's data on PMRs/PMCs are current and accurate. When identified, data discrepancies are addressed as expeditiously as possible and/or are corrected in later reports.

B. Publicly Available PMR/PMC Data

FDA also maintains online searchable and downloadable databases that contain information about PMRs/PMCs that is publicly reportable (i.e., for which applicants must report on the status of the study or clinical trial, as required under section 506B of the FD&C Act (21 U.S.C. 356b)). The data are a subset of all PMRs/PMCs and reflect only those postmarketing studies and clinical trials that, at the time of data retrieval, either had an open status or were closed within the past year. Information on PMRs/PMCs closed more than a year before the date the data are extracted (i.e., September 30, 2023) are not included on the public website. The FDA website is updated quarterly.[14] The FDA website does not include information about PMCs concerning chemistry, manufacturing, and controls. It is FDA policy not to post information on the website until it has been verified and reviewed for suitability for public disclosure.

III. About This Report

This report is published to fulfill the annual reporting requirement under section 506B(c) of the FD&C Act. Information in this report covers any PMR/PMC that was established in writing at the time of approval or after approval of an application or a supplement to an application (see section I.A.), and summarizes the status of PMRs/PMCs in fiscal year (FY) 2023 (i.e., as of September 30, 2023). Specifically, the report summarizes the status of all open PMRs/PMCs through the end of the fiscal year, and the status of only those PMRs/PMCs that were closed in the fiscal year. If a requirement or commitment did not have a schedule, or an ASR was not received in the previous 12 months, the PMR/PMC is categorized according to the most recent information available to the Agency.[15]

[14] https://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm

[15] Although the data included in this report do not include a summary of reports that applicants have failed to file by their due dates, the Agency notes that it may take appropriate regulatory action in the event reports are not filed on a timely basis.

This report reflects combined data from CDER and CBER. Information summarized in the report includes the following: (1) The number of applicants with open PMRs/PMCs;[16] (2) the number of open PMRs/PMCs; (3) the number of applications for which an ASR was expected but was not submitted within 60 days of the anniversary date of U.S. approval or an alternate reporting date that was granted in writing by FDA; (4) FDA-verified status of open PMRs/PMCs reported in 21 CFR §§ 314.81(b)(2)(vii) or 601.70 ASRs; (5) the status of closed PMRs/PMCs; and (6) the distribution of the status by fiscal year of establishment[17] (FY2017 to FY2023) for PMRs and PMCs open at the end of FY2023, or those closed within FY2023. The tables in this report distinguish between all PMRs and PMCs, PMRs/PMCs for NDAs and BLAs, and on-schedule and off-schedule PMRs/PMCs, according to the original schedule milestones. Additional information about PMRs/PMCs is provided on FDA's website at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarketing-requirements-and-commitments-introduction.

Numbers published in this report cannot be compared with the numbers resulting from searches of the publicly accessible searchable and downloadable databases. This is because this report incorporates data for all PMRs/PMCs in FDA databases as of the end of the fiscal year, including PMRs/PMCs whose status and status explanation have not yet been verified for public posting on the FDA public searchable and downloadable databases. The publicly accessible searchable and downloadable databases include a subset of PMRs/PMCs, specifically those that, at the time of data retrieval, either had an open status or were closed within the past 12 months.

[16] At the end of FY2023, there were no PMRs/PMCs for ANDAs that met the reporting requirements under the Food and Drug Administration Modernization Act of 1997. Therefore, this report reflects information for only NDAs and BLAs.

[17] The establishment date is the date of the formal FDA communication to the applicant that included the final FDA-required (PMR) or -requested (PMC) postmarketing study or clinical trial.

In addition, the status information in this report is updated annually while the publicly accessible searchable and downloadable databases are updated quarterly (i.e., at or around the end of January, April, July, and October).

IV. Summary of Information on PMR/PMC Status

This report provides information on PMRs/PMCs as of September 30, 2023 (i.e., for FY2023). It is important to note that a comparison of the number of open and on-schedule or off-schedule PMRs/PMCs from one time period to a later time period can be misleading because it does not take into account that the cohort of open PMRs/PMCs is not static from year to year. New PMRs/PMCs are continually being established for studies and clinical trials with varying start dates and durations; and other PMRs/PMCs are closed because they are either fulfilled or released. Therefore, the number of on- and off-schedule PMRs/PMCs can vary from year to year, and a year-to-year comparison of on- or off-schedule PMRs (e.g., to assess for a potential trend) is not appropriate. Finally, due to rounding, the percentages in the tables may not add up to 100 percent.

