Demonstration Webinar for Opening a JINAD eSubmitter Template Transcription

This webinar will assist you in creating a submission for Opening a JINAD in eSubmitter. My name is Jennifer Kodak and I am a Consumer Safety Officer in the Division of Generic Animal Drugs.

Before we get started with the demonstration there are a few details that have been discussed earlier today in the morning webinar sessions, that will not be repeated in this demonstration. This demonstration will be recorded and at the end of the demonstration there will be a question and answer session utilizing the chat box in WebEx. Please type your questions in the chat box at any time. If there are questions that are outside the scope of this demo, CVM would be happy to address your question/concern if you contact us directly. If we run out of time for questions there will be another Q&A webinar hosted on September 19th.

Before we move to the eSubmitter template tool itself I would like for everyone to click and view the full screen.

A dummy file has been created to illustrate the eSubmitter template for **Opening a JINAD**.

As mentioned, this webinar will not cover the following pieces of the eSubmitter template already covered in the webinar session earlier this morning:

As you see on the screen we have CVM ONADE SUBMISSIONS Tab Information and the following sections will not be covered-the firm information, us agent information if applicable, responsible official information and the submitter information. also, the details of the product description information section will not be covered along with the packaging the complete submission.

I would like to briefly revisit how to move between tabs and folders in eSubmitter. On the screen you will see tabs broken down into folders. For you to access those folders you can double click on the folder and the question or information areas will come up. You can also use the arrows in the green circles above and they will take you to each folder and once you finished with on the last folder it will take you to the next tab.

I would also like to make you aware of the different icons you will see throughout the eSubmitter template. If you see these icons the indicate the following: light bulb-Display hint and will help guide you to answer the question or provide the appropriate information. You also have a blue dot which required an answer and a red exclamation point which indicates critical to answer in order to move forward.

Let's get STARTED

Under the document information folder under the CVM ONADE Submissions tab, this is the first screen you will see when using the Opening a JINAD eSubmitter template.

I would like to mention that when opening a JINAD as you now can see on the screen under the Document Information you see on the screen, the main difference between the Opening a JINAD template from all other JINAD templates is the second question. Let's take a look. The document type of course is the generic investigational new animal drug file or JINAD file from the drop down list. The second question is "Is this submission for a currently established file or application?" Here is the indicator for opening a JINAD. This is going to be your first submission opened under the generic investigational drug file, so you would answer NO on the radial buttons.

Ok. Let's go to our Submission Type Selection tab. Here we know that it is a JINAD but now we need to indicate what of JINAD we are submitting. So in the drop down since we said No to the original question "Is this submission for a currently established file or application" then the only option you have is **Establish JINAD File (A).** The second question is **select the Submission Classification Code. Here** in the drop down the only option you have is **Other; Unclassified (OT).** And for the Review Division to which you are submitting, the only option here is the Division of Generic Animal Drugs or HFV-170.

So now we have determined our submission type code. We can move on to our next tab which is the initial JINAD Submission. As you can see your first folder in this tab is General Information. Because you are a generic product copying a reference listed product it is going to ask you what that reference listed new animal drug product document number is and the firm name associated with that reference listed new animal drug you are copying.

Ok we can move on to the product description where I will give you a brief overview. Here to start the process of the product description for your generic drug product you would select the plus button and what would come up are questions in detailed form. Here it is requesting that you provide the information whether this is a drug product for a USP monograph, your generic Product Established Name, your generic Proprietary Name, if applicable at this time, your Pharmacological Category, your dosage form and there is a drop down list, if specified you will need a Dosage Form Variation, there is also a drop down list secondary to your initial dosage form. You will move on to select your Route of Administration, again you will have a drop down list, I have chosen injection and here injection requires a route administration Variation. So then you chose from the drop down list, I choose subcutaneous. Ok, we move on to the common animal name. Here I selected horse but there is a drop down list which includes some species to require you to select a class from the list and if applicable a subclass. As part of the generic product description, the eSubmitter template is requesting that you provide us with proposed strengths, including units of measurement and sizes. So what you would do is click on the memo field and type in your text of your proposed strengths and sizes. Again, in the second field you would click on the memo field and enter the text and providing us your Proposed Indications for use of your generic product description. And lastly, under the product description of your generic drug product the question here is there an associated suitability petition. I have No on the screen now, but if it is associated with a suitability petition, then you would select Yes and your next question is "Was a suitability petition approved?" If yes, it will highlight the area for you to enter the date of approval. If no, it shades it out. If yes or no, you would still need to provide the FDA dockets number for the suitability petition along

with all that was requested under the suitability petition and you can select all that apply. This includes dosage form, route of administration, strength or active ingredient. For the purposes of this demonstration I am going to select no.

