

**NWX-HHS FDA (US)**

**Moderator: Irene Aihie**

**November 5, 2014**

**12:30 pm CT**

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen only mode. Today we'll only be taking questions by phone, will not be taking questions by a live meeting. Therefore to ask a question by phone during our question and answer session you'll need to press star 1 and record both your name and company when prompted.

This conference is being recorded. If you have any objections you can disconnect at this time. And I'd like to turn today's conference over to Irene Aihie. Good afternoon. You may begin.

Irene Aihie: Hello and welcome to today's FDA webinar. I'm Irene Aihie of CDRH's office of communication and education. Today we'll be discussing the final guidance document titled Distinguishing Medical Device Recalls from Medical Device Enhancements which published on October 15.

The guidance clarifies for manufacturers how to determine when changes to a device constitute a recall and when they're considered a product enhancement. Today Ron Brown, branch chief in the division of Analysis and Program

Operation in CDRH's Office of Compliance will present an overview of the guidance document.

After his presentation we'll host a Q&A session during which Ron will be joined by other CDRH subject matter experts. Now I give you Ron.

Ron Brown: Thank you Irene for that wonderful introduction. So we'll jump right into our presentation for today. As Irene mentioned we're going to be discussing FDA's guidance document on distinguishing medical device recalls from medical device enhancements.

Okay and we're going to start out with our objectives for today's discussion. The objectives for today are ... to emphasize that the key factor in distinguishing a medical device recall from an enhancement is existence of a violation of the Food, Drug and Cosmetic Act. We want to ensure that everyone understands that correctly categorizing a change to a device as a recall or an enhancement impacts the applicability and nature of industry responsibilities and the FDA oversight.

We'll also provide guidance and examples to facilitate the decision-making process for when a report of correction and removal, also known as an 806 report, to the center for devices in radiological health, and that's CDRH, would be necessary.

Okay a little bit of background on why the guidance was created. It's because we received some feedback from industry identifying concerns about making modifications to devices. And basically industry identified they wanted - they had concerns with the enhancing of a device caused existing devices to become violative. Will FDA request a recall if these changes are made? When

is the change an enhancement and when is it a recall? What needs to be reported to the FDA?

Our next slide talks about some comments on the draft guidance. There was request for clarification of definitions, requests for more examples and clarification of reporting obligations pertaining to medical device reports of corrections and removals as referenced or as required by 21 CFR part 806.

Okay our next slide covers recurrent themes that were captured in public comments on the draft guidance. So some of the identified recurrent themes were more clarity on what would be considered a stock recovery, asked for an increase in the number of examples provided, asked to remove the flow chart, requests to withdraw the guidance, considerations of point of use, appearance of rule-making. It was identified that it was a subjective and what is the applicability to future devices as well as does it cover technical violations?

And as identified at the bottom of the slide there were 14 responses and that contained 111 comments. Okay some key points that we want to identify. This guidance is intended to clarify when a change to a device constitutes a medical device recall, distinguish those instances from device enhancements that do not meet the definition of a medical device recall and clarify reporting requirements on a medical device reports of correction removal that's requirements of 21 (CFR Part 806).

Okay some important factors to be considered. It's important to note that this guidance does not alter our current expectations regarding medical device recalls. It only applies to medical devices regulated by CDRH. Please note that this rule applies to devices that require or are exempt from premarket

review. Additionally this guidance seeks to address concerns that firms may have about making enhancements.

Factors that do not apply, this guidance does not address nor does it apply to whether or not a new pre-market submission is required. Radiation emitting electronic product defects or failures to comply with radiation safety performance standards that are contained in 21 CFR parts 1020 to 1050, nor does it apply to methodologies for risk management or risk assessment.

Our next slide goes over the recall definition as defined at 21 CFR 7.3(g). A recall means a firm's removal or correction of a marketed device that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, example given seizure. Recall does not include a market withdrawal or stock recovery nor does it include routine servicing. Additionally, a recall does not include an enhancement as on by this guidance.

So what is an enhancement? Our next slide has an enhancement definition. A device enhancement is a change to improve the performance or quality of a device that is not a change to remedy a violation of the Food, Drug and Cosmetic Act. Device enhancements include but are not limited to changes designed to better meet the needs of the user, changes to make the device easier to manufacture, changes to improve the device's safety or performance and changes to the appearance of the device that don't affect its use.

So, recall identification, things that firms should consider. Is your product a device? Why are you considering making a change to your device? Are you currently marketing the device to which you are considering or making changes?