A. Applicants with Open PMRs/PMCs

An applicant may have multiple approved drug products, and an approved drug product may have multiple PMRs and/or PMCs. Table 1 shows that as of September 30, 2023, there were 399 unique applicants with open PMRs/PMCs under 800 unique NDAs and BLAs. There were 279 unique NDA applicants (and 583 associated applications) and 120 unique BLA applicants (and 217 associated applications) with open PMRs/PMCs.

Table 1. Applicants and Applications (NDA/BLA) With Open Postmarketing Requirements and Commitments
[Numbers as of September 30, 2023]

	NDA	**BLA[1]**	**Total (NDA and BLA)**

Number of unique applicants with open PMRs/PMCs	279	120	399
Number of applications with open PMRs/PMCs	583	217	800

[1] Includes BLAs managed by both CDER and CBER.

B. Annual Status Reports Received

As previously mentioned, applicants must submit an ASR on the progress of each open PMR/PMC within 60 days of the anniversary date of U.S. approval of the original application or an alternate reporting date that was granted by FDA (21 CFR §§ 314.81 and 21 CFR 601.70).[18] Table 2 shows that there were 759 NDAs and BLAs with an ASR due in FY2023 (549 NDAs and 210 BLAs).[19] Of the 549 NDA ASRs due in that fiscal year, 82 percent (448/549) were received on time, 8 percent (46/549) were received, but not on time, and 10 percent (55/549) were expected but not received during FY2023. Of the 210 BLA ASRs due, 70 percent (148/210) were received on time; 20 percent (42/210) were received, but not on time; and 10 percent (20/210) were expected but not received during FY2023.

Table 2.—Annual Status Reports Received
[Numbers as of September 30, 2023][1]

	Expected[2]	Received on Time[3]	Received Not on Time[4]	Expected but not received
NDA	549	448 (82%)	46 (8%)	55 (10%)
BLA	210	148 (70%)	42 (20%)	20 (10%)
Total	759	596 (79%)	88 (12%)	75 (10%)

[1] Percentages may not total 100 due to rounding.
[2] ASR expected during fiscal year (within 60 days (before or after) of the anniversary of original approval date or alternate agreed-upon date) are those required to be submitted by the applicant under section 506B of the FD&C Act and 21 CFR 314.81(b)(2)(vii) or 21 CFR 601.70.
[3] ASR was received within 60 days (before or after) of the anniversary of the original approval date or alternate agreed-upon date.

[18] Some applicants have requested and been granted in writing by FDA alternate annual reporting dates to facilitate harmonized reporting across multiple applications.
[19] The number of ASRs that were expected is different from the total number of unique applications with open PMRs/PMCs because not all applications had an ASR due during FY2023. Applicants with PMRs/PMCs associated with multiple applications may have submitted the ASR to only one of the applications. In addition, if all the PMRs/PMCs for an application were established in the preceding fiscal year, or if all PMRs/PMCs for an application were closed before the ASR due date, submission of an ASR would not have been expected.

[4] ASR was received, but not within 60 days (before or after) of the anniversary of the original approval date or alternate agreed-upon date.

C. Overview of On- and Off-Schedule Open PMRs/PMCs

Tables 3.a. and 3.b. show that as of September 30, 2023, most open PMRs (70 percent (1098/1575) for NDAs and BLAs combined) and most open PMCs (78 percent (282/360) for NDAs and BLAs combined) were progressing on schedule.

Tables 3.a. & 3.b.—Summary of On- and Off-Schedule Postmarketing Requirements and Commitments
[Numbers as of September 30, 2023][1]

Table 3.a.	Open PMRs		
	NDA (% of Open NDA PMRs)	BLA (% of Open BLA PMRs)	Total On- and Off-Schedule PMRs
On-schedule	758 (65%)	340 (85%)	1098 (70%)
Off-schedule	415 (35%)	62 (15%)	477 (30%)
Total	1173	402	1575

[1] Percentages may not total 100 due to rounding.

Table 3.b.	Open PMCs		
	NDA (% of Open NDA PMCs)	BLA (% of Open BLA PMCs)	Total On- and Off-Schedule PMCs
On-schedule	146 (78%)	136 (79%)	282 (78%)
Off-schedule	41 (22%)	37 (21%)	78 (22%)
Total	187	173	360

[1] Percentages may not total 100 due to rounding.

