Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen only mode. During the Q and A session, you may press Star 1 on your touchtone phone if you would like to ask a question.

Additionally, today's conference is being recorded. If you object to this, you may disconnect at this time. I would now like to turn our meeting over to Ms. Irene Aihie. Ms. Aihie, you may begin.

Thank you for calling. May I have your pass code please? Hello? This is a live Operator. May I have your pass code?

Irene Aihie: Hello and welcome to the second of today’s FDA webinars on UDI. I am Irene Aihie, of CDRH’s Office of Communication and Education. In a moment, you’ll be hearing from Indira Konduri, the CDRH program manager for the Global Unique Device Identification Database, also called the GUDID. Indira will present “Getting Ready for GUDID”—FDA’s recommended best practices based on our experiences and on feedback from industry. After Indira’s presentation, we will host a Q&A session, during which Indira will be joined by Loretta Chi, Regulatory Policy Analyst in the Office of Surveillance
and Biometrics and Anita Rayner, Associate Director for Policy and Communications, also with the CDRH Office of Surveillance and Biometrics. Our main goal today is to help labelers of Class II, implantable/life-supporting/life-sustaining and new Class III devices be better prepared to get a GUDID account and submit information to the database efficiently and correctly. Now, I give you Indira…

(Indira Konduri): Good afternoon, it's a pleasure to have all of you tuned in today to listen to the Webinar. The topic of today's Webinar is "Getting Ready for GUDID". GUDID stands for the "Global Unique Device Identification Database". As many of you are probably are aware by now, the UDI final role requires the device identification information be submitted to the GUDID by device labelers.

So what I plan to do today is to start with a very brief introduction to the GUDID and followed by a details on the recommended preparatory steps to get you ready to submit to the GUDID. So let's get started. And for those of you who listened to the UDI 101 Webinar which was just provided a few minutes ago, you have the basic information.

For those of you who did not, we highly encourage you to take time to listen to the UDI 101 Webinar. The recordings will be available next week on our Web site and that will provide you a lot of information to get you going. So, again, just to recap for those of you who have listened before, UDI stands for "Unique Device Identifier" which is composed of the device identifier portion and the production identifier component.

The "DI" stands - is the static portion of the device identifier and it identifies the specific version or model of the device and the labeler for that device. The PI is the variable portion that changes. And as you can see, it can be the lot of
the batch, serial number, expiration date, manufacturing date, and for human tissue and cellular based products, it is the distinct identification code.

So these things change frequently and therefore this is the dynamic component of the UDI. So together, the DI and the PI, will basically make your UDI. So what is the Global Unique Device Identification Database? So the GUDID as we lovingly call it is a repository of key device identification information. Our goal is to have information available to the public once it's populated and we're working to provide that.

The GUDID contains only the static component of the UDI, which is the Device Identifier Component. The production identifiers are not submitted to or stored in the GUDID. So this means that we're not going to have every single device which is the out in circulation that are captured in the GUDID. All we will have is a record for a given version or model of the device which is identified by the device identifier.

We will, however, capture information about which of the PI's attributes -- meaning the lot or the batch, the serial, the expiration, manufactured date which is included in the UDI's. That information we will have in GUDID and I'll show you in just a couple of minutes what I'm talking about.

This slide is a fictitious medical device label. And the purpose here that I'm trying to convey is to tell you that a majority of the information in GUDID is directly found on the device label. So, if you see here on the top, you will see the Compu HyperGlobal Med -- that would be the brand name. You see the GMDN description. GMDN stands for "Global Medical Device Nomenclature" which is a way to categorize medical devices into broad categories. And in the right - in the middle here, you see the UDI. It is composed of the DI and the PI components.
The PI components I have identified for you as a production identifier of the expiration date, manufacturing date, lot and the serial number as you move from left to the right. And on the bottom here, you see the labeler name and physical address. So this basically shows you that a lot of the information that is captured in the GUDID come directly from the label of the medical device. We captured additional attributes, but a majority are directly found on the device label.

So moving right along to the next slide, here I'm just showing you screen shots from the GUDID which shows you what we capture for device information. On the top you see the primary DI number which stands for Primary Device Identifier Number. And you see I have captured a brand name here -- the version or model of the device and device description.

And the commercial distribution end date if the product, for example. If you were to stop distributing the product, you would have to come back and update the GUDID with that information. On the left-hand side here in the bottom, you look at the DI record publish date. Just make note of that and we'll talk about it in just a minute.

On the next slide here, - I'm showing this to you just to show you what I meant when I said, "production identifiers". We don't actually capture the lot of the batch number. What we're asking you to do, however, is to let us know which of these production identifiers are actually included as part of your UDI.

So if the lot or the batch is part of your UDI, your answer would be, "Yes" for this question. If its serial number, then your answer would be, "Yes" -- so on and so forth. So that's the information we captured about the PI. But really, the
main component we use is the device identifier. So moving on, the next slide is a sort of a pictorial overview of GUDID.

The blue box shows you the submission options that are available. And the pink box on the right-hand side shows you the "search and retrieval" option. And we will go through this in detail one by one. As you can see, there are two submission options. There is a file submission option and there is a Web interface option. And for "search and retrieval" also, we have a Web option and we also have some Web services and download capabilities.

So let's take them one at a time starting with the GUDID Web interface. GUDID Web interface is basically a secured Web application. Folks that are wanting to submit information to GUDID such as labelers will need to get a GUDID account. We'll get into that a little bit more later also. And, it's basically a manual data entry option. You will get a username and a password. Once you log in, you can put information in one record at a time. And this option is suitable for people who may not have a ton of the articles to submit to GUDID.

