FDA Webinar: Final Guidance-General Wellness: Policy for Low-Risk Devices

Moderator: Irene Aihie
September 01, 2016
12:00 pm ET

Coordinator: Welcome and thank you for standing by. All participants will be able to listen only until the question-and-answer session of today's conference. At that time if you would like to ask a question, you may do so by pressing Star then 1 and recording your first and last name.

Today's conference is being recorded, if you have any objections you may disconnect at this time. I would now like to turn the call over to your host for today, Ms. Irene Aihie. Ma'am you may begin.

Irene Aihie: Hello, and welcome to today's FDA Webinar. I am Irene Aihie of CDRH's Office of Communication and Education. On July 28, 2016, the U.S. Food and Drug Administration issued the final guidance document General Wellness, Policy for Low Risk Devices which explains that the FDA does not intend to actively regulate low-risk technologies that are intended for general use only - general wellness use only.

The focus of today's webinar is to share information and answer questions about the final guidance document. Today's presenter is Simon Choi, Senior Science Health Advisor from the Office of the Center)Director.

Following the presentation, we will open the lines for your questions related to topics in the final guidance only. Additionally, there are other (Center) subject matter experts available to assist in the Q&A portion of our Webinar. Now I give you Simon.

Simon Choi: Thank you, Irene. Good afternoon. This afternoon we'd like to cover the overview of the guidance that went out last July and also provide you access to a Q&A session.

First a little background about the guidance. The draft went out January 20 of 2015, we received 12 comments. The basics tenants of the guidance remained unchanged and the final guidance was published July 29 of 2016.

I'm going to provide you with an overview. FDA encourages development of general wellness products such as fitness trackers which can empower individuals to take a more active role in managing their health.

The final guidance takes a hands-off approach to the regulation of low risk, general wellness products that only promote a healthy lifestyle or promote a well-known association between a healthy lifestyle and a certain chronic disease or condition. FDA will continue to focus its oversight on products that are invasive, implanted or pose greater risk to patients.

The key principles in the guidance. CDRH does not intend to examine low-risk general wellness products to determine whether they are devices within the meaning of the Food and Drug Cosmetic Act, or if they are devices, whether they comply with the pre-market review and post-market regulatory requirements.

Some of those requirements are registration and listing, pre-market notification, labeling requirements, good manufacturing practice requirements as well as MDRs, also known as medical device reporting requirements.

In the guidance, we define general wellness products that have to meet two criteria. They are only intended for general wellness use and present a low risk to safety of users and other persons. This is the highlight for the entire call this afternoon. Your product must have only a general wellness claim and it must meet the criteria of low risk as defined in the guidance to equate to a low-risk general wellness product.

To go a little bit more in-depth, this describes the details of what's in the guidance. For low risk, the product must be meeting these three criteria. The product must not be invasive, it must not be implanted, and it must not pose risks. Going back to the first one, when the product is not invasive as defined in the guidance, it must not penetrate or pierce the skin.

In Addition, I'll refer you to page five of the guidance that says the FDA recommends that you look at whether we currently regulate the product of the same type.

The other criteria was the claims or intended use. So you can have a general wellness claim that does not mention any reference to a disease or a condition so the intended use is pretty straight forward, it just relates to maintaining a healthy lifestyle.

The other sub category is intended use relates to a healthy lifestyle with reference to a disease or a condition. And if you do that, the role of the healthy lifestyles may play an important role in the health outcome for the disease or condition but that must be well understood and accepted.

For the purpose of this guidance, the claims or the intended uses are twofold. Intended use that relates to maintaining incurred in general state of health or healthy activity, or intended use relates to the role of healthy lifestyle and it mentions a chronic disease or a condition.

The first category of intended use relates to encouraging general state of health or healthy activity but does not make any reference to disease or condition. Some examples, a claim to promote or maintain a healthy weight, encourage healthy eating or assist with weight loss goals, or claims to promote relaxation or manage stress. I refer to section three of the guidance for additional examples of these claims.

Again, this first category is when there is no mention of disease or condition, you can claim to promote relaxation or manage stress, claim to improve mental acuity, concentration, problem solving, multi-tasking, or you can claim to enhance learning capacity. Claims to promote physical fitness, promote sleep management, to promote self-esteem, all examples of the first category of intended use.

The second category of intended use relates to the role of the healthy lifestyle where you do mention a chronic disease or condition. When you mention a chronic disease or condition, there are two sub-categories.

