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Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Docket Number FDA-2026-D-9429; Electronic Submission Template for Premarket Approval Applications (PMA), Draft Guidance

To Whom It May Concern:

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to submit comments in response to the Food and Drug Administration's (FDA or Agency) draft guidance entitled "Electronic Submission Template for Premarket Approval Applications (PMA),"[1] hereafter referred to as the "Draft Guidance."

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical technology. AdvaMed's member companies range from the largest to the smallest medical product innovators and manufacturers. They produce innovations that transform health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, timely product approvals, appropriate reimbursement, and access to international markets.

AdvaMed appreciates FDA's efforts to promote regulatory efficiency and submission completeness through the development of an electronic submission template for PMA submissions. The Draft Guidance provides the Center for Devices and Radiological Health's (CDRH) and the Center for Biologics Evaluation and Research's (CBER) proposed interpretation of key provisions in section 745A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that were amended by section 207 of the FDA Reauthorization Act of 2017 (FDARA) related to providing standards for the submission by electronic format, a timetable for establishment of these standards, and criteria for waivers of and exemptions from the requirements. We believe the Draft Guidance is an important step towards a more modern and streamlined review process for PMA submissions. We agree that the electronic Submission

[1] Issued Sept. 18, 2026, and available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-premarket-approval-applications-pma.

Template and Resource (eSTAR) offers many benefits, and we believe our suggestions will help refine the template and guidance to better suit submitter needs, particularly considering the Agency's proposal to require use of eSTAR to submit a PMA submission in the future.

We respectfully offer our recommendations and comments below. Our recommendations are intended to assist FDA as it works to develop the final guidance on an electronic submission template for PMA submissions and eSTAR templates, more generally.

I. GENERAL COMMENTS

A. Preserve Content Flexibility Currently Afforded under eCopy Format

We support FDA's objective in the development of eSTAR templates to improve submission consistency and enhance review efficiency. However, we urge the Agency to ensure that the eSTAR templates preserve the flexibility that submitters currently have under the eCopy format. While structured eSTAR templates can support improved review efficiency, they should not impose restrictive limitations that could inadvertently increase regulatory burden or that are not supported by existing statute or regulation. A restrictive and inflexible approach to PMA submission eSTAR content, questions, and functionality could lead to fragmented communications that would otherwise be a single comprehensive submission under the eCopy program. For example, FDA's understanding of the device can be facilitated by the inclusion of images, videos, and supporting tables, which can often be large files. The ability to include such attachments in the eSTAR template is an essential feature. Based on experience with eSTAR templates to date, we recommend the template be able to accommodate large submission sizes and large file attachments. Alternatively, the guidance should explain how submitters can submit large files to FDA to ensure they are considered during the review and included in the administrative record for the submission. Further, we believe improvement could be made to the eSTAR template to permit inclusion of embedded attachments. All eSTAR templates should retain the current flexibilities afforded under the eCopy program and should avoid prescriptive content requirements or constraints that are not tethered to regulation or statute.

B. Implement Transparency Best Practices That Align with FDA Priorities

FDA's Transparency Roadmap[2] outlines its "intention to maximize disclosure" while "maintaining IP protections that cultivate a healthy innovation environment." In alignment with this intention, we offer the following recommendations to support FDA's commitment to transparency.

[2] U.S. Food & Drug Admin., *Transparency Makes Modern Regulatory Science Stronger – FDA's Transparency Roadmap*, FDA Voices (Oct. 2, 2026), https://www.fda.gov/news-events/fda-voices/transparency-makes-modern-regulatory-science-stronger-fdas-transparency-roadmap.

1. *Transparency on the Use of AI Review Tools*

   Earlier this year, FDA announced an initiative to update its internal AI tool, Elsa, and the consolidation of its data systems into a new platform, HALO.[3] The announcement described a "significant upgrade" to Elsa and the consolidation of more than 40 "application and submission data sources, systems and portals" into HALO. FDA has not publicly specified what data sources HALO and Elsa have access to. Presumably, content submitted to FDA within eSTAR templates is considered a "submission data source" and submission content submitted through the CDRH Customer Collaboration Portal (CCP) and/or via email can be queried by FDA review staff through Elsa and associated internal platforms. As FDA expands the use of structured eSTAR submissions and AI-assisted review tools, we request the Agency provide transparency regarding how these tools and capabilities are used during the review and what data sources Elsa has access to. In the context of the eSTAR submission templates, we request clarity on whether and how reviewers can use Elsa, or other internal review tools, to query the eSTAR content and how such queries can influence or inform FDA review decisions.

