DuVal CLIENT ALERT

Passing on Tribal Knowledge of FDA Law

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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 share best practices to optimize eSTAR submission presentation.

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

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

Act III: GETTING TO LIKE YOU

(If you missed Act one, click here. Act II, click here)

SCENE I: Providing Advocacy

In the King and I musical, Anna advocates for her role as the governess, her value, and her influence. At our submission training events, we speak about the importance of advocating for your device in a premarket submission vs. simply providing the required evidence. Advocacy involves explaining why the device is important and why the testing completed is appropriate and sufficient to meet the statutory requirements to support a 510(k) substantial equivalence determination or a De Novo grant decision.

A traditional eCopy submission flows easily from section to section, building from an Executive Summary to device information, to a substantial equivalence discussion or classification information, and then to the details of the testing and labeling. Each section can be created to be like a "chapter" in the book with connecting content between chapters. In contrast, the eSTAR submission format, although also organized in sections,

is more disjointed than a traditional eCopy, and thus more challenging to create the device story. The change in submission format requires a change in submission strategy to create this essential advocacy. Below are a few tips to accomplish this:

1) **Executive Summary:** The eSTAR template includes the option to provide an Executive Summary at the end of the document in the Administrative Section. We consider the Executive Summary to be essential and recommend always providing one. We have also provided feedback to the eSTAR program staff to make this document a requirement and move its location to the start of the template.
2) **Cover Letter:** The eSTAR template starts with a Cover Letter as the first attachment. Due to its current prominent location vs. the unfortunate location of the Executive Summary, we recommend that the Executive Summary be discussed in the Cover Letter so that the review team knows that it has been prepared and is the appropriate starting point for the review process.
3) **Advocate Along the Way:** In the text fields or individual attachments within each major content section of the eSTAR template, provide information to help FDA understand the device clearly and to provide rationale for why the testing completed is appropriate and sufficient to support a decision determination.

SCENE II: Managing Attachments

When you have completed the population of an eSTAR submission, you will end up with what feels like a mountain of attachments. Organization of these is key. Below are a few tips on strategic use and organization of attachments:

1) **Naming:** Name the PDF files in alignment with the content section they belong to. Use concise names and follow a consistent format. Reference eCopy rules for appropriate naming conventions as some characters (such as an em dash) will result in not being able to attach

the PDF document. Including version notation in the filename is helpful if you later need to update an Attachment in response to a request from FDA for Additional Information. For a numbering scheme, FDA recommends using the IMDRF TOC chapter numbers that display as hover text when you hover over an attachment.

2) Consolidating: Attachments can be in PDF format, Microsoft Word or Excel. On FDA's eSTAR website, the FDA recommends that applicants combine attachments of similar content (e.g., biocompatibility test reports) when possible, to reduce the number of individual attachments. A helpful way to do this is to create an attachment and include exhibits to that attachment. Particularly for large PDF attachments, add bookmarks and potentially even a Table of Contents to help you and the FDA easily navigate to specific reports and information. However, some FDA reviewers have expressed a preference for individual test reports vs. compiled attachments of similar information. Our recommendation is to consider how many individual files you have and then combine them, if appropriate, in a practical way with attention to easy navigation for a reviewer.
3) Ordering: As you populate the eSTAR template, the attachments remain wherever attached in each section, however, when you open the Attachment Navigation Pane on the left side of the template, the attachments are listed in alphabetical order by file name. If you want the attachments in the Navigation Pane to reflect the order as attached in the eSTAR template, you will need to add a sequential numbering prefix to each attachment to force that order. A related tip is to name the Executive Summary attachment with a "00" or "000" prefix so that it shows up at the beginning of the attachment list.
4) Compressing: Processing of an eSTAR submission may be delayed if the eSTAR PDF exceeds 1 GB in size. To reduce file size, compress images and video files and use appropriate resolution as needed to support accurate review.

SCENE III: Addressing Text Box Limitations

The eSTAR template is sophisticated but not yet sufficiently designed to manage all the complexities and permutations of premarket submission content. To address current limitations, we offer the following tips:

1) Text Boxes: Information in text boxes cannot be formatted (bold, italicized, underlined, bulleted, etc.). Therefore, we recommend limiting information provided in text boxes and instead point to information provided in relevant attachments. Because the text boxes are small with scroll bars, it may be easier to write the text in a Word document and then cut and paste it into a text box. This can also be helpful for managing team reviews of submission content during publication of the template while preventing inadvertent changes.
2) Canned Choices: If the template does not provide flexibility to provide requested data appropriate for a new device, use the text boxes to provide an explanation and/or reference an attachment that provides further explanation. For example, when providing shelf-life information, there is a field for entering the claimed shelf life. However, the available options for units do not include "weeks" as an option; a workaround is to enter "days" and provide the explanation in the accompanying text field.

SCENE IV: Using Latest Technology

FDA notes on their eSTAR website that there is a JavaScript bug in certain Adobe Acrobat Pro applications that causes dynamic PDFs that use JavaScript, such as the eSTAR template, to run slower than normal. The slowness bug is not present in FoxIt PDF Reader, any version of Adobe Acrobat Pro 2017, Adobe Acrobat Pro DC, the latest Adobe Acrobat Pro

Windows version, or Mac Adobe Acrobat Pro CD 64-bit. If you are experiencing slowness, FDA recommends that you:

1) Disable Protected Mode by going to Edit->Preferences->Security (Enhanced) and uncheck the "Enable Protected Mode" checkbox at the top, or
2) Switch to one of the unaffected applications listed above, or
3) Contact FDA for help at esubpilot@fda.hhs.gov if you are unable to switch to an unaffected application and are experiencing slowness.

SCENE V: FDA eSTAR Support

FDA continues to refine the eSTAR template based on user feedback and changing guidance, including updating eSTAR popups, help text, FAQ section, and the supporting eSTAR website. When we have experienced issues and could not find the answer within the eSTAR website or guidance, we have found the eSTAR support staff to be incredibly prompt and helpful. To maintain this valuable resource without overburdening them, we recommend that if you run into issues, first check the FAQ section of the template or FDA's eSTAR website before contacting eSTAR staff.

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.