**CVM ESUBMITTER WEBINAR 2: AFTERNOON BREAKOUT SESSION; PRIMARY REVIEW DIVISION 2**

DR. ANNA O'BRIEN: Good afternoon and welcome to the target animal review division 2 afternoon breakout session of webinar 2 on the use of the eSubmitter tool. This afternoon session is scheduled from 1:30 to 2 pm and we'll demonstrate the eSubmitter template for NADA-A-OT submissions. All attendees are on mute so be sure to have your speakers adjusted for your best audio experience. We will be using the chat pod in WebEx for all questions. Please submit any questions that you have in the chat box at any time during this module but we will wait until the conclusion of the module to provide answers. If there are questions outside the scope of this demo, CVM would be happy to address your question or concern if you contact us directly. If you choose to do so, we recommend that you use the CVM eSubmitter mailbox and that email address is: CVMeSubmitter@fda.hhs.gov.

Now we will get started with our demonstration of the NADA-A-OT template.

Good afternoon and welcome to the webinar where we are going to run through the eSubmitter template for NADAs. We'll be looking both at traditional NADAs, briefly, but mostly leaning toward running through as if it were an administrative NADA. I'll be explaining the difference once we get to those specific template pages here shortly. I also wanted to let you know that some specific nuanced differences as they apply to free choice feeds and ADAA combos will be covered in separate webinars this afternoon. So let's go ahead and get started.

Some of this very basic starting information like firm information, submitter information, has already been covered in previous webinars. These are sort of pre-

populated for this example so we won't take the time to go through those. We'll navigate here using these green arrow bars and we have already selected that this is an NADA that we are applying for. Then there are a couple of drop down menus that we need to run through. We are choosing an original NADA and the sub-class code is the only one that is an option is the other, the OT sub class code.

And then, after that, we need to select what target animal review division you are submitting to. The only three options are 110, 120, and HFV-130. Select whatever division is applicable to your product.

Moving right along, the third and final tab that pops up is the one for the original NADA so this is the template that has all the various specific information that we'll run through so we'll look at this a bit more closely.

The first screen here is the General Information screen, screen 1.0. You should have a User Fee cover sheet that goes with your NADA and this is your chance to attach that as a PDF. So wherever you have that saved on your computer you will simply click this green plus button and it will pull up files from which to choose. Select your cover sheet saved again as a PDF and it will attach it here. The file should then be listed in this box here so you can see which ones you have selected.

The next question is: is this an administrative NADA? We will be coming back to this question and running through it in a different scenario as well. Basically, there are two types of NADAs that drug companies can apply for: the administrative and traditional NADA. The administrative NADAs are far simpler. A sponsor will apply for an administrative NADA if they have technical section complete letters for all of their technical sections already finished and this work is usually done under an

INAD file. If a sponsor has all of those technical sections in hand then you would apply for an administrative NADA and I'll show you how that applies to this template.

The other type of NADA is the traditional NADA and because of its name, this was the very original way sponsors were able to apply for drug approvals. This was done prior to the INAD process where all of the studies, all of the technical sections were applied for and received the data sent in under the NADA. That is quite a bit more burdensome and I'll demonstrate very briefly a couple of examples of how that would be uploaded in this sort of template if that is the type of NADA that you're pursuing.

For this run through, we are going to say that this is an administrative NADA so that means we've already done all of our studies and have receive technical section letter completes for all of these technical sections. So we're going to select yes. Now, your answer as yes or no will then determine what other subsequent questions are available for answering.

This is grayed out: does the submission reference other documents, and then you have some other questions to answer as they apply to your product including whether you are submitting patent information. You do have to check a box that says you attest that there is no patent that claims the drug or using such drug in the manner prescribed, and the next question is this application requesting approval of a combination that meets the criteria outlined in the Animal Drug Availability Act. As I said before, ADAA combos are a little bit different and will be covered in another webinar so for this example we are going to say no. Then you have a chance with a white text box here at the bottom to briefly describe your

application. In our particular example here that we've put together, we're going to go with a theoretical anthelmintic so we wrote a brief description here.

Moving along with our administrative NADA, the product description page, that is screen 2.0, pops up. So this was covered in previous webinars and is where you list out all the specifics like the established name, the proprietary name, dosage form, route of administration for your product. We have theoretical answers here but I will not take the time to go through all these drop downs.

Then the next page gets to the technical sections. There are several different technical sections. Now remember because we selected administrative NADA, we have all of our technical section complete letters. For screen 3, this is your chance to check what technical sections you are submitting to support your NADA. Usually for an original NADA, it would apply to all of the technical sections but you would check which ones apply to your project. The last question is: is this application for a Conditional Approval? You would select yes or no depending on how it applies to your product.

Depending on what boxes you have checked for your technical sections, those are going to highlight what sub-folders and sub-templates you have to fill out. Because we have selected all technical sections, that has highlighted the different sub-folders here.

Going through, we click the next arrow and the first technical section that pops up is Target Animal Safety. Again, because this is an administrative NADA, all we have to do for each of these technical sections is to attach our Technical Section Complete Letter or a copy of a Memorandum of Conference where CVM affirmed that the technical section was complete. Sometimes sponsors don't actually receive

the technical section complete letter but have a spoken agreement in an MOC. Either is appropriate to attach here. So again you select that green arrow button and that will bring up your different files so for here we have a test Technical Section Complete letter PDF and we're going to pretend like that is our letter and we are going to move on.

