**Center for Veterinary Medicine Second eSubmitter Webinar, Afternoon Break-out Session Target Animal Review Divisions 1, Webinar for Demonstration of the Opening a New Investigational New Animal Drug (INAD) File**
**August 22, 2018**

Hello and welcome to the CVM eSubmitter webinar training for the template for opening a new Investigational New Animal Drug file, or INAD, also known as an A-0000 (A- quad-zero) submission.

First, you will click on "Create New Submission". However, for the purposes of this demonstration, I have already filled out the template and will be walking you through it. So, I will click on "Open Existing Submission".

On the first screen you will select your document type from the drop-down menu. In this scenario, you will select "Investigational New Animal Drug File, or document type I. Because you are opening a new INAD you will answer the question, "Is this submission for a currently established file or application with "No". Because of your response to this question, no information can be input into the text box beneath the question. The Document Number will be assigned to you upon submission of this request.

Next, you will use the right arrow to advance to the next screen.

Please see the webinar on "How to Use the eSubmitter Tool" for more information on filling out the various fields for screens on this page.

Depending on your response to the question if you are a US company, the screens available on this tab will differ. If you are not a US company, you will complete screen 3 to provide information for the US Agent or US employee.

If you are a US company, alternatively, you will fill out screen 4. Screen 4 is for the responsible official, which is the person to whom correspondence will be addressed from CVM.

And lastly, on screen 5, you will complete the information for the individual who is submitting the information to the Agency.

Next, on screen 6, from the drop-down menu, you will select the INAD Submission Type. In this case, because we selected "No' on the first screen to the question, there is only one option, "Establish INAD File" or submission type A; likewise, there is only one option for the second box for submission classification code.

Next, you will select the review division to which you are submitting the application. Based on the type of the investigational drug, select the appropriate review division. For our demonstration today, I have selected my division, HFV-120, the Division of Production Drugs.

For the last question on the page, you'll note that again, because of the submission type, this question is grayed out, as it is used only to indicate an amendment to a current pending submission.

Click the right arrow to proceed to the next tab.

On screen 1.0 specific to the submission type, you provide the general information.

The first question asks if you are requesting that information in the INAD be made publicly available. If you answer "yes" to this question you will need to either provide information in

the text box or attach a PDF document, by clicking on the button with the green plus sign, to attach a PDF that details the scope of the disclosure.

The next question asks if you wish to include "Early Information", as described in this note. For the purposes of this demonstration, I will select "yes" so that we can demonstrate that screen.

On the next screen, you will provide the product description.

First, you will click "New" which will bring up a page that looks like this. You can see that for the purposes of this demonstration, I have used placeholder information not reflective of the information you would actually provide in your submission.

First, you will answer the question if this drug has a USP monograph. Next, you will provide the established name. For the Proprietary Name, it is understood that you may not yet have a proposed proprietary name for your product. If this is the case, feel free to leave this information blank.

Next, you provide information on the pharmacological category, dosage form, dosage form variation, route of administration, and route of administration variation.

In the last two text boxes at the bottom of the screen, please provide the target animal species and class. We refer you to Guidance For Industry #191, Appendix III, for more information on CVM's current thinking for animal class nomenclature.

If you have a proposed indication, please provide it in the last text box. Again, we understand that you may have multiple indications or are unsure of the proposed indication at the time of opening the INAD. Please provide what information you do have.

Once this screen is completely filled out, you'll proceed to the next screen.

If you have additional information about the drug or drug product, you may attach a PDF at this time. Note that this is information that does not rise to the level of Early Information and provides more high-level information. Once you've added this information or if you do not have additional information and click "No", please proceed to the next screen.

If you indicated that you have Early Information to provide to CVM by clicking "yes" to the question on screen 1, this screen will be provided for you to give additional information. First, you will select the types of Early Information included, such as pilot study reports, peer reviewed literature references, or a white paper discussion supporting specific elements of the product development plan. If you have a different type of Early Information, please select, "Other", and then, you are prompted to provide a description in the text box beneath.

In the second text box, please provide a narrative describing the context in which the Early Information should be reviewed, as instructed in the memo field. Lastly, don't forget to attach the documentation by clicking the button with the green plus sign.

Screen 4 reminds you of the requirement to utilize appropriate investigational labeling for studies using the investigative drug product and it requires you affirm, by clicking the box at

the right of the screen, your acknowledgement of this requirement. You must check this box to have your request to open a new INAD processed.

Next, we move to the last screen where you can provide additional comments for CVM's consideration. If you have additional information or comments, you can provide those in text box or by attaching a PDF by clicking on the green plus sign. And with that, this concludes our walk-through demonstration of the Opening a New Investigational New Animal Drug File, and we refer you back to webinar on "How to Use the eSubmitter Tool" for more information on closing, packaging, and uploading your completed submission. Thank you.