Your product can promote, track and or/ encourage choices which as part of a healthy lifestyle may help to reduce the risk of a certain chronic disease or condition, or your product promotes, tracks and encourages choices which as part of the healthy lifestyle may help to living well with certain chronic disease or conditions, and I'll be going over specific examples of these.

So one example is a product that promotes physical activity as part of a healthy lifestyle that may help to reduce the risk of high blood pressure. Another example is software that tracks your calories, helps you manage a healthy eating plan, and may help living well with high blood pressure and type II diabetes.

Another example, product tracks your sleep patterns and promotes healthy sleep habits that may help reduce the risk of developing type II diabetes. Again, I refer you to section three, page four to five for additional examples.

The concept of low risk is not to be confused with low risk and classification of devices. As defined in this guidance, you may be - you must be able to answer yes to these three questions. Is the product invasive, implanted, or does it pose an intervention or technology that poses a risk to the safety of users if regulatory controls are not applied?

There are some examples of products that present risk to the user's safety and will not be considered low risk and therefore not a general wellness - low-risk general wellness product.

A laser product that claims to improve a user's appearance by rejuvenating the skin. Although the claims of rejuvenating the skin and improving confidence in the user's appearance are general wellness claims, the technology itself poses a risk of skin and eye burns. That's referenced in section four of the guidance, page six.

Implants promoted for enhanced sexual function. Implants pose risk to users such as rupture or adverse reaction to implant materials and risks associated with the implantation procedure.

So what are some examples of low-risk general wellness products? A mobile app that solely monitors and records your daily energy expenditure and cardiovascular workout activities to allow awareness of one's exercise activities to improve or maintain good cardiovascular health, this claim relates to a specific organ only in the context of general health, does not refer to any disease nor medical condition.

The monitoring or recording of exercise activities present risk such as inaccuracy when made in the absence of disease or medical claims but the technology itself does not pose a risk to the safety of users. Therefore this product will be considered a low-risk general wellness product.

Another example is an app that monitors and records food consumption to manage dietary activity for weight management. This claim relates to dietary choices and is a general wellness claim and the technology does not pose risk to the users or other persons.

Another example is a portable product that is intended to monitor the pulse rate of users during exercise. This claim also relates only to exercise and hiking, does not refer to a disease or a condition. It is a general wellness claim and therefore considered a low-risk general wellness product. Now I'd like to transition to the Q&A session.

Coordinator: Thank you. At this time we would like to begin the question-and-answer session of the conference. If you would like to ask a question, please press Star then 1. You must record your first and last name to ask your question. And to withdraw your question, you may press Star then 2.

Once again, to ask your question, please press Star then 1 and record your first and last name clearly. One moment for the first question please. The first question comes from (Jennifer Lieb). You may ask your question.

(Jennifer Lieb): Hi. Just want to make sure you can hear me all right.

Irene Aihie: Yes. We can hear you.

(Jennifer Lieb): Great. Thank you. So my question is the final guidance includes two examples of - that are not eligible for enforcement discretion where there is an element of prediction included based on a test result.

One is a web-based product in the form of a computer game that claims to diagnosis or treat autism, and the other was one that claims to enhance athletic performance by providing suggestions bases on the results of an invasive blood test. So my question is I was hoping that you can describe or provide an example of what types of predication when combined with promotion or encouragement would be eligible for enforcement discretion.

((Crosstalk))

Irene Aihie: One second while we get that answer for you.

(Jennifer Lieb): Thank you.

Simon Choi: Thank you for the question, I'd like to introduce to you Bakul Patel, Associate Director of Digital Health (for CDRH).

Bakul Patel: Hi, this is Bakul. So just reflecting back on your question, I think you asked about what kinds of product that would - that will fit the general wellness

claim or general wellness which would be for athletic performance. I think when we talk about exercise, we are talking about general healthy lifestyle and healthy living.

There may be no answers that we - I'm not getting from your question but it's mostly from the guidance perspective, we've been talking more - mostly importantly about healthier living, and if products are helping folks be healthier and it not about cardiovascular performance or anything like that but it just happens to be about healthy living is what we are trying to say that's general wellness. I hope that's helpful.

(Jennifer Lieb): Yes, I think what I was more referring to was the aspect of prediction when it's combined with promotion. So I don't know if you could speak to, you know, would it matter if a wellness product was - a prediction was based upon like a proprietary unpublished algorithm but I was hoping you could speak towards the prediction aspect of it.

Bakul Patel: Yes. So I think it's important (to sort of) differentiate what's - what we are calling out in this policy as general wellness products and the claims where we are saying are for healthy wellness living as opposed to diagnosing or a prediction or screening.