The GUDID HL7 SPL submission option. So quickly to go over some acronyms here. HL7 stands for "Health Level 7". And Health Level 7 is a standards development organization. And what they do is work on developing messaging standards in the healthcare space.

And they have put together a structured product labeling standard which is the SPL standard. And we've taken the SPL standard and constrained it to the GUDID space. You take your device identification information that you want to submit to GUDID and instead of submitting it manually by typing it in, you take that information and you put it as an XML file if you want to use the HL7 SPL submission option.
And once you have your file together, if you look at the right-hand side pictorial, there you have your green XML file, you then send it through the FDA Electronic Submissions Gateway. So what is the FDA ESG? The FDA Electronics Submissions Gateway is a way that the FDA receives all electronic regulatory submissions. The gateway basically makes sure that the submission is secure. And the gateway also authenticates who the sender is.

So we know if Labeler A is sending a file through the GUDID we have a way to verify that it is, in fact, Labeler A sending the submission. So once you send it through the FDA ESG, they - they route it to CDRH. Once it comes to our Center, we will process it and load it to the Global Units Device Identification Database.

So in this case and you are taking your information and you are putting as an XML file, we want to make sure that the way you put your XML files together works and we are able to take it and load it and process it. Therefore, we're going to ask you to do some testing. So there is testing required and we have information on what testing and how much testing you need to do on our Web site.

So once you complete testing, then we will allow you to submit information to the production system. And testing helps you and it helps us because we all make sure that once you get to production, we have no issues. So the technical spec's on how to do all of this, how to format your file as an XML file is all available on our Web site.

And, again, this option is suitable for those of you who may have a large number of records to submit to GUDID. It's resource intensive, as you can see. There are a number of steps involved in getting your XML together and testing is required. But once you set it up, it should be fairly smooth sailing.
So, all the labelers come in and they put the data in GUDID and what do we do with it if we don't release it to the public? And, of course, we want to get it out to the public. So we are working with the National Library of Medicine as we speak, to provide for GUDID public search and GUDID database download and Web services. Initially, we will start out with a basic search and download capabilities and then down the road we plan to provide Web services.

And what type of information are we going to release? Not everything that you submit will be released. But there are certain data elements which we consider to be confidential such as the listing number will not be released. What we are releasing and not is on our Web site. I will point that out to you shortly.

But if you remember, the DI record publish date that I asked you to keep in your mind, that's how you tell us when your record is ready get released to the public. So you have the ability to indicate that this record is good to go, it can be released to the public. So once the record hits the DI record publish date, then a published DI record is what we're going to send - make available for the public.

And we're looking to have this capability available by Spring 2015. So stay tuned for more information on that as we get closer to the date. A quick word about data quality. If you listened to the UDI 101 Webinar, you know that an important step in UDI implementation is adoption of UDI. And we are already actively working to get UDI adopted in electric health records and claims data and registries and so on. It's very important to us to make sure that the data you submit to GUDID is of top quality. And we are working actively with labelers. And the things that we are looking for and the things that we have learned so far is that it's very important for you to take the time to make sure
that your UDI is constructed as it should be according to the Issuing Agency standard's.

For example, if you are using the GS1 standard and you construct your device identifier number -- which for you would be a GTIN -- the GTIN has a tech check digit number. The check digit has to validate if not the GTIN is not constructed correctly. We are finding DI's submitted to GUDID that are not validating correctly against the check digits. So we ask, you know, we're checking those sorts of things. That's number one.

The other thing to - for you to keep in mind is, devices come into CDRH. They get approved. And you provide us some information. And we approve the device based on the information provided. Then you come in and you register and list the device. You provide information there. And then you're going to come into GUDID and provide us the device identification information.

So we're looking to see that there is consistency across all these different touch points and if there any discrepancies we may contact and try to understand, you know, what the source of those discrepancies are. So, the point here is, as you gather your data, and as you get ready to work on GUDID, please keep in mind, data quality.

Make sure your source systems are accurate and correct -- and then maybe cleanup, if necessary. Basically, data quality has to be a main theme for you as you work on GUDID. All right. Moving on. So that’s a introduction - a very brief introduction into GUDID. Now let's talk about - "How you prepare to submit information to the Global Unique Device Identification Database?"

There are, based on our experience working with Class III labelers over the last year, we have these nine recommended steps that we have that help you
prepare and be more ready to submit GUDID and hopefully give you a smooth sailing, if you will.

That's our hope for you and for us so let's start right into it. So everybody likes to say everything is on everybody's Web site. You know, you want information, they say, "Go to this Web site, go to that Web site. It's all on our Web site." So somebody told me, "You know, it would be really helpful if you kind of give me a map. There is so much information on the Web site."

And Web sites by nature kind of take you tangentially to different places. So, here is a proposed map. You don't have to follow it. But this is a map that we think might be helpful. So start with simple, beautiful URL -- www.fda.gov/udi. You come into this page. Then I recommend you go to the UDI basic section.

And what does this tell you? This will tell you -- What is a UDI? Who is a labeler? And information that tells us if you are already new to it, it doesn't hurt to repeat. The more you repeat, you know, the better it gels and that's what helps me -- repetition. So there is, "What is a UDI?" And, "Who is a labeler?" The question of, "Who is the labeler?" is something that we heard a lot come up in the UDI 101 Webinar. And it does - can be confusing.

