

SOPP 8415: Procedures for Developing Postmarketing Requirements and Commitments

Version: 3

Effective Date: April 10, 2017

I. Purpose

- A.** This Standard Operating Policy and Procedure (SOPP) serves as a guide for Center for Biologics Evaluation and Research (CBER) staff to define and develop Postmarketing Requirements (PMRs) and Postmarketing Commitments (PMCs) for drug and biological products.
- B.** It is intended to improve clarity and transparency by defining procedures to discuss PMRs/PMCs with the applicant prior to the action goal date; document the rationale for a PMR/PMC; ensure that the PMR/PMC is clearly written and is developed in accordance with Good Review Management Principles and Practices (GRMP) recommendations.

II. Scope

- A.** This SOPP covers PMRs and PMCs issued to CBER-regulated human drugs approved with New Drug Applications (NDAs) and biological products with Biologics License Applications (BLAs) or updated with a supplement to an NDA (sNDA) or to a BLA (BLS).
- B.** This SOPP also covers PMCs agreed upon for devices approved under a BLA/BLS that meet the definition of a device under Section 201(h) of the Food, Drug, and Cosmetic (FD&C) Act.
- C.** This SOPP applies to the development of:
 - 1.** PMRs related to the Animal Efficacy Rule or accelerated approvals, and safety studies or clinical trials required under the Food and Drug Administration Amendments Act (FDAAA);
 - 2.** Agreed-upon, reportable 506B PMCs; and
 - 3.** Agreed-upon non-506B commitments (non-506B PMC, i.e., Chemistry, Manufacturing, and Controls (CMC) and certain product stability studies).
- D.** This SOPP does not:
 - 1.** Address PMRs required under the Pediatric Research Equity Act (PREA);

2. Describe the criteria for determining whether a postmarketing study or clinical trial should be a PMR or a PMC;
3. Describe the criteria for determining non-compliance with the conduct of PMRs or the required reporting for PMRs/PMCs;
4. Include procedures and responsibilities for PMR/PMC tracking and review (i.e., after a PMR/PMC is issued/agreed upon). Those topics are addressed in *SOPP 8413: Postmarketing Commitment Related Submissions – Administrative Handling, Review, and CBER Reporting*.

III. Background

- A.** In the past, the Food and Drug Administration (FDA) used the term “postmarketing study commitments (PMCs)” to refer to studies or clinical trials conducted by the applicant after FDA approved or licensed a product for marketing. These studies or clinical trials were intended to further refine the safety, efficacy or optimal use of a product or to ensure consistency and reliability of product quality. These commitments were either agreed upon by the FDA and the applicant or required by FDA in the following situations:
 1. Accelerated approval confirmatory studies (21 CFR 314.510/Subpart H and 601.41/Subpart E), where subsequent studies are required to describe and verify clinical benefit.
 2. Deferred pediatric studies (21 CFR 314.55(b) and 601.27(b)), where studies are required under the Pediatric Research Equity Act (PREA) **NOTE:** Reference to PREA related PMRs are included to maintain background completeness.
 3. Animal Efficacy Rule, Clinical Efficacy and Safety Studies (21 CFR 314.610(b)(1)/Subpart I and 601.91(b)(1)/Subpart H) where studies to demonstrate safety and efficacy in humans are required at the time of use.
- B.** Section 130(a) of Title I of the Food and Drug Administration Modernization Act of 1997 (FDAMA) added a new provision (section 506B) to the FD&C Act which mandates applicants to report annually on the status of postmarketing requirements (PMRs) and reportable PMCs, and obligated FDA to make certain information about these PMRs/PMCs is publicly available.
- C.** In 2007, Section 901 of the FDAAA created section 505(o) of the FD&C Act which authorized FDA to require postmarketing studies or clinical trials at the time of approval or after approval if FDA becomes aware of new safety information. FDAAA states that studies and clinical trials may be required for one of three purposes:

1. To assess a known serious risk related to the use of the drug,
2. To assess signals of serious risk related to the use of the drug, or
3. To identify an unexpected serious risk when available data indicate the potential for a serious risk.