Slide 13, what is the violation? I want to re-emphasize that the key factor in distinguishing a medical device recall from an enhancement is the existence of a violation of the Food, Drug and Cosmetics Act.

Slide 14 gives some important information on how to help you differentiate violative devices from non-violative devices. Are the changes intended to resolve a failure to meet represented specifications or failure of the device to perform as represented? Is the labeling for the device to which you are considering making changes also misleading? Does it fail to have adequate directions for use or does it otherwise violate the Food, Drug and Cosmetics Act or FDA regulations? Also, you need to consider are you otherwise out of compliance with FDA regulations.

806 reporting requirements, medical device enhancements do not require the submission of an 806 report.

Slide 16 talks about other regulatory considerations. Once a determination has been made, whether the change represents a medical device recall or an enhancement, additional regulatory obligations should be considered.

So now we're going to move in to slide 17, that has our first comparison example and identifies what we'd consider a recall. An In Vitro Diagnostics or IVD device firm markets a test to detect the level of a specific antigen and blood. The device represents 95% sensitivity to the specific antigen. Two years after initial marketing the firm determined that the device sensitivity to the specific antigen as manufactured had decreased to 90%, thus not meeting performance specifications and making the device violative.

As a result the firm modifies the product in the field to improve the sensitivity from 90% to 95%. Because the firm's actions are returning the product to the

quality it was represented to possess, FDA would generally consider these actions a recall.

Slide 18 has a comparison example, what we'd consider an enhancement. An IVD device firm markets a test to detect the level of a specific antigen in blood. The device is represented to have 95% sensitivity to the specific antigen. Two years after initial marketing the firm modifies the product to improve the sensitivity to the antigen from 95% to 98%. This modification is determined to be an improvement to the safety and effectiveness of the device and is determined to be unrelated to any known device violation. FDA will generally regard this action as a device enhancement although it may require a regulatory submission.

We're going to move on to comparison example number two. In our first example would be a recall or what we'd consider possible recall. Shortly after launch, the ergonomics of a marketed electro-surgical unit device are determined to be less than optimal. In that users have reported difficulty guiding the hand piece and the firm has received reports for serious injury associated with its use. The firm's investigation revealed that difficulty guiding the hand piece contributes to the serious injuries in that the hand piece is not performing as represented. The firm replaces all the hand pieces in the field and owns all units currently in inventory, to eliminate the possibility of serious harm. FDA will generally consider these actions a recall.

Slide 20, we have our ultimate comparison example number two of what was possibly considered an enhancement. A firm markets a new electro-surgical unit device. Shortly after launch the ergonomics of the hand piece of the newly marketed device are determined to be difficult to use. The firm determines that this difficulty does not change the risk of the device and no violation of the Food, Drug and Cosmetics Act or regulations are identified.

The firm develops and incorporates a new hand piece into the electro-surgical unit device. FDA will generally consider this action to be a device enhancement although it may require a regulatory submission.

In summary, correctly categorizing medical device recalls and medical device enhancements amplifies, the likelihood that firms will appropriately determine when 806 reports to CDRH are and are not necessary and increases the likelihood that FDA will concur with industry decisions regarding reporting obligations.

The guidance provides added clarity to regulatory terms and definitions specific to medical device recalls and enhancements and doesn't intend to address the comprehensive obligations related to medical device recalls. This concludes our presentation and now we will start the question and answer session.

Coordinator: Thank you. First to ask a question make sure your phone is unmuted. We're only taking questions by the phone. We'll not be taking questions in live meeting. You'll see that there's no Q&A chat box. Now to ask a question by phone press star 1 and record both your name and company. To withdraw from the queue you can press star 2. Once again to ask a question by phone press star 1 and record both your name and your company when prompted.

And our first question comes from (Cynthia Oris) of Phillips. Your line is open. (Ms. Oris) your line is open. Your phone might be muted. All right our next question comes from (Mary Lapsevich) of Phillips Medical Systems. Your line is open. (Ms. Lapsevich) your line is open. (Ms. Lapsevich) can you hear me? All right one moment please. I'll see what the issue is. Our next question comes from Robert Satterfield of Ecaria. Your line is open.

Robert Satterfield: Yes. I'm hearing that since we actually have an enhancement, if we included in a regulatory submission and subsequent to that submission there were problems in the field. Would the post performance in the field, would that subsequently if deemed appropriate to be a recall even though it was submitted as an enhancement? Is that possible?

