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 provides 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

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Director

The eSTAR and I

Act II: GETTING TO KNOW ALL ABOUT YOU

(If you missed Act I, click here)

SCENE I: Choosing Between eCopy or eSTAR Submission Format

Prior to October 1, 2023, any 510(k) or De Novo submission may be completed using either eSTAR or the traditional eCopy process. Beginning October 1, 2023, eSTAR will be mandatory for new 510(k)s but will (for now) remain optional for De Novo submissions.

Before eSTAR use becomes mandatory, how can you make the decision of which format to use, and when should this decision be made? Below are two key factors to consider for this decision:

1) **Avoiding the Acceptance Review**: A principal advantage of the eSTAR program is that the current "Refuse to Accept" (RTA) policies do not apply as the eSTAR templates are designed to automatically verify completeness. In 2022, DuVal and Associates partnered with

IntroWorks and NAMSA to conduct an industry-wide survey regarding experience with the FDA 510(k) program. Over 250 medical technology executives, regulatory affairs, and industry consultants responded to the survey. One of the key findings from the survey results is that there are often issues with the conduct of the RTA policy. Many clients come to us for help to respond to an RTA that was issued, sometimes with requests that exceed the scope of the RTA policy. We have seen cases where the RTA policy has been used to extend the time for review, by including additional review during the Acceptance review (conducted before the official review clock begins). If you have experienced issues with the RTA policy previously or want to avoid this potential delay to the FDA review clock, choosing the eSTAR submission pathway is an attractive option. Note: although the RTA policy does not apply, FDA technical review may identify issues (i.e., if eSTAR template was not used correctly or correct responses provided, preventing relevant fields from becoming enabled), and FDA substantive review may identify additional content requirements (e.g., interactive review requests, or requests for additional information).

2) Timing: Where you are in the submission preparation process is another factor to consider when deciding between eSTAR and eCopy format. Although the data expectations are the same for the two programs, the packaging of the information is significantly different, as described in SCENE II below. It is challenging to switch from eCopy to eSTAR in the middle of the submission preparation process and vice versa. We strongly recommend that this decision be made as part of the submission strategy development before the submission preparation begins. It should not impact the preparation of support documentation such as test protocols and reports or product labeling, so the decision can be made after these pieces are already in draft form.

SCENE II: eSTAR Template Details

Download the Correct Template

From the FDA eSTAR website, download the appropriate eSTAR template for your device type (either a non-IVD device or an IVD device). Each template then allows you to select if this submission is a 510(k) (including traditional, abbreviated, or special) or a De Novo. The templates are free to download. Importantly, once downloaded, the templates are not linked to FDA's website as you complete them; FDA will not have visibility to the contents until after the submission is formally sent to FDA.

The eSTAR Template Content Flow

The data expectations are the same for an eCopy and eSTAR submission, however the content order differs between the two formats as shown in the Table below. Note that with the eSTAR format, you do **not** need to separately prepare the Indications for Use page (Form FDA 3881) or a Declaration of Conformity (if applicable) with your eSTAR submission since these are built into the eSTAR template. The CDRH Premarket Review Submission Cover Sheet (Form FDA-3514) also does not need to be prepared for an eSTAR submission. Use of eSTAR also provides an option for either automatic preparation of a 510(k) Summary generated from text fields in the template, or manual preparation that is provided as an attachment in the eSTAR submission.

eCopy Format (FDA's Guidance *Format for Traditional and Abbreviated 510(k)s*, issued September 2019)	eSTAR Format (FDA's Guidance *Electronic Submission Template for Medical Device 510(k) Submissions*, issued September 2022)
1. User Fee Cover Sheet (Form FDA-3601)	1. Submission Type