2. *Publication of SMART Review Memo Templates and Stock Deficiencies*

   Lines 164-168 in the Draft Guidance indicate the eSTAR template is structured to closely follow the content of the "SMART" review memo template used by FDA reviewers. However, the SMART review memo template is not a publicly available resource. To enhance transparency and promote review efficiency, we request FDA publish the PMA SMART review memo template and other relevant SMART review memo templates as a companion to the respective eSTAR templates. The eSTAR template and the review memo template are related documents, and a greater understanding of how the tools complement each other will help submitters prepare submissions that contain the appropriate level of content and may streamline the review. With the disclosure of the SMART review templates, we also request that FDA provide its list of "stock deficiencies," which is a separate document that is programmatically linked to the SMART review templates.

3. *Transparent Process for Developing and Modifying eSTAR Templates*

   Additionally, we recommend FDA establish a transparent process for the development and modification of eSTAR templates. Lines 122-125 in the Draft Guidance state FDA intends to implement new versions of eSTAR as relevant policies change and there is an opportunity for stakeholders to provide feedback on the template. In practice, FDA has issued ad hoc updates to the templates that are not pre-announced, do not have a transition period, and do not have a traditional comment solicitation and review process.

[3] U.S. Food & Drug Admin., *FDA Expands AI Capabilities and Completes Data Platform Consolidation*, Press Release (May 6, 2026), https://www.fda.gov/news-events/press-announcements/fda-expands-ai-capabilities-and-completes-data-platform-consolidation.

While cross-cutting guidance documents and consensus standards often have transition periods, we believe a comparable transition period for eSTAR template updates would be appropriate, given the potential effect of those updates on the format and content of regulatory submissions. As the use of the PMA eSTAR templates will become mandatory, it is essential that FDA establish a formalized process for developing and modifying the templates that is transparent, predictable, and considers stakeholder input. More specifically, we recommend FDA proactively announce proposed changes to the eSTAR template and formally solicit and address comments from stakeholders before issuing the updated templates for use and allow time for submitters to transition to the updated template. This will be helpful to both industry and FDA as it will allow all stakeholders to better understand the change(s), train relevant teams, and ensure the changes to the template are consistent with stakeholder understanding of the associated guidance/policy.

4. *Open, Machine-Readable Data Format for eSTAR*

Finally, FDA should, over time, transition eSTAR toward an open, machine-readable data format that supports more automated submission preparation. eSTAR is an interactive PDF that captures much of a submission's content as structured data. However, FDA does not provide a publicly available, versioned technical specification or data dictionary identifying the underlying field definitions, permissible values, or attachment mappings. Without these specifications, submitters cannot populate eSTAR directly from their regulatory information management systems and must manually re-enter information they already maintain, adding burden and increasing the risk of transcription errors. As use of PMA eSTAR becomes mandatory, this burden will grow, particularly given the size and complexity of PMA submissions. Consistent with the transparency principles above, we urge FDA to publish a versioned data dictionary and technical specification for each eSTAR template, accompanied by a detailed change log for each update. FDA already does this for drug and biologic submissions, publishing versioned technical specifications and validation criteria for the electronic Common Technical Document (eCTD), which implements the International Council for Harmonisation (ICH) Common Technical Document (CTD). FDA should also ensure the PMA eSTAR, like the 510(k) and De Novo eSTAR templates, aligns with the International Medical Device Regulators Forum (IMDRF) Table of Contents (ToC), and should build on IMDRF's work toward a harmonized dynamic submission template to support greater automation and interoperability. These steps would reduce errors, accelerate submission preparation, and advance a more modern, efficient premarket review process.

C. Ensure eSTAR Guidance Documents Include Sufficient Information to Understand the Technical Standards of the Electronic Submission Template

As noted in lines 113-115, the purpose of the Draft Guidance is to describe the technical standards associated with preparation of the electronic submission template for PMA submissions, as required by section 745A(b)(3) of the FD&C Act. However, the guidance omits

many technical considerations that are relevant for submitters to be aware of when completing the eSTAR template (e.g., specifications to be able to use the eSTAR PDF, maximum file size, permissible file types). Some information regarding the technical specifications appears piecemeal on other CDRH resources (e.g., website for the eSTAR Program[4] and in the Frequently Asked Questions (FAQ) section of the eSTAR template); however, this information is notably omitted from this eSTAR Draft Guidance. We recommend all relevant technical information be included in the guidance document so the guidance may serve as a comprehensive reference tool for submitters when preparing a PMA eSTAR submission.