So take your time and look here. It gives you the basics. Then you might want to meander to the UDI resources section. And here, you have our famous final rule. It is pretty good reading. And you may also want to consider looking at the Small Entity Compliance Guide. You see it on the slide here. It's right about the bottom there with the red circle. The Small Entity Compliance Guide was written to help smaller businesses understand the final role. It may be a little more readable.
And there are also, "Frequently Asked Questions" which we've gathered over the last year. May already have answer to a question that you have. And the training that we worked to put together. So this is definitely worth pursuing the UDI resource section. Then you may want to come over to the GUDID section.

The GUDID section on the left-hand side, really as I was preparing for this webinar, I realized is the correct sequence to how you should review this Web site for the GUDID section." It's pretty well laid out. If you just follow it from top to bottom, you pretty much have it made. So let's look what's there.

If you look at the top, the first thing is "GUDID Guidance". It's an absolute must read if you are going to be submitting data to GUDID. It lays out all the details of the account, the device identifier record, and, of course there is a lifecycle of the device identifier records. It's an absolute must read. So read it in sections. Reread it. Dog-ear it. It will help you.

Then you may want to go to "Preparing for GUDID" which is really what I'm doing now. It's pretty much telling you what's in that Web site. And if you are listening to this Webinar, that means you are a Class II labeler or you are a labeler for life supporting, life sustaining, and implant devices and you should be doing this right now. So good job in listening to this - the information is really on there and the Web site too.

Once you have done that, once you've gone and read the guidance and understood what's needed, then you go on and you're ready to request your GUDID account. And you go to that Web site it tells you what you need to do. Then you can go to the GUDID Web interface. If you remember, the two submission options. If you decide that you want to use the manual data entry, here you have a user manual.
The user manual has screenshots and it will tell you how to actually use the Web interface. So that might be very helpful for you. We talked about the XML file submission option. The HL7 SPL technical specifications files are here. That gives you all the information you need to pursue that option. The GUDID system status -- another important page mainly because, just like any other IT system, we do have to take the GUDID down.

And this is where you will find information on when the system is going to be down. And enhancements and fixes. If we make any changes to GUDID, we keep a running tab of what has been changed, of course here which might be helpful for people to know. So really if you go from top to bottom, I think it's a good map for you. That isbe our recommendation.

Last but not the least, the GUDID resources section is very important. The GUDID Data Elements Reference Table. It's a mouthful. But what it basically does is it provides you a list of GUDID data elements. So all the data elements that we capture in GUDID. And if you look, it will give you a description and some of the data entry notes to keep in mind whether it is a required attribute, what is the length and whether it's numeric field - also numeric field.

This will be very helpful for you as you gather your data to submit to GUDID. So definitely take a look at the GUDID Data Elements Reference Table. In fact, we just updated it this morning so you have a brand new copy there with more clarity and information that we updated based on the all the questions we have received over the last year. We are good to go there. Moving along. So that's the Web site map for you. And let's say you went through all of that, next thing to do is you need to select an Issuing Agency.
And as a lot of you you learned in the UDI 101, what is an Issuing Agency? An Issuing Agency is the organization that basically comes up with the way to create and assign UDIs. And they follow international standards and we have accredited three of them -- GS1, HIBCC and ICCBBA. And you may choose any one that works for you.

Once you choose the issuing agency, you will create the UDI based on their guidelines. And then you need to place it on the label of the device or on the device itself. It has to be human readable and machine readable format. So you did all of that. Then what to do you need to do? Then you need to determine which GUDID submission option you want to choose. Again, we have two of them -- Web interface or the SPL.

The Web interface is probably for, you know, those of you with less records to submit. HL7 SPL is suitable for those with a lot of records. But it's completely up to you. We don't limit you to one or the other. You may want to do both. But the thing to keep in mind though is you must have good standard operating procedures for recordkeeping mainly because it's very easy to send a file through SPL and then somebody in the organization can log into the Web interface and make a change.

So you need to make sure that you have good procedures and make sure your records are all in sync, i.e., what you send to us and what's in our own source system. You also have the option to outsource all of the GUDID work to somebody. We call them the third party submitter. And if you want to do that, you're welcome to do so -- identify them and there are steps that you need to follow to let us know who it is so we can allow them to submit on your behalf. And information on that is in the GUDID's guidance document. So please take a look at that. So then you've done all of that. Now, about the device
identification data. And if you remember, the Data Elements Reference Table, that will be very helpful to do this.

Don't forget data quality. There are some data elements that will take you some time to gather for example, the global medical device nomenclature preferred term. Again, as I mentioned earlier, GMDN basically allows you to categorize devices into broad device categories and the GMDN Agency is the one that manages GMDN preferred terms.

You need to identify one for your device. If you don't have one, then you have to obtain one. So that might take time so please take a look at that right away and work to identify GMDN preferred term. FDA listing number -- only the owner operator within an organization usually has access FDA listing number so make sure you identify the correct listing number for your device. And think about data quality, as I mentioned earlier.

So now you have the data. You've gone through all the material. You know what submission option you want. And you are ready to go. What do you do next? Well, we need you to get a GUDID account. Mainly because we need to know who is putting information into our database. So, GUDID account is needed regardless of which option you choose whether Web interface or the HL7 SPL.