I think that's some - a different topic outside the scope of this guidance to talk about and it's a larger broader topic of where FDA looks at in terms of screening and prediction, and other types of diagnostics that may be related to a particular disease or condition.

Irene Aihie: We'll take our next question.

Coordinator: Thank you. Once again if you would like to ask a question, please press Star then 1 and record your first and last name. One moment please.

Irene Aihie: Operator - excuse me, Operator, do we have any more questions?

Coordinator: One moment, the next question comes from (Bill Jones), you may ask your question.

(Bill Jones): Thank you. I'd just like to quickly thank Simon and Bakul and the Digital Health team at the FDA for (planning) this Webinar. I have two questions for you if that's okay. I'll ask one at a time.

So the guidance states that one factor to consider in determining if a product is a general wellness product is whether CDRH actively regulates products of the same type as the product in question.

At the same time the guidance states that a product that monitors pulse rate would be a general wellness product if the claims relate only to use during hiking or exercise as you mentioned earlier. And products that monitor pulse rate for a clinical purposes would of course be regulated as medical devices.

So can you confirm that a primary factor for consideration as a general wellness product is not whether the FDA regulates a similar product but rather whether it regulates a product with the same or a similar intended use? In other words, I guess what I'm saying is in the guidance, or where you say same type in the guidance that means same intended use, correct?

Bakul Patel: Yes. So you have - you got it correctly. I think it's - I would say in addition to just intended use is what the product does and functionality of the product is also important to consider, and that's part of the calculus to think about is if

your product is a pulse ox and it's use for clinical determination of some kind, then that would be considered to be part of that calculus.

(And) for the longest time I think pulse oximeters have been sort of under such certain portions of pulse oximeters have been under a different type of enforcement discussion so as you can see (to the) (unintelligible). So you have to take that into consideration of where this products fall in our current and what we are doing with those products currently and we regulate them.

That's why when Simon talked about don't misread the lower risk is what we consider low risk, typically when it's regulated and activity overseen, so there is two different things. For purposes of this guidance, you need to think about a product that's just promoting and motivating people to be healthy and then, you know, (if it's) truly low risk from (it's) either (them going to) (unintelligible) risk.

(Bill Jones): Got it. Okay, great. So yes, so same type, and it essentially means seem intended use. My second question is the guidance recognizes that certain general wellness products may present risks such as inaccuracy but that such inaccuracy is not a concern in the absence of disease or medical condition claims as Simon mentioned earlier.

So can you confirm that the FDA would not deem a product to be outside of the scope of a general wellness product solely because it may present a potential for inaccuracy if that inaccuracy does not present risk to the user or other people? Was that clear?

Simon Choi: Right. If I interpreted your question correctly some of the - (all) -- depending on the general wellness claims, this is apparently a general wellness claim and the claims doesn't reference a disease or condition, that example that you

posted or mentioned about the inaccuracy not affecting the overall risk as defined in this guidance is correct.

(Bill Jones): Okay. Great. Thank you.

Coordinator: The next question comes from (Colin Pollard), you may ask your question.

(Colin Pollard): Yes, this may be parsing the guidance a little bit but I just was wondering whether FDA would consider an intravaginal product to be a low-risk product. It doesn't pierce the skin but obviously it's introduced into the vagina like a tampon or something like that?

Bakul Patel: So this is (unintelligible)...

(Colin Pollard): I'm not saying the device would be a tampon, I'm just saying - I'm just giving an example of intravaginal...

Bakul Patel: Yes.

(Colin Pollard): ... product.

Bakul Patel: Yes, understand. This is Bakul, and wanted to express the point I think which was raised by the previous question is in also looking at intended use and what we have current - what we are doing currently with those products - those type of products, and the intended use or placement of into the calculus.

So, yes, so it doesn't have to be under the skin to be called implanted, (it doesn't) - it has -- does it pose a risk to patients and that's what we are talking about some sort of involved intervention or technology that may actually pose a risk to users.

And you would think, and again, that particular -- in this scenario, the hypothetical scenario that you're posing, you know, we could definitely engage with FDA to sort of get deeper into this particular question but we would consider if there is a product that's inserted into the body and could cause a risk and we are regulated in the past, we would continue to do that.

(Colin Pollard): Yes. I agree. Thank you.

Bakul Patel: Yes.

Coordinator: The next question comes from (Ermie Asher), you may ask your question

(Ermie Asher): Hi. Is there a high-risk contraindication for a general wellness product, does that device manufacturer then have to spell out all the potential risky contraindications? Example, pulse rate monitors being used by a patient with (Unintelligible) during exercise.

