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. A supplemental report containing additional information and analyses on the status of PMRs and PMCs is available on FDA's Web site.[1]

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[2] 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)).
- 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)) (§§ 314.510 and 601.41 (21 CFR 314.510 and 601.41)).
- For a drug that was approved on the basis of animal efficacy data because human efficacy trials are not ethical or feasible (§§ 314.610(b)(1) and 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 (§§ 314.81(b)(2)(vii) and 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[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 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.[5] 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.[6]

[1] *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PostmarketingPhaseIVCommitments/ucm064436.htm.*

[2] 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)).

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

[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.

[5] 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.'' We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance Web page at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

[6] 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

Continued

- *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).[7]
- *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.[8]
- *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 closed or open. *Open* PMRs/PMCs comprise those that are pending, ongoing, delayed, submitted, or terminated; whereas *closed*[9] 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.[10] 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.[11] 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.

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, 2015) are not included on the public Web site. The FDA Web site is updated quarterly.[12] 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) 2015 (FY2015) (*i.e.,* as of September 30, 2015). Specifically, the report summarizes the status of all open

''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.''

[7] 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.

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

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

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

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

[12] *http://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm.*

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.[13]

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; [14] (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 [15] (FY2009 to FY2015) for PMRs and PMCs open at the end of FY2015, or those closed within FY2015. 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. A more detailed summary of this information and additional information about PMRs/PMCs is provided on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PostmarketingPhaseIVCommitments/default.htm*. In the supplemental report on FDA's Web site, information is presented separately for CDER and CBER.

Numbers published in this report and in the supplemental report on FDA's Web site 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, 2015 (*i.e.,* for FY2015). 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 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, 2015, there were 269 unique applicants with open PMRs/PMCs under 856 unique NDAs and BLAs. There were 194 unique NDA applicants (and 716 associated applications) and 75 unique BLA applicants (and 140 associated applications) with open PMRs/PMCs.

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 (§§ 314.81 and 21 CFR 601.70).[16] Table 2 shows that there were 575 NDAs and BLAs with an ASR due in FY2015 (451 NDAs and 124 BLAs).[17] Of the 451 NDA ASRs due in that fiscal year, 67 percent (304/451) were received on time, 14 percent (62/451) were not received on time, and 19 percent (85/451) were not received during FY2015. Of the 124 BLA ASRs due, 78 percent (97/124) were received on time, 13 percent (16/124) were not received on time, and 9 percent (11/124) were not received during FY2015.

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

Table 3 shows that as of September 30, 2015, most open PMRs (88 percent for NDAs and 91 percent for BLAs) and most open PMCs (69 percent for NDAs and 78 percent for BLAs) were progressing on schedule.

D. Open and On-Schedule PMRs

Table 4 shows that as of September 30, 2015, the majority of PMRs were pending (53 percent (535/1,010) of open NDA PMRs and 45 percent (100/223) of open BLA PMRs). PREA PMRs and FDAAA PMRs comprised 53 percent (336/635) and 43 percent (270/635) of pending PMRs, respectively. The next largest category of open and on-schedule PMRs comprised those that were ongoing (29 percent (288/1,010) of NDA PMRs and 36 percent (80/223) of BLA PMRs).

E. Open and Off-Schedule PMRs

Table 5 provides additional information on the status of open and off-schedule (*i.e.,* delayed and terminated) PMRs. At the end of September 30, 2015, 12 percent (123/1,010) of the open NDA PMRs and 9 percent (20/223) of the open BLA PMRs were off-schedule. Of the off-schedule NDA PMRs, 97 percent (119/123) were off-schedule because they were delayed and the remaining 3 percent (4/123) were terminated. Similarly, 90 percent of the off-schedule BLA PMRs were delayed (18/20).

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 need for additional time to analyze results).

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

[14] At the end of FY2015, 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.

[15] 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.

[16] An applicant 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 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.

[17] 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 FY2015. 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.