In order to do so, before you ask us, you need to understand the GUDID account structure. And I'm now showing you very busy slide with a lot of boxes and items going all over. And we won't to get into the details of this - the details are in the GUDID Guidance except to note that there is regulatory contact and it is a GUDID coordinate user and there is a GUDID labeler data entry user for each labeler organization. So it is important that you spend time to understand the GUDID account structure and the different user roles.
Identify who in your organization will take on these user roles and make sure they understand the functionality and the responsibility that comes with each of those user roles. So that's very important to do. Once you do that, you also need to identify DUNS numbers. DUNS numbers, many of you may know, stands for "Data Universal Numbering System".

It's mostly used in the financial reporting arena, but it is taking a foothold in the regulatory space and in FDA, particularly. And it's a 9 digit number that's assigned by Dun and Bradstreet. And what we are going to do in GUDID is to use the DUNS number to identify the labeler name and the labeler address.

So, at no point, in all of the submissions you'd be sending to GUDID will you be typing your company name, you will just provide us the DUNS number and then we grab the name of your company and address directly from the DUNS database. And in GUDID we have three types of users for DUNS. We use it to identify the GUDID account for your organization and we call that, "The Organization DUNS".

We also use it to identify the labeler DUNS. And what that is we identify the name -- your company name -- as shown on the medical device label. So if you remember the fictitious medical device label that I had up a while ago, I'm just now showing you the labeler name and address as we have on the label. So in GUDID when you are ready to submit your GUDID account request, you need to provide us a DUNS number that gives us the labeler name as shown on this medical device label. And that's what we have as labeler DUNS.

And then the third party DUNS. This is optional. If you choose to use a third party to do your GUDID submissions for you, you need to let us know who
the third party is and it's important because we associate the third party to your organization so when the submissions come we verify and make sure that that person is authorized to submit on your behalf.

So please take the moment. Understand the GUDID structure. Identify the DUNS numbers for these different types of users within GUDID and let us know if you have any questions. So you have a GUDID account and your all pretty much set. So for those of you who choose to do the Web interface option, the manual data entry option, you basically request to obtain a GUDID account, you don't need to do any testing.

Within the system we have built-in capability for you to get familiar with the system by creating draft records. As the name implies, a draft record is just that -- it's the draft. And then once you're ready, you may submit your records.

Now even when you submit your records, if you remember, you get to tell us when your record is ready for publishing. So you may put a future publish date and that it - could remain in the unpublished state. It won't be available for public view. So when you are ready, you may submit and publish the DI record into GUDID.

Part HL7 SPL submitters -- a few more steps to go here. You would have to work in parallel as you work on GUDID. We recommend you register with the FDA Electronics Submissions Gateway. They have testing that they require you to do. And if you already have a test account -- and some of you do if you are an adverse reporter -- you are familiar with EMDR than you probably already have a FDA ESG account. You can reuse that. If you don't have one, then definitely get a brand new ESG account. And then you get a GUDID test account.
So in your case, you need to start with a test account. And if you remember you have a testing requirement. Then you complete HL7 SPL testing. And please take the time to do that all testing. The more testing you do, the more ready you are to go to production. We have provided a few test scenarios that must be passed before you get production accounts but that's really the bare minimum.

Our recommendation is to think through the DI record life cycle and make changes to the record and make sure they're all successful. And really test all your device lines because there are multiple business rules associated with different data elements. And if you only test the limited ones, you may not run into issues that you may encounter in production. The goal really is to make sure that by the time you go into production, you pretty much are issue free.

And once you're done with testing, you will request and get a GUDID account for production submissions and then you may submit your records. The other thing to note is there are no draft DI capabilities in the HL7 SPL option and that's the reason testing is very important. If there are any third parties listening, and third parties are basically software vendors or companies that may want to put together a software solution to help labelers submit to GUDID, you're welcome to do so.

You're welcome to test your submission audio solution independently of having labeler clients. You can get a test GUDID account. And if you need any data for required attributes, we can provide that for you for testing purposes only. So once you're done with that, we talked about earlier about the GUDID systems status page.

We have capability for you to subscribe to get GUDID email alerts. If we know that the system is going to be down this weekend or this Friday, we send
an email to all the users who have subscribed to this email list and let you
know that the system will be down. When the system is down, please do not
send any submissions or try to send the submissions. It's better you wait
getting the downtime and then send submission form once the system is back
up.

Occasionally, we have unscheduled downtimes. If that happens, visit the Web
site to see if we have any information. If we don't have it, then maybe you are
the lucky user who found the issue - please report it to us through the FDA or
the UDI Help Desk. So what's GUDID status? Well, as a reward for all of you
for listening to the Webinar today -- you are the one first ones to listen to the
news -- we presently are accepting submissions from Class III Medical Device
labelers and devices - labelers of the devices, license under the PHS Act.

On Monday, January 26, we will open for business for labelers of life
supporting, life sustaining and implant devices. So welcome aboard on
Monday, January 26. We look forward to working with all of you. And we
have now provided you plenty of homework to do between now and then. So
there are tons of things that you can be doing to prepare. You know,
hopefully, you will find this helpful and we're happy to work with you starting
the 26th.

We also mentioned to you we're working to provide GUDID "search and
retrieval" Spring 2015. Stay tuned for that and we'll have more information
coming soon. So we provided all this information. How do you contact us?
Before I get into the UDI bit, those of you wanting to do the FDA -- I'm sorry
-- HL7 SPL work, you need to get the FDA ESG account. For all the ESG
questions, please go directly to FDA ESG.
I am sorry, but they have their own Help Desk. They support the entire agency. So we rather they answer questions about their program. So the email address is on there for you. But for all other inquiries regarding UDI and GUDID whether it's regulatory or technical, you contact us via the famous FDA UDI Help Desk.

