Sciences Authority), and the United States (U.S. FDA). The World Health Organization and the Asia-Pacific Economic Cooperation Life Sciences Innovation Forum Regulatory Harmonization Steering Committee are IMDRF Official Observers. The Asian Harmonization Working Party and the Pan American Health Organization are IMDRF Affiliate Organizations.

The IMDRF Management Committee (IMDRF MC) chartered the SaMD Working Group (WG) to develop a regulatory framework for SaMD and to develop converged principles for global regulators to adopt in their respective jurisdictions. The SaMD WG includes representatives from the IMDRF members, industry, academia, and other key stakeholders as well as regional harmonization initiatives from around the world.

The IMDRF SaMD WG considered comments received on the draft guidance that was announced in the **Federal Register** of October 14, 2016 (81 FR 71105). The SaMD WG also considered public comments received by other regulators and from other global stakeholders. The final IMDRF/SaMD WG/N41 document, ''Software as a Medical Device (SaMD): Clinical Evaluation,'' submitted to IMDRF MC was revised appropriately in response to all of the comments. The IMDRF MC in Ottawa, Canada, at the 12th meeting held from September 19 to 21, 2017, unanimously approved the document entitled ''Software as a Medical Device (SaMD): Clinical Evaluation.'' This final IMDRF/SaMD WG/N41 document is available for regulatory implementation according to the regulatory process in each jurisdiction.

This guidance adopts the internationally converged principles agreed upon by the IMDRF. FDA adoption of these principles provides FDA with an initial framework when further developing the Agency's specific regulatory approaches and expectations for regulatory oversight. This guidance does not provide recommendations for FDA Staff and Industry to apply to specific regulatory situations, nor does it modify current regulatory expectations, including those for regulatory submissions, at this time. FDA intends to consider the principles of this guidance in the development of regulatory approaches for SaMD and digital health technologies. In developing regulatory approaches based on the principles of this guidance, the Agency intends to follow a public process, including providing opportunities for public input. For more information on FDA adoption of IMDRF documents as an FDA guidance document, please see *https://www.fda.gov/MedicalDevices/InternationalPrograms/IMDRF/default.htm.*

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Software as a Medical Device (SaMD): Clinical Evaluation.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Software as a Medical Device (SaMD): Clinical Evaluation'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 16039 to identify the guidance you are requesting.

Dated: December 4, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26441 Filed 12–7–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3083]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: Under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), the Food and Drug Administration (FDA or Agency) is required to report annually in the **Federal Register** on the status of postmarketing requirements (PMRs) and postmarketing commitments (PMCs) required of, or agreed upon by, holders of approved drug and biological products. This notice is the Agency's report on the status of the studies and clinical trials that applicants have agreed to, or are required to, conduct.

FOR FURTHER INFORMATION CONTACT: Cathryn C. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6484, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

A. Postmarketing Requirements and Commitments

A PMR is a study or clinical trial that an applicant is required by statute or regulation to conduct postapproval. A 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.

FDA 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 FD&C Act (21 U.S.C. 355(o)(3)), as added by the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85)).
- Under the Pediatric Research Equity Act (PREA) (Pub. L. 108–155), 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

[1] For the purposes of this notice, references to ''drugs'' or ''drug products'' include drugs approved under the 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)).

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 [2] 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 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 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 § 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 §§ 314.81(b)(2)(vii) and 601.70 and are not addressed in this report. Furthermore, section 505(o)(3)(E) of the FD&C Act requires that applicants report periodically on the status of each required study or clinical trial and each study or clinical trial ''otherwise undertaken . . . to investigate a safety issue. . . .''

An applicant must report on the progress of the PMR/PMC on the anniversary of the drug product's approval [3] 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 by describing briefly 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.

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 §§ 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.[4] 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.[5]

• *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 projected date for initiation of subject accrual or initiation of animal dosing has not passed).[6]

• *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.[7]

• *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* [8] PMRs/PMCs are either fulfilled or released. Open PMRs are also described by whether they are on- or off-schedule. *On-schedule* PMRs/PMCs are those 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 FDAAA. In these circumstances, the FDAAA PMR is considered delayed, with or without good cause.

Section 505B(a)(3)(B) of the FD&C Act, as amended by the Food and Drug Administration Safety and Innovation Act, authorizes FDA to grant an extension of the deferred pediatric assessments that are required under PREA.[9] On its own initiative or upon request, FDA may grant an extension of a pediatric assessment deferral,

[2] 21 CFR 314.600 for drugs; 21 CFR 601.90 for biological products.