Ron Brown: Hi, I'm sorry. Do you mind repeating the question?

Robert Satterfield: Sure. If we do an enhancement and we do include it in a subsequent regulatory submission and then after it's been submitted and the enhancement's in the field, if the enhancement is becoming a problematic situation that'd be deemed to be a recall would it actually be a recall if it was submitted as an enhancement to the application?

Ron Brown: Okay, thank you for that question and I think I understand the parameters of the question. Initially you're saying that your firm determined that you wanted to take an action that you considered an enhancement and you went forward and you made changes to the device and you distributed them. And subsequently your device was determined to be violative due to your device not performing as represented after this change was made, correct?

Robert Satterfield: That's correct.

Ron Brown: Okay so there is actually two parts to your question because the initial part of your question is you had a device that was not considered violative and you went forward with making a change that fit within the realm of the guidance document that you identified as enhancement. You documented properly and you proceeded as we would expect.

The second part of your question is now you have a violative device on the market and you need to take action. So then there would be - the second part of this would be yes, we'll still want you to follow the guidelines and the guidance document to say now that you have a violative device on the market what actions would you take and that's when you'd make a determination on whether or not you need to do a recall. Does that answer your question?

Robert Satterfield: Yes it does. Thank you.

Coordinator: Once again to ask a question please press star 1 and record both your name and company when prompted. And please make sure your phone is un-muted both when you record your name and company and when your question comes up and our next question comes from Molly Ray of SoftwareCPR. Your line is open.

Molly Ray: Yes. The slides of the webinar as well as the guidance document both state that the guidance is applicable to the medical devices regulated by CDRH. So my question is, was this an unintentional exclusion of the devices regulated by CBER or will there be an additional guidance specific to those devices issued?

Ron Brown: So, to answer your question this was a guidance document created by CDRH with only the consideration of the devices regulated by CDRH and we don't at this present time have any intention of putting out another guidance document in collaboration with CBER and I can't speak for CBER. At this point in time there's no - a decision hasn't made been made for CBER to put out a guidance document but we can verify after this webinar whether or not any of those actions will be taking place.

Molly Ray: Or is it - is this guidance will also be applicable for those devices?

Ron Brown: I just want to ensure I clarify. When you say those devices, you mean devices that are regulated by CBER?

Molly Ray: Correct.

Ron Brown: This device - this guidance document doesn't apply to those devices. This guidance only applies to devices regulated by CDRH.

Molly Ray: Okay thank you.

Ron Brown: You're welcome.

Coordinator: Our next question comes from Jeff Secunda of AdvaMed. Your line is open.

Jeff Secunda: Thank you and thank you very much for this excellent overview of this document. I think it's outstanding that we do now have a clear definition of enhancements. However, in many places in the document the terms are used that are confusing such as marketed devices, marketed is a fairly vague term.

In 806 the point is made that devices are distributed which is much clearer. They've left the control of the company whereas marketed could mean that there are plans to put the device out. Do you have any plans in the future to make this point clear and to move away from the vague term of marketed towards something more definitive such as distributed?

Ron Brown: Thank you Jeff for identifying your concern. I think that's something that we'll have to capture and will require further discussion internally to see if maybe we could provide some additional clarity what we mean by marketed if it's something like you're saying that may cause some confusion.

Jeff Secunda: Okay thank you. Can I ask one more question? Another term that is used is clarifying or rather minor violations of the FDNC. This is a good provision. However will there be out coming guidance on how to define or how to determine whether a violation is considered minor, not that the FDA could be taking action? Did you get that part of the question?

Ron Brown: Yes. Could you hold on one second for me Jeff?

Jeff Secunda: Sure.

Ron Brown: Hello Jeff. I understand your concern. I know there have been - we've had several discussions regarding minor violations and I understand the concern and it's been expressed by others that industry would like more clarity on what'd be considered a minor violation. That's something that I'll take back from this webinar to see if that's something that we could look at making a possible higher priority but at this point I'm going to have to say that I'm not sure if we'll be able to go back and make changes to the guidance but we'll go back and re- evaluate to see if we could provide further clarity for industry regarding those terms.

Jeff Secunda: Very good, thank you very much.

Coordinator: Once again to ask a question press star 1 and record your name and company. And our next question comes from (Andrew Ecuart) of Johnson & Johnson. Your line is open.