And it has worked very beautifully for us. And I think over time you will - you will come to appreciate it as well. So the FDA UDI Help Desk, you go to our Web site and you complete a very simple form. As you can see, it's just first name, last name, email, phone. Don't forget to give your email. Because if you do not -- and there are people who forget to fill in the email -- you won't hear from us because that's how we communicate with you.

You put your question, and then you hit the "Submit Question" button. And what happens is, it becomes a case in our Help Desk tool. We're using "Sales Force" is our Help Desk tool. Once we get the case, the case gets assigned to folks in our team, regulatory stuff goes to regulatory people, technical stuff gets out to the technical people and we review your stuff and you will hear from a Help Desk staff member and we will respond to you via email.

If you have follow-up questions, all you do is hit, "Reply" and you respond to that same email. And it's important that you do a direct reply because we need to append to the case and the only way we can append it is if you hit the "Reply". There are people who have had issues receiving it because it's gone to the Stamp Holder. So please make sure you can receive emails from the Help Desk. And we are here to help.

We are looking forward to working with all of you. And the last year has been phenomenal for us working with Class III labelers. We've learned a lot. And we have provided FAQ's and training. And this Webinar, honestly, is a direct
response by - is a result of working with the labelers and realizing all the steps involved and we hope that this will help you out.

And whatever you do, whether you submit Help Desk questions, account requests, submit DI records, please or take the time to provide us complete and correct information. Don't forget data quality. And, there is a ton of information already there.

You take the time to review it. If you send us a question on something that's already out there, we pretty much are going to review the answer that's already there anyway. Since you're waiting on us, you might as well take the time to review what's out there. So look forward to working with all of you. Thank you for listening. And we're ready for questions.

Coordinator: Thank you. At this time, we will begin the Question and Answer session. To ask a question from the phone lines, please press Star 1. You will need to unmute your line and record your first and then last name clearly when prompted.

If you choose to withdraw your question, please Star 2. Once again, if you would like to ask a question from the phone lines, please press Star 1. One moment for our first question please. Our first question is coming from (Patricia Rupchuck). Ms. (Rupchuck), your question is up at this time.

(Patricia Rupchuck): Thank you. On Slide 27 it talks about the different DUNS numbers. From the previous Webinar, I understand that if you're a manufacturer and you make a product that is in private labeled for another company, the other company is the labeler. That's as correct, right? Hello?

(Indira Konduri): Yes, that's correct.
(Patricia Rupchuck): Okay, I wasn't sure if I was coming through or not. Okay. Can we though put into our own GUDID account their information? Or do they have to have their own account to put that information in?

(Indira Konduri): Previous, they are the labeler. They would be getting a GUDID account.

(Patricia Rupchuck): Okay, so they would have to actually do that. They could not request that we do that because we would not have their account then. Is that correct?

(Indira Konduri): In that case, you might be the third party if you plan to submit information on behalf of the labeler.

(Patricia Rupchuck): Okay. And in both case - in that case, either way, the organization DUNS and the labeler DUNS would be the other companies numbers?

(Indira Konduri): Right, yes.

(Patricia Rupchuck): Okay, okay, that helps. Thank you very much.

(Indira Konduri): You're welcome.

Coordinator: Our next question is going to come from Mr. (DeGeoffrey Hermonto). Mr. (Hermonto), your question is up at this time.

(DeGeoffrey Hermonto): Oh yeah, hi, thank you for the presentation. It's very informative here. I have two short questions, if I may. The first question that I have -- I have a chance to download the GUDID labels.
And I note that some of the elements or the attributes listed there is marked as optional. Does it mean -- I just like to have confirmation here -- we can keep them as blank when they submit the data?

(Indira Konduri): So in the GUDID Data Elements Reference Table, we have -- yes, you are right. There are optional elements and then there are some that are called, "Conditionally Required". So, if you have an option -- if you fully completely optional element -- yes, you may submit information without providing that.

However, our recommendation is for you to provide complete information where possible as you know the end goal of this is to make sure complete information is available for consumers. But from a record acceptance perspective, yes, you may be able - you will be able to submit it and you do not need to provide the optional data attributes.

(DeGeoffrey Hermonto): I see, okay. Thank you. My second question is to relate to one of the attributes. It's called the "DI Record Publish Date". When I look at the data entry notes, it says that the date if I'm not entering this thing wrong, I have to enter the dates of publishing minus seven calendar dates. Is that correct?

(Indira Konduri): I'm sorry, what's the last part of your question? What calendar dates?

(DeGeoffrey Hermonto): Yes, so on the DI Record Publish Date elements under the GUDID tables, it says that on the dates of entering notes that the date determine the grace period, the second date calendar starts the dates up to the DI Record publish dates.

So my interpretation, the seven days indicate that when we're going to submit the data, we have to identify the DI Record published date minus seven
calendar days to the actual dates where I would like to have that date DI published, is that correct?

(Indira Konduri): So this, again, the presentation was very high overview. We did not talk about the DI record publish date or the grace period. So your question pertains to the grace period and you need to publish the DI record and make sure that there's a publish date to fulfill the UDI file requirements. So that should definitely be a consideration when you determine when your publish date should be.

