Demonstration Transcription-Generic Product Meeting Request -JINAD/ANADA

Welcome to the demonstration webinar for submitting a meeting request under a Generic Investigational New Animal Drug (JINAD) File or Abbreviated New Animal Drug Application (ANADA). This webinar will assist you in creating a request for a meeting in the Division of Generic Animal Drugs. 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 session that will not be covered in this demonstration. This demonstration is recorded and at the end of the demonstration there will be a live question and answer session utilizing the chat box in WebEx. Please type your questions in the chat box at any time. If we are unable to answer your questions during the question period there will be a Q&A webinar hosted on September 19th available to you. 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.

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

A dummy file has been created to illustrate the eSubmitter template for a meeting request under the JINAD file and ANADA application

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

As you see on the screen Under Creating CVM ONADE SUBMISSIONS Tab the sections that will not be included are the document information, Firm Information, US Agent information if applicable, Responsible Official Information and the submitter information. Also, the details of the Product Description Information will not be covered along with the packaging of this submission.

Before we get started with the eSubmitter template I would like to go over some housekeeping items. One would be how to move between tabs and folders. 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 you will see on the screen the questions or information areas that need to be filled in. Once you have done that you can click on the tabs or you can use the arrows above in the green circles and they will move you to the next folder or your previous folder and once you finished with on the last folder it will take you to the next tab.

The other items I would like to go over are the icons you will see throughout the eSubmitter template. One being the light bulb which is a display hint that will help you determine the appropriate information to answer the questions, the blue dot which indicates a response is required and the red exclamation point which also requires a response, but you have to answer in order to move forward in the template.

Let's get STARTED

On the screen you will see the document information folder. Here is where you start the process to activate certain questions within the template. It asks you what the document type is and there is a drop down list to choose from. Here I am going to choose the generic investigational new animal drug file or JINAD. The meeting request template also has the same exact questions under the option Abbreviated New Animal drug application or ANADA. So when referring to the JINAD file the information is applicable to the ANADA for meeting requests.

The next question is "Is this submission for a currently established file or application?" At this point you should have already established a JINAD file or have an application already open and approved so it allows you to request a meeting with CVM. You will select Yes and you would provide the document number of the JINAD.

So let's move forward.

The next section or tab that requires information is your Submission Type Selection tab. We selected the JINAD so now it wants to know what type of JINAD you are looking to submit. And here in the drop down you have a selection. For the purpose of this demonstration we are going to select Request for Meeting. Once we do that it asks you to select the submission classification code and for our purposes the only option is ONADE Meeting (OM). This would be the same and applicable for an ANADA meeting request. Then the template asks for you to choose the review division in which you are submitting. Here it has a few selections, but the selection we will be utilizing is the Division of Generic Animal Drugs or HFV-170. The last question in this folder is "Is this information intended to amend a submission currently pending and under review by CVM?" For the purposes of this demonstration this is an initial meeting request and we select No. If after you submit your meeting and an amendment is requested by CVM, you would select Yes.

Now we have our submission type selection. Now we are getting to the part and details of the actual meeting request. The first folder you see on the screen is General Information under the Request for Meeting tab. Here it is asking you to determine what type of meeting you would like to have with CVM. Will it be an In person, teleconference, video teleconference or Other. If other, specify below the type of meeting in the text box. So teleconference has been selected. The next question is Do the firm participants include any foreign visitors? This is determined if someone is not a US citizen they are considered a foreign visitor. If you select yes, it will not give you an additional screen but alerts the reviewer assigned the meeting request to follow the procedures necessary to have a foreign visitor coming in for an in person meeting. For the purposes of this demonstration, I selected no. The next question is Will the meeting involve discussions about additional Documents? ie NADAs, INADs, JINADs, ANADAs, GC or VMFs. If there are you select YES. If No, you move on to the next question. I will come back to the selection of Yes right after we look at the next question. Here it is asking you the scope of this meeting request. Is it an Other ONADE meeting as described here or is it a Presubmission Conference. Again, the template is describing to you exactly what CVM feels is the definition of a Presubmission Conference. And then you select the radial button below. Now that we have selected the scope of the meeting request I am going to go back to the discussion involving the additional documents. If you select Yes, in 1.1 Document Types and Numbers Table is highlighted and it is requiring me to fill out the information about the document types and numbers of those documents that I determine that need to be involved in this meeting. Let's go to the document types and numbers table screen. Here I don't have anything listed yet, but if you were to list information, you would select the PLUS sign to add a new item and you can see the DETAIL tab has been shaded out because you in the detail screen. It asks for the document type, let's choose NADA, document number, and the product established name. Let's take a look at it in list form. Looks good.

