

**Report to Congress**

**REPORT ON THE ELEVENTH REVIEW OF THE BACKLOG OF POSTMARKETING  
REQUIREMENTS AND COMMITMENTS**

**Submitted Pursuant to**

**Section 505(k) of the Federal Food, Drug, and Cosmetic Act**

**Section 921 of Title IX of the Food and Drug Administration Amendments Act of 2007**

**Food and Drug Administration**

\_\_\_\_\_ Date \_\_\_\_\_  
Norman E. Sharpless, M.D.  
Acting Commissioner of Food and Drugs

## Executive Summary

On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA). Under section 921 of this law, the Food and Drug Administration (FDA) is required to review the entire backlog of postmarketing requirements (PMRs) and postmarketing commitments (PMCs) to determine which PMRs/PMCs require revision or should be eliminated. FDA has performed this eleventh review of the backlog consisting of all PMRs and PMCs that were open (i.e., not yet released or fulfilled) as of the date of enactment of FDAAA. For this eleventh review, FDA identified 1,636 PMRs/PMCs<sup>1</sup> (1,553 in the Center for Drug Evaluation and Research (CDER) and 83 in the Center for Biologics Evaluation and Research (CBER)) that comprise the backlog to which section 921 applies.

The data available for review of the backlog of PMRs and PMCs are constantly changing as submissions are reviewed and statuses are updated. This eleventh annual report shows that as of December 31, 2018, CDER completed the required review for 1,481 of the 1,553 PMRs and PMCs in the backlog. As of September 30, 2018, CBER completed review of 72 of 83 PMRs and PMCs in the backlog.

The number of open PMRs and PMCs will continue to diminish each year as applicants complete studies/trials and submit final reports, and as FDA reviews the final reports and issues fulfillment and release letters.

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<sup>1</sup> FDA originally identified 1,637 PMRs/PMCs in the backlog. However, 2 closed CDER PMRs were combined into a single PMR, reducing the total to 1,636. Please refer to footnote 8 on page 5 for more information.

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## I. Introduction

On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85). Section 921 of Title IX of FDAAA amends section 505(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(k)) by adding a provision requiring the Food and Drug Administration (FDA) to “on an annual basis, review the entire backlog of postmarketing safety commitments to determine which commitments require revision or should be eliminated, report to the Congress on these determinations, and assign start dates and estimated completion dates for such commitments.”

The “backlog” consists of all postmarketing requirements (PMRs) and postmarketing commitments (PMCs) that were open (i.e., not yet released or fulfilled) as of the date of enactment of FDAAA.<sup>2</sup> PMRs and PMCs are studies or clinical trials required of (in the case of PMRs) or agreed upon (in the case of PMCs) by an applicant, and they are conducted after FDA has approved a product for marketing. These studies and clinical trials are intended to further define the safety, efficacy, or optimal use of a product and, therefore, play an important role in fully characterizing the product.

FDA identified 1,636 PMRs/PMCs (1,553<sup>3</sup> in the Center for Drug Evaluation and Research (CDER) and 83 in the Center for Biologics Evaluation and Research (CBER)) that comprise the backlog to which section 921 applies. This is the eleventh annual report on the review of the backlog of postmarketing requirements and commitments. The report includes information about PMRs/PMCs in the backlog that remain open, as well as those that were closed (see Appendix A for these definitions). Past reports are available on FDA’s PMR/PMC Reports web page, located here: <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/post-marketingphaseivcommitments/ucm064436.htm>

[First Annual Report](#)

[Second Annual Report](#)

[Third Annual Report](#)

[Fourth Annual Report](#)

[Fifth Annual Report](#)

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<sup>2</sup> Before FDAAA, all postmarketing studies and clinical trials (both required and agreed upon) were referred to as “postmarketing commitments.” Therefore, the backlog of postmarketing commitments includes required studies and clinical trials as well as those studies/clinical trials an applicant agreed to, but was not required to, conduct. Since FDAAA, the terminology has been clarified to distinguish those studies/clinical trials that are required from those that are agreed upon. Before FDAAA, PMRs/PMCs specifically addressing safety issues were not separately identified; therefore, the backlog includes both PMRs/PMCs intended to address safety issues as well as those addressing non-safety issues (e.g., efficacy studies).