As far as the grace period and the seven calendar days, that is talking about your ability to edit the DI record once it's submitted. And the purpose of the grace period is to give you an opportunity to make any edits after the record is in a publish state noting that once a record is in a publish state, it's available for public view, right?

So our recommendation is by the time you publish the record, it should be locked and ideally you should not have to edit the record unless, for example, commercial distribution end date. You end - discounted the product and you have to come back in and update the record.

So, we would like to see the record as stable as it's possible to have it practically by the time it's published. So the grace period really is giving you an opportunity to edit the record once it's in a published state.

(DeGeoffrey Hermonto): I see, I see. Yes. Because the confusion I'm coming from on the same note it says that, "We recommend you use that this state in this future, but seven days prior to any compliance that - their clients."
(Indira Konduri): Right. The DI record publish date can be set to today or in the future. You can't have a DI record publish date in the past. That is a system business rule. So, that is correct.

(DeGeoffrey Hermonto): Oh, I see. Okay. So I can set the date in the future and seven days prior to release, I have a grace period if I were like to do edit on that data before it goes public?

(Indira Konduri): Right. The grace period is really your choice to - it's just for providing you ability to edit the record once it's published. How you manage it, it's up to you.

(Loretta Chi): But the publish date is? What's the publish date? When does it go public?

(Indira Konduri): It goes published on the date that it's put on the DI record publish date. So if you set DI record publish date to be today, the record will be in publish date today. And if we had public search available today, the public would be able to access your record today.

(DeGeoffrey Hermonto): I see. So...

(Loretta Chi): But what if you have - I'm sorry, but if you have any, we would prefer that you'd not have to make any changes to it, but you have that grace period in which to make those changes but the publish date is still the date that it goes public -- not the one the grace period ends.

(DeGeoffrey Hermonto): I see, okay. So on the Class II medical device, the necessary date to go live is December 24, 2016, correct?

(Loretta Chi): Yes. Class II products, yes.
(DeGeoffrey Hermonto): Correct. And that's going to be the publish date?

(Loretta Chi): That's the date - that is the last date in which you can be in compliance with the data submission requirements under the UDI rule.

(DeGeoffrey Hermonto): I see, so...

(Loretta Chi): Well, we're not saying that we're not in any way saying, "Please wait until September 24, 2016." When we open the GUDID to Class II labelers, we will accept the DI record - the record from that moment on.

(DeGeoffrey Hermonto): I see, I see. I think I get it. Okay, thank you very much.

(Anita Rayner): And may I also add something that if you are a Class III Labeler, and you have Class II products and you already have a good idea account because you had Class III products and submitted DI records, you may submit your records for your Class II products. You do not have to wait.

(DeGeoffrey Hermonto): I see. Got it. Thank you.

(Indira Konduri): And same thing for, you know, if you get a GUDID account now because you have a life supporting sustaining, an implant device with you and once you get those device records in, you don't need to wait. You can continue submitting. So anybody who has an account and who have records to submit you can set the DI record publish date to a future date, but you don't have to.

So you have the capability to submit this whole "open for business" and getting accounts only at first to getting the GUDID account. But as far as
submitting the DI records, once you have an account, you don't need to wait for those device Class compliance dates to hit. You may submit.

The only reason we are opening the accounts and batches, if you will, is to make sure that we have the capability to provide the support that you need in getting your account, making sure that we can turn those requests around quickly, and we are able to address all your questions.

So once you know the system, go right ahead and keep submitting. You don't need to wait for anything.

(DeGeoffrey Hermonto): I see. Your explanation triggered another question for me here. Let's say if the company where I work now also making a drop product and we already have a good idea come, right? So what you saying, we can use the same GUDID account to load the medical device GUDID information? Is that correct?

(Indira Konduri): Did you say a drug product?


(Indira Konduri): No, the GUDID is for medical devices only. It's not for drugs, so...

(DeGeoffrey Hermonto): Okay.

(Indira Konduri): ...if you have medical devices that are covered under the UDI final rule, once you have the GUDID account yes, you may continue to submit.

(DeGeoffrey Hermonto): Okay, all right. Thank you.
(Indira Konduri): You're welcome.

Coordinator: Our next question comes from (Katherine Williams). Ms. (Williams), your question is up at this time.

(Katherine Williams): ...who is currently pending? Are we able to apply for a DI UDI account before we get our final approval? Or do we have to wait for approval before we can apply for the account?

Coordinator: And we're sorry Ms. (Williams), your first part of your question cut off. Do you mind repeating the first half please?

(Katherine Williams): Sure, yes. We currently awaiting final approval of our PMA and we wondered whether or not we can go ahead and apply for a GUDID account before our approval is made final or if we have to wait for final PMA approval before we can actually go ahead and do that?

(Indira Konduri): Do you have any approved products at the moment?

(Katherine Williams): No, we are a single product company.

(Indira Konduri): Yes, no unfortunately you have to wait until you get approval before you can apply for a GUDID account.

(Katherine Williams): That's okay. We're - at least we know what we have to do once we get to that.

(Katherine Williams): Thank you.
(Indira Konduri): Thank you for...your question

(Loretta Chi): But when you - keep in mind though, although the regulations require or the way the regulations are written, the minute you put your product in distribution, you're supposed to be - you supposed to have your data submit in GUDID. But in fact, we're actually giving you 15-day interval of time because we know that it is impossible for you to do this simultaneously.

So - because you have to get a list - registration listing number and so forth. So there is a 15-day period from the day you put your product - first time, you put your product into distribution and then we require you to submit the data to GUDID.