D. Section 901 of FDAAA also requires applicants to submit a milestone schedule for completion of each study/clinical trial.

IV. Definitions

- A. 506B-Reportable Postmarketing Commitment (506B PMC)** – Postmarketing studies or clinical trials concerning clinical safety, clinical efficacy, clinical pharmacology, or nonclinical toxicology that applicants and the FDA have *agreed* to conduct in writing; and applicants are required to report on these PMCs in their PMR/PMC annual report (21 CFR 314.81(b)(2)(vii)(a), 21 CFR 601.70(b), and Section 506B the FD&C Act, *Reports of Postmarketing Studies*).
- B. Clinical Trial** – Any prospective investigation in which an applicant or investigator determines the method of assigning the investigational product or other interventions to one or more human subjects.
- C. Non-506B, Non-Reportable, Postmarketing Commitments (non-506B PMC)** – Any Chemistry, Manufacturing and Control (CMC) study, *agreed* to be conducted in writing, to assess drug or biologic product quality data that was not required for approval; yet, the review committee felt was necessary to provide complete quality information; in addition, these commitments are not subject to 506B's reporting requirements.
- D. PMR/PMC Schedule Milestones** – The specific study dates for completing activities related to conducting a PMR/PMC.
- E. Postmarketing Commitment (PMC)** – Any study or clinical trial that an applicant has *agreed upon*, in writing, to conduct after approval or licensing of a marketing application or supplement that is not a PMR.
- F. Postmarketing Requirement (PMR)** – Any study or clinical trial that an applicant is *required* to conduct post-approval of a marketing application or a supplement. NOTE: Applicants may be subject to legal penalties for not conducting PMRs.
- G. Study** – Any investigation other than a clinical trial, such as an investigation in humans (e.g., an observational epidemiologic study), an animal study or a laboratory experiment.

H. Voluntary Postmarketing Study or Trial – A study or clinical trial conducted on an applicant’s *own initiative* without a request by FDA.

V. Policy

A. CBER will:

- 1.** Use the CBER Safety Work Group (SWG) for review and feedback of all approval letters with PMRs invoking Title IX authorities;
- 2.** Develop and communicate to applicants all PMRs/PMCs using a standardized process;
- 3.** Meet the recommended PMR/PMC communication target dates for providing feedback to the applicant as communicated in the filing letter;
- 4.** Communicate with the applicant any issues that may lead to PMRs/PMCs as early as possible in the review process;
- 5.** Document discussions and agreements with the applicant relating to PMRs/PMCs in CBER’s Regulatory Management System – Biologics License Application (RMS-BLA) as per the appropriate CBER SOPPs;
- 6.** Review the rationale for a PMC.
 - a.** A PMC must be agreed upon, in writing, between FDA and the applicant.
 - b.** A PMC will be requested only if the objectives are important to further the knowledge of the safe and effective use of the product.
- 7.** Review PMR/PMC descriptions within the Office/Division to ensure that they are clearly written and contain the appropriate milestone schedule. The milestone schedule should include a final due date for the data that would result in a submission that addresses the issue for the stated PMR/PMC;
- 8.** Collaborate with the applicant to develop the milestone schedule for the PMR/PMC. FDAAA gives FDA the authority to require PMRs without prior agreement from the applicant;
- 9.** Include a clear and concise justification for the determination of the need for a PMR/PMC, as well as whether the study/clinical trial will be 506B reportable or not;
- 10.** Strive to resolve all potential non-506B PMC issues during the review cycle and minimize the generation of non-506B PMC; and

11. Request status updates on non-506B PMC for BLA/BLS as “Postmarketing Study Commitments – Status Update” and for NDA/sNDA within separate section of the NDA annual report (21 CFR 314.81(b)(2)(viii)).

