



PMR/PMC Quarterly Web Update Downloadable Database Files

Column Descriptions for `pmrpmc_commitments.xlsx` and `pmrpmc_commitments.txt`

For more information regarding postmarketing requirements (PMRs) and postmarketing commitments (PMCs), please visit FDA's website: [Postmarketing Requirements and Commitments: Introduction](#)

<https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarket-requirements-and-commitments>

[Updated as of April 2024](#)

Column Descriptions for pmrPMC_commitments.xlsx and pmrPMC_commitments.txt

Old Column Order	Old Column Name	Old Valid Values	Column Order	Column Name	Valid Values	Comments/Explanation
1	CMT_ID		1	Internal Identifier		A randomly generated number that is unique for each row. It is generated each time the PMR/PMC Quarterly Web Update Database is delivered. It is NOT a unique number for a PMR/PMC (even within a single quarterly release).
21	CDER_OR_CBER	CB - CBER CD - CDER	2	FDA Center	CBER CDER	The center that manages the PMR/PMC.
	Column added		3	Application Type	BLA NDA	The type of application (new drugs application (NDA) or biologics license application (BLA)) under which the PMR was required or 506B PMC was agreed upon in writing.
17	NDA_NUMBER		4	Application Number		The number that uniquely identifies the NDA or BLA under which the PMR was required or the 506B PMC was agreed upon in writing.

Old Column Order	Old Column Name	Old Valid Values	Column Order	Column Name	Valid Values	Comments/Explanation
18	APPLICANT		5	Applicant Name		For NDAs, in accordance with 21 CFR 314.3, the name of any person who submits an NDA (including a 505(b)(2) application) or an amendment or supplement to an NDA under this part to obtain FDA approval of a new drug and any person who owns an approved NDA (including a 505(b)(2) application). For BLAs, the name of the legal entity to which the license has been issued.
19	PRODUCT		6	Product Name		The trade and non proprietary names of the product approved with this application.
14	NDA_BLA_APPROVAL_DATE		7	Original Application Approval Date		The date the original NDA was approved or BLA licensed by the FDA.
3	CMT_DOC_TYPE	B - Original BLA N - Original NDA O - Other S - Supplement	8	Submission Type	Original Supplement Other	Other: Only applies to CBER-managed PMRs/PMCs that are not under an original or a supplement.
4	CMT_DOC_TYPE_NO		9	Submission Number		The number assigned to the submission by the electronic record keeping system.

Old Column Order	Old Column Name	Old Valid Values	Column Order	Column Name	Valid Values	Comments/Explanation
	Column added		10	PMR/PMC Unique Identifier		<p>A combination of various fields to arrive at a unique identifier.</p> <p>CBER: Application number/Submission number-PMR/PMC Number (example: 012345/67-1)</p> <p>CDER: PMR/PMC Set Number-PMR/PMC Number (example: 1234-2)</p>
	Column added		11	PMR or PMC	PMR PMC	<p>PMR= Postmarketing Requirement</p> <p>PMC= 506B Reportable Postmarketing Commitment</p>
22	SUBPART_FLAG	E - Animal Efficacy Rule F - FDAAA Section 505 (o)(3) H - Accelerated Approval P - Pediatric Research Equity Act Blank (for PMCs)	12	PMR/PMC Type	Animal Efficacy 505 (o)(3) Accelerated Approval Pediatric Research Equity Act 506B PMC	Identifies the authority under which a PMR was required and a 506B PMC was agreed upon in writing.
	Column added		13	CDER PMR/PMC Set Number		This only applies to CDER-managed PMRs and PMCs. A number that uniquely identifies the set of which a PMR/PMC is a part.

Old Column Order	Old Column Name	Old Valid Values	Column Order	Column Name	Valid Values	Comments/Explanation
2	CMT_NUMBER		14	PMR/PMC Number		For CDER-managed PMRs and PMCs, this number indicates the number of the PMR/PMC within the PMR/PMC set. For CBER-managed PMRs and PMCs, this is a sequential number starting with one.
5	CMT_DESC		15	PMR/PMC Description		Description of the study or trial communicated in the letter that required the PMR or specified the PMC that was agreed upon in writing (usually the Approval letter or post-approval Acknowledge New PMR/PMC letter)
6	CMT_STATUS	P - Pending O - Ongoing D - Delayed T – Terminated S - Submitted F - Fulfilled R - Released	16	PMR/PMC Status	Pending Ongoing Delayed Terminated Submitted Fulfilled Released	The status of the PMR/PMC. For status definitions, please refer to Postmarketing Requirements and Commitments: Status and Fulfillment Categories ¹ .

¹ <https://www.fda.gov/drugs/postmarket-requirements-and-commitments/postmarketing-requirements-and-commitments-status-and-fulfillment-categories>

Old Column Order	Old Column Name	Old Valid Values	Column Order	Column Name	Valid Values	Comments/Explanation
7	CMT_STATUS_DESC		17	PMR/PMC Status Explanation		The PMR/PMC Status Explanation field will be populated for PMRs/PMCs that are in a Delayed or Terminated status and all Accelerated Approval (AA) and PREA PMRs. Otherwise, this field will be blank.
15	FINAL_REPORT_DUE_DATE		18	PMR/PMC Original Final Report Due Date		<p>The final report submission milestone date established in the original timetable of a PMR or PMC.</p> <p>Note: For only PREA PMRs: when a Deferral Extension Request for a new final report submission is granted, the Original Final Report Due Date will be replaced by the new final report submission date that was granted by FDA.</p>

Old Column Order	Old Column Name	Old Valid Values	Column Order	Column Name	Valid Values	Comments/Explanation
13	ANNUAL_RPT_RECV_DATE		19	Last Annual Status Report Received Date		<p>For CDER, the date FDA received the applicant's last Annual Report that includes the status of PMRs and PMCs.</p> <p>For CBER, the date FDA received the applicant's Annual Report and an Annual Report with the status of PMRs and PMCs.</p> <p>The Annual Report should be submitted each year within 60 days of the anniversary of the FDA's approval of the NDA or BLA or within 60 days of the alternate date agreed to with the applicant.</p>
8	STUDY_TYPE	Intentionally left blank.				Column removed
9	STUDY_START_DATE	Intentionally left blank.				Column removed
10	PROTOCOL_SUBMISSION_DATE	Intentionally left blank.				Column removed
11	FINAL_RPT_RECV_DATE	Intentionally left blank.				Column removed
12	ANNUAL_RPT_DUE_DATE	Intentionally left blank.				Column removed
16	CURRENT_PROJ_COMPL_DATE	Intentionally left blank.				Column removed