D. Open and On-Schedule PMRs

Table 4 shows that as of September 30, 2023, most open NDA PMRs were pending (39 percent (454/1173)) while most open BLA PMRs were ongoing (36 percent (143/402)). Most open and on-schedule PMRs were under the 505(o)(3) and PREA authorities (41 percent (638/1575) and 23% percent (360/1575), respectively).

Table 4.—Summary of Open and On-Schedule Postmarketing Requirements
[Numbers as of September 30, 2023][1]

	NDA N = 1173[2] (% of Open NDA PMRs)			BLA N = 402[3] (% of Open BLA PMRs)			Total Open and On-Schedule PMRs
Reporting Authority/PMR Status	Pending	Ongoing	Submitted	Pending	Ongoing	Submitted	
Accelerated approval	17 (1%)	22 (2%)	4 (<1%)	11 (3%)	22 (5%)	6 (1%)	82 (5%)
PREA[4]	183 (16%)	48 (4%)	17 (1%)	54 (13%)	45 (11%)	13 (3%)	360 (23%)
Animal efficacy[5]	6 (<1%)	0 (0%)	1 (<1%)	8 (2%)	3 (1%)	0 (0%)	18 (1%)
505(o)(3) safety	248 (21%)	130 (11%)	82 (7%)	70 (17%)	80 (20%)	28 (7%)	638 (41%)
Total Open and On-Schedule	454 (39%)	200 (17%)	104 (9%)	143 (36%)	150 (37%)	47 (12%)	1098 (70%)

[1] Percentages may not total 100 due to rounding.
[2] Total number of open PMRs for NDAs
[3] Total number of open PMRs for BLAs
[4] Many PREA studies have a pending status. PREA studies are usually deferred because the drug product is ready for approval in adults. Initiation of these studies may be deferred until additional safety information from other studies has first been submitted and reviewed before beginning the studies in pediatric populations.
[5] PMRs for drug products approved under the animal efficacy rule (21 CFR 314.600 for drugs; 21 CFR 601.90 for biological products) can be conducted only when the drug product is used for its indication and when an exigency (or event or need) arises. In the absence of a public health emergency, these studies or clinical trials will remain pending indefinitely.

E. Open and Off-Schedule PMRs

Table 5 provides additional information on the status of open and off-schedule PMRs (i.e., delayed and terminated). At the end of September 30, 2023, 35 percent (415/1173) of the open NDA PMRs and 15 percent (62/402) of the open BLA PMRs were off schedule. Of the off-schedule NDA and BLA PMRs, the majority (approximately 99 percent) were off schedule because they were delayed (414/415 and 61/62, respectively). The remaining off-schedule NDA and BLA PMRs were terminated (1/415 and 1/62 (<1 percent), respectively).

In certain situations, the original PMR schedules were adjusted for unanticipated delays in the progress of the study or clinical trial (e.g., difficulties with subject enrollment in a clinical

trial for a marketed drug or the need for additional time to analyze results). In this report, study or clinical trial status reflects the status in relation to the original[20] study or clinical trial schedule regardless of whether FDA has acknowledged that additional time was required to complete the study or clinical trial.

Table 5.—Summary of Open and Off-Schedule Postmarketing Requirements
[Numbers as of September 30, 2023][1]

	NDA N = 1173[2] (% of Open NDA PMRs)		BLA N = 402[3] (% of Open BLA PMRs)		Total Open and Off-Schedule PMRs
Reporting Authority/ PMR Status	Delayed	Terminated	Delayed	Terminated	
Accelerated approval	19 (2%)	0 (0%)	5 (1%)	1 (<1%)	25 (2%)
PREA	223 (19%)	0 (0%)	14 (3%)	0 (0%)	237 (15%)
Animal efficacy	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
505(o)(3) safety (since March 25, 2008)	172 (15%)	1 (<1%)	42 (10%)	0 (0%)	215 (14%)
Total Open and Off Schedule	414 (35%)	1 (<1%)	61 (15%)	1 (<1%)	477 (30%)

[1] Percentages may not total 100 due to rounding.
[2] Total number of open PMRs for NDAs
[3] Total number of open PMRs for BLAs

F. Open On-Schedule and Off-Schedule PMCs

Table 6 provides the status of open on-schedule and off-schedule PMCs. As of September 30, 2023, most open, on-schedule NDA PMCs were pending (40 percent; 75/187) and most open, on-schedule BLA PMCs were ongoing (42 percent; 73/173). Fewer open NDA and BLA PMCs were considered off schedule (22 percent (41/187) and 21 percent (37/173), respectively). The majority of off-schedule NDA and BLA PMCs were delayed according to the original schedule milestones.