Bakul Patel: (Yes). We may have missed your first part of your statement, can you repeat that please?

(Ermie Asher): So I'll repeat the question. If there are high risk contraindications for a general wellness product, does the device manufacturers have to spell out all potential risky contraindications.

Example, you know, the continuous heart rate monitors that are being used during exercise, and if the patient has (Unintelligible), does the manufacturer have to spell out everything head of time or the onus is on the patient to make the decisions on their own?

Bakul Patel: Yes, give us one second. I'm going to give the microphone to Linda Ricci) who can address this.

(Linda Ricci): Hi, this is (Linda Ricci) from the Office of Device Evaluation. So I'm going to get at your question in a little different way. If you have a product that meets the general wellness definitions as, you know, we've talked about pulse rate being for exercise, that does not mean that we expect anybody that is using that general wellness product to be free of risk.

So in terms of the medical device aspects for that device, if it is a general wellness product, then it is incumbent upon the manufacturer for that device just like with any other general purpose device to make sure that they have appropriate cautions on that device. That that is outside of what the FDA would regulate at that point.

Simon Choi: Simon again. Let me just add that on page two, section two of the guidance, the last sentence reads product inclusion under the general wellness policy of this guidance...

(Ermie Asher): Sorry, I can't hear the gentleman speaking right now.

Simon Choi: Sorry, let me try this again. On page two of the guidance, section two, let me just read this one sentence that says a product's inclusion under this general wellness policy in this guidance does not establish that it has been shown to be safe and/or effective for its intended use.

(Ermie Asher): So then the problem can be tackled in two different ways. One is either spell out all the contraindications upfront and, you know, specify in detail the intended use which automatically puts all the contraindications out of that basket?

Bakul Patel: I'm going to just talk to what (Linda) just mention and maybe in a slightly different way. I think what (Linda) mentioned was I think like any other general purpose product, there are things that manufacturers will do and claim and share with their users that may not necessarily be for medical purposes.

And there may be things that maybe they may say, or the functionality of the product is limited that it does not do any medical purpose as defined under the definition of a device.

So it's a choice that manufacturers - we rely on the choice the manufacturers make and we are providing guidelines in this guidance document to say that we expect people who are making general wellness products to be in this category except if they're - only if they are in the low-risk as we have defined.

So, and again, we leave it back to the manufacturer to sort of define what those indications, cautions, warnings, whatever contraindications if you think may want to be - you want to share with your users.

(Ermie Asher): Thank you.

Coordinator: The next question comes from (Mirage Patel), you may ask your question.

(Mirage Patel): Does FDA cover certain wellness products in the home health benefit?

Bakul Patel: Can you expand on that because I'm not quite sure...

(Mirage Patel): (Unintelligible) under Medicare that had to go on the Home Health Benefit due to recovery from a medical condition or a medical impairment, how does FDA reckon that? They explain what general wellness products are covered

under the Home Health Benefit because I did not get a proper explanation when I broke a knee and my leg and I needed to get recovered.

(Linda Ricci): Hi, this is (Linda Ricci) again from Office of Device Evaluation. So in this guidance we're discussing the regulatory framework for products that have general wellness. When it gets to decisions on insurance and how things would be covered for these types of products, that is really outside of...

(Mirage Patel): Okay.

(Linda Ricci): ... the purview of this agency.

(Mirage Patel): Do you think that's fair in America for some people to get facts and evidence - instructions from wherever they're getting them for general wellness while other American citizens have to research things on their own for general wellness?

Do you think that's fair that there are people getting like general wellness information from the part A Medicare claims system, those worksheets and information from ISF and other people have to put in their own self sufficiency to figure that out?

Irene Aihie: Thank you so much for question. Unfortunately, that question is out of the scope of today's presentation but if you could please send your question or your comment to DICE, that's D-I-C-E, at FDA.HHS.gov and someone will get back to you as soon as possible. Thank you and we'll take our next caller.

Coordinator: The next question comes from (Doug Atkins), you may ask your question.

(Doug Atkins): Hello. In some recent guidance documents that have been issued, the term enforcement discretion has been used by FDA whereby devices or particular products may be medical devices but the FDA's choosing not to enforce requirements.

So my question is, for products that would meet the definition of general wellness products in this guidance, is the policy - or is the position of FDA that these products don't indeed meet the definition of a medical device, or is it more that FDA is going to practice enforcement discretion in these instances?