We recognize that use of eSTAR submissions may enhance review efficiency and transparency by standardizing the format and content for each premarket submission type. To further enhance efficiency and transparency, we suggest the Draft Guidance describe technical specifications and tips for preparing a PMA eSTAR submission, similar to the content in the eCopy guidance.[5] For example, we recommend the guidance list the file types (e.g., PDF, JPEG) that are acceptable for attachments to the eSTAR template. The guidance should also provide options for submitting content that is relevant for the review but is not able to meet the technical specifications (e.g., how to submit content in a file type that is not supported by eSTAR). The eCopy guidance includes recommendations on file naming conventions that we have found helpful, and we request this eSTAR guidance include similar recommendations for attachment naming conventions that will facilitate the review.

D. Allow Waivers and Exemptions under Appropriate Circumstances

The Draft Guidance indicates that, following finalization and the implementation date, Designated Application Types other than those identified as exempt in lines 237 through 246 must be submitted electronically unless an exemption or waiver applies. The Draft Guidance does not explicitly address participants in FDA's Voluntary Improvement Program[6] (VIP). This valuable program promotes consistency and regulatory efficiency, in part, by allowing participating sites to use modified submission formats for certain PMA submissions. We recommend the guidance clarify that submitters may continue to leverage the modified submission formats available to VIP participants, where applicable, in lieu of eSTAR templates.

Additionally, the Draft Guidance states, "…FDA has not identified any particular circumstances appropriate for a waiver… and does not intend to grant requests for waiver" (lines 249-251). We believe FDA should afford some flexibility for waivers in the unique circumstances that invariably arise. We recommend the Draft Guidance replace the referenced prohibitory language

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[4] U.S. Food & Drug Admin., *eSTAR Program* (updated June 1, 2026), https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program.
[5] U.S. Food & Drug Admin., *eCopy Program for Medical Device Submissions* (Dec. 3, 2025), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions.
[6] U.S. Food & Drug Amin., *Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program* (Sept. 15, 2023), https://www.fda.gov/media/158180/download.

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with "[t]he applicant should work with FDA if they believe a waiver from electronic requirements is needed." The Draft Guidance should also describe a process through which waivers or exemptions may be sought by submitters and granted by FDA in specific cases.

II. SPECIFIC COMMENTS

AdvaMed's specific comments are attached in tabular form below, which include detailed recommendations along with our specific rationale to assist FDA as it works to finalize the Draft Guidance.

Collectively, the recommendations above and in the accompanying table will help submitters to better understand the functionality of the PMA eSTAR template and ensure the capabilities align with the submitters' needs, which in turn, will help promote efficiency in the preparation and review of complete submissions.

AdvaMed appreciates the opportunity to provide comments. Please do not hesitate to contact me at 202-434-7208 or ALoloei@advamed.org if you have any questions.

Respectfully Submitted,

Ana Loloei

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Vice President
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No.	Line #	Comment/Rationale	Proposed Change
1.	General Comment	FDA is proposing making the eSTAR template mandatory for the Designated Application Types with the exception of PMA modules and certain exempted submissions (e.g., annual reports). It has been experienced with other eSTAR submissions, such as IDEs, that while using PreSTAR, the maximum file size limits can be restrictive and cause issues with the submission process. As such, we recommend the Agency address this file size limitation to ensure that the eSTAR template is sufficiently ready to handle the larger submission types such as original PMA, panel track supplements and 180-day supplements including extensive data and supporting documentation.	Suggest increasing the maximum allowed file size while ensuring the usability of the eSTAR template is maintained (e.g., not significantly slowed or laggy in responsiveness).
2.	General Comment	With eSTAR comes improved opportunities for reporting and tracking of file status. As part of the move to mandatorily use eSTAR templates for PMA submissions, it is recommended that there should be updates on the inspection request, Day 100 meeting, and scheduling status of such requests. This is needed to better understand the PMA review process. We propose showing this on the Customer Collaboration Portal (CCP) for better transparency to review staff and the sponsor. This is needed to better clarify the PMA review process and ensure timely tracking of review status so that the sponsors can plan the appropriate PMA submission timelines ensuring timely commercialization of safe and effective medical devices to patients.	Suggest enhancing the PMA review-tracking functionality within the CCP to include visibility into critical review milestones such as Day 100 meetings, GMP/QMSR inspections, BIMO inspections, and other key PMA review activities. Displaying estimated timelines for these activities would provide sponsors with greater clarity into the overall PMA review process and progress of FDA's review to help support planning for submission and commercialization activities.
3.	General Comment	FDA is proposing the mandatory use of the eSTAR template for 30-day notices. In the current voluntary version, there is only a single section to upload data supporting the proposed change for the subject device. This is deficient because the section should expand out to match the required sections as outlined in the FDA guidance for 30-day notices. This is needed to avoid confusion and review delays because reviewers are unable to find	Suggest ensuring that the eSTAR template documentation sections match those listed in the FDA guidance for 30-Day notices.

