

Report to Congress

**REPORT ON THE TWELFTH 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**



**U.S. FOOD & DRUG
ADMINISTRATION**

A handwritten signature in black ink that reads "Stephen M. Hahn".

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs

Date

Executive Summary

On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85). Under section 921 of this law, the Food and Drug Administration (FDA) is required to review, annually, 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 12th review of all PMRs and PMCs that were open (i.e., not yet released or fulfilled) as of the date of enactment of the FDAAA, which are considered the “backlog” for purposes of the section 921 review. For this review, FDA has identified 1,636 PMRs/PMCs¹ (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 12th annual report shows that as of December 31, 2019, CDER completed the required review for 1,491 of the 1,553 PMRs and PMCs in the backlog. As of September 30, 2019, 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.

¹ 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 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 amended 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 postmarket 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.² PMRs and PMCs are studies or clinical trials required of, or agreed upon in writing, 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)³ 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 twelfth annual report on the review of the backlog of PMRs and PMCs. This 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 at the following links:

- [First Annual Report](#)
- [Second Annual Report](#)
- [Third Annual Report](#)
- [Fourth Annual Report](#)
- [Fifth Annual Report](#)
- [Sixth Annual Report](#)

² 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).

³ 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 4 additional PMR/PMCs that had previously been excluded from the backlog (e.g., never entered into database). During the fifth annual review, one additional PMR/PMC was discovered; 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 two 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).

29 [Seventh Annual Report](#)
30 [Eighth Annual Report](#)
31 [Ninth Annual Report](#)
32 [Tenth Annual Report](#)
33 [Eleventh Annual Report](#)
34

35 This report is based on data that had “data lock” dates of September 30, 2019 (CBER backlog),
36 and December 31, 2019 (CDER backlog).⁴
37

38 **II. Background**

39 Section 130(a) of the Food and Drug Administration Modernization Act of 1997 (Public Law
40 105-115) amended the FD&C Act by adding a provision requiring reports of certain
41 postmarketing studies for human drug and biological products (section 506B of the FD&C Act
42 (21 U.S.C. 356b)). Section 506B of the FD&C Act provides FDA with the authority to monitor
43 the progress of a PMC by requiring the applicant to submit an annual report providing
44 information on the status of the PMC, which was defined to include agreed-upon commitments
45 and required studies (including clinical trials).⁵
46

47 The annual reports that applicants submit must also include the reasons, if any, for failure to
48 satisfy the commitment. This provision is implemented per 21 CFR 314.81(b)(2)(vii) and
49 601.70.⁶ Under section 506B(b) and (c), FDA is required to track these PMCs and report on
50 them annually in the *Federal Register*.⁷ As described previously, as of the date of enactment of
51 FDAAA, there were 1,636 (CDER and CBER) open PMRs and PMCs that are considered the
52 “backlog” for purposes of the section 921 backlog review.⁸

⁴ 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 31st.

⁵ 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 <https://www.fda.gov/files/drugs/published/Reports-on-the-Status-of-Postmarketing-Study-Commitments—Implementation-of-Section-130-of-the-Food-and-Drug-Administration-Modernization-Act-of-1997.pdf>.

⁶ 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 [section 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.

⁷ These annual reports are available on FDA’s Postmarketing Requirements and Commitments: Reports website at <https://www.fda.gov/drugs/postmarket-requirements-and-commitments/postmarketing-requirements-and-commitments-reports>.

