Original Food Use Authorization Request

Good afternoon and welcome to the webinar that is going to run through the template for how to submit an original food use authorization request. I'd like to remind all participants that if you have any questions, please type them in the chat pod and we can address them as they come in. Thank you very much.

So to begin with this template, this is under the INAD submissions, you will choose from this pull down menu, again like you have with all other submissions, what type of submission you want. So for this being an original food use authorization-so meaning this is the very first time for your particular product that you are applying for a food use authorization. That is what is meant by when it says original. This is an O submission so you would select O from the drop down menu. I do want to mention that there is another type of food use authorization request and that is an amended food use authorization and that code as you see here is under the letter D for dog. Now you would only submit an amended food use authorization after you had an original one in place. And the reason that you would submit a D or amended food use authorization is if you needed to change or update the food use authorization for any reason, say if you needed more animals under the authorization or something about your formulation or dosage that had changed. So for right now we are going to run through the original food use authorization request again that is under the code O.

So then there is a submission classification code. There's a drop down menu but the only option there is 'other' so it comes in as an OT for this submission classification code, so you would select that. The next question on this beginning template screen is what division are you submitting this to. There are only two options because these types of submissions only apply to products that are being used in food producing species. So your choices are Division of Production Drugs which is HFV-120 or Division of Therapeutic Drugs for Food Animals in HFV-130.

In this particular example we're going to have a hypothetical drug that we are running through the templates so in this example we are going to choose HFV-130 for the review division. And then if this intended to amend a submission that is currently in house and under review you would indicate 'Yes'. In this case this is going to be a very original submission so we would click 'No'. So that is all you have to answer for this particular screen. So to move forward you click the next button which is the green arrow up here and this is going to take you to the very specific information that you need to fill out for this submission. So the first screen that pops up here is screen 1.0 is General Information. And the first question that you will have to fill out an answer to is the proposed total number of investigation animals that might be receiving this product and then entering the food chain. So this is just a fill in text box, a white box here that you would put that number in. For our theoretical example we are just going to put in the number 1000. So then the next question that you have to provide is the name of the investigational drug product. So we have already backlogged product description information into this template, so this is pulling this up from previous submissions. If you needed to add anything you would just click the green button here, the add item, and that would pop up an additional place for you to add information about your investigational drug product.

Next question: 'In your studies is there going to be any other concomitant drugs that will be used that also will need to be included in a food use authorization?' That is a yes/no question. If you answer 'yes', that will highlight this next sub question which asks you to provide then the name of the concomitant drug that will be used. And then here you can click the Add Item button and add what you need to add here. But in our example here to keep things a little more simplistic, we are going to choose 'no'.

Next question on this particular page is 'Would you like to request a waiver from notification of the date and place of slaughter?' And again, that is a yes or a no question. So you answer as you see fit. So that completes screen 1.0. So we click the green arrow up here to move us right along.

And this is the Product Description page. And this has been covered in previous webinars in the morning and this is your chance to list out your drug product and all the details that go with it. So for this particular example again we've already pre-filled this. If you needed to fill it from scratch you would hit 'new' and that would allow you to add new details to your product. So we'll just go over this really quickly. For our example again we have a wormectin which would be a hypothetical antiparasitic drug. And then once you have selected your particular investigational drug product, then you have a chance to list all the active pharmaceutical ingredients including their concentrations, all of the excipients, other information, any other ingredients and their concentrations, product established name and a proprietary name if you had it. So I just want to go back to this list and you'll see that once you, whenever you hit 'new', new drug product line item will pop up underneath the List tab. And if you want to see the details of it, then you go to the Details tab. So if you've made a mistake or you need to delete something, you can also hit the delete button and that will get rid of that. So let's just take a really quick look at the details for our hypothetical drug. I just wanted to show you how it's important show you how it is important to have the concentrations of each of the line item things that you have listed here in order for a proper food use authorization to be granted. So that's the information you need on that template.