Bakul Patel: So this is Bakul, let me take that question. I think it's a really good question. So one of the very first things in section two of - on page two of the guidance which we talk about is, and Simon covered this in his presentation, was there may be general wellness products that do not meet the definition of a medical device and there may be general wellness products that do meet the definition of a medical device for all kinds of various reasons either its functionality or the claims.

Just to keep that in perspective, and when we are exercising our option and discretion to enforce or for compliance to the rules and regulations, we only can - we only do that for those that potentially could meet the definition of a medical device.

So it's important to - for manufacturers and others to sort of think about it from the perspective of if there are products that we don't - FDA does not currently think would meet the definition of a medical device, we would continue to be that way. That does not mean there will be calling them or including them as medical devices.

But in case there are products that are medical devices and they fit the scope of the description of the products that are described in this guidance document that i.e., low risk, then we would not be enforcing or complying - or enforcing compliance towards a regulation.

(Doug Atkins): Just a question follow up to that is so in some of these categories of things for which FDA for which there - they may be devices, the FDA is going to be having a policy of enforcement discretion, are there plans to issue any regulations for these categories of devices such that they could be rightfully classified as class one or class two.

As opposed to being unclassified and, you know, automatically class three just for purposes of understanding what, if any - if FDA did - had the policy to enforce regulations what would be applicable?

Bakul Patel: Yes. For those -- I mean this document specifically talks about those low-risk general wellness products that we are saying that we will not enforce which means that regardless of -- that means we are not even going to the exercise of classification for these type of products that are low risk.

And for those that we are currently regulating, we will continue to do that but that's the approach. So we have not crossed that thought process - for this low risk we don't think it's necessary for us to go engage in a classification activity.

(Doug Atkins): So just one quick follow up. So just trying to square that with the MDDS example where a classification regulation was enacted and for classification for MDDS but still they're under enforcement discretion, how is that - how in your mind does that - is a that a different case or is that just a different activities that were taking place a couple years ago?

Bakul Patel: Yes. So thank you, and probably you'll have to get off to the next question but...

(Doug Atkins): Yes.

Bakul Patel: ... I'll just touch on this. MDDS classification was done prior to our policy of enforcement or choosing to not to enforce on those products so that's the difference. And we are - here we are proactively looking at low risk and setting a policy that we would not be choosing to enforce on some on these low-risk products.

((Crosstalk))

Coordinator: The next question comes from (Martin Cohen), you may ask your question.

(Martin Cohen): Okay. To get a perspective, I have a - there is a product that is, you know, non -- it has a theory behind it so, you know, kind of a scientific theory behind it, but is there any need to go into the background theory.

I mean do they care about that, you know, something may activate something in the thalamocortical system to change the way that it, you know, say a general wellness feeling when the product itself is just - is non-invasive, non-implanted and it wraps around a part of the body that has, you know, kind of a pressure point, you know, similar to acupressure, I mean, you know, do I need to go into the theory to or do they...

Bakul Patel: Yes.

(Martin Cohen): ... care at all, or do they just want to - they don't care about the claims, they just want to know is it safe, you know? So, you know...

Bakul Patel: Yes.

(Martin Cohen): ... or is it okay to refer back to a book that, you know, the theory behind it, you know? I mean how, you know, how much do I need to go into anything like that?

Bakul Patel: Yes, I mean, and so one of the things for today's presentation and discussion, we don't intend to get into a specific topics because it may just derail the conversation but we would welcome you reaching out to, again, the e-mail address is DICE@FDA.HHS.gov.

And we probably can help get back to you with specific response in terms of your scenario you're posing. It's D-I-C-E at FDA.HHS.gov. Hopefully we can get you an answer once you pose the question to that e-mail address.

(Martin Cohen): Okay, yes, and thank you for all the -- other questions have helped me a lot too, similar to my ideas of mine. But - and also, and the other few were kind of going around this issue, is there any way to look at a product that already exists and find out if that has been classified as a general wellness products, you know, just as, you know, is there any access to information like that?

Bakul Patel: Those products - so those products, I think this is related to previous question, those products that are currently classified in - are present in our classification database, you should be able to look that up online. And part two of your question was if there are general wellness products that we call them, or we have identified them and by this guidance of low-risk, obviously they are not classified.

And this was a discussion we just had in the previous caller who talked about we have - we are - where we talked about we are take - FDA is taking a proactive approach towards not engaging in that discussion and also not enforcing when they meet the definition of what we call low-risk general wellness products.

Coordinator: The next question comes from (Michael Tilleson), you may ask your question.

(Michael Tilleson): Yes. Thank you so very much for taking the questions. In the example of an accessory to a class two device such as a piece of exercise equipment intended to be attached to an AC-powered articulating hospital bed, would that be considered a low-risk wellness product under the enforcement discretion of this guidance?