[3] An applicant must submit an annual status report on the progress of each open PMR/PMC within 60 days of the anniversary date of United States 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.

[4] 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.*

[5] The definitions for the terms ''pending,'' ''ongoing,'' ''delayed,'' ''terminated,'' and ''submitted'' are adapted from §§ 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.''

[6] 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.

[7] In some instances, an applicant may have justifiable reasons for delay of its PMR/PMC (see section I.D).

[8] Previous FDA reports on the status of PMRs/PMCs used the term ''completed'' to refer to PMRs/PMCs that are closed.

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

provided that certain applicable PREA criteria for deferral are still met and the applicant submits certain materials in support of the extension.[10] 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 study deferral, this new deferral date is considered the original due 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, and 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). FDA strives to maintain as accurate information as possible on the status of PMRs/PMCs.

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.

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

B. Publicly Available PMR/PMC Data

FDA also maintains an online searchable and downloadable database that contains 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, 2016) is not included on the public Web site. The FDA Web site is updated quarterly.[11] The FDA Web site does not include information about PMCs concerning chemistry, manufacturing, and controls. It is FDA policy not to post information on the Web site 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 made, 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) 2016 (*i.e.,* as of September 30, 2016). 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.[12]

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; [13] (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 by FDA; (4) FDA-verified status of open PMRs/PMCs reported in § 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 [14] (FY2010 to FY2016) for PMRs and PMCs open at the end of FY2016, or those closed within FY2016. The tables in this report distinguish between 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 Web site at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PostmarketingPhaseIVCommitments/default.htm.*

Numbers published in this report cannot be compared with the numbers resulting from searches of the publicly accessible and downloadable database. 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 undergoing review for accuracy. The publicly accessible and downloadable database includes 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. In addition, the status information in this report is updated annually while the downloadable database is updated quarterly (*i.e.,* in January, April, July, and October).

IV. Summary of Information on PMR/PMC Status

This report provides information on PMRs/PMCs as of September 30, 2016 (*i.e.,* for FY2016). It is important to note that a comparison of the number of open and on-schedule or off-schedule PMRs/PMCs over time 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. Also, ongoing PMRs/PMCs are carried forward into the subsequent fiscal year. Therefore, the number of on- and off-schedule PMRs/PMCs can vary from year to year, and a year-to-year

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

[12] 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.

[13] At the end of FY2016, 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 NDAs and BLAs only.

[14] 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.

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, 2016, there were 285 unique applicants with open PMRs/PMCs under 890 unique NDAs and BLAs. There were 207 unique NDA applicants (and 734 associated applications) and 78 unique BLA applicants (and 156 associated applications) with open PMRs/PMCs.

TABLE 1—APPLICANTS AND APPLICATIONS (NDA/BLA) WITH OPEN POSTMARKETING REQUIREMENTS AND COMMITMENTS

[Numbers as of September 30, 2016]

	NDA [1]	BLA [2]	Total (NDA and BLA)
Number of unique applicants with open PMRs/PMCs	207	78	285
Number of applications with open PMRs/PMCs	734	156	890

[1] As of September 30, 2016, there were only NDAs with associated PMRs/PMCs managed by CDER.
[2] 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 United States approval of the original application or an alternate reporting date that was granted by FDA (§§ 314.81 and 601.70).[15] Table 2 shows that there were 764 NDAs and BLAs with an ASR due in FY2016 (622 NDAs and 142 BLAs).[16] Of the 622 NDA ASRs due in that fiscal year, 66 percent (411/622) were received on time, 11 percent (66/622) were not received on time, and 23 percent (145/622) were not received during FY2016. Of the 142 BLA ASRs due, 72 percent (102/142) were received on time, 17 percent (24/142) were not received on time, and 11 percent (16/142) were not received during FY2016.