In this report, study or clinical trial status reflects the status in relation to the original[18] study or clinical trial schedule regardless of whether FDA has acknowledged that additional time was required to complete the study or clinical trial.

F. Open On-Schedule and Off-Schedule PMCs

Table 6 provides the status of open on-schedule and off-schedule PMCs and shows that as of September 30, 2015, the largest category of all open NDA PMCs were those that were pending (36 percent; 71/197). Most of the open BLA PMCs were ongoing at the end of FY2015 (39 percent; 80/204). Off-schedule PMCs accounted for 31 percent (62/197) of open NDA PMCs and 22 percent (45/204) of open BLA PMCs. The majority of off-schedule NDA and BLA PMCs were delayed according to the original schedule milestones.

G. Closed PMRs and PMCs

Table 7 provides details about PMRs and PMCs that were closed (released or fulfilled) within FY2015. The majority of closed PMRs were fulfilled (69 percent of NDA PMRs and 90 percent of BLA PMRs at the end of FY2015). Similarly, the majority of closed PMCs within FY2015 were fulfilled.

H. Distribution of the Status of PMRs and PMCs

Tables 8 and 9 show the distribution of the statuses of PMRs/PMCs as of September 30, 2015, presented by the year that the PMR/PMC was established[19] (FY2009 to FY2015).[20] [21] Note that the data shown for closed (fulfilled or released) PMRs/PMCs are for all PMRs/PMCs that were closed as of FY2015. 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 254 PMRs were established each year since FY2009.[22] Most PMRs that were established in the earlier years were either fulfilled or released. For example, as of September 30, 2015, 44 percent (109/248) of the PMRs that were established in FY2009 were fulfilled, and 22 percent (55/248) 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, 2015, 89 percent (250/280) of the PMRs established in FY2015 were pending, and 6 percent (16/280) were ongoing. Overall, of the PMRs that were pending as of September 30, 2015, 86 percent (527/616) were created within the past 3 years (FY2013, FY2014, and FY2015). Finally, table 8 shows that, on average, 6 percent of the PMRs established since FY2009 were delayed as of September 30, 2015. Table 9 provides an overview of PMCs in a similar manner as table 8 does for PMRs and shows similar results for PMCs as those for PMRs as described above and in table 8.

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

[Numbers as of September 30, 2015]

	NDA [1]	BLA [2]	Total (NDA and BLA)
Number of unique applicants with open PMRs/PMCs	194	75	269
Number of applications with open PMRs/PMCs	716	140	856

[1] Includes two NDAs with associated PMRs/PMCs managed by CBER.
[2] Includes BLAs managed by both CDER and CBER.

TABLE 2—ANNUAL STATUS REPORTS RECEIVED

[Numbers as of September 30, 2015] [1]

	Expected [2]	Received, on time [3] (% of expected)	Received, not on time [4] (% of expected)	Expected but not received (% of expected)
NDA	451	304 (67%)	62 (14%)	85 (19%)
BLA	124	97 (78%)	16 (13%)	11 (9%)
Total	575	401 (70%)	78 (14%)	96 (17%)

[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.

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

[19] 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.

[20] Tables 8 and 9 include data for only the past 7 fiscal years. Data on the distribution of statuses for PMRs/PMCs established in FY2008 and as of FY2014 are presented in the FY2014 status of postmarketing requirements and commitments report (81 FR 75411) (*https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/html/2016-26247.htm*).

[21] The total number of PMRs/PMCs established in FY2009 through FY2014 reflects the data in FDA's databases as of September 30, 2015. As a result 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 (FY 2014) **Federal Register** report.

[22] 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) have 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.