<sup>3</sup> In the second annual backlog review, which was completed on March 12, 2010, the external contractor who conducted the review determined that the CDER backlog cohort consisted of 1,551 PMRs and PMCs. During the third annual review, CDER discovered one PMR/PMC that did not qualify as a PMR/PMC and was subsequently removed from this cohort. During the fourth annual review, CDER discovered four additional PMR/PMCs that had previously been excluded from the backlog (e.g., never entered into database). One additional PMR/PMC was discovered during the fifth annual review. This PMR/PMC was subsequently determined to be a duplicate and was removed from the cohort during the seventh annual review. During the ninth annual review, CDER discovered that 2 closed PMRs were administratively combined into a single PMR in the CDER internal database, decreasing the number of PMRs in the backlog by 1 (i.e., to 1,553).

[Sixth Annual Report](#)  
[Seventh Annual Report](#)  
[Eighth Annual Report](#)  
[Ninth Annual Report](#)  
[Tenth Annual Report](#)

This report is for both the open and closed PMRs/PMCs in the backlog and is based on data that had “data lock” dates of September 30, 2018 (CDER backlog), and December 31, 2018 (CDER backlog).<sup>4</sup>

## II. Background

Section 130(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115) amended the FD&C Act by adding a new provision requiring reports of certain postmarketing studies for human drug and biological products (section 506B of the FD&C Act (21 U.S.C. 356b)). Section 506B of the FD&C Act provides FDA with authority to monitor the progress of a PMC by requiring the applicant to submit an annual report providing information on the status of the PMC, which was defined to include agreed-upon commitments and required studies (including clinical trials).<sup>5</sup>

The annual reports that applicants submit must also include the reasons, if any, for failure to satisfy the commitment. This provision is implemented per 21 CFR 314.81(b)(2)(vii) and 601.70.<sup>6</sup> Under section 506B (b) and (c), FDA is required to track these PMCs and report on them annually in the *Federal Register*.<sup>7</sup> As described previously, as of the date of enactment of FDAAA, there were 1,636 (CDER and CBER) open PMRs and PMCs that are considered the “backlog” for purposes of the section 921 backlog review.<sup>8</sup>

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<sup>4</sup> Because database updates were ongoing as of September 30, 2017, the data for the CDER backlog were locked and extracted as of December 31, 2017, to ensure the most current and accurate information for this review. Therefore, subsequent database updates for CDER are now locked and extracted on December 31<sup>st</sup>.

<sup>5</sup> See the guidance for industry *Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997*, available at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM077374.pdf>.

<sup>6</sup> In addition, new drug application applicants are required by 21 CFR 314.81(b)(2)(viii) to report annually to FDA on postmarketing studies or clinical trials that are not 506B studies or clinical trials. Such studies or clinical trials are not required by statute, and they include both CMC commitments (chemistry, manufacturing, and controls studies that applicants have agreed with FDA to conduct) and stability studies (product stability studies that applicants have agreed with FDA to conduct). The reporting requirement under 21 CFR 314.81(b)(2)(viii) also includes “any postmarketing study not included under [§314.81](b)(2)(vii) . . . that is being performed by, or on behalf of, the applicant.” Reports on the status of these types of studies are not reports required under section 506B.

<sup>7</sup> The reports are available on the FDA website at:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/ucm064436.htm>.

<sup>8</sup> At the outset of this evaluation, CDER provided a list of 1,643 open PMRs and PMCs derived from the internal PMR/PMC tracking systems as of September 27, 2007. During the course of the annual reviews, CDER identified a number of PMRs/PMCs that were erroneously included in (e.g., duplicate entry, previously released/fulfilled study/clinical trial, non-PMR/PMC element from action letter) or excluded from (e.g., never entered into database) this group. After these corrections were made, the CDER backlog consisted of 1,553 PMRs/PMCs. Together with the 83 CBER PMRs/PMCs, FDA identified the total 1,636 PMRs/PMCs that are the subject of this report.