⁸ 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

53
54 Before the passage of FDAAA, FDA required studies or clinical trials in the following situations:
55

- 56 • Subpart H and subpart E accelerated approvals for products approved under section 505(b) of
57 the FD&C Act or section 351 of the Public Health Service Act, respectively (so-called
58 “accelerated approval”). These require postmarketing studies to verify clinical benefit (21
59 CFR 314.510 and 601.41, respectively);
- 60
- 61 • Deferred pediatric studies, where studies are required under the Pediatric Research Equity
62 Act (PREA); and
- 63
- 64 • Animal efficacy rule approvals, where studies to demonstrate safety and efficacy in humans
65 are required at the time of use (21 CFR 314.610(b)(1) and 601.91(b)(1)).⁹
- 66

67 Under FDAAA, FDA has been given additional authority to require applicants to conduct and
68 report on postmarketing studies or clinical trials to assess a known serious risk, assess signals of
69 serious risk, or identify an unexpected serious risk related to the use of a product. These required
70 safety studies/clinical trials—as well as those required under accelerated approval, PREA, and
71 the animal rule (as described above)—are now considered PMRs. Studies or clinical trials
72 required after the passage of FDAAA are not included in the annual backlog review because the
73 backlog has been interpreted in this context to refer to all required or agreed-upon studies or
74 clinical trials that had not been released or fulfilled before the passage of FDAAA.
75

76 **III. Methods**

77 The first and second annual CDER reviews were conducted by an external contractor who
78 reviewed internal FDA systems and documents to determine the status for all PMRs/PMCs. This
79 was accomplished by first identifying the status of each PMR/PMC listed in the internal
80 PMR/PMC databases and comparing these statuses to the milestone dates established in each
81 product’s approval letter. When the milestone dates were inconsistent with the statuses in the
82 PMR/PMC databases, the correct status was determined by examining existing documentation
83 (e.g., PMR/PMC annual status reports, PMR/PMC final study/clinical trial reports, FDA-
84 applicant communications, and internal FDA memos and reviews).
85

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 a total of 1,636 PMRs/PMCs that are the subject of this report.

⁹ 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 an evaluation of the safety and clinical benefit if circumstances arise in which a study would be feasible and ethical (i.e., in the event of 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.

86 After the accurate statuses were determined, additional review of the backlog of PMRs/PMCs
87 was performed to identify candidates for revision or release.¹⁰ The PMRs/PMCs that were off-
88 schedule (i.e., delayed or terminated) or had no milestone dates were prioritized for review over
89 those that were on-schedule (i.e., pending, ongoing, or submitted) based on established milestone
90 dates.

91
92 The contractor provided CDER with the results of the review as well as recommendations
93 regarding potential re-evaluation or release of PMRs/PMCs in the backlog. CDER has
94 conducted all subsequent annual reviews, including this twelfth review, and continues to monitor
95 the progress of the PMRs/PMCs recommended for revision or release in addition to assessing the
96 current status for the entire backlog.

97
98 The data available for PMRs and PMCs in the backlog are constantly changing as submissions
99 are reviewed and the statuses of the PMRs/PMCs are updated. CDER has policies and
100 procedures to help ensure that its data on PMRs/PMCs, including the PMRs/PMCs in the
101 backlog, are current and accurate. When identified, data discrepancies are addressed and/or are
102 corrected in later reports. The information in this report reflects the status information in
103 CDER's database at the time the data were extracted and reflects CDER's data quality control
104 processes.

105
106 CBER has a comprehensive module in its biologics license application database system for
107 tracking PMRs/PMCs. Information from CBER's system is extracted monthly and quarterly,
108 and the information is subjected to quality control processes external to the review offices for the
109 Center's and FDA's reports. Their processes, along with clearly defined CBER staff
110 responsibilities for managing PMRs/PMCs, help ensure that data available from the system are
111 accurate and relatively current.

112

113 **IV. Findings**

114 **A. CDER's Summary of Progress**

115

- 116 • The number of open PMRs/PMCs in the CDER backlog continues to decrease. The data
117 show that as of December 31, 2019, 96 percent (1,491/1,553) of PMRs/PMCs have been
118 closed (i.e., fulfilled or released). Of the 62 PMRs/PMCs that remain open, 86 percent
119 (53/62) have studies/trials either in progress or completed (i.e., ongoing, delayed, or had final
120 reports submitted) at the time of the twelfth annual review.
- 121
122 • As shown in Table 1 and Figure 1, as of December 31, 2019, the status of the CDER backlog
123 of PMRs/PMCs was as follows: pending: less than 1 percent (5/1,553); ongoing: less than 1
124 percent (11/1,553); delayed: 2 percent (29/1,553); terminated: less than 1 percent (4/1,553);