TABLE 2—ANNUAL STATUS REPORTS RECEIVED

[Numbers as of September 30, 2016] [1]

	[2] Expected	Received, on time [3] (% of expected)	Received, not on time [4] (% of expected)	Expected but not received (% of expected)
NDA	[5] 622	411 (66%)	66 (11%)	145 (23%)
BLA	142	102 (72%)	24 (17%)	16 (11%)
Total	764	513 (67%)	90 (12%)	161 (21%)

[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).
[3] ASR was received within 60 days (before or after) of the anniversary of the original approval date or alternate agreed-upon date.
[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.
[5] The total number of NDA ASRs expected in FY2016 (622) increased compared to the number of ASRs expected in FY2015 (451). The increase is primarily due to the establishment of several FDAAA safety PMRs for which a serious safety issue applied to a class of drug products. In those cases, each applicant with a drug product (*i.e.,* application) in the class was required to conduct the same postmarketing safety study or trial, and each applicant was required to submit an ASR for that PMR. As a consequence, multiple ASRs were expected during FY2016 for the same FDAAA safety PMR.

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

Table 3 shows that as of September 30, 2016, most open PMRs (84 percent for NDAs and 91 percent for BLAs) and most open PMCs (71 percent for NDAs and 83 percent for BLAs) were progressing on schedule.

TABLE 3—SUMMARY OF ON- AND OFF-SCHEDULE POSTMARKETING REQUIREMENTS AND COMMITMENTS

[Numbers as of September 30, 2016] [1]

	Open PMRs *N = 1,323*		Open PMCs *N = 365*	
	NDA (% of open NDA PMRs)	BLA (% of open BLA PMRs)	NDA (% of open NDA PMCs)	BLA (% of open BLA PMCs)
On-schedule	882 (84%)	247 (91%)	123 (71%)	159 (83%)
Off-schedule	169 (16%)	25 (9%)	51 (29%)	32 (17%)

[15] Some applicants have requested and been granted by FDA alternate annual reporting dates to facilitate harmonized reporting across multiple applications.

[16] 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 FY2016. Applicants with PMRs/PMCs associated with multiple applications may have submitted the ASR to only one of the applications. In addition, if all of 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.

TABLE 3—SUMMARY OF ON- AND OFF-SCHEDULE POSTMARKETING REQUIREMENTS AND COMMITMENTS—Continued

[Numbers as of September 30, 2016] [1]

	Open PMRs *N = 1,323*		Open PMCs *N = 365*	
	NDA (% of open NDA PMRs)	BLA (% of open BLA PMRs)	NDA (% of open NDA PMCs)	BLA (% of open BLA PMCs)
Total	1,051	272	174	191

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

D. Open and On-Schedule PMRs

Table 4 shows that as of September 30, 2016, nearly half of the open NDA and BLA PMRs were pending (49 percent (517/1,051) and 45 percent (123/272), respectively). PREA PMRs and FDAAA PMRs comprised 55 percent (349/640) and 39 percent (249/640) of pending PMRs, respectively. The next largest category of open and on-schedule PMRs comprised those that were ongoing (29 percent (306/1,051) of NDA PMRs and 37 percent (100/272) of BLA PMRs).

TABLE 4—SUMMARY OF OPEN AND ON-SCHEDULE POSTMARKETING REQUIREMENTS

[Numbers as of September 30, 2016] [1]

Reporting authority/PMR status	NDA *N = 1,051* *(% of open NDA PMRs)*			BLA *N = 272* *(% of open BLA PMRs)*		
	Pending	Ongoing	Submitted	Pending	Ongoing	Submitted
Accelerated approval	16 (2%)	19 (2%)	3 (<1%)	13 (5%)	10 (4%)	4 (1%)
PREA [2]	300 (28%)	124 (12%)	14 (1%)	49 (18%)	29 (11%)	8 (3%)
Animal efficacy [3]	4 (<1%)	0	1 (<1%)	9 (3%)	0	0
FDAAA safety	197 (19%)	163 (16%)	41 (4%)	52 (19%)	61 (22%)	12 (4%)
Total	517 (49%)	306 (29%)	59 (6%)	123 (45%)	100 (37%)	24 (9%)

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

[2] 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.

[3] 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, 2016, 16 percent (169/1,051) of the open NDA PMRs and 9 percent (25/272) of the open BLA PMRs were off schedule. Of the off-schedule NDA PMRs, 97 percent (164/169) were off schedule because they were delayed and the remaining 3 percent (5/169) were terminated. Similarly, 88 percent of the off-schedule BLA PMRs were delayed (22/25).