Before the passage of FDAAA, FDA required studies or clinical trials in the following situations:

- Subpart H and subpart E accelerated approvals for products approved under section 505(b) of the FD&C Act or section 351 of the Public Health Service Act, respectively (so-called “accelerated approval”). These require postmarketing studies to verify clinical benefit (21 CFR 314.510 and 601.41, respectively);
- Deferred pediatric studies, where studies are required under the Pediatric Research Equity Act (PREA); and
- Animal efficacy rule approvals, where studies to demonstrate safety and efficacy in humans are required at the time of use (21 CFR 314.610(b)(1) and 601.91(b)(1)).<sup>9</sup>

Under FDAAA, FDA has been given additional authority to require applicants to conduct and report on postmarketing studies or 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 product. These required safety studies/clinical trials—as well as those required under accelerated approval, PREA, and the animal rule (as described above)—are now considered PMRs. Studies or clinical trials required after the passage of FDAAA are not included in the annual backlog review because the *backlog* has been interpreted in this context to refer to all required or agreed-upon studies or clinical trials that had not been released or fulfilled before the passage of FDAAA.

### III. Methods

The first and second annual CDER reviews were conducted by an external contractor who reviewed internal FDA systems and documents to determine the status for all PMRs/PMCs. This was accomplished by first identifying the status of each PMR/PMC listed in the internal PMR/PMC databases and comparing it to the milestone dates established in the product’s approval letter. In cases where the milestone dates were inconsistent with the status in the PMR/PMC database, the correct status was determined by examining existing documentation (e.g., PMR/PMC annual status reports, PMR/PMC final study/clinical trial reports, FDA-applicant communications, and internal FDA memos and reviews).

After the accurate statuses were determined, additional review of the backlog of PMRs/PMCs was performed to identify candidates for revision or release.<sup>10</sup> Those PMRs/PMCs that were off-schedule (i.e., delayed or terminated) or had no milestone dates were prioritized for review over those that were on-schedule (i.e., pending, ongoing, or submitted) based on established milestone dates. The contractor provided CDER with the results of the review as well as recommendations regarding potential re-evaluation or release of PMRs/PMCs in the backlog. CDER has

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<sup>9</sup> PMRs for drug products approved under the animal efficacy rule (21 CFR 314.600 for drugs; 21 CFR 601.90 for biological products) are to provide evaluation of safety and clinical benefit if circumstances arise in which a study would be feasible and ethical (i.e., in the event an emergency arises and the drug is used). In the absence of a public health emergency, these studies or clinical trials will remain open indefinitely.

<sup>10</sup> There were 1,049 PMRs/PMCs that did not require a review because they were determined to be already fulfilled or released.

conducted all subsequent annual reviews, including this eleventh review, and continues to monitor the progress of the PMRs/PMCs recommended for revision or release in addition to assessing the current status for the entire backlog.

The data available for PMRs and PMCs in the backlog are constantly changing as submissions are reviewed and the statuses of the PMRs/PMCs are updated. CDER has policies and procedures to help ensure that its data on PMRs/PMCs, including the PMRs/PMCs in the backlog, are current and accurate. When identified, data discrepancies are addressed and/or are corrected in later reports. The information in this report reflects the status information in CDER's database at the time the data were extracted and reflect CDER's data quality control processes.

CDER has a comprehensive module in its biologics license application database system for tracking PMRs/PMCs. Information from CDER's system is extracted monthly and quarterly, and the information is subjected to quality control processes external to the review offices for Center and FDA reports. Their processes, along with clearly defined CDER staff responsibilities for managing PMRs/PMCs, help ensure that data available from the system are accurate and relatively current.

## IV. Findings

### CDER Summary of Progress

- The number of open PMRs/PMCs in the CDER backlog continues to decrease. The data show that as of December 31, 2018, 95 percent (1,481/1,553) of PMRs/PMCs have been closed (i.e., fulfilled or released). Of the 72 PMRs/PMCs that remain open, 86 percent (62/72) have studies/trials either in progress or completed (i.e., ongoing, delayed, or had final reports submitted) at the time of the eleventh annual review.
- As shown in Table 1 and Figure 1, as of December 31, 2018, the status of the CDER backlog of PMRs/PMCs was as follows: pending: less than 1 percent (6/1,553); ongoing: 1 percent (17/1,553); delayed: 2 percent (30/1,553); terminated: less than 1 percent (4/1,553); submitted: 1 percent (15/1,553); fulfilled: 70 percent (1,087/1,553); and released: 25 percent (394/1,553). In comparison to the previous year,<sup>11</sup> 2 fewer PMRs/PMCs were delayed, 5 fewer were ongoing, and 13 more were closed (released or fulfilled).
- The data for the previous year showed the status of the CDER backlog of PMRs/PMCs as follows: pending: less than 1 percent (6/1,553); ongoing: 1 percent (22/1,553); delayed: 2 percent (32/1,553); terminated: less than 1 percent (3/1,553); submitted: 1 percent (22/1,553); fulfilled: 69 percent (1,076/1,553);<sup>12</sup> and released: 25 percent (392/1,553). (See Appendix A for the status definitions.)

