

NWX-HHS FDA (US)

Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. At this time all participants are in listen only mode until the question and answer portion of today's call. If you would like to ask a question at that time please press star 1 on your touchtone phone.

Leaders would like me to remind you that they will only be accepting audio questions today. Please do not submit any questions over the Web for today's conference. This call is also being recorded. If you have any objections you may disconnect at this time.

Now I will turn the call over to your host, Ms. Irene Aihie. Thank you. You may begin.

Irene Aihie: Thank you. Hello and welcome to today's FDA's - today's FDA webinar. I am Irene Aihie of CDRH's Office of Communication and education. Today we will be discussing the guidance document, Design Considerations for Devices Intended for Home Use, which was published on August 5th.

The guidance is intended to improve design and quality of home use device to reduce errors that occurred during their youth. It provides recommendations that take into account the device user, the environment, the device itself and its labeling.

Today Mary Weick-Brady, Senior Policy Advisor from the Office of the Center Director here in CDRH, will be present an overview of the guidance document.

During the question and answer portion of today's call, both Mary and Jeff Silberberg of CDRH's Office of Science and Engineering Laboratories, will be available to take your questions.

Following the webinar, the slide presentation, audio recording and written transcript of today's program, will be available on the CDRH Learn section of the FDA Web site. Now I give you Mary.

Mary Weick-Brady: Thanks Irene and thank you everybody for joining me this afternoon. I really appreciate this. This was a journey of 3-1/2 years to get to this point of final home use guidance.

And I really appreciate anybody who might have sent us comments during the draft period, or who worked with us during the workshop, when we first started to work on this document. So I'm just going to go, briefly, through why we focus on the home.

Well there are two main reasons why we do focus on the home environment. And - also in addition to the Affordable Care Act, sending people home with their devices. But there are faster discharges from clinical facilities.

People are getting a lot more of the endoscopy surgery and they're going home within a day or within a few hours of having surgery. And typically they will go home with technology.

We have a growing elderly population and quite a few of those, if they don't have one morbidity they have comorbidities. And a lot of time they will be using technology if not for themselves, for the person that's living with them and they're the caregiver.

And the third reason, these are - there are a lot more chronic diseases. People are living longer with chronic diseases such as arthritis or Crohn's Disease or other things that require them to have technology in some way. And they're using it on a daily basis in order to stay as healthy as possible.

So what is considered home? In the final guidance, I think you probably saw that we had some definitions there for the purpose of the guidance document.

And a home use device is considered - it's a very broad definition- and it's considered a medical device that is labeled for use in any environment outside of a professional healthcare facility or a clinical laboratory where a device might be used. And it's not limited to just the home then.

It can be in transit, it could be on a farm, it could be in a school, it could be on the beach. Wherever somebody who needs technology and wants to live a healthful life, they will be taking that with them.

So that's what we have in mind that it is any environment outside of what we would consider maybe a safe or a controlled environment versus an uncontrolled environment which could be outside of - outside of those clinical facilities.

If the device is intended to be used in both a clinical facility and in the home then it will be considered a home use device. So it will need to be labeled as such. And again, home use devices are quite variable. You're not looking just at what we could call the durable medical equipment.

And that's a lot of times where people go and that's at the bottom of the list there. They tend to think of that as being the only home care devices around. But they are quite frequently used in many different areas.

In fact I think we did a study and we found out that close to 80% of people go home with some type of technology. The disposals and accessories are part of this. This is looking at your syringes, your IV catheters, your oxygen therapy.

You have your implantables and those are becoming more and more frequent. And it's anything from the shunts to the defibrillators to the left ventricular assist devices and implants. And you have your computerized medical systems.

And those include infusion pumps and dialysis and some of your glucose meters and some of the other things where you have to program something in. And you're also looking at reagents such as your fecal occult blood test and your Lyme disease, pregnancy tests.