Part of opening a JINAD eSubmitter template, we are requesting reference listed product description also along with your generic product description. Here you would select the plus sign to add a new item. It would bring a list of detailed questions. As you can see on the screen they are identical to the questions as seen in the beginning for the generic product description, so you would enter whether the drug product has a USP monograph, your product established name, the proprietary name for the reference listed drug product, the pharmacological category and again the dosage form whether it requires a dosage form variation, the route of administration and the route of administration variation, along with the common animal name and whether you are required to add the class and/or subclass. And as you can see, the answers to those questions are identical to the generic product description unless there was a suitability petition. If you have multiple species, you will have to continually add those until you have all the species indicated along with the dosage form and the rest of the questions answered. For the purposed of this demonstration we only did one species. Here it is asking for the approved strengths of the reference listed drug, again you would click on the memo field and enter the text for the approved strengths and sizes. The next field is requesting we enter the indications for use. You would click on the memo field and enter the text. The difference here for the reference listed drug product in comparison to the generic drug product are there existing patents for the reference listed drug. If yes, please indicate those in the memo field along with the patent numbers and corresponding expiration dates. For the purposes of this demonstration I am going to select no. Also, it is requesting are there any unexpired marketing exclusivities. If yes, please indicate those marketing exclusivities protected and the corresponding expiration dates in the memo field as text. So we have finished the reference listed product description folder. Let's move on to the next folder.

Here it is asking if you any supporting information for the drug or drug product. For the purpose of this demonstration I have selected no, but if you select yes, it brings up a screen to attach that supporting information. This can multiple documents or one document. And for you attach those documents you can select the plus sign and add the file from your file system, that file system being your computer or desktop. The other way to attach the supporting information is adding it from your submission list that you created earlier before submitting your eSubmitter template. Here is the submission list file manager. This was discussed in detail in the earlier webinars this morning. For the purposed of this demonstration we are going to select no.

The next folder or screen is requesting investigational labeling. Here it is asking you to affirm that the appropriate investigational labeling required under 21 CFR 511.1(a) or (b) will be affixed to the investigation drug product for studies conducted under 21 CFR 511.1 (a) or (b), respectively. If you do not check the box there is failure to accept the affirmation and you will not be able to process the new JINAD request.

And lastly, you will have a section for comments. Here you can attach or enter any additional information you would like to include in the submission. Here you select the memo field and enter your text. Otherwise, you can attach a pdf file based on the desktop system or your file manager.

I would also like to go back to the product description and reference listed product description. One of the things I would like to mention is that when we answered the questions in the detailed screen there is also an option for viewing a list screen which you can see what you entered from the detail screen allowing you to see if you added the appropriate species, the appropriate established name, and you can scroll through and take a look. I just wanted to add that in there.

Ok, let's go back to comments. We have finished completing our eSubmitter template but have we. There are two ways to determine if your eSubmitter template is complete. One way is to take a look at the folders under each tab. Each folder will have a green check mark if complete. Those check marks indicate that each folder or section is complete. Go to your next tab, it is complete and then your last tab you take a look and there is a folder with a question mark. It is indicating that you have not completed something specific in that section. Here again it looks like another folder is not complete in the investigation labeling section. What you can do is click on the folder and look to see what information was missed. Another way to determine exactly what was missed or incomplete in the template is to go to the top tab output, click missing data/validation issues report, you will receive a report output dialog, the options on the screen for viewing are determined by the sponsor, you click ok, and you will receive a missing data/validation issue report. Here it says I missed under the Initial JINAD submission, section for the reference listed product description, specifically the list of indications protected by the marketing exclusivity and expiration dates. In section 4.0 Investigational labeling, I did not affirm the appropriate labeling was required under 21 CFR 511.1(a) or (b) was affixed.

So let's go ahead and correct those so that we have a complete eSubmitter template. I need to look at it the detail screen in order to determine what is missing. Here under are there any unexpired marketing exclusivities I selected yes but did not indicate what was protected by those marketing exclusivities. I will go ahead and select no. The second area I found incomplete under investigational labeling was that I didn't check that I affirm that the appropriate investigational labeling that was required was affixed. Let's go ahead and check that. It looks like I have all my check marks on the folders. If you truly want to confirm that the template is complete before you package your template, you go ahead and run the validation report again and see if any information is missing and it will show up no issues with your eSubmitter template.

We have completed the opening a JINAD or establishing a JINAD eSubmitter template demonstration.

LET'S GO TO OUR QUESTIONS IN THE CHAT BOX

Silence

Do we have any questions?

If no one has any questions, then our next eSubmitter demonstration will be submitting a meeting request under a JINAD file or ANADA application at 1:30 pm. If you have any Additional questions or issues later after the recordings you can be send them to cvmesubmitter@fda.hhs.gov

Thank you for joining us.