B. CBER will not:

1. Include in the approval letter or track in RMS-BLA, voluntary studies or trials.
2. Request a PMR/PMC for a study/clinical trial that is covered by other regulations (e.g., safety data updates or adverse event reports under 21 CFR 600.80).

C. Types of 506B PMC studies include:

1. **Clinical Efficacy** – Human studies intended to further characterize the effectiveness or optimal use of a product.
2. **Clinical Pharmacology** – Human studies to further determine the effects of the product on the body, including pharmacokinetics (what happens to the product while in the body), pharmacodynamics (the effects of the product, as pertaining to a subject’s biochemistry and physiology), toxicity, and drug interaction.
3. **Clinical Safety** – Human studies intended to gather additional information on the safety of a product, e.g., at different dosage levels. These include immunogenicity studies intended to further define an immune response elicited by the introduction of an antigen (e.g., protein.)
4. **Non-Clinical Toxicology** – Non-human studies (e.g., animal studies, in vivo animal models) to further characterize carcinogenicity, teratogenicity, reproductive toxicology, biopharmaceutic and pharmacokinetic properties of a product.

D. Additional information concerning non-506B PMC:

1. CMC studies may include manufacturing, stability, and other studies that do not have a safety endpoint.
2. Non-506B PMC studies are not subject to 506B reporting requirements described under 21 CFR 601.70 for BLAs. Although for NDAs, 21 CFR 314.81(b)(2)(viii) requires an applicant to advise the FDA on the status of non-506B PMCs in a separate section of the NDA annual report.

E. Additional information concerning voluntary studies:

1. Voluntary studies or clinical trials are not required or agreed upon.

2. Voluntary studies or clinical trials are not subject to 506B reporting requirements. Although for NDAs, 21 CFR 314.81(b)(2)(viii) requires the applicant advise the FDA on the status of voluntary studies or clinical trials in a separate section of the NDA annual report.

F. There are no provisions to modify the *original* milestone dates as stipulated under 21 CFR 314.81(b)(2)(vii)(a)(8) and 21 CFR 601.70(b)(8). A revised schedule can be submitted along with reasons for the revision; however, FDA will use the *original* study schedule to determine the study progress.

G. The following milestone dates should be included in the schedule and in the approval letter or alternative correspondence (e.g., PMC Study Schedule Notification letter) when the PMR/PMC is required or agreed upon. These dates should be captured and updated as necessary in RMS-BLA, and may include:

1. Final protocol submission date;
2. Study/clinical trial completion date or a date in relation to another milestone listed above (e.g., X months after final protocol submission);
3. Final report submission date or time related to the actual completion date (e.g., within X months after study completion)

VI. Responsibilities

A. Branch/Lab Chief

1. Participates in discussion and provides input on the PMR/PMC
2. Ensures that a clear and concise justification for requiring or recommending a PMR/PMC is clearly described in the discipline review memo;
3. Ensures that the PMR/PMC description clearly communicates the objectives of the PMR/PMC in order for the applicant to adequately address the PMR/PMC;
4. Ensures that the Review Committee Members resolve differences with the applicant;
5. Ensures that the final milestone schedule is both feasible and reasonable; and provides concurrence on the PMRs/PMCs.

B. CBER Safety Working Group (SWG) Office Representative

1. Serves as the point of contact between the Review Committee Members and the CBER SWG Executive Secretary, and
2. Participates in the SWG meeting.

C. CBER SWG Executive Secretary

1. Schedules CBER SWG meeting, and
2. Invites appropriate participants to the meeting.

D. Center PMR/PMC Liaison

1. Serves as the Center point of contact to address any questions associated with the development, tracking, or closing of PMRs/PMCs; and
2. Reviews all letters containing PMRs/PMCs prior to issuance of the letters.

