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. My name is Dr. Anna O'Brien and I'll be your host for this afternoon. This afternoon session is scheduled from 1 pm to 4 pm and encompasses the following three demonstrations: from 1 to 1:30 this afternoon we will be demonstrating the INAD-M template; from 1:30 to 2 pm we'll be demonstrating the NADA-A-OT template; and from 2 to 4 this afternoon we will be demonstrating the templates for meeting requests. All attendees are on mute but be sure that you have your speakers adjusted for your best audio experience. We will be using the chat pod in WebEx for all questions. Feel free to submit your questions at any time in the chat box but we will wait until the conclusion of the module to provide answers. If there are questions outside the scope of this demonstration, we will be happy to address your question or concern if you contact us directly. We recommend that you use the CVM eSubmitter mailbox. The email address for that is: CVMeSubmitter@fda.hhs.gov.

For our first session, again from 1 to 1:30 this afternoon, we will be demonstrating the eSubmitter template for the INAD-M submission. So we'll get started here.

DR. LEA CRANFORD: Hello. I'm Lea Cranford. I'm going to present the INAD-M submission eSubmitter template. Once you've finished the document information, firm information, responsible official and sponsor information, click the next button

which will bring you to the submission selection screen. Click on the dropdown menu and choose final technical section M. The next drop down menu gives you the submission classification code. There are only two options for the M submission: all other information and labeling. We are going to start with all other information.

The next question asks you to select the review division into which you are submitting. We are going to choose 110. The next question is is this information intended to amend a submission currently pending and under review by CVM? This is not an amendment so we're going to choose no.

The next screen is general information in regards to the all other information technical section. The first question is to please provide the CVM submission number for the most recently submitted technical section, the P submission, to which the M submission will be tied. We're going to say number 25. The second question asks you to please select the final action letter you are requesting from CVM with this submission. We are going to request a technical section complete letter, submitted information acceptable. Technical section incomplete letters are generally reserved for your P submissions.

The next question, is this in response to a previous technical section incomplete letter? There are two options: yes and no. For example, we're going to choose yes which will illuminate the next question which is to provide the CVM submission number associated with your CVM technical section incomplete letter. You're going to press the plus sign and enter the previous M submission, we're going to say number 15, in which you received a technical section incomplete letter. Then click OK. It will show up below. If this M submission is not in response to a previous technical section incomplete letter, choose no.

The next question: is there additional information about your drug since the last technical section submission that you wish to submit? There are two options: yes or no. We'll start with no. You'll choose no when you do not have any additional information; no new final study reports, no new pilot studies, no new adverse event information to submit. When you click no, click the next button and you come to the product description screen which is covered in a separate webinar.

Then you come to the certification screen. It asks you to check the box to certify that there's no additional information that needs to be included in the AOI technical section. Click the box. However, let's go back. If there is additional information since your last technical section, you choose yes and click the next button. Then you come to the product description screen again, covered in another webinar. And this time, you're allowed to upload all other information documents. You click the plus sign, choose your PDF, and it'll attach it here. You can attach as many PDFs as you need to which will include all your all other information documents. Then you click the next button and it brings you to the comments. This text box allows you to add any sort of additional comments or instructions that you feel are pertinent to your all other information submission. Also, if you'd rather do it via file attachment, you can. This is also a good place to attach a cover letter if you have a cover letter. And that completes the all other information technical section. Let's move backwards and do a labeling submission.

So once again, you've entered your document, firm, and responsible official and submitter information and you click the next button. You click the submission type, the M submission, which has two options: all other information and labeling. We're going to choose labeling this time. And again we're going to be submitting to

HFV-110. And this is not an amendment so we choose no and click the next button and this brings you to the general information in regards to your labeling submission. Again it asks you to provide the CVM submission number for the most recently submitted technical section P submission. Our last technical section P submission was number 25. Then it asks you to select the final action letter you are requesting from CVM. Again we are requesting a technical section complete letter. The submission information acceptable technical section incomplete letter is usually reserved for your P submissions. Is this in response to a previously CVM technical section incomplete letter? If you say yes, again it will alloq you to enter the submission number associated with that technical section incomplete letter. If you say no, the question will not be illuminated for you to answer.

The next question: Is this drug used in a medicated animal feed? We're going to say no as it's being submitted to 110. We'll come back and say yes later. And then you will press the next button.

The product description, again, is covered in a different webinar. Then we proceed to the labeling section. It asks you to put a check next to all of the labeling components that are included in the labeling submission. For this demonstration, we will select all of them. Then you click the next button and it allows you to upload all of the labeling components. This first question, attach your immediate container label files. Choose the plus button to pick your PDF and attach them. The next is the same for outside container labels. Press the plus button and choose your PDF and attach it here. You keep doing that over and over for your multi-unit display carton labeling, shipping labeling. You would attached your package insert here, and if you have a client information sheet, you would attach it here.

Scroll down. If you have any other additional label files that were not included in the text above you can describe them here. Click add and you can attach a separate labeling file that was not covered in the text above. And then you click the next button. This is the last field and is the comment button for the comment box. If you have any other additional instructions or comments you can enter the text here or you can add file attachments, where you can add a cover letter or a PDF of your comments or additional instructions.

So let's go back and choose that this labeling, this drug is used as a medicated animal feed. You'll note that different sections then light up when you choose medicated animal feed. Click the next button. Again, product description is covered in a separate webinar. For animal feed labeling, you put a check box next to all of the labeling that applies. Just for example, say we are going to choose all of them. And again, similar to the previous examples, for the first one, attach your VFD, press the plus button, click your PDF, and it's added. For Type A medicated feed, again press the plus button to choose your PDF. You can do multiple attachments. Your Type B medicated feed, your Type C and then shipping labeling, press the plus button, select your file and attach it here. Once you've attached all your labeling, you click the next button and come to the comments section if you have any additional comments or instructions that you feel are important or relevant to your submission you can type this here or you can attach a file as a PDF. Or if you have a cover letter, this is also a good place to attach your cover letter. And that concludes your INAD-M submissions template.

DR. ANNA O'BRIEN: OK. That is the end of the module for the INAD-M template on eSubmitter that encompasses both all other information and the

labeling technical sections. If anyone in attendance has a question on the module you just saw, please type your question in the chat box and we can try our best to address any questions at this time. I'll leave a few minutes for anyone who wants to gather their questions. [silent break] OK. Seeing as we don't have any questions coming up we are going to end this module a little bit early but I do invite anyone who is interested to check back in at 1:30 as we'll be going over the NADA-A-OT template. So the Webex box will stay up and we will just be on mute until we will reconvene in 15 minutes. Thanks so much for your attention and time.