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

[Numbers as of September 30, 2015] [1]

	Open PMRs N = 1,233		Open PMCs N = 401	
	NDA (% of Open NDA PMRs)	BLA (% of Open BLA PMRs)	NDA (% of Open NDA PMCs)	BLA (% of Open BLA PMCs)
On-schedule	887 (88%)	203 (91%)	135 (69%)	159 (78%)
Off-schedule	123 (12%)	20 (9%)	62 (31%)	45 (22%)
Total	1,010	223	197	204

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

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

[Numbers as of September 30, 2015] [1]

Reporting authority/PMR status	NDA *N = 1,010* (% of Open NDA PMRs)			BLA N = 223 (% of Open BLA PMRs)		
	Pending	Ongoing	Submitted	Pending	Ongoing	Submitted
Accelerated approval	12 (1%)	25 (3%)	3 (<1%)	7 (3%)	7 (2%)	1 (<1%)
PREA [2]	290 (29%)	121 (12%)	18 (2%)	46 (20%)	18 (8%)	9 (4%)
Animal efficacy [3]	4 (<1%)	0	1 (<1%)	6 (3%)	0	0
FDAAA safety [4]						
(since March 25, 2008)	229 [3] (23%)	142 (14%)	42 (4%)	41 (18%)	55 (25%)	13 (6%)
Total	535 (53%)	288 (29%)	64 (6%)	100 (45%)	80 (36%)	23 (10%)

[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 (§ 314.600 for drugs; § 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.

[4] Includes one NDA PMR FDAAA safety study from CBER in pending status.

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

[Numbers as of September 30, 2015] [1]

Reporting authority/PMR status	NDA N = 1,010 (% of Open NDA PMRs)		BLA N = 223 (% of Open BLA PMRs)	
	Delayed	Terminated	Delayed	Terminated
Accelerated approval	3 (<1%)	2 (<1%)	1 (<1%)	0
PREA	64 (6%)	2 (<1%)	5 (2%)	2 (<1%)
Animal efficacy	0	0	0	0
FDAAA safety				
(since March 25, 2008)	52 (5%)	0	12 (5%)	0
Total	119 (12%)	4 (<1%)	18 (8%)	2 (<1%)

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

TABLE 6—SUMMARY OF OPEN POSTMARKETING COMMITMENTS

[Numbers as of September 30, 2015] [1]

	NDA N = 197 (% Open PMCs)	BLA N = 204 (% Open PMCs)
On-Schedule		
Pending	71 (36%)	54 (26%)
Ongoing	40 (20%)	80 (39%)
Submitted	24 (12%)	25 (12%)
Total	135 (68%)	159 (77%)
Off-Schedule		
Delayed	59 (30%)	43 (21%)

TABLE 6—SUMMARY OF OPEN POSTMARKETING COMMITMENTS—Continued

[Numbers as of September 30, 2015] [1]

	NDA N = 197 (% Open PMCs)	BLA N = 204 (% Open PMCs)
Terminated	3 (2%)	2 (1%)
Total	62 (31%)	45 (22%)

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

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

[Numbers as of September 30, 2015] [2]

Postmarketing requirements	NDA N = 195	BLA N = 40
Closed PMRs (% of Total Closed PMRs)	.....	.....
Requirement met (fulfilled)	134 (69%)	36 (90%)
Requirement not met (released and new revised requirement issued)	31 (16%)	1 (2%)
Requirement no longer feasible or drug product withdrawn (released)	30 (15%)	3 (8%)
Postmarketing Commitments	**NDA *N = 56***	**BLA *N = 32***
Closed PMCs (% of Total Closed PMCs)	.....	.....
Requirement met (fulfilled)	46 (82%)	27 (84%)
Requirement not met (released and new revised requirement issued)	1 (2%)	2 (6%)
Requirement no longer feasible or drug product withdrawn (released)	9 (16%)	3 (9%)

[1] The table shows data for those PMRs/PMCs that were closed (fulfilled or released) within FY2015. Therefore, data for PMRs/PMCs that were closed in prior fiscal years are not included.
[2] Percentages may not total 100 due to rounding.