E. Division Director

1. Participates in discussion and provides input on the PMR/PMC;
2. Ensures that staff are aware of and adhere to established policies regarding PMR/PMC development;
3. Ensures that all PMRs/PMCs are applied consistently across the Office/Division and meets the general policy guidelines in this SOPP;
4. Ensures that adequate resources are committed to review, track and close each PMR or PMC;
5. Receives periodic updates on PMR/PMC status within the division; and
6. Provides concurrence on all PMRs/PMCs prior to issuing the action letter.

F. Office Director

1. Reviews potential Title IX-related PMRs prior to CBER SWG meeting; and
2. Receives concurred PMRs prior to final regulatory decision.

G. Office PMR/PMC Coordinator

1. reviews PMR/PMC for clarity and study milestones
2. Enters PMR/PMC into the tracking system; and
3. Uses the *RMS-BLA Data Entry for Postmarketing Requirements/Commitments and Related Submissions* for detailed instructions on entering and updating RMS-BLA.

H. PMR/PMC Lead

1. Serves as the technical lead in the development, negotiation, and documentation of a PMR or PMC; and
2. Participates in contacting the applicant after determining the need for a PMR or PMC.

I. Regulatory Project Manager (RPM)/Chair

1. serves as point of contact and communicates with appropriate personnel, sends the draft PMRs/PMCs to the applicant;
2. Ensures that each PMR/PMC is drafted and numbered sequentially in the approval letter;
3. Checks to ensure that RMS-BLA is populated post-approval with the PMRs/PMCs, including the study schedule milestones;
4. Coordinates review-specific communications (e.g., protocol review comments from the review committee members) with the applicant for PMR/PMC content-related issues pre- and post-approval; and
5. Uses the *RMS-BLA Data Entry for Postmarketing Requirements/Commitments and Related Submissions* for detailed instructions on entering and updating RMS-BLA.

J. Review Committee Members

1. identifies potential PMR/PMC issues, participates in discussions and provides input on the development of the PMR/PMC;
2. Fully describes in the discipline review memo a clear and concise justification for why each PMR/PMC was needed;
3. Drafts the PMR/PMC description to clearly communicate the objectives of the PMR/PMC for the applicant to address;
4. Circulates the PMR/PMC description to the Branch/Lab Chief(s) for concurrence prior to communication to the applicant by the RPM;
5. Reviews and participates in resolving any differences between the objectives and study schedule milestones after the draft PMR/PMC descriptions have been circulated.

K. SWG Co-Chairs

1. Lead the CBER SWG meetings; and
2. Review “mature” draft approval letters containing safety-related PMR/PMC to assess accuracy and completeness of safety related PMR/PMC.

VII.Procedures

A. Develop, Review and Process of Title IX, Safety-Related PMRs

1. Identify a potential PMR review issue [**Review Committee Members**]
NOTE: The identification of potential Title IX, safety related PMRs should occur during the initial review of the submission; presentation to SWG should occur around Mid-Cycle.
2. Participate in discussions and provide input on potential PMR review issues at a pharmacovigilance planning meeting [**Review Committee Members, Branch/Lab Chief, Product Division Director, OBE/DE Division Director**]
NOTE: These discussions could occur during review committee meetings, at office specific OBE/DE-Division Level Safety Assessment Meeting (SAM) or other meetings as appropriate.
3. Participate in the review of draft PMR descriptions and milestone schedules for clarity, feasibility and consistency with similar PMRs [**RPM, Chair, Office PMR/PMC Coordinator, Review Committee Members, Branch/Lab Chief, Division Director**]
4. Include the technical rationale for the PMR in the discipline review memo(s) [**Review Committee Members**]
5. Notify Office Safety Working Group (SWG) Representative of potential PMRs [**RPM/Chair**]
6. Informally notify SWG Exec Sec of potential Title IX PMRs or safety related PMCs [**SWG Office Reps**]
7. Provide the PMR concept, which may include a projected milestone schedule, to supervisors for review and agreement [**Review Committee Members**]
8. Provide concurrence on PMR concept [**Branch/Lab Chief, Division Director**]
9. Provide concurred PMR concept to Office Director, Division Director, CBER Office SWG Representative [**RPM/Chair**]
NOTE: Obtain CBER SWG concurrence on the PMR concept before notifying the applicant