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

125 submitted: less than 1 percent (13/1,553); fulfilled: 70 percent (1,094/1,553);¹¹ and released:
126 26 percent (397/1,553). In comparison to the previous year,¹² the number of PMRs/PMCs
127 decreased in all but one¹³ of the open statuses, and 10 more PMRs/PMCs were closed
128 (released or fulfilled).
129

- 130 • The data for the previous year show that the status of the CDER backlog of PMRs/PMCs was
131 as follows: pending: less than 1 percent (6/1,553); ongoing: 1 percent (17/1,553); delayed:
132 2 percent (30/1,553); terminated: less than 1 percent (4/1,553); submitted: 1 percent
133 (15/1,553); fulfilled: 70 percent (1,087/1,553);¹⁴ and released: 25 percent (394/1,553). (See
134 Appendix A for the status definitions)

¹¹ During the ninth review, CDER determined that 12 PMRs/PMCs in the backlog that were previously identified as fulfilled were released and that one PMR/PMC previously identified as released was fulfilled.

¹² See the eleventh annual backlog report to Congress, available at <https://www.fda.gov/media/130519/download>.

¹³ In comparison to the previous year, the number of PMRs/PMCs with an open status of terminated remained the same; therefore, the number of open PMRs/PMCs with a status of terminated neither increased nor decreased.

¹⁴ 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’s PMR/PMC Statuses After Annual Reviews

Number of PMRs/PMCs After the ...												
Status	First Review	Second Review	Third Review	Fourth Review ¹	Fifth Review ²	Sixth Review	Seventh Review ³	Eighth Review	Ninth Review	Tenth, Review	Eleventh Review	Twelfth Review
Pending ⁴	208	114	93	77	51	46	49	32	25	6	6	5
Ongoing	212	156	132	106	71	60	49	37	26	22	17	11
Submitted	565	366	197	113	79	63	30	15	19	22	15	13
Delayed	225	264	223	199	171	124	73	65	54	32	30	29
Terminated	16	13	13	10	11	7	8	10	7	3	4	4
Fulfilled	209	483	701	827	900	953	1,018	1,050	1,047 ⁷	1,076	1,087	1,094
Released	47	146	191	222	272	302	327	345	375	392	394	397
Undetermined ⁵	39	9	0	0	0	0	0	0	0	0	0	0
Not Available ⁶	30	0	0	0	0	0	0	0	0	0	0	0
Total	1,551	1,551	1,550	1,554	1,555	1,555	1,554	1,554	1,553⁸	1,553	1,553	1,553

¹ 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 the database). After this correction was made, the CDER backlog consisted of 1,554 PMRs/PMCs.

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

³ 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.

⁴ 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 an evaluation of the 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.

⁵ 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.