(Andrew Ecuart): Thank you. First question, would we have access to these slides? Hello?

Ron Brown: Yes. I'm sorry. The slides are posted. If you look at the last slide -- number 22 here -- it shows where it has the information about the slide presentation, transcript and webinar recording will be available.

(Andrew Ecuart): Thanks. My other question is I think in most of the examples you gave, I'm going by memory. The one that were called recall had within the element of making a correction of products in the field as well as a new release product. I'm not sure how much of a significance that has on it because a lot of the time it's subtle to determine if something is violative.

And what I mean by that is you may have a certain compliant in the field and it's not a one to one root cause but you determine that you can make an enhancement maybe like you handle example where you can make a device a little bit easier to use and you make that enhancement of future products, of products that are still in your control or future manufactured products but you don't change anything in the field. Does that have any bearing on whether we consider enhancement or recall?

Ron Brown: So, I think that's a very good question and I think that is in line with what we've had in our examples because you're talking about something that may not be considered violative and if it's not something that you'd consider violative and you're making a change, I think that'd be something that we'd consider, would be an enhancement.

But that's going to be based on your evaluation because I think that, of course, we were only allowed to share so much information because webinars have a limited number of slides. But there's information in the guidance document that really clearly defines or adds more definition of what we'd consider something being violative.

So some of the things that you're talking about is whether it's a one time issue versus some trending and some other things that may be identified. I think that you have to really closely evaluate that yourself and to see what the significance of it is. And if it's something minor like you're saying, like the hand piece changed, that you're saying there's not anything that'd be considered a violation. Then I'd say that I'd feel comfortable with going forward, proceeding and documenting it properly.

(Andrew Ecuart): Okay thank you Mr. Brown.

Ron Brown: You're welcome.

Coordinator: And our next question comes from (Robin Thasener) of Esculop. Your line is open.

(Robin Thasener): Yes thank you. I had the same question about minor violation so I think you already addressed that. Thank you.

Coordinator: Once again to withdraw from our queue you can press star 2. To ask a question by phone press star 1 and record your name and company. And our next question comes from Madubuike Okafor of Orthozon Technologies. Your line is open.

Madubuike Okafor: Yes hello. The first product comparison number one, part one, where the company improved the sensitivity to match what was actually advertised on the label. You called this a recall but you didn't actually go into whether or not they - would they have to have withdrawn it from the market or did they just have to improve the sensitivity of newer products that they began to distribute. Was it recalled? Was it physically actually recalled from the market, distributors and everything?

Ron Brown: Okay, so thank you for that question and I just want to point out first and foremost that these are hypothetical examples so there aren't any - there weren't any actual actions taken. But if you're really asking I guess about expectations -

Madubuike Okafor: I understand. I understand they're hypothetical but I just think or make sure that I orient myself and understand what exactly was - you're trying to get across. I just want to understand it. Are you calling it a - in order for it to be a recall do they actually have to - in this hypothetical situation did it actually have to be removed from the shelves or was it - hypothetically was it okay for them to just increase the sensitivity?

Ron Brown: Hypothetically, I think what you're really asking is what are the FDA's expectations for this hypothetical example. And if it's a violative product that's on the market and you're going to make this change this should be one of those situations where I think firms should consider performing a removal and then the product that has been improved to meet the represented - the specifications that were identified when this product was cleared, should be distributed as a replacement product.

Madubuike Okafor: Okay, so it should be what as a replacement product? Advertised as a replacement product?

Ron Brown: No. I'm sorry. I'm just going to take a step back and just go through recall process here because this is more of a recall process type of question. So a recall is - could be a correction or removal and for a medical device recalls, particularly IVDs, there may be two parts to this action that may take place. And, so you have a device that's violative- so you have a device that's

violative. You have to make a determination whether or not the device needs to be corrected or a removal.

So, in some cases a correction may be a short term fix where you've identified a customer that this labeling - this error, maybe you need to bring this to your attention and your customer notification that we're going to replace.

So please quarantine your products to be recalled and we'll send replacement devices. And that's something that your firm will have to identify in your recall strategy but the expectation is that if you have a violative device on the market, that you should cease distribution and in most cases remove the product and replace it with a product that is not violative.

Madubuike Okafor: Okay.

Ron Brown: All right, the next one.

Coordinator: And our next question comes from Michael Fales of GE. Your line is open.

Michael Fales: Hello guys, appreciate you having this. This is very informative. We - again industry thanks you, I have a question regarding cyber security vulnerability and what your position would be regarding that.

