DuVal CLIENT ALERT

Passing on Tribal Knowledge of FDA Law

Volume 23
Issue 02

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 provides an overview of the FDA's eSTAR program and templates.

Act II: Getting to Know All About You – This dynamic Act will provide 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 will 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

Kathy Herzog
Sr. Regulatory, Quality, Compliance Consultant
Director

The eSTAR and I

Act I: GETTING TO KNOW YOU

SCENE I: What is eSTAR?

In early 2022, FDA released a voluntary program called "electronic Submission Template And Resource" (eSTAR) to help improve 510(k) and De Novo submission quality and consistency through use of guided, standardized templates. Two interactive eSTAR PDF templates are available for free download from FDA's eSTAR website: one for in vitro diagnostic (IVD) devices and one for non-IVD devices. Each of these templates allows you to select if the template will be used for a 510(k) or De Novo submission for that device type.

The eSTAR templates provide an alternative submission format to traditional electronic copy (eCopy) submissions for use by all medical device applicants who plan to submit a 510(k) or De Novo submission to the Center for Devices and Radiological Health (CDRH) or the Center for Biologics Evaluation and Research (CBER). At this time, eSTAR cannot be used to

submit 510(k) or De Novo applications for combination products and is not yet available for PMA submissions.

The eSTAR program facilitates implementation of FDA's mandate under section 745(A)(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and as amended by section 207 of the FDA Reauthorization Act of 2017 (FDARA), to advance the preparation, submission and review of regulatory submissions for medical devices solely in an electronic format.

In FDA's guidance for the eSTAR 510(k) program FDA notes the following benefits of eSTAR:

- Automation (form construction, autofilling);
- Content and structure complementary to CDRH internal review templates;
- Integration of multiple resources (guidances, databases);
- Guided construction;
- Training not required;
- Use of familiar software application (Adobe Acrobat Pro);
- Automatic verification of completeness; and
- Free to use.

SCENE II: Getting to Know the eSTAR Templates

The eSTAR templates are interactive PDF documents that guide you through submission preparation by automatically generating required information fields based on responses to questions. Help features are provided throughout and include links to applicable guidance documents, Special Control guidances, and tips for what type of information to provide. Information is provided through a combination of free text fields and attachments, as allowed by the template.

To begin an eSTAR submission, you must first choose the correct eSTAR template for your device type from FDA's eSTAR website:

- Non-in Vitro Diagnostics eSTAR (currently Version 2.0)
- In Vitro Diagnostics eSTAR (currently Version 1)

Once you select the appropriate template, begin by following the directions in the Introduction, Key, FAQ, and Version History sections. To learn the range of possible information requested in the template, it is helpful to exercise all response options and review resulting data fields. When completing the template for a premarket submission, it's critical that you correctly answer all questions accurately for your device as required content will only appear based on how you answer questions. Inadequate or incorrect responses that led to omission of subsequent and relevant content may lead to an early hold in the technical review of your submission.

The content requirements in the eSTAR template are the same as for an eCopy 510(k), however, the content order differs and some of FDA's forms are built into the templates and don't require independent submission. Another key advantage of the eSTAR submission is that eCopy rules do not apply (e.g., file naming conventions, size limitations).

SCENE III: Submitting an eSTAR Submission

eSTAR submissions are subject to the same user fees associated with the submission type (510(k) or De Novo). You must pay the user fee in advance of submission as the user fee payment confirmation form must be included as an attachment in the eSTAR template.

The eSTAR templates feature an automated verification for completeness: when the eSTAR template is fully populated and ready for submission, the banner at the top of the first page will change from red to green. This final pdf document is your eSTAR submission. You may then submit the eSTAR submission through the FDA's Document Control Center (DCC) as you would an eCopy submission, or you may submit an eSTAR submission

through FDA's Client Collaboration Portal (CCP). This portal allows you to directly upload the eSTAR submission to FDA with no requirement for any physical (CD or paper copy) submission to DCC. For more information on FDA's CCP, see our Client Alert on this topic here.

Note that beginning October 1, 2023, use of the eSTAR template and submission using either the CCP (for submissions to CDRH) or Electronic Submission Gateway (for submissions to CBER) will be mandatory for new 510(k) submissions. These requirements will be waived for interactive review responses, amendments, appeals/requests for supervisory review, substantive summary requests, change in correspondent amendments, and amendments after final decision (i.e., add-to-files).

An exciting development in eSTAR submissions is the announcement of a new pilot program in which an eSTAR may be submitted for joint review by FDA and Health Canada. Information about the program is available on the Health Canada and FDA eSTAR Pilot page. This pilot program is seeking 9 device sponsors who will be ready to submit an eSTAR to both Health Canada and FDA within 6 months of acceptance. This program is only open for non-IVD non-combination medical devices that are considered Class III or IV for Health Canada. Submission pathway for the U.S. may be 510(k), De Novo or PMA. The released eSTAR template does not yet include functionality for PMA submissions, so inclusion of PMA-eligible products in this pilot signals eSTAR function for these products is not far away. Pilot participants will receive an eSTAR template that includes information enabled for both FDA and Health Canada. While it appears that this pilot will support preparation of one submission (providing efficiencies for submission preparation), it also appears that they will undergo separate review processes by each of the regulators. This could be an interesting consideration for companies planning submissions to both geographies near the same time and hopefully will pave the path for further harmonization of global submission requirements in the future.

SCENE IV: eSTAR Submission Review

The formal review time allowed for an eSTAR submission is the same as a traditional eCopy submission for a 510(k) (90 days) or a De Novo (120 days for De Novo). Because the eSTAR templates verify completeness, eSTAR submissions are (currently) exempt from the standard Acceptance Review used with eCopy submissions. This provides a significant advantage to avoid a Refuse to Accept (RTA) Hold and associated delay in starting the FDA review clock. A pre-screening assessment is still done by FDA within the first 15 days after eSTAR submission acknowledgement which includes virus scanning and a technical review to assess if all required information is provided. If the FDA identifies missing information, the submission will be placed on hold and the FDA will notify the applicant via email. Applicants then have 180 days to provide a replacement eSTAR submission or the submission is considered withdrawn.

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.