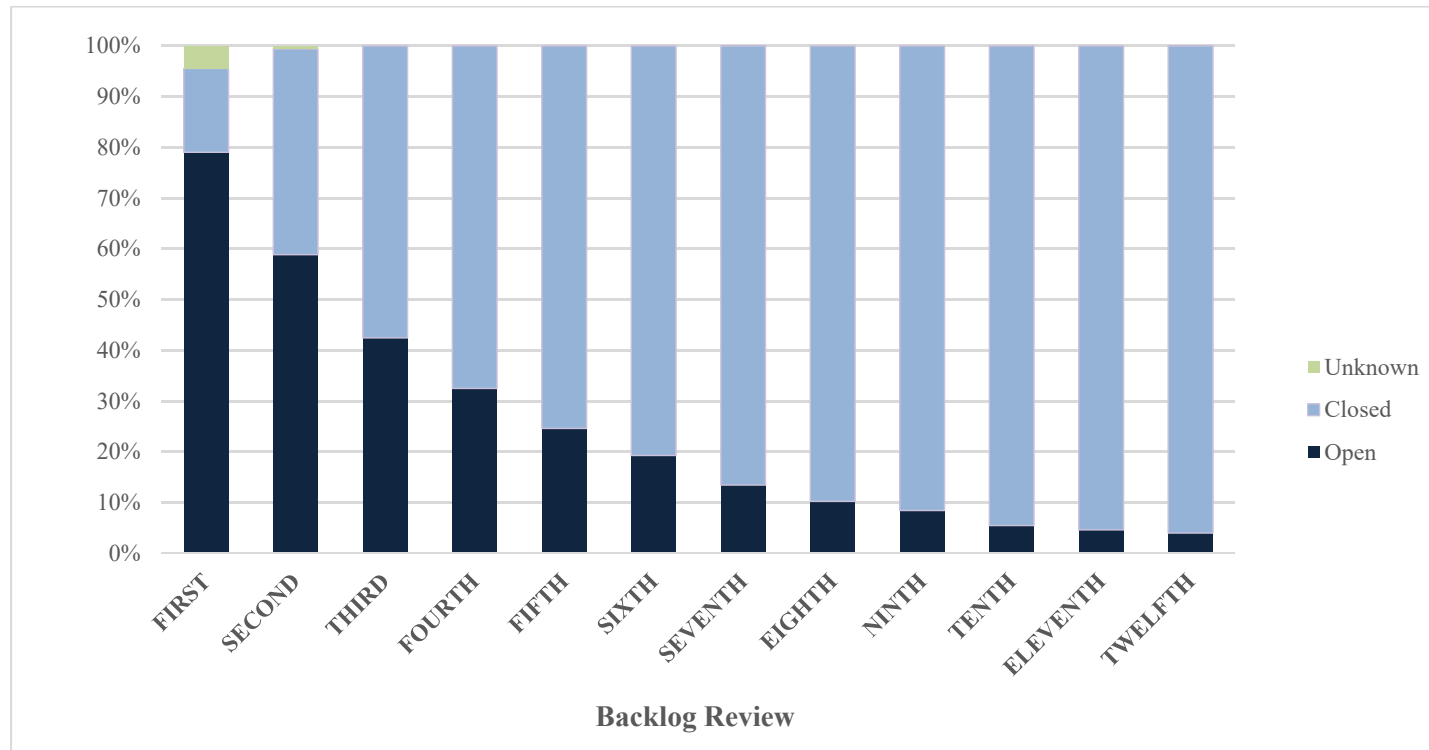
⁶ The status of 30 PMRs/PMCs was not available after the first annual review because the PMRs/PMCs had not been entered into the PMR/PMC database. These PMRs/PMCs were subsequently entered and reviewed.

⁷ 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.

⁸ 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, 2019, the number of open PMRs/PMCs in the CDER backlog decreased to 4 percent (62/1,553) from 5 percent (72/1,553) in the previous year.

Figure 1: CDER’s 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 twelfth annual review, the status of 16 PMRs/PMCs in the CDER backlog was updated as a result of study/trial completion or termination, final report submission, or missed milestone dates.¹⁵
 - Of these updated PMR/PMC statuses, 44 percent (7/16) were updated to fulfilled, 19 percent (3/16) were updated to released, 13 percent (2/16) were updated to delayed, and 25 percent (4/16) were updated to submitted. None was updated to ongoing or terminated.
 - The 7 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 eleventh annual review.
- Of the 20 open PMRs/PMCs with a status of pending, ongoing, or terminated that originally had no specific milestones or completion dates, 4 (20 percent) PMRs/PMCs remain open, which are the same PMRs/PMCs as the previous year. These 4 PMRs/PMCs represent less than 1 percent of the original 457¹⁶ PMRs/PMCs in the CDER backlog that had no milestones or completion dates.¹⁷ Of these 4 PMRs/PMCs:
 - One maintained its status of terminated
 - One maintained its status of ongoing
 - Two maintained their status of pending

Between December 30, 2018, and December 31, 2019,¹⁸ there was no decrease in the number of these PMRs/PMCs (with pending, ongoing, or terminated statuses that originally had no specific milestones or completion dates) from the previous year.