10. Review PMR concept prior to CBER SWG meeting [**Division Director, OBE and Product Office Directors**]
11. Provide Review Committee Member names that should be invited to the CBER SWG to CBER Office CBER SWG Representative [**RPM, Chair**]
12. Receive PMR concept and Review Committee Member's names. Forward the information to the CBER SWG Executive Secretary [**CBER SWG Office Representative**]
13. Place PMR concept on an upcoming CBER SWG meeting agenda and invite Review Committee Members to CBER SWG [**CBER SWG Executive Secretary**]
14. Conduct the CBER SWG meeting. [**CBER SWG Co-Chairs**]
 - a. Attendees should include, as appropriate:
 - i. RPM,
 - ii. Chair,
 - iii. Review Committee Members,
 - iv. Branch/Lab Chief,
 - v. Division Director,
 - vi. CBER SWG Office Representative,
 - vii. CBER SWG Executive Secretary,
 - viii. SWG Co-Chairs,
 - ix. Office PMR/PMC Coordinator
15. Provide a presentation or handouts summarizing key points of each Title IX PMR [**Review Committee Members**] **NOTE:** To ensure that SWG has the full understanding of the PMR, include summaries of any other potential PMR and reportable PMC anticipated to be included in the approval of the application or supplement.
16. Contact applicant, after CBER SWG meeting, to initiate PMR negotiations [**Lead, RPM/Chair**]
 - a. Serve as Lead to negotiate study design and milestone schedules for Title IX Epidemiological Observational PMR studies [**OBE DE Committee Member**]
 - b. Serve as Lead to negotiate all other Title IX clinical trial design, details and milestone schedules [**Product Office Clinical Review Committee Member**]
17. Participate in discussions about content and schedule milestones for draft PMRs. Obtain general agreement on PMR studies and request written

agreement from applicant on the study design, milestones, and other details of the PMRs [**Lead, RPM/Chair**]

18. Receive written agreement from the applicant as an amendment to the file and send the amendment to the Review Committee for review [**RPM/Chair**]

19. Review the amendment to ensure that it is accurate and complete. If the amendment is not accurate and complete, contact the applicant to correct the amendment [**Lead, RPM/Chair**]

20. Prepare draft approval letter containing PMRs [**RPM/Chair**]

B. Develop, Review and Process of Accelerated Approval (AA) or Animal Efficacy Rule (AER) related PMRs

21. Identify studies not included in the AA or AER applications and begin to discuss appropriate postmarketing required studies or clinical trials [**Review Committee Members**]

22. Participate in discussions and provide input on anticipated AA or AER PMR studies [**Review Committee Members, Branch/Lab Chief**]

23. Notify management of anticipated AA or AER PMRs [**RPM, Chair**]

24. Prepare discipline review memos including technical rationale of the AA or AER PMRs and forward to RPM and Chair [**Review Committee Members**]

25. Provide concurrence on discipline review memos [**Branch/Lab Chief, Division Director**]

26. Provide concurred AA or AER PMRs to Office Director, Division Director, Office PMR/PMC Coordinator and the Center PMR/PMC Liaison [**RPM, Chair**]

27. Receive concurred AA or AER PMRs prior to final regulatory decision [**Division Director, Product Office Director, Office PMR/PMC Coordinator, Center PMR/PMC Liaison**]

28. Contact applicant, after internal meetings, to initiate AA or AER PMR negotiations [**RPM/Chair**]

29. Participate in discussions about content and schedule milestones for draft AA or AER PMRs. Obtain general agreement on AA or AER PMR studies and request written agreement from applicant [**Lead, RPM/Chair, Branch/Lab Chief, Division Director**]