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<sup>11</sup> See the tenth annual backlog report to Congress here: <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/UCM617801.pdf>

<sup>12</sup> During the ninth review, CDER determined that 12 PMRs/PMCs in the backlog that were previously identified as fulfilled were released, and that 1 PMR/PMC previously identified as released was fulfilled.

**Table 1: CDER PMR/PMC Statuses After Annual Reviews**

Status	Number of PMRs/PMCs After...										
	First Review	Second Review	Third Review	Fourth Review <sup>1</sup>	Fifth Review <sup>2</sup>	Sixth Review	Seventh Review <sup>3</sup>	Eighth Review	Ninth Review	Tenth Review	Eleventh Review
Pending <sup>4</sup>	208	114	93	77	51	46	49	32	25	6	6
Ongoing	212	156	132	106	71	60	49	37	26	22	17
Submitted	565	366	197	113	79	63	30	15	19	22	15
Delayed	225	264	223	199	171	124	73	65	54	32	30
Terminated	16	13	13	10	11	7	8	10	7	3	4
Fulfilled	209	483	701	827	900	953	1,018	1,050	1,047 <sup>7</sup>	1,076	1,087
Released	47	146	191	222	272	302	327	345	375	392	394
Undetermined <sup>5</sup>	39	9	0	0	0	0	0	0	0	0	0
Not Available <sup>6</sup>	30	0	0	0	0	0	0	0	0	0	0
<b>Total</b>	<b>1,551</b>	<b>1,551</b>	<b>1,550</b>	<b>1,554</b>	<b>1,555</b>	<b>1,555</b>	<b>1,554</b>	<b>1,554</b>	<b>1,553<sup>8</sup></b>	<b>1,553</b>	<b>1,553</b>

<sup>1</sup> During the fourth annual review, CDER discovered a total of four PMR/PMCs that had previously been excluded from the backlog (e.g., never entered into database). After this correction was made, the CDER backlog consisted of 1,554 PMRs/PMCs.

<sup>2</sup> During the fifth annual review, CDER discovered one PMR/PMCs that had previously been excluded from the backlog (e.g., never entered into database). After this correction was made, the CDER backlog consisted of 1,555 PMRs/PMCs.

<sup>3</sup> During the seventh annual review, CDER discovered a duplicate PMR entry. After the duplicate entry was removed, the CDER backlog totaled 1,554 PMRs/PMCs.

<sup>4</sup> PMRs in pending status include those issued under the PREA and the animal efficacy rule (21 CFR 314.600 and 21 CFR 601.90). PREA PMRs are often deferred because the drug product is ready for approval in adults before pediatric studies are complete. Initiation of the PREA studies may also be deferred because FDA finds that pediatric studies should be delayed until additional safety or effectiveness data have been collected. Postmarketing studies required under the animal efficacy rule are to provide evaluation of safety and clinical benefit if circumstances arise in which a study would be feasible and ethical (i.e., in the event an emergency arises and the drug is used). In the absence of a public health emergency, these studies/clinical trials will remain pending indefinitely.

<sup>5</sup> After the first and second annual reviews, the status of 39 and 9 PMRs/PMCs, respectively, was undetermined because of insufficient documentation to determine the correct status at the time of the review. During the third annual review, CDER determined the status of the remaining 9 undetermined PMRs/PMCs.

<sup>6</sup> The status of 30 PMRs/PMCs was not available after the first annual review because the PMRs/PMCs had not been entered into the PMR/PMC database. These PMRs/PMCs were subsequently entered and reviewed.

