Demo Transcripts for an Administrative ANADA (A/A/OT)

Welcome to the webinar for creating an administrative abbreviated new animal drug application (ANADA) in eSubmitter. This webinar will assist you in creating an Administrative ANADA in eSubmitter for 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 sessions that will not be repeated or covered in this demonstration. This demonstration is recorded and at the end of the demonstration there will be live 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 demonstration, CVM would be happy to address your questions or concerns if you contact us directly.

Before we move to the eSubmitter template tools 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 the administrative ANADA and does not include any proprietary information.

As mentioned before this webinar will not cover the following pieces of the eSubmitter template already covered in the webinar sessions earlier this morning. On the screen you will see CVM ONADE SUBMISSIONS tab and under that tab the sections firm information, us agent information if applicable, responsible official information and the submitter information will not be covered. Along with the detailed description of Product Description Information tabs and folders and also packaging the complete submission.

I would like to revisit how to move between tabs and folders. On the screen you will see under CVM ONADE SUBMISSIONS and under the tab you have the folders listed under each tab. One way to get to a folder and look at the information is to double click on the folder. If you want to go between tabs click once, and you can also use above the arrows in the green circles above and one goes to Next and one goes back. Once you get to the last folder it will take you to the next tab.

I would also like to make note that there are icons located in the template. One being the light bulb, a descriptive hint to help you determine the appropriate information you need to submit. The blue dot that is also an indicator of answering the questions that is required and the red exclamation point indicates also that the question is required to be answered and you need to that in order to move forward.

Great now that the logistics are out of the way, let's move to the template.

The first folder document information you see appears under the CVM ONADE Submissions tab and to fill this out is an indicator for the rest of the questions to be activated in the template. First it is asking you the document type. Here you would select the abbreviated new animal drug application from the drop down list and as you can see there are multiple selections. The next question is "Is this submission for a currently established file or application?" Now that this is an administrative ANADA you did work for the approval under the generic investigation new animal drug file as part of the phased review process, so you would have a currently JINAD file available, so you would check Yes.

Ok. Let's go to our Submission Type Selection tab. The first question is "Are you submitting to an Abbreviated New Animal Drug Application (ANADA) that has received a prior approval of a section 512(b)(1) supplement?" if you select Yes, then this activates questions further down in the template. If you select No, then

we can move on to our submission selection. We know it is an ANADA, so we need to determine our submission type and from the drop down select the only option, Original ANADA. Then select the submission classification code from the drop down, which the only one available is Other; Unclassified (OT). The next information required is selecting the Review Division to which you are submitting this administrative ANADA. Because we previously selected ANADA the only option available is the Division of Generic Animal Drugs or HFV-170. The last question under this folder is "Is this information intended to amend a submission currently pending and under review by CVM?". Because you are submitting an administrative original ANADA then there is no amendment at this time. But if you complete and submit this template and CVM requests an amendment then you would go through the same folders and tabs up to this point and select yes if amending.

So now we come to the detailed information for an original Administrative ANADA. One of the questions we saw before was about a B1 supplement and if you selected a B1 supplement it would activate the ADUFA user fee cover sheet, which is part of the generic hybrid approval process. For the purposes of this demonstration we selected no. Here it would like you to provide the AGDUFA user fee cover sheet. You can do that by clicking on the plus symbol (select a file from your computer or desktop) or add a file from the submission list file manager. Here is my own submission list I established before I started the template. I have uploaded my AGDUFA cover sheet. The next question is the most important question for the purposes of this administrative ANADA template is "Is this an Administrative ANADA?" This webinar is for an administrative ANADA, so we will select YES. The next question is Does the application contain safety or effectiveness data to support a hybrid generic approval? We do not have a hybrid generic approval. For the purposes of this demonstration we will select no. If yes, you can see that the ADUFA User Fee Cover Sheet was activated. Again, you can attach by the plus sign or the submission list file manager. If you selected yes, it also proceeds to ask if there is patent information and enter the patent numbers if applicable. For the purposes of this demonstration we will select no. Move on to our next question "Does the submission reference other documents (A)NADA, (J)INAD, master files that contain information that support the application?" This is not applicable to the Administrative ANADA since we already referenced the JINAD file. The next question is "Is the application requesting approval of generic Type A Medicated Article for use in the manufacture of Type B or C Medicated Feeds?" For the purposes of this demonstration we selected no. But if we select yes, the node under labeling will be activated under animal feed labeling. Lastly, it asks to briefly describe the application**.** This can be done directly in the text box or click on the notepad and pencil icon to the right and you will get another screen or free form dialog box where you would enter the text.

We finished this section and can move to the referenced listed product folder. Here it is requesting we provide a referenced listed product information. Because you are a generic copying a reference listed product you are asked to enter the number, proprietary name and established name.