And don't forget your mobile medical apps. So go ahead. This is as a result of announcing a home use medical device initiative back in April of 2010. And at that point we did say that we were going to look at five different areas. And we were going to develop guidelines for manufacturers.

We wanted to look at a home use device labeling repository, work with the accrediting bodies, look at more oversight of adverse events that were happening in the home and also increase public awareness.

I would consider this as increasing public awareness today here and educating you about this guidance. But we really are focusing on number one which is why I have it highlighted. That's the guidelines for manufacturers.

And in this guidance, we have many different areas but there are three main considerations that we'll be discussing. And those could be switched from when it was a draft. We're looking at the environment in which the device will be used.

We're going to look at the user and we're also going to look at the design of the device. And I'm going to go through each of those sections a little bit more in depth because they're very, very important and they are integral to each other, to having a safe product in the home environment.

And then I'll discuss the rest of the guidance as well. So the first area that we're going to look at are the environmental considerations when you're designing something for the home.

Having been a home care nurse at one time, I can relate to just about everything that we talk about in this particular guidance. You have to look at the location. Where do you consider that that device will be used? And as an - as an industry, don't feel like you have to think of every single place.

But in general, where do you think that device is going to mostly be used? So if you have somebody with an insulin pump, more than likely they're going to

be going to work, they're going to be going on vacation, they're going to be going to school.

So think of what types of things might interfere in those types of environments. You're also going to want to look at contaminants. And a lot of people laugh at this but there were many times where I was taking roaches out of tubing and out of machines and we had rodents eating the tubing.

And there is just a lot of different things you have to think about there. But not only just vermin and pets and dander. You also have to think about tobacco and smoke and many chemicals that might be around the house.

Many times we were in bathrooms where it hadn't been cleaned for quite a few weeks and you're competing with hair that's in the sink and things. So you do have to think about contaminants. And as you're putting your device together, how can we prevent ingress of those types of things into the device?

And then you also want to look at the water supply and this is only if your device needs water in some way, in which to function. So you can be looking at well water, distilled water. Can you use chlorinated water in that? Can you use regular tap water or city water?

Can - do you have to go to reverse osmosis? What type of water is safe with your particular device, if indeed you are using water with your device? You want to look at temperature fluctuations and extremes.

In this I'm talking about let's say you're going from a very warm environment out into the cold to get into your car. Are you going to have problems with condensation? Are there other issues that could happen if you are out in the heat for a very long period of time, with your device?

And just think of those different things as you're designing the device, what it is that might be necessary for a temperature fluctuation. You're going to look at dampness and humidity. If it's too dry are you going to have problems with static? Can you get sparking?

Can - can that affect how your device is functioning if you have too much static with your device? Or is there a propensity for it to grow mold? And that has happened as well in too humid of an environment. And then you have very damp tubing or - I keep going back to tubing but that is a big problem.

And can you get mold in that? When you're looking at air flow, do you need to keep that device away from the wall or can it be pushed up against the wall? Do you have a problem with overheating if it is up against the wall? And that's just considerations for your particular device.

Atmospheric pressure changes and basically looking at low pressures. We did have high and low pressure in there. And one of the comments that came into us was well where would we have a problem with high pressure?

So we're looking at low pressures like in mountains and air travel where there's a little bit more of a problem. We did remove child proofing and tampering from the environmental considerations, from the final guidance.

And we did put in a separate sentence and I'll tell you where we put that later on. But it's basically a very general sentence in one of the areas of introduction in the - I believe it's the user section.

And then finally, the other environmental consideration that you want to think about, are the voltage, any converters that are needed for travel back up

batteries. If you're passing through security is there a problem? Is there a problem with pat down or backscatter or x-ray, anything like that.

Is that going to affect the device? And how much do you need to let the TSA know? And we do talk about looking on the TSA Web site in there, to find out what their newest rules are with that kind of thing.