Bakul Patel: So, again, this maybe - that question particularly on accessories is a little bit outside the scope of this guidance because we do have a draft document on accessories out there and we are working on finalizing it but I think your question clearly falls into that.

And again, this document - this guidance document focuses only on those things that are back to the fundamentals of the document is about promoting, encouraging and motivating people to stay healthy. So your scenario may not necessarily fit into that situation and we may want to look for when we have the discussion on accessories.

(Michael Tilleson): Okay, thank you very much.

Coordinator: The next question comes from (Gabe Jarred), you may ask your question.

(Gabe Jarred): Yes, hi. When you read the guidance it seems to refer basically to encouraging and promoting a healthy lifestyle. By definition it seems that it's - and a lot of the examples given are either mobile medical apps or pulse monitors, things of that nature, whereby the user is given the information which he or she can then use to make decisions. In other words, the promotion is something which the user is doing.

There is not a lot of examples, in fact I don't think there's any where the use of promotion is definitive to what the actual device itself is doing in terms of the fact that maybe a device does something physiological to a part of the body which can lead to improvement or a maintaining a wellness.

The guidance gives an example of improved self-esteem by improving skin rejuvenation but gives a negative example of say using a laser which would pose a hazard. I guess my question is if there is a device which is low risk, but the device itself is doing something, again, physiological, whatever that is, and as a result of that, that process may help to improve general health or wellness of the individual.

I might have asked that in a bit of an awkward way but as you can see a lot of the examples are, you know, I guess what's throwing me is the use of the word promote and encourage. You know, that sort of implies something consciously done by the user rather than the actual device itself.

Bakul Patel: So thank you for your question, I think you're pointing out sort of the boundaries of where we don't consider products to be general wellness and they may be - they may actually fit into what we have been regulating in the past as products (that made) - I mean today we regulate products that are non-invasive but are still providing physiological signals or understanding of the

physiology of the person, or with - in relation to disease or even general condition.

And one of the things that we have said in this guidance document as part of the - determining the risk of the product is also what regulations we have currently that we felt - that we feel today are - where controls are necessary to provide the level of confidence and reduce the level of - reduce the risk from any - when those products don't work as intended.

(Gabe Jarred): Right. So if I could just quickly follow up. So in the guidance example of the - the example of improving self - a product that is improving self-esteem by improving skin rejuvenation but that the laser component would pose a risk. If that was say a product which didn't involve a laser but something else, would that product still be a general wellness device?

Bakul Patel: Yes, so any harm that could happen because of either laser or other energy that's exposed to - into a human body would be concerning and we would not think at this time as meeting the criteria of low risk.

(Gabe Jarred): Right. I understand. Okay, I think that explains it. Thank you.

Bakul Patel: Thank you.

Coordinator: The next question comes from (Ginger Emmrick), you may ask your question.

(Ginger Emmrick): Yes, and my question might fall into this accessory category that you discussed earlier but I'm wondering if you had a software that fit within this general wellness category and data from that general wellness software was pushed and pulled between regulated software, how the FDA would view that scenario.

Irene Aihie: One moment as we get that answer for you.

(Linda Ricci): Hi, this is (Linda Ricci) from ODE. There is a lot to be said about getting to the details. I'm not going to get into accessory policy - so getting back to the general wellness policy, if the device meets the definitions that we've laid out in this guidance and it can be considered general wellness.

There may be circumstances where regulated devices use information that was gathered by general wellness products.

But I think it's important to understand that this guidance is about those devices that are for general wellness and that determining whether or not your product is a general wellness product should follow the guidance that is set forth.

Irene Aihie: We'll take our next question.

Coordinator: The next question comes from (Claire Higgman), you may ask your question.

(Claire Higgman): Yes, hi. My question might be somewhat similar to other questions that have been asked but it's a related to a specific example provided within the guidance for a general wellness claim.

It states in the guidance claims to improve general mobility or to assist individuals who are mobility impaired or in a recreational activity, for example sport wheelchairs, speech access wheelchairs. My question is how is FDA differentiating these wheelchairs to those that require a 510 K as an example?

Irene Aihie: One second while we get that question for you, or that answer for you.

Bakul Patel: Would it be better -- so we need - we may need to do some a little bit of research on that part.

(Claire Higgman): Okay.

Bakul Patel: (Is it) - if we can get your contact information and write to us, we would get back to you on that.

(Claire Higgman): Okay.