[20] With the exception of PREA PMRs for which a deferral extension of the final report submission date has been granted.

Table 6.—Summary of Open Postmarketing Commitments
[Numbers as of September 30, 2023][1]

	NDA N = 187 (% Open NDA PMCs)	BLA N = 173 (% Open BLA PMCs)
On-Schedule		
Pending	75 (40%)	33 (19%)
Ongoing	42 (22%)	73 (42%)
Submitted	29 (16%)	30 (17%)
Total	146 (78%)	136 (79%)
Off-Schedule		
Delayed	40 (21%)	35 (20%)
Terminated	1 (1%)	2 (1%)
Total	41 (22%)	37 (21%)

[1] Percentages may not total 100 due to rounding.

G. Closed PMRs and PMCs

Table 7 provides details about PMRs and PMCs that were closed (fulfilled or released) within FY2023. The majority of closed PMRs were fulfilled (60 percent of NDA PMRs and 69 percent of BLA PMRs) at the end of FY2023. Similarly, the majority of closed PMCs were fulfilled at the end of FY2023.

Table 7.—Summary of Closed Postmarketing Requirements and Commitments
[Numbers as of September 30, 2023][1,2]

	NDA	BLA
Postmarketing Requirements		
Closed PMRs (% of Closed PMRs)	N = 226	N = 65
Requirement met (fulfilled)	136 (60%)	45 (69%)
Requirement not met (released and new revised requirement issued)	24 (11%)	6 (9%)
Requirement no longer feasible or drug product withdrawn (released)	66 (29%)	14 (22%)
Postmarketing Commitments		
Closed PMCs (% of Closed PMCs)	N = 45	N = 35
Requirement met (fulfilled)	38 (84%)	30 (86%)

	NDA	BLA
Requirement not met (released and new revised requirement issued)	2 (4%)	0 (0%)
Requirement no longer feasible or drug product withdrawn (released)	5 (11%)	5 (14%)

[1] The table shows data for those PMRs/PMCs that were closed (fulfilled or released) within FY2023. Therefore, data for PMRs/PMCs that were closed in prior fiscal years are not included.
[2] Percentages may not total 100 due to rounding.

H. Distribution of the Statuses of PMRs and PMCs

Tables 8 and 9 show the distribution of the statuses of PMRs/PMCs as of September 30, 2023, presented by the years that the PMRs/PMCs were established[21] (FY2017 to FY2023).[22,23] Note that the data shown for closed (fulfilled or released) PMRs/PMCs are for all PMRs/PMCs that were closed as of FY2023. Therefore, data for PMRs/PMCs that were closed in prior fiscal years are included.

Based on the data shown in Table 8, an average of 295 PMRs were established each year since FY2017. Most PMRs that were established in the earlier years were either fulfilled or released. For example, as of September 30, 2023, 51 percent (142/281) of the PMRs that were established in FY2017 were fulfilled, and 21 percent (58/281) were released. The majority of PMRs that were established in more recent years were either pending (i.e., not yet underway) or ongoing (i.e., still in progress and on schedule). For example, as of September 30, 2023, 92 percent (210/229) of the PMRs established in FY2023 were pending, and 3 percent (8/229) were ongoing. Overall, of the PMRs that were pending as of September 30, 2023, 77 percent

[21] The establishment date is the date of the formal FDA communication to the applicant that included the final FDA-required (PMR) or -requested (PMC) postmarketing study or clinical trial.
[22] Tables 8 and 9 include data for only the past 7 fiscal years. Data on the distribution of statuses for PMRs/PMCs established in FY2016 and as of FY2022 are presented in the FY2022 status of postmarketing requirements and commitments report (89 FR 30381) (https://www.fda.gov/media/177988/download?attachment).
[23] The total number of PMRs/PMCs established in FY2017 through FY2023 reflects the data in FDA's databases as of September 30, 2023. Because of data corrections and improvements in ascertaining the PMR/PMC establishment date, some of the total numbers of PMRs/PMCs established in each fiscal year are different from those reported in the prior fiscal year's (FY2022) *Federal Register* report.

(445/580) were created within the past 3 years (FY2021, FY2022, and FY2023). Finally, based on the data in Table 8, on average, 15 percent (314/2066) of the PMRs established since FY2017 were delayed as of September 30, 2023.