And also fluid exposure - if you're going to the beach are you going to have problems with it getting wet? Or if you're going to take a shower, is there a problem there? Any issue with some submersion, if you were to accidentally get that soaking wet is there a problem there?

So just keep that in mind as you're designing your device and any problems with potential fluid exposure. And then finally, looking at storage. And is this - can it be stored in the sun? Does it have to stay out of the sun? Can it be in a very warm environment? Can it be in a closet?

Can it be stored where the pets are and there's no problem? Just also keeping that in mind as you're designing your device. And let me just reiterate that with these environmental considerations you, as a manufacturer, do not have to take all of these into consideration when you're designing your device.

You only need to take into consideration those pieces that pertain to your device and the environment in which it will be used. Okay. So the second area that we're going to be looking at are user considerations. So you have your environment, your user and your device design.

So this is the second one with user considerations. A lot of times people consider home use devices to be over the counter and they need to have

instructions for use to be used by somebody at the 7th or 8th grade level.

That's a minor piece of this whole.

There are many prescription devices that are going out into the hands of the lay user and you need to think about that user as you're designing your device.

So here we had physical where you're looking at possibly a 75 year old woman taking care of her 80 year old husband in their home and she has to have the strength and the stamina to be able to lift him let's say in that patient lift, and move him from his bed to his chair and back without tipping him over, without her falling over and without him falling out of the lift.

So thinking about the size and strength and mobility of that particular individual. And then you have the sensory and perceptual. A lot of people have vision or hearing abilities or disabilities that have tactile sensitivities, especially diabetics.

Their ambient light conditions and if you look at this particular picture here, you can see this gentleman has ambient light problems. He cannot read his machine and he's using a flashlight in order to read it. So try to think about designing your device with that type of user in mind here.

And then the alarm visibility and what the alarm means so that they can understand that. And then we go into the cognitive area. Again, this is where a lot of people think that's the only issue with home use. And it's one piece of it. And what is the literacy level?

What is the English speaking level? Are there any cognitive impairments that you need to be mindful of, of that particular individual? And then finally, we

have the emotional area. And some people are saying well why does that belong here?

Well if you are working with somebody who has a new diagnosis and they're being taught how to use this device before they leave the hospital or as soon as they get home there's a lot of anxiety and fear there. And there's not a lot of learning going on in that area.

So they're either taking care of their - themselves or they're taking care of a loved one. And there's - they're just very fearful that they're going to hurt that person.

So keeping in mind that your instructions for use and your design, should be, you know, looking at their needs as well as the environment and the simple device design that you will do much better. And here - this is where we had the statement where we removed the child proof and tampering.

So if you look under user considerations in the first paragraph where we explain what user considerations is. We do say you should consider that children or adults might interact with the device in inappropriate ways. So that's how we replaced child proof and tampering.

We did get a lot of comments on that during the draft comment period where people said let's not use child proof. Let's not use tampering. They have bad connotations and child proofing really is not a term that is used all that often. So that's why we changed it to inappropriate use.

Okay. Now the third part that's integral to good device design for devices going into the home environment would be the design consideration. So you

have the environment, the user and now the design. And the first thing that we want to look at here are lockout mechanisms.

And we understand that lockout mechanisms do have to exist in certain areas, especially like if it's medication changing or pressure changing on a device.

You don't want somebody inadvertently or trying to change that to, you know, they say well if this dosage is good for me let me up the dosage and it's probably even better. So there is a need for lockout mechanisms.

And the design, then, with a lot of care and understanding that it's better not to have them but then, but if you do need them that you're taking a lot of care in how you design them. Maintenance - many people now, lay users, do have to start maintaining their own devices.

If they're using them once a day, for example, that device is going to be there with them at all times. So they need to understand how to keep it clean, how to keep it dry or whatever else that they need to do - how to clean the components or the accessories.

And a lot of times too, with reimbursement issues, people tend to own their device after a few months of use. They only get reimbursed up to a certain period of time and then they become owners of that device. So they are going to need to know how to maintain it.