(Katherine Williams): Okay, great. Thank you for the clarification.

Coordinator: Our next question comes from (Brian McBrin). Mr. (McBrin) your question is up at this time.

(Brian McBrin): Yes, I was wondering is it required to use the third party accredited issuers for UDIs?

(Indira Konduri): Sorry, what was your question? Can you repeat?

(Brian McBrin): Yes. Is it required to use third party accredited issuers for UDIs?

(Brian McBrin): Such as GS - such as GS1?
(Indira Konduri): Oh, yes. So I think you're asking about issuing agencies? So just to clarify third party the way that we use that term in the GUDID and UDI world is third party somebody you are using to submit information on your behalf...

(Brian McBrin): Yes.

(Indira Konduri): So I just wanted to...

(Brian McBrin): So I guess I consider them as third parties, but, yes, I mean the accredited issuers such as GS1.

(Indira Konduri): Right. So if your question is, "Who should you use to create and define your UDIs?" Then, yes, you have to use one of the three accredited issuing agencies GS1...

(Brian McBrin): Okay.

(Brian McBrin): Well, I guess my question is, from what I understand is the accrediting issuers are - is a quite costly thing to take into consideration for small businesses? And I'm just wondering how that's going to adversely affect these businesses that are not aware of these costs?

Coordinator: Thank you. Our next question comes from (Katherine Wong).

(Brian McBrin): Hello?

(Loretta Chi): No, we're looking at...

Coordinator: My apologies.
(Loretta Chi): We're looking at each other.

Coordinator: My apologies.

(Loretta Chi): We don't get into the fee Structure that the issuing agencies charge. However, my understanding is they are volume based. So...

(Brian McBrin): I’m just wondering if it was taken into consideration before your final guidance?

(Loretta Chi): It was taken into...

(Brian McBrin): And why - I guess why - what - why isn't the FDA issuing...

(Loretta Chi): Okay, so...

(Brian McBrin): ...you know, DI's? And why are they - why are they looking towards these (unintelligible) solutions?

(Loretta Chi): ...first of all, let me say that -- and I don't have the regulations in front in me -- but the regulations do provide that if for some reason the fee structures charged by the issuing agencies become so cost prohibitive that it adversely impacts the small businesses, at that point FDA may come - may intervene and become an issuing agency.

But, we're not at that point yet. So - or nor do we hope - or expect to ever be at that point. But that provision was made in the final regulations.
(Brian McBrin): And whose determination was that? Is that congressional? FDA? I'm just wondering, you know, who decides and who I would write to?

(Indira Konduri): Well, the UDI final rule was reviewed, you know, by multiple entities before it was approved...

(Loretta Chi): There was the - there was the economic analysis done by the Office of...

(Brian McBrin): Yes, it just seems like it's not covered in a lot of these things and I think it's kind of - was an overlooked subject, that's all. I mean does it cost - and just implementing it alone and whether it's revalidating for direct marketing, you know, or whatever it may be, I might have to submit another 510K for whatever reason just because of the direct marketing alone. So I'm just wondering if anyone thought about the costs involved for small businesses?

(Loretta Chi): All I can say is - well, first of all, the purpose of this Webinar really is to talk about getting ready for GUDID, so...

(Brian McBrin): Yes. Well, I guess I need to prepare myself financially and then other businesses need to do too. So it would be kind of nice to get an understanding of the costs that are involved in just signing up when - for instance, we're a Class II device and I understand you're only working, you know, trying to get these inflammable Class III devices and the higher end Class II devices and in the works first, but companies like us need to, you know, understand these costs two or three years ahead of time before, you know, we're ready to go.

(Indira Konduri): You know, we wish we could help you, but all we can say is there were - there was a commenting time when the proposal was out there before it became final. There were several opportunities provided for folks to comment on the
rule and the requirements in it. So at this point, we're focusing on helping people getting ready to submit...

(Brian McBrin): Sure.

(Indira Konduri): ...to GUDID.

(Brian McBrin): Just one last quick question. How long after I submit - like I understand after I get the initial DI from GS1, for instance, if I added an additional product, how long will that take to be reviewed and be okay to use?

(Indira Konduri): Oh, you're asking about an approval for...

(Brian McBrin): I'm talking approval?

(Indira Konduri): pre market approval, you know, you will have to ask their - the correct group about that.

(Loretta Chi): We do not handle...

(Brian McBrin): No, no I’m talking about, let's just say I have a new product that's already readily available. I want to add it to the list and the GUDID.

(Indira Konduri): Oh, once you have an approved product and you have a GUDID account, it takes no time. It takes the time that it takes you to enter the information or send you...

(Brian McBrin): Oh, okay. So there's no one like to have to review it and then they'll send it back and they say, "Okay, you can use it."
(Indira Konduri): No. once you come - if you do the SPL, once you do testing, you're good to go. We don't - we're not going to look at every DI record and we're not - we don't need to approve every DI.

(Brian McBrin): Okay, all right. That's it. Thank you very much.

(Loretta Chi): Great, thank you.

(Brian McBrin): Bye-bye.

Coordinator: Our next question comes from (Katherine Wong). Ms. (Wong), your question is up at this time.

(Katherine Wong): Hello?

(Indira Konduri): Hi there.

(Katherine Wong): Hello? Can you hear me?

(Indira Konduri): Yes.

(Katherine Wong): Okay, all right. My company makes a combination product. It is actually a biologic, a drug. But in the same kit, there are the packaging for devices like transfer steps, syringes - some are pre-filled syringes, so who is the labeler?