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 [17] 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, 2016] [1]

Reporting authority/PMR status	NDA *N = 1,051* *(% of open NDA PMRs)*		BLA *N = 272* *(% of open BLA PMRs)*	
	Delayed	Terminated	Delayed	Terminated
Accelerated approval	9 (1%)	1 (<1%)	1 (<1%)	0
PREA	84 (8%)	2 (<1%)	6 (2%)	2 (1%)
Animal efficacy	0	0	0	0
FDAAA safety	71 (7%)	2 (<1%)	15 (6%)	1 (<1%)

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

TABLE 5—SUMMARY OF OPEN AND OFF-SCHEDULE POSTMARKETING REQUIREMENTS—Continued

[Numbers as of September 30, 2016] [1]

Reporting authority/PMR status	NDA N = 1,051 (% of open NDA PMRs)		BLA N = 272 (% of open BLA PMRs)	
	Delayed	Terminated	Delayed	Terminated
Total	164 (16%)	5 (<1%)	22 (8%)	3 (1%)

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

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, 2016, most open, on-schedule NDA PMCs were pending (36 percent; 62/174) and most open, on-schedule BLA PMCs were ongoing (43 percent; 83/191). Fewer open NDA and BLA PMCs were considered off schedule (29 percent (51/174) and 17 percent (32/191), respectively). The majority of off-schedule NDA and BLA PMCs were delayed according to the original schedule milestones.

TABLE 6—SUMMARY OF OPEN POSTMARKETING COMMITMENTS

[Numbers as of September 30, 2016] [1]

	NDA N = 174 (% open PMCs)	BLA N = 191 (% open PMCs)
On-Schedule:		
Pending	62 (36%)	52 (27%)
Ongoing	40 (23%)	83 (43%)
Submitted	21 (12%)	24 (13%)
Total	123 (71%)	159 (83%)
Off-Schedule:		
Delayed	50 (29%)	30 (16%)
Terminated	1 (1%)	2 (1%)
Total	51 (29%)	32 (17%)

[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 FY2016. The majority of closed PMRs were fulfilled (72 percent of NDA PMRs and 82 percent of BLA PMRs) at the end of FY2016. Similarly, the majority of closed PMCs were fulfilled at the end of FY2016.

TABLE 7—SUMMARY OF CLOSED [1] POSTMARKETING REQUIREMENTS AND COMMITMENTS

[Numbers as of September 30, 2016] [2]

	NDA	BLA
Postmarketing Requirements		
Closed PMRs (% of Total Closed PMRs)	*N = 174*	*N = 33*
Requirement met (fulfilled)	126 (72%)	27 (82%)
Requirement not met (released and new revised requirement issued)	19 (11%)	4 (12%)
Requirement no longer feasible or drug product withdrawn (released)	29 (17%)	2 (6%)
Postmarketing Commitments		
Closed PMCs (% of Total Closed PMCs)	*N= 54*	*N=28*
Requirement met (fulfilled)	44 (82%)	23 (82%)
Requirement not met (released and new revised requirement issued)	1 (2%)	1 (4%)
Requirement no longer feasible or drug product withdrawn (released)	9 (17%)	4 (14%)

[1] The table shows data for those PMRs/PMCs that were closed (fulfilled or released) within FY2016. 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, 2016, presented by the years that the PMRs/PMCs were established [18] (FY2010 to FY2016).[19] [20] Note that the data shown for closed (fulfilled or released) PMRs/PMCs are for all PMRs/PMCs that were closed as of FY2016. 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 261 PMRs were established each year since FY2010.[21] Most PMRs that were established in the earlier years were either fulfilled or released. For example, as of September 30, 2016, 54 percent (122/224) of the PMRs that were established in FY2010 were fulfilled, and 12 percent (27/224) 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, 2016, 86 percent (232/269) of the PMRs established in FY2016 were pending, and 8 percent (22/269) were ongoing. Overall, of the PMRs that were pending as of September 30, 2016, 83 percent (510/614) were created within the past 3 years (FY2014, FY2015, and FY2016). Finally, table 8 shows that, on average, 7 percent (137/1,829) of the PMRs established since FY2010 were delayed as of September 30, 2016.

