I-A-OT Transcript

Hi, my name is Laura Moussa and I'm a reviewer on the Animal Bioengineering and Cellular Therapies (ABCT) Team. Today I'll be demonstrating how to establish an INAD file using CVM's eSubmitter tool. The template that I'm using is currently in our test environment, which means it will not be available on the eSubmitter on your computers after this demonstration. All of our templates will be available on October 1. To begin with, when you are making an ABCT submission, after you've opened eSubmitter, you want to click on the left-hand side of the screen under Menu Options: the button called "Create New Submissions". You can see that the ABCT team has their own set of templates and a little summary that shows what types of products are eligible to use these templates. If you click the "Next" button, then you are prompted to enter a descriptive name and a file name, and then click "Create".

Now I'm going to move over to the test environment to show you the INAD. On the first screen, under the "Document Type" question, you will specify that this is an investigational new animal drug (INAD). The next set of questions asks for some product information. We ask that you identify the product category [intentionally genetically altered (IGA) animals, cell-based products, gene therapy products, or other; other products are anything that doesn't fit into one of the first three categories]. We next ask for a product description and information on whether or not the animal comes from a food-producing species. If you identify that the animal is from a food-producing species, you will be prompted to identify whether the animal is intended to enter the food supply. If you say no to this question (Is the animal from a food-producing species?), then the sub-question (Is the animal intended to enter the food supply?) will not activate. Because this is a submission where you are trying to establish the file, you will click "No" under the question "Is this submission for a currently established file or application?".

The next couple of screens are for administrative information. On Screen 2.0, you are requested to input information about who owns the file. On Screen 3.0, you are requested to identify the Responsible Official as well as input contact information for that person. On Screen 4.0, you will input information regarding who is putting the information into eSubmitter. If that person is the same as the Responsible Official, then you can click "Yes" on the first question and the subsequent questions will be grayed out. If "No", then you will be prompted to input the information for the user of eSubmitter.

On Screen 5.0, you are selecting the type of submission: "Establish INAD File (A)". Because you already stated on the first screen that it is for a file that is not currently established, there is only one option in the drop-down menu. There is also only one drop-down option under Submission Classification Code. Also, you only have one option in the "Select Review Division". The final question will be grayed out because you have previously said that is for a file that has not been established. If you are trying to amend an A-0000 submission, then you will need to go back to the first screen and say that the file has already been established in order to answer the amendment question.

The next screen is "Product Description", so we ask for a summary of the product identification (this can be information regarding what the product is and how you intend to use it), as well as the product established name and proprietary name. You are also prompted to select the animal name, and depending on what you select there, you might be prompted to select the class. The next question is for the proposed indication and the next question is for route of administration. The "Route of Administration" question does not have the blue circle next to it to indicate that it is a required question. This is because for

some of our products, there is no route of administration in the traditional sense, and so this is an optional question. There's a drop-down menu so that you can choose the route if it applies to your product. The final question on the screen is whether or not the product has been granted a MUMS designation.

Under the "Initial INAD Submission" tab, you can see that the first screen is general information. We ask whether you are requesting that the information be publicly available. If you select "Yes", then we ask that you detail the scope of the disclosure. If you select "No", then that sub-question will go away.

The next screen is the "Referenced File Node", so if you're using information that's in another file, then you will be prompted to input that information here and provide the submission number(s). As you can see in the help text, the information that you input here must begin with a character (V for VMF, I for INAD, N for NADA, or G for General Correspondence) followed by six digits in order to be validated by the system. The next question asks you to provide a summary of the information in the referenced file(s). If you say that there's no information provided in referenced files, then the sub-questions will go away.

If you have selected on the first screen that you have an IGA animal product, then Screen 3.A will populate and all of the questions will be required. We ask you to provide an overview of the project as well as a description of the construct or alteration. The latter question allows input in both freeform text as well as the attachment of files. We ask that you state the species and class as well as describe the methods or technologies use to produce the alteration. The final question is to allow you to provide us with any additional information that you think that we might benefit from knowing (this is not a required question, as seen by the lack of the blue dot). You can input information in the text box or as an attached file.

If you have indicated that you have a cell-based product, then Screen 3.B will activate and its questions will be required. These are very similar product identification questions where we ask for the objective and a description, and then there's some product-specific information. For cell-based products, these include a description of the donor animal, the cell/tissue source, the relationship of the donor and recipient, and the formulation. We also ask whether the product is combined with any other article. If you say yes, then we will ask for a description of the article. If you say no, then the sub-question will go away. Then we have our catchall for any additional information at the end.

For gene therapy products, Screen 3.C will activate and there are very similar questions: an overview of the objective and a description of the product. Then we ask for a description of the recombinant DNA constructs as well as the technology and the formulation; a description of the target cells, any assessment for shedding viral vectors, any information on off-target effects, and again we end with the additional information question.

For other products, we have kept the questions very high level: an overview of the project objectives, a product description, identification of the species and class, a list of indication(s), the dose and route of administration (these questions are optional, if they apply to that product).

As stated before, if you have not selected the product category on the first screen, then the product screens will not populate. You do need to select at least one product category for your INAD. If you select IGA animals on the first screen, then Screens 3.B, 3.C, and 3.D will not activate.

The final screen is the overview of any competed studies. We ask that you summarize the pilot studies or completed studies in the text box and you can also attach study reports if you choose to do so. If you have any additional information, there is a box at the end to put it in.

If you have any questions about your product, what types of templates you should be using, or any other product-specific questions, then you can route all of your inquiries to this email address: AskCVM@fda.hhs.gov. If you have any issues with eSubmitter itself and require technical help, then you can email CVM eSubmitter@fda.hhs.gov.