Irene Aihie: So just send your question to DICE. That's D-I-C-E at FDA.HHS.gov and we'll get back to you as soon as possible.

(Claire Higgman): Okay. Thank you very much.

Irene Aihie: You're very welcome.

Coordinator: The next question comes from (Patel Gubalyinen), you may ask your question.

(Patel Gubalyinen): Hello, good afternoon. My question is about the use of these products, how the potential use of these products outside what they are marketed for. So basically sort of off label use and a use that would have made them medical devices if that was the original intent of the design of the device.

So whether this is because of word of mouth or because some doctors suggest or recommend that the use of these devices to their patients. So I would like to know if you have any perspective around this potential problem.

Bakul Patel: I may not have gotten completely your question but if you're asking the question whether these products that we are describing in this guidance document, how would users know that they're available and is that -- am I heading in the right direction?

(Patel Gubalyinen): No, it's more because I have a specific example. One of these arm bands that's used to monitor the heart rate was used by a doctor to determine when the person was wearing it had a heart attack. So say that these type of use becomes more widespread and this device was not intended to actually do - be used in this way so, but say that these become more widespread.

Bakul Patel: I see what you're asking now, thank you for clarifying that. I think what you're asking is a little bit out of the scope of this particular guidance document but it is more on sort of practice of medicine and how the FDA looks at it from either off-label use or uses that doctors and take -- doctors conduct between their patients and - between their particular patients. So it's outside of the scope I think.

This guidance document talks about what we consider low risk and what we don't consider low risk and if those (meet) - if we are providing criteria for that, and helping folks sort of predetermine either (if) doctors or for users to see where FDA's position is. And when they don't meet low risk, they should engage with FDA in terms of determining when - (if) such product is actively overseen by FDA or not.

(Patel Gubalyinen): Thank you.

Coordinator: Once again, if you would like to ask a question, please press Star then 1 and record your first name clearly. One moment please. The next question comes from (Robert Darin), you may ask your question.

(Robert Darin): Hey, guys. Does the CDRH Digital Health Group intend to create a Web page for general wellness similar to the page that exists right now for mobile medical apps where you can post additional examples of general wellness claims like the ones that you guys have on page three of the guidance. It would obviously be for informational purposes and not exhaustive.

Bakul Patel: Yes. and there is plans -- this is Bakul -- and there is plans, some updating it and sort expanding as we learn more as we get questions through either (Unintelligible) of Digital Health. We haven't finalized anything yet and we are exploring what that would look like but, yes, that would - that's something that we are exploring.

(Robert Darin): Thanks.

Coordinator: The next question comes from (Holly Drake), you may ask your question.

(Holly Drake): Hi. I was - I have a similar question that might be related to a bullet point example on page six that talks about a product that uses blood samples to inform suggestions.

If my product was a mobile app and I was a separate manufacturer from another manufacturer of let's say a BG meter and I just partnered with them to say I wanted to import their downloads into my app to make suggestions, obviously they would continue to be regulated by FDA but would my app be part of their system in that case and have to be regulated as well?

Bakul Patel: Yes. So that particular example on page six that you referred to is to highlight the fact that if there is a system that collects blood and if that - and collection of blood and storing, transporting is public health - from a public health perspective, it can be risky and that's really what we are trying to expose on that - to that example.

I think what you're talking about maybe slightly different and may have a little bit more nuance which includes MDDS policy and other things that may be outside the scope of this document. But this is primarily, I mean primarily more geared and focused towards when you are promoting healthy life choice (Unintelligible) lifestyle choices, that's something that we would consider under this particular guidance.

(Holly Drake): Okay. So we - if it was just taking the readings but not displaying it and just making a suggestion that maybe at this point, your blood glucose is high, you should have a salad?

Bakul Patel: So it might be better if I think you may pose that question to either DICE or Digital Health on this particular use case that you're raising and we can work through (there) and folks can work through the nuances and get back to you.

(Holly Drake): Okay, thank you.

Coordinator: The next question comes from (Jonathon Helska), you may ask your question.

(Jonathon Helska): Yes, thanks again for the FDA team for putting together this very helpful Webinar. Generally speaking, would either a mobile app or a sensor collecting data directly from a patient that is used exclusively to support an FDA regulated clinical trial, would you consider this to be a general wellness device or simply a tool that's used within the context of clinical research that

would have to conform to the applicable regulatory requirements in either 21 CFR part 3.12 or 8.12?

Bakul Patel: So this - since this is a medical device sort of guidance, we are laying out policy in terms of whether it's a medical device and what compliance (Unintelligible) we would do regardless.