TABLE 8—SUMMARY OF STATUS OF POSTMARKETING REQUIREMENTS ESTABLISHED [1] BETWEEN FY2010 AND FY2016 [2]

[Numbers as of September 30, 2016] [3]

PMR status as of FY2016 (% of total PMRs in each establishment year)	Fiscal year of PMR establishment						
	2010	2011	2012	2013	2014	2015	2016
Pending	8 (4%)	16 (6%)	24 (11%)	56 (20%)	114 (39%)	164 (58%)	232 (86%)
Ongoing	26 (12%)	49 (19%)	52 (24%)	69 (25%)	80 (27%)	52 (18%)	22 (8%)
Submitted	15 (7%)	7 (3%)	9 (4%)	8 (3%)	12 (4%)	16 (6%)	2 (1%)
Delayed	26 (12%)	18 (7%)	25 (11%)	30 (11%)	25 (9%)	13 (4%)	0
Terminated	0	2 (<1%)	1 (<1%)	0	0	1 (<1%)	0
Released	27 (12%)	59 (23%)	30 (14%)	33 (12%)	14 (5%)	5 (2%)	4 (2%)
Fulfilled	122 (54%)	110 (42%)	79 (36%)	82 (29%)	48 (16%)	33 (12%)	9 (3%)
Total [4]	224	261	220	278	293	284	269

[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 FY2016. 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 FY2010 through FY2016 reflects the data in FDA's databases as of September 30, 2016. 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 (FY2015) **Federal Register** report.

Table 9 provides an overview of PMCs in a similar format as table 8 for PMRs. The results for PMCs are similar to those for PMRs as described above and in table 8.

TABLE 9—SUMMARY OF STATUS OF POSTMARKETING COMMITMENTS ESTABLISHED [1] BETWEEN FY2010 AND FY2016 [2]

[Numbers as of September 30, 2016] [3]

PMR status as of FY2016 (% of total PMCs in each establishment year)	Fiscal year of PMC establishment						
	2010	2011	2012	2013	2014	2015	2016
Pending	1 (1%)	3 (4%)	0	3 (7%)	8 (14%)	25 (40%)	48 (80%)
Ongoing	11 (12%)	17 (21%)	11 (27%)	16 (35%)	19 (34%)	18 (28%)	4 (7%)
Submitted	8 (9%)	1 (1%)	2 (5%)	3 (7%)	7 (13%)	1 (2%)	2 (3%)
Delayed	13 (14%)	5 (6%)	4 (10%)	3 (7%)	0	5 (8%)	0
Terminated	0	0	0	0	0	0	0
Released	10 (11%)	12 (15%)	1 (2%)	1 (2%)	0	1 (2%)	0
Fulfilled	51 (54%)	42 (53%)	23 (56%)	20 (43%)	22 (39%)	13 (21%)	6 (10%)
Total [4]	94	80	41	46	56	63	60

[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.

[18] 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.

[19] Tables 8 and 9 include data for only the past 7 fiscal years. Data on the distribution of statuses for PMRs/PMCs established in FY2009 and as of FY2015 are presented in the FY2015 status of postmarketing requirements and commitments report (81 FR 85573) (*https://www.federalregister.gov/d/2016-28442*).

[20] The total number of PMRs/PMCs established in FY2010 through FY2016 reflects the data in FDA's databases as of September 30, 2016. 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 (FY2015) **Federal Register** report.

[21] The number of PMRs issued at any particular period is determined by a variety of factors including but not necessarily limited to: (1) The number of NDAs approved in that period; (2) whether additional efficacy or clinical benefit issues were evaluated; (3) if any drug-associated serious risk(s) had been identified; and (4) whether or not FDA determines that a postmarketing study or clinical trial is necessary to further assess risk(s) or efficacy issues.

[2] The table shows data for PMCs that were closed (fulfilled or released) as of FY2016. 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 FY2010 through FY2016 reflects the data in FDA's databases as of September 30, 2016. Because of data corrections, as well as 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 (FY2015) **Federal Register** report.

Dated: December 4, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26470 Filed 12–7–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6607]

Oncology Center of Excellence Listening Session; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Oncology Center of Excellence (OCE): Listening Session.'' The purpose of the public meeting and the docket for comments is for stakeholders to provide recommendations to the Agency regarding FDA's OCE. Specifically, the Agency solicits comments regarding what stakeholders desire of the OCE in terms of structure, function, regulatory purview, and activity.

DATES: The public meeting will be held on Thursday, March 15, 2018, from 9 a.m. to 12 noon. Submit either electronic on written comments on this public meeting by April 16, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 16, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 16, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–6607 for ''Oncology Center of Excellence (OCE): Listening Session.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tamy Kim, Oncology Center of Excellence, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2206, Silver Spring, MD 20993–0002,