Moving on to screen three is the Species Details. So again this is kind of populated like the Product Description page was. So the drug product pops up and then the species for which it is being used. So to see the details of this; again, we have our hypothetical antiparasitic, and so then the first question you'll have to answer is the common animal name and this is where you are going to choose the species for which your product is going to be used in. So for our example, we'll pick cattle. However, if you do pick 'Other', if for some reason your product is not used in any of these major food producing species, you could click 'Other' and that would allow you to type into this text box if you have a more unique food animal in which your product is going to be used in. So if we have a product that is being used in cattle, then we have to get a little bit more specific into the class of cattle. So, selecting class, this again brings down a drop down box; you can get a little bit more specific. So, for our example that is 'beef cattle'. Again, if it was other, if you selected 'Other', or something that isn't applicable to this list then you would have the opportunity to write it in this box. And then, not only do we have to be specific for class, but there is also subclasses. So then another drop down menu and another subclass menu pops up so pick whatever is applicable to your product. And then any additional information such as gender, age, production class, however specific you are able to get is very helpful if you type it into this box here.

Then the last question on this page is 'Will the investigation and the Food Use Authorization need to address the disposition of offspring from treated animals?' So if you have pregnant animals that are

going to receive your product, you are asked then to write down what your proposed plan is for those specific offspring. If they too are going to be entering the food chain, that has to be entered here in this box below.

So that finishes up this screen so we will hit, 'Next'. And this is where you get into the details of the Proposed Dosing Regimen. So again the prepopulated drug product pops here so let's take a look at the details and all the specific questions that you are asked to answer. So this is where you are entering things such as dosage form, if there is a variation on the dosage form and route of administration. So in most of these cases there are drop down menus again to help you with your choices. So you will pick whatever applies to your particular product. Now if you have multiple dosage forms or multiple routes of… excuse me…administration, that is totally fine. We just ask that you list them out one by one and you can just hit new and then all of your dosage form variations or route of administrations will pop up as a new line item.

So looking at the different drop down menus, we have Pick Solution up above and then we get a little more specific. Say if it's a powder, or if it's a concentrate or however applies to your product, you pick from these drop down menus. And again, if something doesn't match or you don't see something on the menu that applies to your product, click 'Other' and then you will get a chance to specify whatever applies to your particular product.

So for this example we are just going pretend it's an Injection, this is the Route of Administration and then the opportunity to say, 'Well, what kind of injection?' and we are going to pick subcutaneous.

Now the very last box, this is a very important piece of information. This is where you have a chance to describe your dosing regimen. So very explicitly in the text box you would type out anything that applies to your product: as dose range, frequency, duration, up to the number of animals as it relates to the particular dosing regimen, any sort of information that would be helpful and relevant here. If you need to attach a bigger file, I'll get into a little bit more detail if you have more complicated product, you also have the ability to attach a pdf file that contains the information.

So that finishes this screen, moving on to the next one. Here is where you are going to type your Proposed Withdrawal Period and any conditions or restrictions. So this is just a text box. Then, if your product is going to be used in an animal that is going to produce milk for human consumption, so applying to dairy cattle, you'll also have to propose a milk discard time. Because we just said that our theoretical product would be used in beef cattle so that does not apply. So we click 'No'. But f you click, 'Yes', that would highlight this next box and you would enter your proposed milk discard time.

So, the next screen then comes a chance to attach any data or supportive information to back up the food use authorization request that you are submitting. So, if you have toxicological data, residue chemistry data, any information if your product has antimicrobial activity or any other relevant data, this is where you would attach that. So you start off with a 'Yes' or 'No' question where 'you have data or not'. If you do, you have a chance to press this green button and this is again is where you would attach any of your files as a pdf. And so you would run through each of these differing questions separating out the data that you have depending on what subject it applies to and then attach the file.

And the last screen, Screen 8.0 is a chance to type any other additional comments that you think might be helpful for us to process your request and so this is just a text box. Feel free to type in any

information you might think is helpful but doesn't otherwise fit anywhere. So those are all the screens as they apply to an original food use authorization. If you have any questions, please type them in the chat pod.

Second speaker: Alright everyone, we have a couple of minutes before our next session. If you have any questions please feel free to put them in the chat box or if you'd like to come off mute, I'd be happy to take them at this time.