In the area of calibration we prefer no calibration or minimal calibration understanding that some devices do need to be calibrated.

For instance, glucose meters, if you have a new box of test strips or of strips you will want to use the test strip to make sure that it's calibrated to that

particular lot number. We prefer that you do have step by step instructions when you are - if you do have to have a calibration.

And then finally looking at mechanical strength and how portable is that particular device? You want it to be portable. Is somebody going to make it portable if it shouldn't be portable? And how can it withstand transport conditions? Can somebody be bumping into things?

Can it fall? The fall test is really very important here because we tend to drop a lot of things. And how can this withstand good transport conditions. Electrical issues are very big in design considerations for devices going into the home environment.

Again, you're looking - in the clinical environment you're looking at controlled environments. And outside of the clinical environment it is not so controlled. And you have to look at supply names and what an interruption of power could be with the supply names.

And voltage limitations with that particular device or with the home or wherever it's going to be used. What is the internal electrical power source and what is the typical operation time? Does it need recharging?

And if it needs recharging, is there any time that - where you have to replace anything? There are permanently installed devices that you need to have protective grounding. I think of hemodialysis here where they do need to have protective grounding with these permanently installed devices.

Outlets and adaptors - you can - it's not safe to put a three pronged outlet into a two pronged home. And you need to be designing your devices in

accordance with that, understanding that that could be happening quite frequently, and looking at good surge protection.

And then there's power outages. What is the backup power? What is the emergency contact information? What should somebody do in the event of a power outage? And again, what is the battery life of the - of your particular product and letting people know what that is.

And is that sufficient in different areas where somebody might be using this product? Also in design considerations - continuing on with electrical. We're looking at electromagnetic compatibility. What kind of EMC testing has been done?

Can you safely walk into stores and things and walk through the security area and there's not going to be a problem with - with EMC? What about wireless technology and radio frequency?

I know of an instance where somebody was wearing a Holter monitor and she lives in the basement of an apartment building. And she was trying to send her messages to a place in Texas from Maryland and it wasn't transmitting.

She didn't realize that she had to be standing up on the hill in order for this to be transmitted. And just instructions to say this is where you need to be when you're transmitting your information, would have been very helpful. Some of these things cannot be designed out. Some of them can.

And then finally, alarm systems. You're - you have to understand there's going to be a lot of noise inside and outside the home environment. There can be construction going on. There can be fans, there can be loud TVs, there can be music. There's all sorts of things.

A lot of people might have hearing impairments and so they're not going to hear an alarm go off. We do suggest you try to have two different types of alarm systems on your devices that are going into the home.

And it could be a combination of visual and auditory, auditory and tactile, tactile and visual.

But something so that if a person is not in the room and they are taking care of somebody else - let's say they're out in the garden, they're out in the kitchen, that they can find out that that alarm is going off and that it's not just showing a red light in the room by the person - by the patient.

So those were the three big areas - the three integral areas where you're looking at again, the design of the device, the environment in which it's going to be used and then the user themselves. The other pieces of the guidance document that we had were human factors.

And I can't emphasize enough, you should be looking at human factors and usability testing of your device. Go to the people who will probably be using that device on a regular basis, and get them involved at the beginning, at the inception of your device.

And work with them throughout the device design, up until the end, including the instructions for use. Also test your user training and if there's certification needed for your device as well. Make sure that they have tested that too. Outline your responsibilities.

If there's a care partner or a caregiver or a care recipient they might all have different types of responsibilities. And tell them specifically what they should be doing.

If there is a need for recertification every year, every few months or any type of retraining - if there has been a recall of a portion of your device and you need to educate them on what that is, find ways to get that to the individual who is going to be using that device.

Labeling is also extremely important. And in your labeling you should include ways for handling the device in an emergency, for any natural disasters or power outages. I don't know how many power outages we had in this area this summer but we had quite a few.

