DuVal CLIENT ALERT

Passing on Tribal Knowledge of FDA Law

Volume 23
Issue 07

PLAYBILL

The eSTAR and I

An adaptation of the classical musical The King and I!
Directed by DuVal & Associates

The eSTAR and I

Prologue

In Rodgers and Hammerstein's Broadway hit The King and I, set in the 1860's, the King was fascinated with science and innovation. He hired a schoolteacher, Anna, to be a governess to his children and educate them, to help modernize the country. In our adaptation, set in 2022, the King (FDA) implemented the voluntary eSTAR program to help modernize (and standardize) 510(k) and De Novo submissions. This submission format becomes mandatory starting October 1, 2023, for new 510(k) submissions in the kingdom. To help you gain experience and fully leverage this new submission format, we have created a four-part Client Series in tune with lyrics of the popular song from this musical "Getting to Know You":

Act I: Getting to Know You – This Act provided an overview of the FDA's eSTAR program and templates.

Act II: Getting to Know All About You – This dynamic Act provided more detail and strategy for how to use the eSTAR submission format and complete the templates.

Act III: Getting to Like You – In this riveting Act, we shared best practices to optimize eSTAR submission presentation.

Act IV: Getting to Hope You Like Me – This final Act provided insights as to what to expect from the FDA review process of eSTAR submissions.

Encore: We hope you enjoyed the eSTAR series and are actively using the eSTAR templates to prepare your 510(k) or De Novo submissions, and now Pre-Subs ("PreSTARs"). ***As the eSTAR program continues to evolve, please check the Encores of this Client Alert series for updates on the eSTAR program***. We also invite you to join us for two

eSTAR discussions to be held during the upcoming RAPS Convergence in Montréal, Canada from October 3 - 5, 2023. The eSTAR discussions will both occur on October 5, 2023.

Meet the Cast and Crew

FDA
THE KING

FDA'S eSTAR PROGRAM
& I

Lisa Pritchard
VP Regulatory, Quality, Clinical & Engineering
Director

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Director

The eSTAR and I

Encore – Additional Performance Information

Please periodically check the Encores of the DuVal & Associates eSTAR Client Alert series for eSTAR program updates.

SCENE I: Scope of the eSTAR Program

FDA continues to evolve the eSTAR program to include additional electronic submission templates and FDA Centers. As of June 2023, eSTAR templates are available for the following submission and device types to the Centers listed in the table below. Note that IVD or non-IVD devices include device-led or biologic-led combination products.

Submission Type	Device Type		CDRH	CBER
	IVDs	Non-IVDs		
Pre-Submission	✓	✓	Pre-STAR available now for voluntary use	Not available
510(k)	✓	✓	Available now:	In pilot phase for up

Submission Type	Device Type		CDRH	CBER
	IVDs	Non-IVDs		
(Traditional, Abbreviated, Special)			**Voluntary**: through Sep 31, 2023 **Mandatory**: starting Oct 1, 2023 (except for exempt submissions)	**to nine participants.** Submit a statement of interest to FDA to participate
De Novo	✓	✓	**Available now for voluntary use** (no mandatory transition defined at this time)	**Not available**
Premarket Approval (PMA) / Health Canada Harmonized Submission	✓	✓	**In pilot phase for nine participants.** Pilot program closed to enrollment.	**Not available**

The most recent update to submission types is the beta release on June 9, 2023, of an eSTAR template for submission of Pre-Subs through the CDRH Q-Submission program. Dubbed the "PreSTAR," while this template is currently limited only to Pre-Subs to CDRH, it is expected that this will expand to include other types of Q-Submissions, 513(g) submissions, and Investigational Device Exemptions (IDEs), and other Centers, in the future. Current estimates from FDA are to include 513(g) functionality late in 2023, original IDEs in 2025, other Q-Sub types in 2026 and IDE supplements in 2028. Like a weather forecast that is more than a few hours out, these estimates are subject to change.

FDA is currently evaluating eSTAR content for PMA submissions within its pilot program for submission to Health Canada (discussed below). Before the PMA functionality can be released, approval of the Paperwork Reduction Act (PRA) is required. It is currently estimated that the earliest the PMA

content will become available in the eSTAR template is November 2023 (watch for updates on this). The initial release is expected to include functionality for traditional original PMA submissions and certain supplements (e.g., 180-day, panel track, real time review). Other types of PMA submission types to follow (e.g., modular original, 30-day notifications, and annual reports).

In Jan 2023, FDA initiated a pilot program for nine manufacturers to use the eSTAR template to complete a submission for Class III or Class IV Health Canada devices in parallel with submission of a 510(k) or De Novo to FDA. At this time, FDA reports that 7 of the 9 participants have completed submissions. At this time, the pilot is closed, and FDA is evaluating the results. This functionality will not be finalized and opened to users outside of the pilot until after all submissions have completed their review process. Stay tuned for updates!

