



Electronic Submission Template for Premarket Approval Applications, eSTAR Becomes the Required Format for PMAs and Most Supplements (CDRH and CBER Draft Guidance, September 2026)



What is This About?



- *The FDA issued the draft on September 18, 2026 with a 60 day comment window, covering Original PMAs, Panel-Track, 180-Day and Real-Time Supplements, and 30-Day Notices, which it calls the Designated Application Types*
- *Once final and after a transition period of at least one year, a PMA that does not arrive as an eSTAR will not be considered received unless an exemption applies*
- *The refuse to accept review goes away for Original PMAs and Panel-Track Supplements, replaced by a 15 day technical screen that checks completeness, not content*
- *The standards, timetable, and waiver and exemption criteria issue under section 745A(b)(3) and will be binding when final, and the FDA has said it does not intend to grant waivers*



Implications or More Details of What's Happening



- *The technical screen asks two questions, do the template answers describe the device accurately, and does every applicable attachment question have at least one relevant file behind it*
- *The screen does not start until the user fee is paid, so a payment that lags the upload by a week costs a week of clock*
- *A failed screen puts the submission on hold by email, and you have 360 days to respond before the FDA closes it as withdrawn*
- *A response restarts the review clock at day zero, with a fresh screen inside the first 15 days, and the 45 day filing review for originals and panel-track supplements still follows a passed screen*



Implications or More Details of What's Happening



- *The 510(k) version of this has been mandatory since October 2023 with a 180 day hold, and the records a submission draws on are ones I've produced for several submissions, including 510(k)s.*
- *Exempt items include interactive review responses, appeals, correspondent and address changes, post-decision amendments like final labeling, withdrawal requests, and annual and post-approval study reports, and they still follow eCopy rules*
- *Table 1 runs 22 sections, from Submission Type through Administrative Documentation, and the starred technical sections are mapped to 21 CFR 814.20(b)(3)(v) and (b)(6)*
- *The portal caps each attachment at 1 GB and the whole eSTAR at 4 GB, rejects zip files, limits file names to 124 characters, and the template cannot be edited by two people at the same time*



Thoughts & Analysis



- *The template mirrors the FDA's internal review memo, so the order your reviewer reads in is now the order you have to write in*
- *A completeness check is faster than a content judgment and far less forgiving, because one missing attachment stops a 5,000 page submission cold*
- *A day zero restart turns a small administrative miss into a schedule event that has to be modeled, not hoped away*
- *No waivers means the work is template readiness, and readiness is a document control and program management problem before it is a regulatory one*



Recommendations/Considerations



- *Run a voluntary eSTAR on a real supplement during the transition, with a named owner, a frozen attachment list, and a self-run screen before upload*
- *Map your current PMA outline against the 22 Table 1 sections and record every place a document has to be split, merged, or written to fit*
- *Build the attachment check the FDA runs, a column for every applicable question, a file name in every cell, and a second signature before the package locks*
- *Tie user fee payment to the upload date in the project plan, and treat the fee confirmation as a gate, not a formality*

Recommendations/Considerations



- *Reorganize the design history file index to Table 1 headings now, so the next submission is assembled from the file rather than rebuilt from it*
- *Put the portal limits into your document control procedure, size caps, file naming, no zip archives, one editor at a time on the template*
- *Train the people who will touch the template and keep the record, since training is the first thing an investigator asks for, and cite ISO 13485 clause 6.2 under the QMSR, not the retired 820.25*
- *Comment on the docket before the window closes, because the binding provisions are still open and the 360 day hold and no-waiver position are worth a view from industry*



References



- *Electronic Submission Template for Premarket Approval Applications (PMAs), CDRH and CBER Draft Guidance, GUI00007079, September 18, 2026*
- *Providing Regulatory Submissions for Medical Devices in Electronic Format, Submissions Under Section 745A(b) of the FD&C Act*
- *Acceptance and Filing Reviews for Premarket Approval Applications (PMAs), FDA Guidance*
- *FDA eSTAR Program page, including the CDRH Portal technical requirements and current template versions*