- a. Serve as lead to negotiate study/clinical trial design and details, and milestone schedules for all AA or AER PMR studies [**Product Office Clinical Review Committee Member**]
 - b. Participate in the study design and milestone schedules discussions for AA or AER Epidemiological Observational PMR studies [**OBE DE Committee Member**]
30. Receive written agreement from the applicant as an amendment to the file and send the amendment to the Review Committee for review [**RPM/Chair**]
31. Review the amendment to ensure that it is accurate and complete. If not accurate and complete, contact the applicant to correct the amendment [**Lead, RPM/Chair**]
32. Prepare draft approval letter containing the PMR(s) [**RPM/Chair**]
- C. Develop, Review and Process Postmarketing Commitments (506B PMCs or non-506B PMCs)**
33. Identify potential review issues [**Review Committee Member**]
34. Participate in discussions and provide input on potential PMC review issues. [**Review Committee Member, RPM/Chair, Branch/Lab Chief**]
NOTE: The PMC objectives should include the following:
- a. What does CBER want the applicant to do?
 - b. What type of information or data is needed to fulfill the PMC? For example, the type of study results or information we expect.
 - c. When does CBER want the results or report? **NOTE:** If an exact date cannot be determined, then include an estimated date.
 - d. Refer to *Appendix A: Development of Non-506B Postmarketing Commitments (PMC) – Questions and Answers* and Regulatory Reference *R 910.01: Development of Non-506B PMC* for additional information on how to develop and write non-506B PMCs.
35. The PMC should be reviewed for clarity, feasibility, and consistency with other similar PMCs [**Review Committee Member, RPM/Chair, Branch/Lab Chief, Office PMR/PMC Coordinator, Center PMR/PMC Liaison as needed**]
36. Determine if potential review issue should be made an inspectional recommendation or a non-506B PMC. See *R 910.01: Development of Non-506B PMC* for additional information. [**Review Committee Member**]

37. Include the scientific and regulatory rationales for the PMC in the discipline review memo [**Review Committee Member**]
38. Contact the applicant, after internal discussions, to initiate PMC discussions [**RPM/Chair**]
39. Participate in discussions about what needs to be studied, what data or information are expected to fulfill the commitment, and a fulfillment date for the PMCs. Obtain general agreement on PMC studies and request written agreement from the applicant [**RPM/Chair**] NOTE: A fulfillment date should be listed for all PMCs, even if the date is estimated.
40. Review the amendment to ensure that it is accurate and complete. If not accurate and complete, contact the applicant to correct the amendment. [**RPM/Chair**]
41. Prepare draft approval letter containing PMCs [**RPM/Chair**]

D. Draft Approval Letter containing PMRs or PMCs

42. Draft the approval letter using the appropriate letter template. Please refer to CBER's Letter Templates on CBER's Intranet Web page for the most recent approved template. Ensure that the agreed upon PMR/PMC is represented in the letter as submitted by the applicant [**RPM/Chair**]
43. Ensure that each PMR/PMC included in the letter is numbered sequentially [**RPM/Chair**]
44. Provide the "mature" draft approval letter to the Office PMR/PMC Coordinator, the CBER SWG Executive Secretary (for Title IX-related PMRs and clinical, safety-related PMCs), and the CBER PMR/PMC Liaison [**RPM/Chair**]
45. Review the PMRs and PMCs for Office level consistency [**Office PMR/PMC Coordinator**]
46. Forward the "mature" draft approval letter that contains the type of PMR/PMC listed below to the indicated person: [**CBER SWG Executive Secretary** for Title IX-related PMRs and clinical, safety-related PMCs and **Center PMR/PMC Liaison** for all other approval letters containing PMRs/PMCs] NOTE: A letter may need to be reviewed by more than one person, depending on the types of PMRs/PMCs it contains.
 - a. Review Title IX-related PMRs and clinical, safety related PMCs and provide feedback to the CBER SWG Executive Secretary [**CBER SWG Co-Chairs**]