- As a result of the first annual backlog review, 74 PMRs/PMCs were recommended for re-evaluation by CDER reviewers because of possible issues with feasibility or relevance,¹⁹ suggesting that the vast majority of PMRs/PMCs were sufficiently well conceived when established. Of these 74 PMRs/PMCs, 3 percent (2/62) remain open.

¹⁵ The status changes do not reflect status changes made for the purposes of data correction, as described in footnotes 2 and 8 of Table 1.

¹⁶ 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 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.

¹⁷ See the first annual backlog report to Congress, available at <http://wayback.archive-it.org/7993/20170111225514/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/UCM291522.pdf>.

¹⁸ Refer to the eleventh annual backlog report to Congress, available at <https://www.fda.gov/media/130519/download>.

¹⁹ See the first annual backlog report to Congress: <http://wayback.archive-it.org/7993/20170111225514/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/UCM291522.pdf>

- This represents no change since December 31, 2018, in the number of open PMRs/PMCs that were initially recommended for re-evaluation.

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 (53/62, 85 percent).
- The number of fulfilled PMRs/PMCs continues to increase (from 1,087 in 2018 to 1,094 in 2019), although the percentage remains the same (70 percent) for both 2018 and 2019. The numerical increase in fulfilled PMRs/PMCs reflects 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 re-evaluation 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 15 PMR/PMC final reports received as of December 31, 2018, 60 percent (9/15) were under review and 40 percent (6/15) were reviewed by FDA, and the corresponding PMR/PMC was subsequently closed (i.e., fulfilled) as of December 31, 2019.

B. CBER's Summary of Progress

- The data show that as of September 30, 2019, 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 twelfth 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, 2019, was as follows: pending: 1 percent (1/83); ongoing: 1 percent (1/83); delayed: 7 percent (6/83); submitted: 4 percent (3/83); fulfilled: 84 percent (70/83); and released: 2 percent (2/83).
- The data for the previous year²⁰ show the status for the backlog of PMRs/PMCs 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).

²⁰ See the eleventh annual report at: <https://www.fda.gov/media/130519/download>.

- During the twelfth annual review, the status of two PMRs/PMCs changed.
 - For those PMR/PMC statuses that were updated, two were updated from delayed to submitted status upon receipt of the 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 the missing dates. This effort reduced the number of PMRs/PMCs without a projected completion date to two (two percent). The number of PMRs/PMCs without an original completion date did not change from FY 2018 to FY 2019.

Thus:

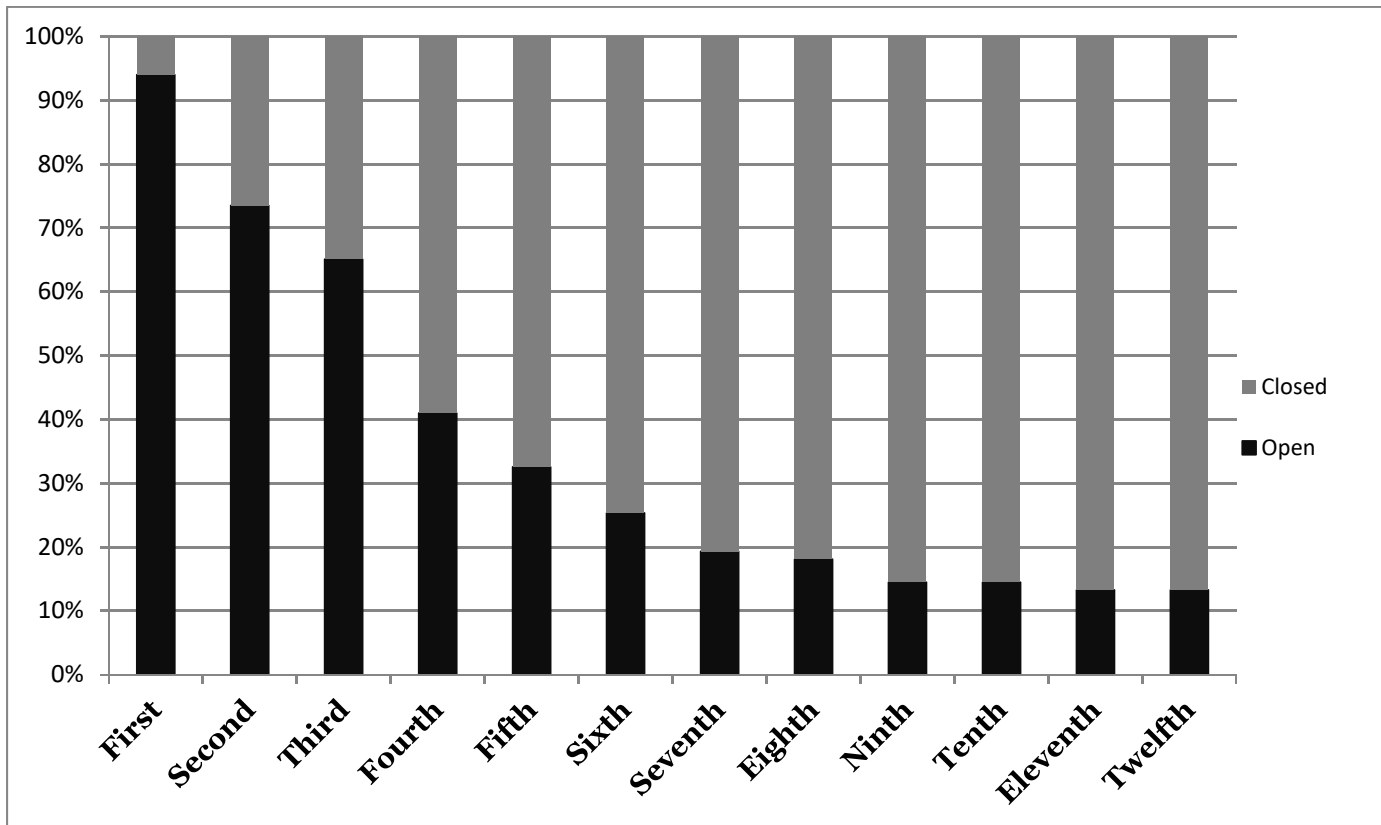
- Of 11 open CBER PMRs/PMCs in the backlog, 10 (91 percent) have a study/clinical trial either in progress or delayed.

Table 2: CBER’s PMR/PMC Statuses After Annual Reviews

Number of PMRs/PMCs After the...												
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	Twelfth Review
Pending	10	5	4	2	2	2	1	1	2	1	1	1
Ongoing	21	19	18	7	4	5	5	3	3	3	3	1
Submitted	24	14	14	7	8	3	3	4	0	0	1	3
Delayed	23	23	18	18	13	11	7	7	7	8	6	6
Terminated	0	0	0	0	0	0	0	0	0	0	0	0
Fulfilled	5	22	29	47	54	60	65	66	69	69	70	70
Released	0	0	0	2	2	2	2	2	2	2	2	2
Total	83	83	83	83	83	83	83	83	83	83	83	83

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 2018 and the end of FY 2019.

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



V. Conclusions

- Upon completion of the twelfth annual review and as of December 31, 2019, 96 percent (1,491/1,553) of the PMRs/PMCs in the CDER backlog have been closed (i.e., fulfilled or released). As of September 30, 2019, 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 72 to 62 of 1,553 (4 percent). The number of open PMRs/PMCs in the CBER backlog remains unchanged from the previous year at 11 of 83 (13 percent).
- For CDER and CBER combined, 96 percent (1,563/1,636) of the PMRs/PMCs in the backlog have been closed (i.e., fulfilled or released), up from 95 percent in the previous year. For the two Centers combined, the number of open PMRs/PMCs decreased from 83 to 73 of 1,636 (4 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.