And do these devices are not manufactured by my company, yes, supplied all ready to go in its own individual sterile plastic case - plastic container. So, who is the labeler? Or, who are the labelers? And is an UDI needed?
(Loretta Chi)  Okay, so when you have an instance of a combination product that is both a combination of a drug and a device, the question of who is - first of all, it, a UDI is required or whether a NDC is required, is a determination that's made under the Office of the Combination Products.

And then once that determination is made, then it either goes to Cedar or it comes to us. So without knowing more, we can't really answer that question.

(Katherine Wong):  Well, I know for sure that it is an NBC because it's a main one - the biologic. And it's registered on the list - in the drug listing. So what about all the little packaging that goes with them - the device packaging? Do they need UDIs? Because right now, it does say, "Manufactured by the device manufacturer." Not under my company's name for the individual wrapped units.

(Loretta Chi):  What - yes, what - this is a little bit complicated, so it's hard to sort of answer this at - in this form. So can you submit this to Help Desk and we can answer you more thoroughly?

(Katherine Wong):  Okay, all right. Thank you.

(Loretta Chi):  Sure.

(Katherine Wong):  And I have another very small question probably down the road. If this FDA UDI system universal? Is it coastal? Can it be used for Canada EU?

(Loretta Chi):  No.

(Katherine Wong):  (Unintelligible).
(Loretta Chi): No, this UDI system is only for the United States and solely for products that are in commercial distribution in the United States.

(Katherine Wong): Okay.

(Loretta Chi): Other countries are - there are other countries creating their own UDI systems, but this system that we're talking about is only for products that are in commercial distribution in the United States.

(Katherine Wong): Can it be - we should ask - okay. Hang on. We have another question.

(Woman): Sorry, I'm with (Katherine Wong). But if the company in EU has their own identifier system, can that - does that meet the UDI? Do we have to have this - because it's important to the U.S. for now?

(Loretta Chi): As I understand it, the U.S. is the first country to have this UDI system so whatever you have in the - is first of all, is not official yet. And second of all, no you have to be in compliance with the U.S. UDI requirements in order to commercially distribute the product in the United States.

(Katherine Wong): Thank you.

(Indira Konduri): Thank you

Coordinator: Our next - okay. Our next question comes from (Paul Hazelwood). Mr. Hazelwood, your question is up at this time.

(Paul Hazelwood): Thank you. With regard to Class II devices, when would we be able to apply for a GUDID account?
(Indira Konduri): At the moment, as we mentioned, we are trying to do the batches to make sure that, you know, we are able to provide the assistance. The group that does - in trying to make the compliance deadline needs. So we will open up Class II accounts for ability for Class II labelers to GUDID accounts sometime this year, and we'll keep you posted as we get closer to the date. At the moment, unfortunately, I don't have a date that I can share with you.

(Paul Hazelwood): Okay, thank you.

(Indira Konduri): You're welcome.

Coordinator: Our next and final question is going to be coming from (Dillon Aloo). Mr. (Aloo), your question is up at this time.

(Dillon Aloo): Okay, yes. Good afternoon and good presentation. Not to rehash what the former gentleman had already asked, but I have a little bit of confusion about the Issuing Agency. Basically, what is their primary role? What do they provide? And is it - are they mandatory? In other words, we have to go through the Issuing Agency?

(Indira Konduri): Yes. So the Issuing Agency what they provide is they are basically accredited by us. They use the International ISO Standard to establish a way to create, generate and maintain the unique device identifiers.

So we have accredited the three agencies that we have been talking about. GS1, (unintelligible), and (unintelligible). And if you would basically choose one of them. And if you choose one of them, then you are in compliance with the UDI rule as long as you follow their system to uniquely generate and assign UDI s. So once you go with...
(Dillon Aloo): Are they physically generating them? Or, they're just guiding us on how to generate them?

(Indira Konduri): Exactly. They have guidelines that you will follow once you decide which one you want to use and you will follow their guidelines to generate the UDIs yourself. So you will be generating. They'll just provide you the guidelines on how to do it.

(Dillon Aloo): Okay, so they're a middleman basically for the FDA.

(Loretta Chi): No, well, no they're not a middleman for the FDA. What we need is to have a standardized UDI system that...

(Dillon Aloo): Oh, right, I'm sorry, I shouldn't say, "middleman" but I guess I understand now why the other gentlemen was saying, "Well, why didn't you provide those guidelines?"

(Indira Konduri): Well, these three, you know, systems have been operating in the marketplace already and we did not want to introduce another entirely new UDI system that would probably be more burdensome to companies than going with what's already existing.

(Dillon Aloo): Okay. All right, well, thank you very much for your help.

(Indira Konduri): You're welcome.
Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Recordings of today's UDI Webinars along with the slide presentations and transcripts will be available at www.fda.gov/training/CDRHLearn by Friday, January 23rd under the tab "Unique Device Identification System".

If you have additional questions about the UDI or the GUDID systems, please use the contact information provided at the end of the slide presentation. As always, we appreciate your feedback. Again, thank you for participation and this concludes today's Webinar.

Coordinator: Thank you for joining today's conference. As Ms. Aihie has said, today's conference has ended. Please disconnect all audio lines at this time. Again, this does conclude today's conference. You may disconnect all audio lines at this time. Ms. Aihie, if you'd like to remain on the line, we will debrief in the post conference. One moment please.

END