DuVal CLIENT ALERT

Passing on Tribal Knowledge of FDA Law

Volume 23
Issue 05

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 provides 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 IV – GETTING TO HOPE YOU LIKE ME

(Previous Acts: Act I, Act II, Act III)

SCENE I: Completing and Submitting your eSTAR Submission (Opening Night)

At last, your eSTAR submission is complete! How can you be sure? At the top of page 1 of the eSTAR, the banner will be in bold green underline font that reads "STATUS: eSTAR COMPLETE." If you see this, do a little happy dance to congratulate yourself on a job well done – seeing this banner after hours of submission preparation is strangely satisfying. If instead you see a banner in bold red underline font that reads "STATUS: eSTAR INCOMPLETE.," do not dance. Instead, use your energy to navigate to the end of the eSTAR form, to the section titled "Verification" to identify what information is missing. Note, it is possible to submit the eSTAR PDF while the banner is red but will result in an eCopy hold.

After completing your eSTAR submission and your happy dance, the next step is to submit your beautiful eSTAR submission to FDA using either a traditional eCopy process or FDA's Customer Collaboration Portal. We strongly recommend using the CCP, as it is much faster, simpler, and provides status updates for 510(k) submission during the review process. We love it! If you don't have a CCP account, you can easily sign up for free and still do this faster than the time to create an eCopy, print out the cover letter, burn a CD-ROM or flash drive, package to send to FedEx, get the package to FedEx, pay to have FedEx ship it, and then wait until it is delivered to determine if it passes the eCopy review and can be acknowledged. To use FDA's CCP, just log in to your account, select "Send Submission," select "eSTAR," drag and drop the completed eSTAR file to upload it, and once it is uploaded, click "send." This leaves much more time for dancing than the traditional eCopy option.

SCENE II: The FDA Review Process (The Review Critique)

Just as a Broadway production has to endure the reviews that come after opening night, the eSTAR submission will have to undergo FDA review after it is submitted. At least the eSTAR review is a bit more predictable than a Broadway review.

After the submission has been received by FDA, an Acknowledgement Letter will be issued, starting the FDA review clock. Because of the design of eSTAR, the submission will go directly into substantive review, with no acceptance review required. Note that there is a technical review completed within the first 15 days to ensure the eSTAR submission is complete and no applicable sections were omitted. Issues can happen during this review if questions throughout the eSTAR are answered incorrectly for the specific device, preventing fields that should have been required from becoming visible to allow their completion. If the FDA identifies missing information, they will place the submission on eCopy Hold and notify the applicant via

email. Applicants then have 180 days to provide a replacement eSTAR submission to address the issues or the submission is considered withdrawn.

The formal review time allowed for an eSTAR submission is the same as a traditional eCopy submission; 60 days for substantive interaction and 90 days (statutory) for full review for a 510(k), or 120 (statutory)/150 (MDUFMA) days for a De Novo (no substantive interaction goal for De Novo submissions). Our experience has indicated that the initial substantive interaction can often occur much faster for an eSTAR submission, thanks to its format that aligns with FDA internal review templates.

Like an eCopy, the review process for an eSTAR may lead to a decision for interactive review if the review team questions are easy enough to address through emails, while the review clock continues. Alternately, it may lead to a formal request for additional information, which will pause the review clock – or, since we have a Broadway theme going – will cause an intermission.

Scene III: Intermission (Responding to Additional Information Requests)

Additional Information (AI) requests will pause the FDA review clock, which will not be resumed until a complete response to the request for Additional Information is submitted. Beware of sending a response that does not address all the questions, as this can lead to an Incomplete Response letter, which again stops the FDA review clock, and resets it to where it was originally paused. When developing responses to deficiencies, make sure to review the associated FDA guidance for developing and responding to deficiencies.

For now, the AI response can either be submitted as a traditional eCopy or as an eSTAR; beginning October 1, 2023, the eSTAR format will be required to respond to AI requests for new 510(k)s. Note that if a 510(k) is submitted as an eCopy before October 1, 2023, responses to AI requests for that submission are not required to be submitted in eSTAR format.

In our experience, responding to AI requests is the most challenging aspect of the eSTAR template at this time. This is because the AI section of the eSTAR template does not allow for attachments, instead requiring that AI responses be provided in text boxes for each deficiency. This format is fine for very straightforward questions that do not require any additional documentation and can be adequately handled through plain text in a text field but it does not work for complex responses with graphs, tables, etc. To address this shortcoming, we recommend the following process:

1) Responding to AI requests via the eSTAR template requires an update of the original eSTAR file that was submitted to FDA. Open your original eSTAR submission and on page 2, change the "Application/Submission Type" from "New Application/Submission" to "Additional Information" and enter the assigned submission number (e.g., K###### or DEN#####). This will update the eSTAR PDF form with a new section located near the end of the PDF form titled "Additional Information Response."
2) The AI Response section of the template provides text fields for you to enter each deficiency (enter multi-part deficiencies in separate areas) and your response for each. If more information is needed beyond what can be provided in a text field, update the original attachment related to the deficiency topic with the response, and then reference that update in the text box. The Executive Summary and formatting of the attachment will be important at this step. Use the Executive Summary to indicate which eSTAR attachments have been updated and provide specific location information where FDA can find the response content. To help provide visibility for both FDA and you, add the submission and supplement number to the eSTAR attachment name so it is clear what attachments have been amended.

Epilogue

The FDA deserves the honor of a center stage bow for their excellent work to create the eSTAR templates for IVDs and non-IVD devices for 510(k) and De Novo submissions. We expect eSTAR will work well for 90% of submissions; for the remaining 10% of submissions that have unique and complex content demands, more interaction with FDA eSTAR staff may be needed to address template limitations. When these situations arise, we have found the eSTAR staff to be incredibly helpful and prompt with their responses (special recognition and thanks to Patrick Axtell and Sajjad Syed). After completing many eSTAR submissions, we appreciate and applaud the FDA for their efforts to advance fully electronic 510(k) and De Novo submissions!

We hope that this Client Alert series helped you in 1) Getting to know eSTAR (what is it), 2) Getting to know all about eSTAR (strategies for use), 3) Getting to Like eSTAR (best practices for making it work for you), and 4) Getting to hope eSTAR likes you (expectations from review and responding to deficiencies). We encourage you to download the eSTAR template and become familiar with this format before its use becomes mandatory on October 1, 2023. Once you gain experience, you may find yourself singing more lines from the song "Getting to Know You":

Getting to know you
Getting to feel free and easy
When I am with you
Getting to know what to say

Haven't you noticed
Suddenly I'm bright and breezy?
Because of all the beautiful and new
Things I'm learning about you
Day by day!

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.

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