eCopy Format (FDA's Guidance *Format for Traditional and Abbreviated 510(k)s*, issued September 2019)	eSTAR Format (FDA's Guidance *Electronic Submission Template for Medical Device 510(k) Submissions*, issued September 2022)
2. Premarket Review Cover Sheet (Form FDA-3514) 3. 510(k) Cover Letter 4. Indications for Use Statement (Form FDA-3881) 5. 510(k) Summary or Statement 6. Truthful and Accuracy Statement 7. Class III Summary and Certification 8. Financial Certification or Disclosure Statement 9. Declarations of Conformity and Summary Reports 10. Device Description 11. Executive Summary/Predicate Comparison 12. Substantial Equivalence Discussion 13. Proposed Labeling 14. Sterilization and Shelf Life 15. Biocompatibility 16. Software 17. Electromagnetic Compatibility and Electrical Safety 18. Performance Testing – Bench 19. Performance Testing – Animal 20. Performance Testing - Clinical	2. Cover Letter/Letter of References 3. Submitter Information 4. Pre-Submission Correspondence and Previous Regulator Interactions 5. Consensus Standards 6. Device Description 7. Proposed Indications for Use 8. Classification 9. Predicates and Substantial Equivalence 10. Design/Special Controls Risks to Health, and Mitigation Measures (for Special 510(k) submission only) 11. Labeling 12. Reprocessing 13. Sterility 14. Shelf Life 15. Biocompatibility 16. Software/Firmware 17. Cybersecurity/Interoperability 18. Electromagnetic Compatibility (EMC), Electrical, Mechanical, Wireless and Thermal Safety

eCopy Format (FDA's Guidance *Format for Traditional and Abbreviated 510(k)s*, issued September 2019)	eSTAR Format (FDA's Guidance *Electronic Submission Template for Medical Device 510(k) Submissions*, issued September 2022)
	19. Performance Testing (Bench, Animal, Clinical) 20. References 21. Administrative Documentation a. Executive Summary b. Financial certification and disclosure statement (Form FDA-3454 and/or 3455) c. Clinical Trials Certification Form (Form FDA-3674) d. Truthful and Accurate Statement e. User Fee Form 22. Amendment/Additional Information (AI) responses

Populating the eSTAR Template

The eSTAR templates are designed as interactive PDF files. The files start off very short and grow based on the responses provided to various questions. It is very important to carefully review each question for applicability to your device. If you miss an applicable section, your submission may be incomplete (even if the banner at the top of the eSTAR template has turned green and states that it is complete) and could result in FDA placing your submission on hold during the technical review process. It can be helpful at the beginning of an eSTAR journey to walk through the applicable template with key members of the product team to ensure all

questions are assessed and answered correctly so you fully understand the data expectations.

The eSTAR templates include help features that provide links to applicable FDA guidances, Special Control guidances, and other information to help ensure complete expected information is in each section. We encourage you to click on the help links and review this information to ensure that the expected information is addressed and to minimize requests for additional information.

As you advance through the template, requested information is provided either in text boxes or with attachments. If an attachment is required, you cannot skip it and must provide an attachment as requested, otherwise the template will not register as complete. Attachments can be in PDF, Microsoft Word or Excel format. 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 with its own exhibits (e.g., like its own topic-focused submission). Particularly for large PDF attachments, add bookmarks and potentially even a Table of Contents to help you and the FDA easily navigate to separate reports and information.

If you have complex information (e.g., graphs, large tables, etc.), this will need to be provided in an attachment. Text boxes in the eSTAR PDF templates are small and include scroll bars. Unfortunately, at this time, you cannot provide any formatting in a text box (bold, underline, bulleting, etc.) so consider limiting the information in the text boxes and use attachments strategically.

Some eSTAR template sections require a lot of information and others are simple to complete. For example, the biocompatibility section is very comprehensive and requires a significant amount of information to address applicable biological endpoints for each tissue contacting material based

on contact type and duration. The amount of information requested in this section exceeds the information that is typically summarized in a 510(k) or De Novo submission – it typically resides within the test reports but will need to be pulled forward for population of the template. If biocompatibility testing is considered to not be needed (e.g., previous testing is being utilized, or patient contact is limited to commercially available components that are not being modified), note that the template will require justifications for each biocompatibility assessment that applies based on the nature of patient contact. To minimize burden, we have found it helpful to devise a justification that can encompass all the assessments so that the text field information can be copied and pasted into the individual text fields. Therefore, previewing the template prior to preparing submission content is important to avoid surprises and ensure you have the data needed to complete the template.

510(k) Summary Options

The eSTAR template for 510(k) submissions provides an option to automatically generate the 510(k) Summary based on applicable content from the many text fields within the eSTAR template. Alternatively, you can also prepare and provide a 510(k) Summary as an attachment to the eSTAR submission. If using the auto-populate feature, ensure text fields do not include any confidential information that you would not want to become publicly available. The eSTAR template does not provide a preview of an auto-generated 510(k) Summary. Because of this, we have chosen to manually prepare the 510(k) Summary to help manage the content of this public-facing content of the 510(k) submission.

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.