So I think, well, your question may be a little bit outside the scope of this particular discussion today where we don't discuss how these types of products may play a role in the clinical trials or clinical research for that matter, and that's a discussion for clinical trials part. And again, it's more about use of tools in a clinical trial as opposed to whether it's a device or not a device and this guidance focuses mostly on that - on the latter.

(Jonathon Helska): Thank you, that's very helpful. So if the device was used as part of a clinical trial, that doesn't necessarily designate it as a medical device or not, correct?

Bakul Patel: Yes, typically that's a trial and a research by research question whether it's a medical device or not, different considerations the researchers and the trial sponsors should think about as you - as most folks know, and that's a choice that the trial and the end points of the trial would probably determine. So, again, it's out of the scope of this particular discussion but (Unintelligible) that's the - just the basis of what we are talking about here.

(Jonathon Helska): Great. Thanks for your helpful response.

Coordinator: The next question comes from (Michelle Gwynithe), you may ask your question.

(Michelle Gwynithe): Hi, this is (Michelle Gwynithe). I -- does the FDA have any intention to perhaps look through prior device classifications or clearances to determine whether any products that were previously classified might fall within general wellness.

And for example, I think Bakul, you or someone had mentioned the pulse oximeter example where there's a classification for oximeters intended for sporting and aviation uses. In the current classification database under the product code OCH these are still listed as class two devices, exempt from 510K requirements but not GMPs or other general controls.

So those seem to be like something that could possibly fall on to the general wellness guidance now but there's still that existing classification in the classification database. Is there any effort to maybe go through those to sort of reconcile those with the new guidance document?

Bakul Patel: I think that's a great suggestion for us to take back, (Michelle) and look at sort of -- I mean there are not very many of those kind of things, (as I) pointed out but in the pulse oximeter case, we need to go look at it and see whether we need to update anything that's currently on our databases. So great, thank you for that suggestion.

(Michelle Gwynithe): Well, and similarly if someone had previously gotten their product either listed or cleared based on prior guidance from ODE, would - what would be the appropriate mechanism for them to consider withdrawing that listing or clearance if they believed it fell within general wellness now under the new guidance document?

Bakul Patel: I think that would be something we would recommend discussing with the branch or division.

(Michelle Gwynithe): Okay.

Bakul Patel: And coming to an agreement on sort of how moving forward, if that is the case or not.

(Michelle Gwynithe): Thank you.

Bakul Patel: Yes.

Coordinator: The next question comes from the (Juan Persala), you may ask your question.

(Juan Persala): Hi, good afternoon. I probably knew the answer to this already but I thought I'd ask it anyways. I see in the guidance document that laser technology is not considered a wellness product because it presents a risk to skin and eye burns.

I - my thing is what if we had a device that we knew that did not cause burns to eyes and skin, it's a laser device, and I was kind of wondering if this device still would not be considered a wellness product because it would still be a regulated product by the FDA?

Bakul Patel: In those cases I would, again, go back to recommending you contacting FDA and getting in touch and (for) discussing with the appropriate branch or division. That's the best way to resolve this without...

(Juan Persala): Okay.

Bakul Patel: ... getting into -- with understanding the details of what you're talking about.

(Juan Persala): Okay. All right, thank you. Would that be the DICE that you were mentioning before?

Bakul Patel: Yes.

(Juan Persala): Okay. All right, thank you very much.

Coordinator: The next question comes from (Colin Pollard), you may ask your question.

(Colin Pollard): Yes thanks, and this is just more general comment. There were several really insightful questions from the audience that you ended up just suggesting that they write it in within an e-mail to DICE, and I was wondering is there a way that you might share those responses for us all?

Bakul Patel: And so there was one question which asked about us creating a Website or a page that sort of parses out some of the decisions and the discussion that we are getting through some of the - from the e-mails. We will not be able to share exact responses or the product descriptions that we get back, we get on DICE or on Digital Health but as we learn and we have knowledge to share, we would - we will look at ways to sharing that.

(Colin Pollard): That would be great.

Coordinator: Once again, if you would like to ask a question at this time, please press Star then 1 and record your first and last name. One moment please. At this time I am showing no further questions and would like to turn the call back over to Ms. Irene Aihie.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made

available on the CDRH Learn Web page at www.FDA.gov/training/CDRHlearn by Friday September 9th.

If you have additional questions about the final guidance, please use the contact information provided at the end of this slide presentation. As always we do appreciate your feedback. Again, thank you for participating and this concludes today's Webinar.

Coordinator: Thank you for your participation, you may disconnect at this time.

END