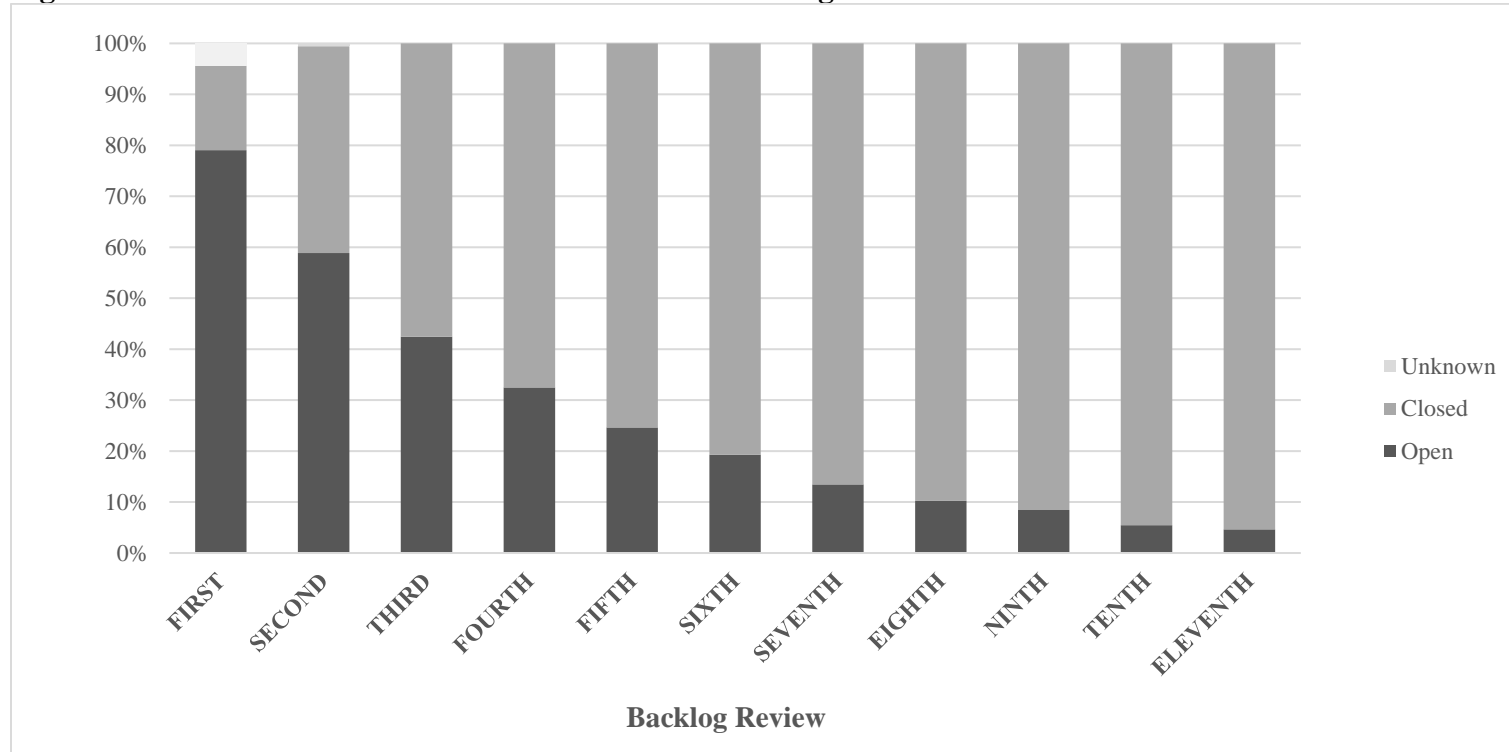
<sup>7</sup> During the ninth review, CDER determined that 12 PMRs/PMCs previously identified as fulfilled were released, and that 1 PMR/PMC previously identified as released was, in fact, fulfilled.

<sup>8</sup> During the ninth annual review, CDER discovered that 2 closed PMRs were administratively combined into a single PMR in the CDER internal database, decreasing the total number of PMRs in the CDER backlog to 1,553.



**Figure 1:** displays the data from Table 1 in graphical form. The figure shows that the number of open (i.e., pending, ongoing, delayed, terminated, or submitted) PMRs/PMCs in the CDER backlog has progressively decreased. As of December 31, 2018, the number of open PMRs/PMCs in the CDER backlog decreased to 5 percent (72/1,553) from 6 percent (85/1,553) in the previous year.