- b. Review Accelerated Approval PMRs and provide feedback to the Center PMR/PMC Liaison [**ADRM or designee**]
 - c. Review Animal Efficacy Rule PMRs and provide feedback to the Center PMR/PMC Liaison [**Senior Advisor for Counterterrorism/Medical Countermeasures or designee**]
 - d. Review device related non-506B PMCs and provide feedback to the Center PMR/PMC Liaison [**Senior Advisor to the Associate Director for Review Management**]
 - e. Review all other types of PMC [**Center PMR/PMC Liaison**]
47. Ensure that the individuals designated above reviewed the “mature” draft approval letter and provide any collected feedback to the RPM/Chair [**CBER SWG Executive Secretary** for Title IX-related PMRs and clinical, safety-related PMCs and **Center PMR/PMC Liaison**]
48. Edit, finalize, and issue the approval letter [**RPM/Chair, Review Committee Members, Branch/Lab Chief, Office PMR/PMC Coordinator**]

E. Enter PMRs or PMCs into Regulatory Database

49. Ensure the approval letter or other notification letter establishing a PMR or PMC is entered in RMS-BLA and uploaded into CBER’s EDR; notify the Office PMR/PMC Coordinator [**RPM**]
50. Enter all PMRs/PMCs from the approval letter into RMS-BLA following the detailed instructions found in the *RMS-BLA Data Entry for Postmarketing Requirements/Commitments and Related Submissions* document [**Office PMR/PMC Coordinator**] **NOTE:** The Office, responsible for approving the submission is responsible for entering all PMRs and PMCs included in the approval or notification letter into the regulatory database.
51. Perform a quality check to ensure that the appropriate fields within RMS-BLA are populated with the PMRs and PMCs from the approval letter or notification letter [**Center PMR/PMC Liaison**]

VIII. Appendix

- A. [Appendix A: Development of Non-506B Postmarketing Commitments \(PMC\) – Questions and Answers](#)

IX. References

- A.** References below are located on CBER's Intranet Web page (unless otherwise noted):
1. RMS-BLA Data Entry for Postmarketing Requirements/Commitments and Related Submissions, located within RMS-BLA
 2. R 910.01: Development of Non-506B PMC
- B.** Web links to the references below can be found in the list following the History Table:
1. Food and Drug Administration Amendments Act (FDAAA) of 2007
<https://www.gpo.gov/fdsys/pkg/PLAW-110publ85/html/PLAW-110publ85.htm>
 2. Food and Drug Administration Modernization Act (FDAMA) of 1997
<https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/significanntamendmentstothefdact/fdama/fulltextoffdamalaw/default.htm>
 3. Federal Food, Drug, and Cosmetic Act, Section 506B
<http://uscode.house.gov/browse.xhtml>
 4. CFR – Code of Federal Regulations Title 21
https://www.ecfr.gov/cgi-bin/text-idx?SID=3ee286332416f26a91d9e6d786a604ab&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl
 5. FDA 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
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM080569.pdf>
 6. FDA Guidance for Industry: Postmarketing Studies and Clinical Trials – Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM172001.pdf>
 7. Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079748.pdf>

8. Postmarketing Study Commitments Public Web site
<http://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm>
9. SOPP 8413: Postmarketing Commitment Related Submissions – Administrative Handling, Review, and CBER Reporting
<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm223772.htm>
10. SOPP 8401: Administrative Processing of Biologics License Application (BLA)
<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm073074.htm>
11. SOPP 8401.2: Administrative Processing of Biologics License Application Supplements (BLSs), [Except Blood, Blood Components, and Source Plasma]
<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm073082.htm>

X. History

Written/ Revised	Approved By	Approved Date	Version Number	Comment
Menzies/Office PMR/PMC Coordinators	Christopher Joneckis, PhD	April 3, 2017	3	Added the role of Center PMR/PMC Liaison,
Menzies/RMCC Working Group	Christopher Joneckis, PhD	December 19, 2014	2	Updated to include revised procedures
Eastep/RIMS	Robert A. Yetter, PhD	Sept 12, 2008	1	Original version