SCENE II: eSTAR Submission Options

Manufacturers may submit completed eSTAR submissions to FDA as shown in the table below. If submitting by mail to the FDA's Document Control Center (DCC) (option only available prior to Oct 1, 2023), you can find the relevant DCC address in FDA's eCopy Guidance document. For information on how to use the Electronic Submission Gateway for CBER 510(k)s or combination products where CBER is the lead, please refer to Regulatory Submissions in Electronic Format for CBER-Regulated Products through the Electronic Submission Gateway. For CDRH submissions through the Customer Collaboration Portal (CCP), available now and required starting October 1, 2023, refer to Act IV of the eSTAR and I Client Alert series for details on using this convenient technology that has likely caused much sadness among FedEx personnel.

Submission Type	Device Type		CDRH	CBER
	IVDs	Non-IVDs		
Pre-Submission	✓	✓	**CCP:** Available now and mandatory after Oct 1, 2023 **By Mail to DCC:** Only allowed before Oct 1, 2023	Not Applicable
510(k)	✓	✓	**CCP:** Available now and mandatory after Oct 1, 2023 **By Mail to DCC:** Only allowed before Oct 1, 2023	Electronic Submission Gateway OR by Mail during the pilot phase
De Novo	✓	✓	**CCP:** Available now and mandatory after Oct 1, 2023 **By Mail to DCC:** Only allowed before Oct 1, 2023	Not Applicable

SCENE III: eSTAR Template Updates

The eSTAR templates continue to evolve. Always check the FDA's eSTAR Program website to ensure you are using the most current template. Major version changes in the template have a grace period (typically 60 days), but if you use an older version when a newer version is available, this may result in receiving more Additional Information questions. As FDA's requirements change (e.g., recognized standards, new product codes), the eSTAR templates are updated to request the latest information. If an eSTAR template changes after you have started writing your submission, you can use the Import feature in the eSTAR template to import data from the previous version template to the new version template. Note that the Import feature will import XML data from the previous eStar template but will not import attachments.

Unfortunately, at this time, the FDA does not provide a list of changes between template versions. Therefore, continue to check for template updates during your submission writing, and update if necessary to the most

recent version using the "Import Data" feature in the "Verification" section near the end of the eSTAR template to ensure your submission is as complete as possible.

SCENE IV: Tips and Tricks

E-Signature Signed eSTAR Submissions: The current eSTAR templates for 510(k) submissions have an option to provide the required Truthful and Accurate statement via an e-signature or via a separate signed statement provided as an attachment. If you use the e-signature option, once the Truthful and Accurate Statement is signed, Attachments to the eSTAR cannot be changed unless that e-signature is cleared from the pdf form. For example, if you receive a request for Additional Information (AI) and you need to open the original eSTAR submission to respond to an AI request, the person who signed the Truthful and Accurate Statement must clear their signature. If that person is not available to clear their signature, you cannot make any updates to the document. Tips to avoid this issue are to either 1) save a copy of the eSTAR submission just before e-signature and use that copy for future updates, or 2) provide the Truthful and Accurate statement through a signed attachment.

Adobe Enhanced Security: Adobe Acrobat and Acrobat Reader enable enhanced security by default. FDA recommends that you bypass this restriction when completing the eSTAR pdf template to speed up content input time. To do this, in Adobe:

1) Choose **Preferences**.
2) From the categories on the left, select **Security (Enhanced)**.
3) **Deselect** the **Enhanced Security at Start Up.**

The End

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DuVal & Associates
Drug, Device and Food Law

DuVal & Associates is a boutique law firm located in Minneapolis, Minnesota that specializes in FDA regulations for products at all stages of the product life cycle. Our clientele includes companies that market and manufacture medical devices, pharmaceuticals, biologics, nutritional supplements and foods. Our clients range in size from Global Fortune 500 companies to small start-ups. As one of the only dedicated FDA regulatory law firms in the United States, our mission and absolute focus is providing our clients appropriately aggressive, yet compliant, guidance on any FDA related matter. We pride ourselves not only on our collective legal and business acumen, but also on being responsive to our client's needs and efficient with their resources. DuVal & Associates understands the corporate interaction between departments like regulatory affairs, marketing, sales, legal, quality, and clinical, etc. As former industry managers in the drug and device spaces, we have been in your shoes. Our firm has extensive experience with government bodies. We understand what it takes to develop and commercialize a product and bring it successfully to the market and manage its life cycle. Impractical or bad advice can result in delays or not allow for optimal results; while practical, timely advice can help companies succeed.

CALL ON US FOR ASSISTANCE WITH YOUR REGULATORY NEEDS

For more information, visit our website at www.duvalfdalaw.com or call Mark DuVal today for a consult at 612.338.7170 x102.