Let's move on. Now it comes to the product description. I am briefly going to go over the product description for the generic drug. Here you would select the green plus sign to select a new item, but I already have one screen selected. You would answer the following questions: Does your drug product have a USP monograph, what is the Product Established Name, what is the Proprietary Name, if applicable, please include in trademark symbols, click the omega symbol and you will get a screen that looks like this where you would select either the copyright sign, registered trademark sign or the trademark sign. You would enter the dosage form and if required the Dosage Form Variation

from the drop down list. Here you would select your Route of Administration and any route administration Variation from the drop down list. You would choose your common animal name. There are some common animal names on the drop down list that may require you to enter the animal class from the list and if applicable a subclass. As part of the generic product description, the eSubmitter template memo field is requesting that you provide the proposed indications for use. Here you would click on the memo field and enter the text of your proposed indications for use. And the last question is has this new animal drug been formally granted minor use/minor species, MUMs, designation status for the indication proposed in the submission? If you select yes, it alerts the reviewer and if you choose no, you can move on to the next folder.

So now we're to the point where it wants to know when you want to have the meeting or teleconference. The first section is provide use with a proposed date or a proposed time. There is a drop down list for times. And then the proposed duration of the meeting in minutes. There is a maximum of three numbers for instance 2 hours would be 120 minutes. Then we ask you to provide an alternate date and the proposed time of the alternative date. And then an additional alternative date and proposed time. Alright, let's now move on to the firm participants. For you to enter the firms participants you will need to click on the green plus sign to add your participants. And what that will do is bring up your detailed screen and you would enter the information for the firm's participants. You can enter multiple participants. Here you would choose the title, first name, last name, position/title or expertise and the firm name. I am going to take a look at the information in the list form and see if all the participants I need will be on the list for this meeting or teleconference. Looks good. So we are going to move on to the requested CVM participants folder. Would you like to request a CVM participant? It gives you the option of requesting them by name, program support area, or both. If you choose **Name**, you will get a screen that will highlight the participants names. Again you will add the participants with the green plus sign which will give you select questions to enter information. Take a look in list form and see if that is who I want from CVM to attend the meeting. Now if we choose **Program Support Area**, it will remove the highlighted participants folder and ask you to provide the program support area information. Here you would click the green plus symbol and select the support area that you are requesting to participate from CVM. Lastly, if you choose **BOTH**, you can select the CVM participant by name and the program support areas if you don't know the name of the individual. You can do this multiple times. So let's take a look. We enter our participants name and then we enter choose the program area that we are interested in. If we need to add another participant's name, we go ahead and proceed. For the purposes of this demonstration we hit name. Now that we know who firm participants are and the CVM participants, we can move to the meeting agenda and supporting materials folder. Here it is asking you to provide CVM with an agenda for the requested meeting. Will you provide it in text and if you do go ahead and enter the agenda in the text field or in the memo field. Do you prefer to attach it as a pdf file? Again, you can attach it from your computer file system or from your file manager list. If you want to both then you enter the text in the memo field for CVM to be aware of and you can attach an agenda as a pdf file. Lastly is the folder for comments. Here if you have any additional comments you would like CVM to be aware of you for this meeting request you could provide it in the text box or memo field as text or you can attach a pdf file. Again, from the computer or the file manager list.

Now that we are at the end of the template, before you gather and package your meeting request, always make sure you have completed the template. There are two ways to do this. One way would be to take a look at the folders under each tab. Here you see each folder with green check marks. What the check marks indicate is that you have completed that folder section. Take a look under each tab, to make sure they are complete, and it looks like we have two folders that are incomplete. The indicator here is the question mark. You can go back to that folder and see what you have missed. There is also another way to take a look at this in more detail. In the tab above you have tab output. You select missing data/validation issues report. What that provides you is an output dialog. You select ok, and what it does is provide you with a report of all the areas, folders, sections, subsections of the actual items that you missed so that you can go back into the template and

correct. It looks like in the 1.1 Document Types and table I did not provide the product established name. In 5.1 participant name, I didn't include the first and last name of the participant. And here in 6.0 section, I did not include the meeting agenda or any supporting materials. Let's go back and correct those areas. I don't think I have any document types I would like to involve in our discussion, so I will select no to including additional documents. Let's go to participants name, look there are no participants names. Let's proceed to the detailed screen. I would like for the title Dr. *typing in the first and last name*. I have entered my information and look at it in list form. Great. Do I have a check mark on the folder? Yes I do. Let's move on to the next section that is incomplete. You can double click on the folder or move by arrows. Here I selected that I would provide an attachment and don't see one here. Let's go ahead and attach. I am going to use my file manager list, and here is my file manager list. I already have a list of all the documents that I may want to attach in my template. Here I am going to choose it and click the select button and it has attached the pdf file I selected. Let's see if… now we have a green check mark on the folder. So all corrections are done and complete. And if you feel like you still want to know if the template is truly complete or missed anything you can ask for another validation report.

So now is the time you would begin your packaging which learned to do in the earlier webinar sessions this morning.

Great, are there any questions? Let's look in the chat box.

Silence

Do we have any questions?

If no one has any questions, then our next eSubmitter demonstration will be a two part series that includes a demonstration of the Administrative ANADA and Traditional ANADA application at 2 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.