Now we move to our next folder for the generic product description. As mentioned I will briefly cover this. Here you select NEW to activate the details and fill in the questions. Here it is asking Does the drug product have a USP monograph? Yes or No, provide the Product Established Name, provide the Proprietary Name for your generic product, provide the pharmacological Category for your generic product, what is the Dosage Form, from the drop down you can select the dosage form and the Dosage Form Variation (if applicable). Here it is asking for the Route of Administration from the drop-down list, and if applicable the Route of Administration Variation. For the purposes of this demonstration I chose subcutaneous. Then select the common animal name, I selected horse. There are some common animal names in the drop-down list that require you to select the Class and if applicable the Sub-Class. Also, please include the memo field the Proposed Indications for use. Here you would select the memo field and enter the proposed indications. The last few questions have to do with suitability petitions. Is there an associated Suitability Petition?" For the purposes of this demonstration we selected no. But if you choose Yes, the next question asks, "was the Suitability Petition approved?". If yes, when was the Date of Approval. If you choose yes or no, you still must provide the FDA Dockets Number for the

Suitability Petition and what was requested under the Suitability Petition (select all that apply)? Dosage Form, Route of Administration, Strength, Active Ingredient.

Now it is taking us to the Technical Sections folder, to determine what technical sections are in support of the administrative ANADA. For the purposes of this demonstration I selected bioequivalence, chemistry, manufacturing and controls, patent certification and marketing exclusivity, environmental impact, and labeling. If you have a product that is for a food producing animal, you may be required to provide information under the human food safety technical section. For the purposes of this demonstration, I have not selected human food safety because we have horse as our common animal name.

Now what the template is going to do is take us to each technical section to provide more information. The first technical section is bioequivalence. Here it asks you to add or attach your technical section complete letter by selecting the green plus sign or selecting from your submission list file manager you created earlier. So, we attach and move on to our next technical section chemistry, manufacturing and controls. Here again, you will attach the pdf of your technical section complete letter you received from CVM affirming that the technical section was complete. The next technical section is your patent and marketing exclusivity technical section. Here again you will attach the technical section complete letter you received from CVM. You can see as I move down the left side, this is also a good viewing area to look at the technical sections. Here it is asking about your environmental impact technical section. If you received a technical section complete letter you attach that letter here. Now we are to the labeling technical section. As mentioned before if you selected you had a submission with Type medicated article or Type B and C medicated feed, this where the labeling would be activated under the Animal Feed labeling. Let's go ahead a take a look at it highlighted. For the purposes of this demonstration this is not a medicated animal feed. As you noticed there are a few additional questions as part of the labeling technical section. Here it wants you to attach your technical section Complete Letter as done in all the other technical sections. But it also wants you to determine "What type of labeling are you submitting?" Is it final printed labeling-FPL, Facsimile labeling, or Combination of both final printed labeling and facsimile? And "Is the drug used in a Medicated Animal Feed?" For the purposes of this demonstration we selected no. Now we are to the specifics of the labeling technical section. Remember previously it asked you what type of labeling for the labeling technical section and here it what labeling components are you submitting. For the proposed generic product and the RLNAD product you are copying. Here we have selected immediate container labeling, outside container labeling, and a package insert for the generic product. The same goes for the reference listed product labeling selection. So now it goes to an area where it wants more specific information about each labeling component selected and to provide that labeling. So, let's take a look. I would like to not to everyone to pay attention to the blue areas and what they are asking. To let you know what type of labeling component it is asking you to attach. There could be errors if you attach the incorrect labeling to that section. So here it asks you to attach your immediate container file and you go ahead and attach by the two ways discussed earlier. Here it is asking you to attach an outside container label. Let's go ahead and do that. Then lastly, it is asking you to attach the generic product package insert. We are finished with the generic labeling, so let's move on to the reference listed product labeling components. Here again, you have to pay attention to what labeling component you are attaching to what section. Here it is asking you for the immediate container file, here it is asking you to attach an outside container label and attach the package insert.

So, we are coming to the end of the administrative ANADA template. One of the folders is your freedom of information summary. Here you should have received under the JINAD file phased review process a Freedom of Information Summary Acknowledgement Letter. Here is where you would attach that acknowledgement letter. You would go ahead and attach as you did with all the other letters of the technical sections.

The last screen or folder is your comments folder. Here is where you can provide additional comments to include in this submission for CVM to review. Click on the memo field and type in your additional comments or attach as a pdf document.

Before we finish, see the areas on the left column that are shaded out, what that is applicable to will be the traditional ANADA eSubmitter template. You will see a demonstration of this in our next webinar.

Let’s go ahead and take some questions.

No questions? Ok, thank you all very much.