So that is pretty straight forward and that is basically what you do for all the technical sections. Again, for effectiveness, CMC, environmental, and human food safety. Then we get to the labeling technical section. This also has either a technical section complete letter or MOC referencing that so you would attach either one here but you also need to select what type of labeling you are submitting. This is either FPL which is final printed labeling, facsimile, or it can be a combination so depending on what fits with your submission, you will select that.

Then there is a question: is the drug used in a medicated animal feed? If you select yes here, the next sub category that pops up in the far left corner here is because medicated feeds have different sub types of labeling and you're also asked to choose what type of labeling of medicated feed you are submitting.

Then the next screen is called all other information and this is one of the minor technical sections the same as labeling and again this is where you attach the technical section complete letter or the MOC that says that this technical section is complete and again you would attach it with that green plus button.

The final screen is to attach your freedom of information summary. Then after that, there is a brief area on Screen 5.0 where there is a white text box in which you can type any other additional comments that you feel might need to

include for your submission. You can also attach your files here using the green plus button.

So for an administrative NADA this is basically a bunch of attaching technical section complete letters or your MOCs that state that the technical section is complete. That's pretty much all you have to do.

Now if we go back and remember that we selected administrative NADA in this very first screen 1.0 General Information. If we instead selected that this is not an administrative NADA, that means this is then a traditional NADA and that means we are going to be submitting data here. So now you can see that some of these boxes have become active where before they were grayed out. This is your chance now to answer if this submission references other documents and there is a yes/no toggle button. And again you have the same information about patent information, attesting there are no patent claims against the drug, and [indiscernible].

So moving through with our hypothetical example with a traditional NADA, again the product description stays the same and we won't go over that.

Now this is a little bit different here. Again, we have to select what technical sections we are submitting to. Typically, again, this will be all of them. And then yes or no whether this is for a conditional approval.

The first box that pops up again is the target animal safety technical section. There might be a case in a traditional NADA where sponsors have a technical section complete letter for one or more technical sections but to keep it clean we're going to say in this example that we do not have a technical section complete letter. So we will select no. Because of this, we have a range of examples of different types of studies that could apply to the target animal safety technical

section. For a traditional NADA, like I said, you're not going to have a technical section complete letter so instead you're going to have data or information for each of the technical sections. If this is the case for you, you would select what target animal safety specific studies you are submitting data for. In this example, let's just keep it simple and say that we are submitting a margin of safety study. Looking on the left hand side here, you will notice that all these studies are listed out in gray. As soon as I select the study over here on the right, it will make this active. So we said we are submitting a margin of safety study so let's click next. This is your chance to specifically write a brief summary about the study you are submitting and then attaching the relevant files. You can see as we go back, there might be people that have a handful of different target animal safety relevant studies so let's pick a couple more. See how each of these are hightlighting? Each of these sub templates then is your chance to specifically put a summary and then attach files that go with each piece.

I'll flip through a couple of these just so you can see these are the same sub template no matter what.

Once you have attached all of your relevant studies that apply to a particular technical section, then when you click the next button, it takes you to the specific sub template for the FOI text as it applies to that particular technical section. You might recall that with the administrative NADA, this box was grayed out and you were asked to attach your FOI summary as a complete document at the end. This time, the FOI summary is built in pieces. You are asked for your different bits of your FOI summary as they are teased out and applicable to the different technical sections. So that's a little bit different there. On the screen it asks you: are you

submitting Freedom of Information summary text? If you select no, this still stays grayed out. For our example, we'll say yes. You can type your brief summary in the text box here or attach it as a file. That's a run through of the target animal safety technical section.

If you go to the other technical sections for a traditional NADA, they are sort of the same. For effectiveness, because this is a traditional NADA example, we will say no, we don't have a technical section complete letter so that will then bring us to this screen where we will check the different effectiveness studies that might apply to this application. Again, depending on what ones you select, those then become active over here. Just say we have a field study. Again, a brief summary can be written in the text box and then you can attach the applicable files containing the data you are submitting.

Then again, just like with target animal safety, you have a chance to submit FOI text for this technical section.

And then again. So it moves forward through CMC. We do not have a technical section complete letter, then it will ask you some very specific questions that apply only to CMC, for example are you submitting sterility information or feed method trial information. Depending on your answers to these questions, some of these grayed out sub template boxes will then become active and allow you to attach information as needed.

We're not going to go through this as it is basically just attaching different files so we're moving on through CMC to environmental impact. Again, whether or not you have a technical section complete letter will determine what files you have to attach and what type of submission you have.

Then, human food safety. Again, same deal. And then it brings us back to the labeling and all other information templates. These are the same as when we went through the administrative NADA.

That brings us to the end of NADA template webinar. Essentially it's a lot of attaching files, whether they are technical section complete letters or actual data that you have depending on if you have an administrative or a traditional NADA. I hope this has been helpful for you and thank you very much for listening.

OK that has concluded the demonstration of the NADA-A-OT eSubmitter template. I will give attendees a few minutes to collect their thoughts and type any questions that they may have into the WebEx chat box where I will try my best to answer them. I will put myself on mute for a few minutes and if anyone has any questions, now is your chance. [extended silence] OK. I don't see any questions popping up in the chat box. If after you've gone home and sort of thought about these modules this afternoon and have questions later, you can always submit them to the eSubmitter mailbox. Again that email address is: CVMesubmitter@fda.hhs.gov and we will try our best to address them. Our next module starts at 2 pm and that will be covering meeting requests. We will end this module and start again at 2 pm. Thanks so much for your time.