And people need to know what to do in cases of an emergency like that. Disposal - this might seem very easy but it's not. And we know that each state has different requirements for disposal of biological waste and sharp disposal.

But just tell them that - what they need to know - that you need to check with a, you know, either the state or if there's a disposal area. Some manufacturers also provide ways for people to exchange their - let's say their sharps boxes for another one.

Just let them know in the labeling, what they should be considering. And finally is the hygienic maintenance area. And again, I talked about maintenance earlier but this is the cleaning or the disinfecting or the sterilizing or the drying.

Whatever it is that they need to know to do and what types of materials they need to use in order to clean that device properly. And finally, there's the post

market considerations. You should have a customer service number. I think almost everybody has one.

But we did have to have that in the guidance here. And some sort of technical assistance phone number or a Web site or an email address, some way that somebody can get in touch with - with somebody and get their questions answered as they're trying to operate their - their device.

Especially, you know, on weekends when - when they feel so alone anyway and there's typically no medical assistance available. There's the medical device reporting. Encourage people to report problems to MedWatch and you can allow that.

You can also say no, we do not necessarily put that in the guidance. If you want to add that in you are allowed to do that. We did remove - in the final guidance document, we did remove a section about selling and purchasing used prescription devices.

We believe that industry really does not have a lot of control over where their products go after a period of time. And so we did - we did take that out of there. So in closing, let's see here, home use devices - they need to be - this is something I constantly preach.

They need to be useful. And in order - if they're useful, they will be usable. They should be iterative. You should be able to follow step by step, what it is you need to do to operate that device safely. It should be intentional.

Any time you interact with that device there should be an intentional thing that happens. If it's feedback, if it's another step, whatever it is, it should be intentional. Intuitive - people argue what is intuitive?

But as much as possible that you can just operate it kind of like your smartphones, it ends up being pretty intuitive. And if you do make a mistake you can go backward and not feel like you've just hurt somebody. They should be integratable.

You'd be able to integrate them into your - into the person's normal lifestyle. And that it doesn't stand out. And I know a lot of young people with their - with their insulin pumps, they want something that looks really cool.

And so they want to have it integrated into their environment and not have them stand out from the rest of everybody else. It should be informative. And it should be informative to the point where it gives you the information you need.

A lot of people - and this is where you can, you know, do things based on people who have - who are very comfortable with their device, versus people who are not real comfortable with their device. But it gives them the information they need.

And if they like to have a little bit more information that you can add that in there for people who like to have a lot of information. But don't overwhelm people with information that may not be necessary. And it should address those risks that are unique to the home environment.

And allowing people to live the way that they want to live. And these are just a few people with safe and reliable devices that lead to living well. And that concludes my talk.

Irene Aihie: We'd like to open up the line for questions.

Coordinator: Thank you. If you would like to ask a question please press star 1 on your touchtone phone. You will be promoted to record your first and last name. Please check that your phone is unmuted before you record. You'll be called on at your turn.

If you are in the queue and then decide to withdraw your question, you can do so by pressing star 2. One moment to give your participants time to queue up please. We have a gentleman from Summit Medical Products with a question.

Man: Yes. I just had a question about has - is there some mapping between this and the usability standard for medical devices, the IAC, I think it's 62366?

Mary Weick-Brady: We did take a look at 62 - 62366. We looked more at ISO IEC 60601-1-11 which is the home use medical equipment standard. And we also looked at the HE 75 standard for human factors. So it's a little bit of looking at 62366 especially in the quality assurance portion.

But it was mostly with the 60601 and HE 75.

Man: Okay. Thank you.

Coordinator: The next question is from (Kurt Farrell). Your line is open.

(Kurt Farrell): Yes, hello and thank you for setting up the webinars. It's been helpful. Medical devices used internationally for home and the hospital environments - typically in our field they start off in the hospital. And then they're discharged appropriately to - out of the hospital environment.