Table 8.—Summary of Status of Postmarketing Requirements Established[1] Between FY2017 and FY2023[2] [Numbers as of September 30, 2023][3]

PMR Status as of FY2023 (% of Total PMRs in Each Establishment Year)	Fiscal Year of PMR Establishment						
	2017	2018	2019	2020	2021	2022	2023
Pending	4 (1%)	22 (7%)	17 (6%)	92 (23%)	84 (28%)	151 (56%)	210 (92%)
Ongoing	19 (7%)	46 (15%)	43 (15%)	81 (21%)	56 (19%)	56 (21%)	8 (3%)
Submitted	25 (9%)	18 (6%)	10 (4%)	18 (5%)	18 (6%)	8 (3%)	5 (2%)
Delayed	33 (12%)	75 (24%)	59 (21%)	71 (18%)	56 (19%)	20 (7%)	0 (0%)
Terminated	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Released	58 (21%)	54 (17%)	54 (19%)	32 (8%)	21 (7%)	12 (4%)	4 (2%)
Fulfilled	142 (51%)	101 (32%)	97 (35%)	101 (26%)	60 (20%)	23 (9%)	2(1%)
Total[4]	281	316	280	395	295	270	229

[1] The establishment date is the date of the formal FDA communication to the applicant that included the final FDA-required (PMR) or -requested (PMC) postmarketing study or clinical trial.

[2] The table shows data for PMRs that were closed (fulfilled or released) as of FY2023. Therefore, data for PMRs that were closed in prior fiscal years are included.

[3] Percentages may not total 100 due to rounding.

[4] The total number of PMRs/PMCs established in FY2017 through FY2023 reflects the data in FDA's databases as of September 30, 2023. Because of data corrections and improvements in ascertaining the PMR/PMC establishment date, some of the total numbers of PMRs/PMCs established in each fiscal year are different from those reported in the prior fiscal year's (FY2022) *Federal Register* report.

Table 9 provides an overview of PMCs in a similar format as Table 8 for PMRs. Based on the data shown in Table 9, an average of 79 PMCs were established each year since FY2017. Most PMCs that were established in the earlier years were either fulfilled or released. For example, as of September 30, 2023, 84 percent (56/67) of the PMCs that were established in FY2017 were fulfilled, and 7 percent (5/67) were released. The majority of PMCs that were established in more recent years were either pending (i.e., not yet underway) or ongoing (i.e., still in progress and on schedule). For example, as of September 30, 2023, 84 percent (62/74) of

the PMCs established in FY2023 were pending, and 62 percent (34/55) established in FY2022 were pending or ongoing. Overall, of the PMCs that were pending as of September 30, 2023, 91 percent (96/106) were created within the past 3 years (FY2021, FY2022, and FY2023). Finally, based on the data in Table 9, on average, 7 percent (41/553) of the PMCs established since FY2017 were delayed as of September 30, 2023.

Table 9.—Summary of Status of Postmarketing Commitments Established[1] Between FY2017 and FY2023[2] [Numbers as of September 30, 2023][3]

PMC Status as of FY2023 (% of Total PMCs in Each Establishment Year)	Fiscal Year of PMC Establishment						
	2017	2018	2019	2020	2021	2022	2023
Pending	0 (0%)	0 (0%)	1 (1%)	9 (12%)	15 (16%)	19 (35%)	62 (84%)
Ongoing	2 (3%)	16 (16%)	13 (15%)	22 (29%)	29 (31%)	15 (27%)	7 (9%)
Submitted	0 (0%)	4 (4%)	3 (3%)	8 (10%)	14 (15%)	9 (16%)	4 (5%)
Delayed	4 (6%)	7 (7%)	8 (9%)	10 (13%)	6 (6%)	5 (9%)	1 (1%)
Terminated	0 (0%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Released	5 (7%)	11 (11%)	4 (5%)	2 (3%)	6 (6%)	1 (2%)	0 (0%)
Fulfilled	56 (84%)	62 (62%)	57 (66%)	26 (34%)	23 (25%)	6 (11%)	0 (0%)
Total[4]	67	100	87	77	93	55	74

[1] The establishment date is the date of the formal FDA communication to the applicant that included the final FDA required (PMR) or requested (PMC) postmarketing study or clinical trial.
[2] The table shows data for PMCs that were closed (fulfilled or released) as of FY2023. Therefore, data for PMCs that were closed in prior fiscal years are included.
[3] Percentages may not total 100 due to rounding.
[4] The total number of PMRs/PMCs established in FY2017 through FY2023 reflects the data in FDA's databases as of September 30, 2023. Because of data corrections, as well as improvements in ascertainment of the PMR/PMC establishment date, some of the total numbers of PMRs/PMCs established in each fiscal year are different from those reported in the prior fiscal year's (FY2022) *Federal Register* report.