Technical Section Overview Transcript

Hi, my name is Laura Moussa and I'm a reviewer on the Animal Bioengineering and Cellular Therapies (ABCT) Team. We're going to be talking about how the technical sections are structured in eSubmitter. Before we get started, I wanted to say that if you have any broad questions (e.g., what type of submissions are needed for your product), then you can send your inquiries to AskCVM@fda.hhs.gov. That will be routed to the appropriate person within the Center. You can also reach out to our project management team. If you have any issues with eSubmitter itself and require technical help, you can email CVMeSubmitter@fda.hhs.gov. If you have any questions during the presentation, please put them into the chat box and I will answer them at the end.

For this demonstration, we will be working in the eSubmitter test environment because our ABCT templates are still under development. This means that they will not be available on the eSubmitter on your computers after this demonstration. They should be available on October 1, 2018.

Once you have started a template in eSubmitter and you have selected "INAD" as the document and have identified the product category(ies), et cetera, when you get to Screen 5.0, you will choose "Major Technical Section (P)" as the submission type. Then, based on the selection that you made on the first screen regarding what type of product it is [intentionally genetically altered (IGA) animals, cell-based products, gene therapy products, or other], the types of technical sections that are available for your product type will populate the second drop-down menu.

This part of the demo is intended to give you a sense of what type of technical section templates you would expect to see in eSubmitter. We recommend that you work with the ABCT Team and the Center to ensure that all information for your product is submitted. This table is just to show what is will be populated in eSubmitter based on the product category selection.

For an IGA animal, the technical section choices in that drop-down menu that I just showed you would be: Product Characterization, Genotypic and Phenotypic Durability Assessment and Plan, Claim Validation, Human Food Safety, and Environmental Assessment. Those are the major technical sections.

For cell-based products, the technical sections would be: Product Characterization; Target Animal Safety; Effectiveness; Human Food Safety; Chemistry, Manufacturing, and Controls; and Environmental Assessment.

For gene therapy products, you would be looking at: Product Characterization (as needed); Target Animal Safety; Effectiveness; Human Food Safety; Chemistry, Manufacturing, and Controls; and Environmental Assessment.

If you select Other as the product category, then it will allow you to pull up any of the available technical section templates (since we have used that as a catchall category for products that may be combination products or for which templates do not exist right now): Product Characterization; Target Animal Safety as well as Genotypic and Phenotypic Durability Assessment and Plan; Effectiveness as well as Claim Validation; Human Food Safety; Chemistry, Manufacturing, and Controls; and Environmental Assessment.

The minor technical sections for each product type are the same, which are the same as traditional products: Labeling and All Other Information (M submissions)

Audience question: If the animal does not have an intended use in the food chain, why would there be a human food safety assessment.

Answer: When the INAD A-0000 comes in, there is place to indicate whether the animal is intended to enter the human or animal food supply. If the answer is that the animal is not intended to enter the human or animal food supply, then the requirements for human food safety are drastically reduced.

Audience question: Will the presentation be available at a later time?

Answer: Yes, all presentations are recorded and will be available on our website.