TABLE 8—SUMMARY OF STATUS OF POSTMARKETING REQUIREMENTS ESTABLISHED [1] BETWEEN FY2009 AND FY2015 [2]

[Numbers as of September 30, 2015] [3]

PMR Status as of FY2015 (% of total PMRs in each establishment year)	Fiscal year of PMR establishment						
	2009	2010	2011	2012	2013	2014	2015
Pending	14 (6%)	11 (5%)	27 (10%)	37 (17%)	91 (33%)	186 (68%)	250 (89%)
Ongoing	38 (15%)	40 (18%)	54 (21%)	59 (27%)	79 (28%)	46 (17%)	16 (6%)
Submitted	10 (4%)	16 (7%)	11 (4%)	14 (7%)	11 (4%)	9 (3%)	10 (4%)
Delayed	21 (8%)	18 (8%)	16 (6%)	19 (9%)	22 (8%)	7 (3%)	0
Terminated	1 (<1%)	0	0	0	0	0	0
Released	55 (22%)	27 (12%)	56 (22%)	28 (13%)	16 (6%)	7 (3%)	2 (1%)
Fulfilled	109 (44%)	112 (50%)	95 (37%)	58 (27%)	59 (21%)	19 (7%)	2 (1%)
Total [4]	248	224	259	215	278	274	280

[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 FY2015. 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 FY2009 through FY2014 reflects the data in FDA's databases as of September 30, 2015. As a result 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 (FY2014) FEDERAL REGISTER report.

TABLE 9—SUMMARY OF STATUS OF POSTMARKETING COMMITMENTS ESTABLISHED [1] BETWEEN FY2009 AND FY2015 [2]

[Numbers as of September 30, 2015] [3]

PMC Status as of FY2015 (% of total PMCs in each establishment year)	Fiscal year of PMC establishment						
	2009	2010	2011	2012	2013	2014	2015
Pending	3 (6%)	2 (2%)	3 (4%)	1 (2%)	8 (17%)	35 (57%)	49 (90%)
Ongoing	3 (6%)	18 (19%)	23 (28%)	14 (30%)	15 (33%)	14 (23%)	1 (2%)
Submitted	1 (2%)	11 (12%)	3 (4%)	2 (4%)	4(9%)	2 (3%)	2 (4%)

TABLE 9—SUMMARY OF STATUS OF POSTMARKETING COMMITMENTS ESTABLISHED [1] BETWEEN FY2009 AND FY2015 [2]—Continued

[Numbers as of September 30, 2015] [3]

PMC Status as of FY2015 (% of total PMCs in each establishment year)	Fiscal year of PMC establishment						
	2009	2010	2011	2012	2013	2014	2015
Delayed	6 (13%)	12 (13%)	8 (10%)	6 (13%)	4 (9%)	0	0
Terminated	1 (2%)	0	0	0	0	0	0
Released	4 (8%)	7 (7%)	10 (12%)	1 (2%)	1 (2%)	0	1 (2%)
Fulfilled	30 (63%)	44 (47%)	35 (43%)	22 (48%)	14 (30%)	10 (16%)	1 (2%)
Total [4]	48	94	82	46	46	61	54

[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 FY2015. 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 FY2009 through FY2014 reflects the data in FDA's databases as of September 30, 2015. As a result 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 (FY2014) **Federal Register** report.

Dated: November 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–28442 Filed 11–25–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1064]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Application for Participation in the Medical Device Fellowship Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 28, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0551. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Application for Participation in the Medical Device Fellowship Program—OMB Control Number 0910–0551—Extension

Sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of Title 5 of the United States Code authorize Federal Agencies to rate applicants for Federal jobs. Collecting applications for the Medical Device Fellowship Program will allow FDA's Center for Devices and Radiological Health (CDRH) to easily and efficiently elicit and review information from students and health care professionals who are interested in becoming involved in CDRH activities. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of applications being misrouted within the Agency mail system. It will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their expertise with CDRH.

In the **Federal Register** of September 6, 2016 (81 FR 61221), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Application Form (FDA 3608)	250	1	250	1	250

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.