**Figure 1: CDER PMR/PMC Statuses After Annual Backlog Reviews**



Unknown = PMR/PMC status unknown or undetermined  
 Open = PMR/PMC status of pending, ongoing, delayed, submitted, or terminated  
 Closed = PMR/PMC status of released or fulfilled

- During the eleventh annual review, the status of 18 PMRs/PMCs in the CDER backlog was updated as a result of study/trial completion or termination, final report submission, or missed milestone dates.<sup>13</sup>
  - Of these updated PMR/PMC statuses, 61 percent (11/18) were updated to fulfilled, 11 percent (2/18) were updated to released, 6 percent (1/18) were updated to delayed, 17 percent (3/18) were updated to submitted, and 6 percent (1/18) were updated to terminated. None were updated to ongoing.
  - The 11 PMR/PMC statuses updated to fulfilled reflect the consistent effort from the review divisions to complete reviews of the submitted final reports identified by the tenth annual review.
- Of the 27 PMRs/PMCs with status of pending, ongoing, or terminated that originally had no specific milestones or completion date, 4 (15 percent) remain open. These 4 PMRs/PMCs represent less than 1 percent of the original 457<sup>14</sup> PMRs/PMCs in the CDER backlog that had no milestones or completion dates.<sup>15</sup> Of the 4 PMRs/PMCs:
  - One changed from ongoing to terminated status.
  - Two have a pending status.
  - One has an ongoing status.

Between December 30, 2017, and December 31, 2018,<sup>16</sup> there was a 20-percent decrease in open PMRs/PMCs without milestones or completion dates because one PMR/PMC was released.

- As a result of the first annual backlog review, 74 PMRs/PMCs were recommended for reevaluation by CDER reviewers because of possible issues with feasibility or relevance,<sup>17</sup> suggesting that the vast majority of PMRs/PMCs were sufficiently well-conceived when established. Of these 74 PMRs/PMCs, 3 percent (2/72) remain open.
  - This represents a 33-percent decrease since December 31, 2017, in the number of open PMRs/PMCs that were initially recommended for reevaluation.

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<sup>13</sup> The status changes do not reflect status changes made for the purposes of data correction as described in footnotes 2 and 8.

<sup>14</sup> The seventh annual review indicated that there were 458 PMRs/PMCs included in the original CDER backlog cohort of PMRs/PMCs that had no milestones or completion dates. During the course of the eighth annual review, CDER discovered that one PMC should not have been included in this cohort because the PMC had a final protocol due date. Therefore, there were a total of 457 PMRs/PMCs in the original CDER backlog that had no milestones or completion dates.

<sup>15</sup> See the first annual backlog report to Congress:  
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/UCM291522.pdf>.

<sup>16</sup> Refer to the tenth annual backlog report to Congress:  
<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/UCM617801.pdf>

<sup>17</sup> See the first annual backlog report to Congress:  
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/UCM291522.pdf>.

- During this period, one PMR/PMC initially recommended for reevaluation was fulfilled.

Thus:

- Most open CDER PMRs/PMCs in the backlog with a study/clinical trial in progress are delayed, completed, or await CDER review of the applicant-submitted final report (62/72, 86 percent).
- The number of fulfilled PMRs/PMCs continues to increase (from 27 percent in 2017 to 61 percent in 2018), reflecting a significant effort by the review divisions to complete reviews of the large number of submitted final reports identified during prior annual reviews.
- Only 3 percent (2/74) of the PMRs/PMCs that remain open were recommended for reevaluation by CDER reviewers because of possible issues with feasibility or relevance. This effort reflects the consistent effort by the review divisions to review final reports or other data that have subsequently been submitted to determine if these PMRs/PMCs can be released.
- All Office of New Drug review divisions have developed a plan for reviewing the CDER backlog and managing PMR/PMC issues in general. Of the 22 PMR/PMC final reports received as of December 31, 2017, 55 percent (12/22) were under review and 45 percent (10/22) were reviewed by FDA and the corresponding PMR/PMC was subsequently closed (i.e., fulfilled) as of December 31, 2018.