So specifically, the IEC 60601-1-11 it poses an interesting strategy from the design perspective because you need hospitals preferred grounded power devices whereas the dash 11 standard is not. Do you have any comments or thoughts on that?

Mary Weick-Brady: You know, you broke up. If you could just ask your question one more time please?

(Kurt Farrell): Okay. Do you have any thoughts on grounded versus ungrounded in the hospital and then when patients are discharged with medical devices where in the home dash 11 standard requires ungrounded?

Mary Weick-Brady: Yeah. Jeff, did you want to comment on that? Do you want to jump on there?

Jeff Silberberg: Yeah. I had it on mute. Yeah. I'm thinking about it. I believe that you could - I understand the question and I agree that usually equipment in the hospital is - has a protective (earth) but it doesn't have to be.

I mean you can have - you can have equipment in the hospital with just, you know, double insulated with two prongs also.

(Kurt Farrell): Okay.

Jeff Silberberg: That you can use the same equipment - yeah, so then yeah, you could use the same equipment in a hospital and then transfer it to the home.

(Kurt Farrell): Thank you.

Coordinator: (Tom Bliss), you may ask your question.

(Tom Bliss): I'm interested in the definition of home use when applied to ambulances.

Irene Aihie: Oh yeah. Yeah. It will not apply to ambulances. The - that will be - that's something different. We do consider it to be where there is continued healthcare professional care going on. If it's - if there is no continuous, 24/7 healthcare professional there, then it would be considered a home use device.

With ambulances - we did go back and forth about this, both in 60601 and also here. But ambulances do have healthcare professionals with you continuously.

(Tom Bliss): Thank you.

Coordinator: If anyone else still has a question or comment, please press star 1 at this time and you'll be called on. One moment. We have another one coming up. (Khalid Nishma), your line is open.

(Khalid Nishma): Hey. As for a medical device manufacturer it seems like there's a lot of approval requirements for the type of devices that manufacture. I understand there is like a CM - a - EMC requirements. There is an ISO 60601 requirement.

Is there any listing for what kind of approval needs to be performed for what medical device manufacturer? Is there any reference that we could use to see what exact testing and approval that requires for what devices? Thanks.

Mary Weick-Brady: I'm not sure that I understood the question. You're asking is there a reference for...

(Khalid Nishma): Like for example, we're lighting manufacturing. We're manufacturing lights used in the surgical rooms and outpatient rooms. Now there is a certain testing required to approve these kinds of devices. Like we have to do EMC testing, we have to do a safety testing. Those are required for the lighting.

Now let's assume something used in the surgeries like catheters or some other devices used in other end users like clinical or hospital. What other approval or testing required for those catheters, and so on? And so it's - I'm sure there's a huge list for what is required for what.

What are the approval requirements for what devices? Is there any kind of reference for that from the FDA perspective?

Mary Weick-Brady: Yeah. That's a very loaded question because there are so many different requirements depending on the type of device and the medical specialty.

So I think what you should do is - is if you have a particular device that you're concerned about, send it - there's a thing up on there that's called (Dice) at FDA dot HHS dot gov. Go ahead and send your question there. It's a pre-market concern that you have.

And it may be outside the - what we're doing here with the home use. And I would just suggest that you send your question in there. They're very good with getting you real solid answers there, especially if you have a particular device that you're concerned about.

(Khalid Nishma): Okay. All right. Thanks.

Mary Weick-Brady: And there is - there is also on that Web - on the Web site you can look at something called device advice. And it may answer your question as well.

(Khalid Nishma): Okay. All right. Great. Thanks.

Mary Weick-Brady: Okay.

Coordinator: At this time we have no one else queued up with a question.

Irene Aihie: Thank you. This is Irene Aihie. And thank you for participating - for your participation and questions today.

Coordinator: Ma'am, we do have questions coming up again.

Irene Aihie: We'll go ahead and take more questions.