No.	Line #	Comment/Rationale	Proposed Change
		the specific documents called for in the guidance, which have all been grouped together in the eSTAR because of the current implementation.	
4.	General Comment	This comment is not limited to PMA submissions and concerns the Biocompatibility section in the eSTAR template. The eSTAR template appears to require that sponsors need to include a separate section for each material. However, feedback from the eSTAR Help Desk states that sponsors should bundle materials with the same contact type or intended use to better streamline eSTAR preparation and review. Separate materials tables are likely still needed. Updating the help text for this section could greatly help reduce file size and facilitate review of this complex topic.	Recommend updating the Biocompatibility text section to be better in line with FDA review staff expectations and aid with decreasing the file size of the eSTAR package.
5.	General Comment	FDA is proposing requiring the eSTAR template for the Designated Application Types except PMA modules and certain exempted submissions (e.g., annual reports), which will result in a potentially very large and cumbersome submission to navigate. In our experience, the current version of the PMA eSTAR template has resulted in challenges for the review staff and they have requested assistance from the submitter to locate content within the eSTAR template, causing review delays and confusion. As such we recommend including a document architecture site map, or other type of index function, to aid with submission navigation.	Recommend including a document architecture site map, or other similar index-type feature, that contains the links to all the required and expected sections in the eSTAR to aid with submission navigation.
6.	General Comment	Not limited to PMA submissions – the current eSTAR template does not capture interactive review deficiencies, responses, FDA reviewer feedback, and meeting minutes that are part of the complete administrative record of the submission. We recommend implementing a mechanism to allow communications and associated documentation between submitter and review team to be appended within the eSTAR template to ensure an accurate and complete record of the documents, requests, key discussions, and agreements made during the PMA review process.	Suggest ensuring eSTAR can capture and consolidate the complete administrative record, including interactive review, responses to the deficiencies from submitter, FDA review feedback, and meeting minutes, as needed, under a PMA review.

No.	Line #	Comment/Rationale	Proposed Change
7.	General Comment	Not limited to PMA submissions – it needs to be more streamlined to transfer ownership of eSTAR files. Currently, if sponsors wish to assign a new owner of an eSTAR document, they need to essentially build a new one from the ground up. For PMA submissions this is not tenable, especially because the files are so large and the review times are much longer, increasing the probability that the file owner might need to be changed since that person may no longer be at the company or out on medical leave.	Suggest improving the process for file ownership transfer.
8.	General Comment	For the PMA eSTAR template, we recommend the Agency provide more guidance and explicit locations for where documents should go. It has been found with other submission types such as with IDE and 510(k) submissions that some document types did not have specific location(s) identified, e.g., Investigator's Brochure and Performance Testing. As a result, the review staff could not find the documents and had to ask for them interactively or convert the submission to a pre-submission which greatly delayed the sponsor's review timeline. In order to streamline the review process, this issue should be addressed.	Suggest ensuring that the eSTAR template for PMAs has sufficient instructions and explicit sections for where documents should be located/uploaded to ensure review staff can find the needed data and content.
9.	187-189	We recommend harmonizing the wording across the document, by clarifying the process for notifying applicants, including communication mechanisms. The language proposal is consistent with line 183 of the Draft Guidance.	Suggest revising as follows: "If a response is not received within 360 days of the date of technical screening deficiency notification, FDA will consider the PMA/PMA supplement to be withdrawn and the submission will be closed in the system, **with prior notification to the applicant via email**."
10.	192-195	We recommend clarifying when the review clock starts, to align with FDA's guidance titled "Electronic Submission Template for Medical Device 510(k) Submissions," which states that the review clock starts on the day the submission was received by FDA.	Suggest revising as follows: "When a submission passes technical screening (whether it is the first technical screening or multiple have occurred), the review clock **starts on the day the submission was received by FDA and** continues for the rest of the review process. ~~**At this time**~~ **Once the submission passes technical**

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		We also recommend clarifying how FDA will notify applicants, as "electronically" could refer to a wide range of communication means. The proposed language is consistent with line 183 of the Draft Guidance, which states that FDA will notify the applicant via email. Finally, we recommend replacing "At this time" with "Once the submission passes technical screening" to make clear that notification follows technical screening, not receipt of the submission.	**screening**, FDA will notify the applicant ~~**electronically**~~ **via email** and the submission proceeds to substantive review."
11.	210-212	We recommend including a dedicated entry in Table 1 for Predetermined Change Control Plans for Devices (PCCPs), consistent with current regulatory frameworks and industry practice.	Suggest adding the following: **Information requested: Predetermined Change Control Plan (PCCP)** **Description: Include the PCCP, if applicable.**