### **CBER Summary of Progress**

- The data show that as of September 30, 2018, 87 percent (72/83) of the PMRs/PMCs have been closed (i.e., fulfilled or released) and 91 percent (10/11) of the open PMRs/PMCs have studies/trials in progress or completed at the time of the eleventh annual review.
- The data in Table 2 and Figure 2 show the status for the backlog of CBER's 83 PMRs/PMCs as of September 30, 2018, was as follows: pending: 1 percent (1/83); ongoing: 4 percent (3/83); delayed: 7 percent (6/83); submitted: 1 percent (1/83); fulfilled: 84 percent (70/83); and released: 2 percent (2/83).
- The data for the previous year<sup>18</sup> show the status for the backlog of PMRs/PMCs were as follows: pending: 1 percent (1/83); ongoing: 4 percent (3/83); delayed: 10 percent (8/83); submitted: 0 percent (0/83); fulfilled: 83 percent (69/83); and released: 2 percent (2/83).
- During the eleventh annual review, the status of two PMRs/PMCs changed.
  - For those PMR/PMC statuses that were updated, one was updated from delayed to submitted status upon receipt of the final study report and one was updated from delayed to fulfilled status after FDA reviewed the received final study report.
  - Of the 83 PMRs/PMCs, 27 (33 percent) were without an original projected completion date. CBER offices were encouraged to obtain a complete schedule for

<sup>18</sup> See the tenth annual report at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/UCM617801.pdf>

the missing dates. This effort reduced the number of PMRs/PMCs without a projected completion date to 2 (2 percent). The number of PMRs/PMCs without an original completion date did not change from FY 2017 to FY 2018.

Thus:

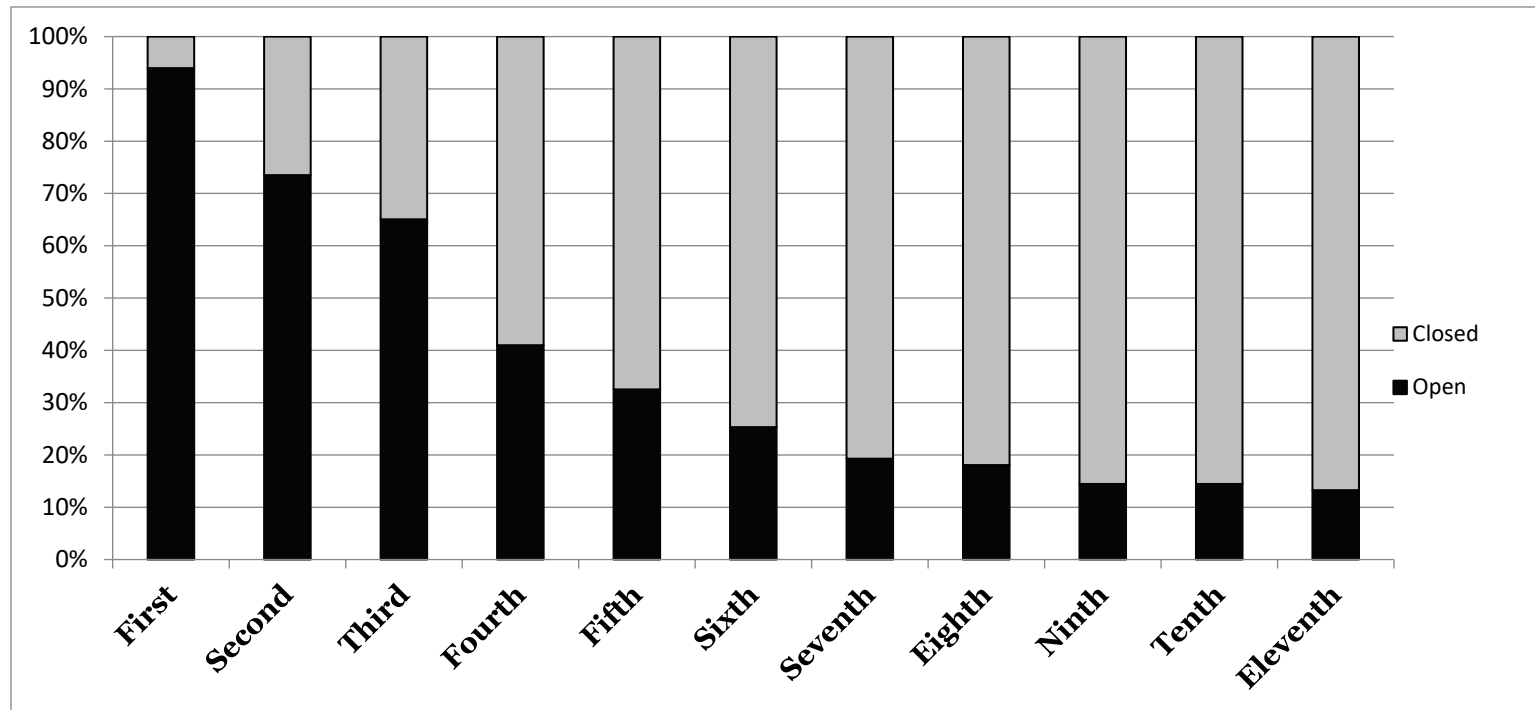
- Of 11 open CBER PMRs/PMCs in the backlog, 10 (91 percent) have a study/clinical trial either in progress or delayed.