Coordinator: Thank you. (Chris Rogers), your line is open.

(Chris Rogers): Hi. My name is (Chris Rogers) and I had a question regarding software. So if the medical device is leveraging hardware that's retail ready but our proprietary software utilizes that hardware in a unique way, how much testing do we need to do on the hardware, especially with the electronic components?

Or is it something that we can - let's say we can utilize what's been done already because it's already accessible to retail?

Mary Weick-Brady: Well that question I know I cannot answer. So I'm - I'm going to ask you to also send that to DICE And I think that they'll be able to answer that for you for required testing. I'm honestly not sure about that.

Jeff Silberberg: Yeah. I might be able to get a start on that. I think as often happens, the answer is it depends. And it really depends on how it's used. If it's - for

example, if it's used in the vicinity of a patient, it might need some of the electrical safety testing.

And we would at least, you know, I would want to see the testing that's been done. In other words, even if you just give us a data sheet that has, you know, and some computers have been tested to the electrical safety standard or - and they'll be tested for EMC and they'll list the standards they've been tested to.

So it also depends on whether you're supplying that piece of hardware with your software or whether you're just selling the software and it's intended for use in any general piece of computing equipment. So there are a lot of - a lot of variables here.

(Chris Rogers): Totally. I appreciate the answer. That was great.

Jeff Silberberg: Sure.

Mary Weick-Brady: Thanks Jeff.

Jeff Silberberg: Sure.

Coordinator: Next we have a question from (Mark Christian). Your line is open.

(Mark Christian): Hello. I just wanted to ask if there is any specific detail on the cyber security and security relationship to the home setting.

Mary Weick-Brady: At this point FDA is still working on the cyber security issue. So we'll be factoring that in as we put the cyber security area together. It's kind of a general work in progress at this point.

And that I chose not to put anything in about cyber security into this particular guidance, because I believe we will be having something out there soon on cyber security.

(Mark Christian): So we should continue refer to draft guidance as it's been published to date?

Mary Weick-Brady: Yes.

(Mark Christian): Thank you.

Coordinator: And the last question we have at this time is (Erasmus Lopez). And I believe you may have your line muted sir. Your name didn't record. Please check your mute button Mr. (Lopez).

(Erasmus Lopez): Oh sorry. I apologize. My question has been already asked. It's about - it was about cyber security also. Thank you.

Coordinator: Okay. (Aditia Suanther)?

(Aditia Suanther): Yeah. My question was that would the devices for home use be given a product/OTC designation?

Mary Weick-Brady: What type of designation?

(Aditia Suanther): Prescription or OTC designation? Or both.

Mary Weick-Brady: Yeah. They can be both. They can be prescribed or they can be over the counter. We're looking at both because so many devices that were prescription before and just being used by healthcare professionals are now going home with the lay user.

So we have to address that particular area to understanding that devices are migrating into the home quite frequently.

(Aditia Suanther): Okay.

Mary Weick-Brady: Okay?

(Aditia Suanther): Thank you. That - yeah, that was my question. Thanks a lot.

Mary Weick-Brady: Okay.

Coordinator: And so far that looks to be our last question.

Irene Aihie: Okay. I'm going to wait ten more seconds if we...

((Crosstalk))

Coordinator: It's star 1 and record your name when prompted.

Irene Aihie: Okay. Thank you.

Coordinator: All right.

Irene Aihie: This - this is Irene Aihie. And thank you for your participation and questions today. Please remember that this presentation will be available on the CDRH Learn section of FDA.gov. The written transcript will take a couple of days but should be posted no later than Monday, September 15th.

If you have additional questions please use the contact information provided at the end of the slide presentation which is (Dice) at FDA dot HHS dot gov. As always, we appreciate your feedback on today's presentation. Again, thank you for participating. This concludes today's webinar.

Coordinator: This does conclude the conference call and all parties may disconnect at this time. Thank you.

END