**Table 2: CBER PMR/PMC Statuses After Annual Reviews**

	Number of PMRs/PMCs After...										
PMR/PMC Status	First Review	Second Review	Third Review	Fourth Review	Fifth Review	Sixth Review	Seventh Review	Eighth Review	Ninth Review	Tenth Review	Eleventh Review
Pending	10	5	4	2	2	2	1	1	2	1	1
Ongoing	21	19	18	7	4	5	5	3	3	3	3
Submitted	24	14	14	7	8	3	3	4	0	0	1
Delayed	23	23	18	18	13	11	7	7	7	8	6
Terminated	0	0	0	0	0	0	0	0	0	0	0
Fulfilled	5	22	29	47	54	60	65	66	69	69	70
Released	0	0	0	2	2	2	2	2	2	2	2
<b>Total</b>	<b>83</b>	<b>83</b>	<b>83</b>	<b>83</b>	<b>83</b>	<b>83</b>	<b>83</b>	<b>83</b>	<b>83</b>	<b>83</b>	<b>83</b>

**Figure 2** displays the data from Table 2 in graphical form. Again, the figure shows that the number of open PMRs/PMCs in the CBER backlog has not changed between the end of FY 2017 and the end of FY 2018.

**Figure 2: CBER PMR/PMC Statuses After Annual Backlog Reviews**



## V. Conclusions

- Upon completion of the eleventh annual review and as of December 31, 2018, 95 percent (1,481/1,553) of the PMRs/PMCs in the CDER backlog have been closed (i.e., fulfilled or released). As of September 30, 2018, 87 percent (72/83) of the PMRs/PMCs in the CBER backlog have been closed.
- Since the previous year, the number of open PMRs/PMCs in the CDER backlog decreased from 85 to 72 of 1,553 (5 percent). The number of open PMRs/PMCs in the CBER backlog decreased from 12 to 11 of 83 (13 percent).
- For CDER and CBER combined, 95 percent (1,553/1,636) of the PMRs/PMCs in the backlog have been closed (i.e., fulfilled or released), up from 94 percent in the previous year. For the two Centers combined, the number of open PMRs/PMCs decreased from 97 to 83 of 1,636 (5 percent).
- The number of open PMRs and PMCs will continue to decrease each year as applicants complete studies/trials and submit final reports, and as FDA reviews the final reports and issues fulfillment and release letters.

## Appendix A: PMR/PMC Status Definitions

PMR/PMC Status	Definition
Pending*	The study/clinical trial has not been initiated, but does not meet the criterion for “delayed.”
Ongoing*	The study/clinical trial is proceeding according to, or ahead of, the original schedule.
Submitted*	The study/clinical trial has been completed or terminated, and a final study report has been submitted to FDA.
Delayed*	The study/clinical trial is behind the original schedule.
Terminated*	The study/clinical trial was ended before completion, but a final study report has not been submitted to FDA.
Fulfilled	The final report for the study/clinical trial was submitted to FDA, and FDA notified the applicant that the 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/clinical trial because the study/clinical trial is no longer feasible, would no longer provide useful information, or the underlying application has been withdrawn.
Open	PMR/PMC status of pending, ongoing, delayed, submitted, or terminated.
Closed	PMR/PMC status of released or fulfilled.

\*Adapted from 21 CFR 314.81.