The example would be that the device itself doesn't actually have a defect in it but it does have a vulnerability and we're able to partner with maybe the software suppliers, got a couple of them that were pretty well known this year, heart bleed and shell shock which impacted a number of companies' products. And when we actually go to the fields to improve and apply patches to improve the vulnerabilities, will this fall under the enhancement paradigm that you've described.

Ron Brown: Okay. I'm going to have to defer you for this question to the cyber security guidance. And we have - if you look at the slide on the screen for questions regarding - some more general questions that aren't specific to the guidance there's a link to notify a division of industry and consumer education also known as DICE and the link is provided. I'd have to refer you to them so they can give you a copy of that guidance document to help you with this question.

Michael Fales: Thank you.

Coordinator: Our next question comes from Steven Sorge of GE Healthcare. Your line is open.

Steven Sorge: Hello. I had a question about the slide deck to find a device enhancement number one a change to improve the performance or quality of the device. So I guess we're saying conversely that if it's not that we want to consider that a recall. In the context of this guidance when I think about 806 and the section 806.10 versus 806.20, are we talking about both of those categories of those field actions or just the reportable category?

Ron Brown: Thank you for that question and I just want to try to repeat the question to make sure that I understand and other people on the phone understand it. So your basic question is you're identifying that, in 806, there are some different reporting obligations whether it's within the realm of 806.10 versus 806.20. And you're asking whether or not those things come into play when you're trying to make a decision of whether it's a recall versus an enhancement.

I'll like to say that I think that if you start going down that path I think you're going a little bit too far because what we're really considering is whether or

not it fits into the realm of 806.10 or 806.20. That's still within the realm of a recall and 806 just states what are the reporting obligations versus whether - it's not getting into whether or not it's a recall. At that point in time you already know it's a recall. It's just whether or not you have to report 806. So the guidance is saying that regardless of if you put in that framework of enhancement versus a recall, the 806 aspect doesn't have as much weight as far as the reporting obligation.

So in summary and what I'm trying to really get to my point here is, those things don't necessarily have weight on whether or not it's a recall versus enhancement because anytime you're at that point where you're saying I'm trying to decide if it's 806.10 or 806.20. You've already decided that it's a recall and you're trying to decide whether or not you need to report it.

Steven Sorge: yep, Great. Thank you. That helps a lot.

Ron Brown: You're welcome.

Coordinator: And our next question comes from Mr. Weiping Zhong also of GE Healthcare. Your line is open.

Weiping Zhong: Hello, thank you Ron. This is great. I have a question regarding page 11. You have - you define the enhancement as to - let's say you change it to make the device safety like equal the safety. So my question would be during the pre-markets let's say you identified some risks and you present in the 510k submission and then when the product is in the field, you have a standard. Now you can make some improvements to let's say eliminate those risks or reduce the risk. Would that be treated as a recall or improvements?

Ron Brown: I have to apologize. I didn't hear part of your question and I'm wondering if you'd mind repeating it please.

Weiping Zhong: Okay. On page 11 on the definition of enhancements, part of it is to make the device easier and the changes to improve the safety during the 510k, let's say I identified in the device, let's say one of the chips will fail and this failure of the chips will cause certain hazards. And that was cleared in the 510k process, and when the product is in the field, they observed the complaints about failed components that are the chips. If it's expected or predictive before we release a product but now with the technology improvements, we have newer chips that can replace that, let's say, and then improve the safety, as by doing it would it become a recall?

Ron Brown: Thank you for that question. And I think I - thank you for repeating the question. I think I have a better idea of what your basic question boils down to, is do you need to consider this device as a recall or as an enhancement and what will be the rationale for it.

And I think that based on that information that you provided to me it sounds like early on in your process you identified some possible complaints or some identified problems in your manufacturing that may identify your product as being (violative). And if that's the case then I'd say that yes, you'd need to look at how this fits into the paradigm of whether or not it's a - what we call recall action.

Weiping Zhong: Okay thanks. Yes I think the difficulty was if you have the baseline safety which was cleared by FDA and then the (unintelligible) to (unintelligible) show that it's truly there as (unintelligible). But I guess probably it's case by case based on your answer.

The other question I have is let's say you've identified a new use cases out of (users in the field), right? And then most new use cases could become - in some cases could have some risks there and now you want to communicate with the users and saying by doing this and by doing that it may not be good, only be good. So would that be taken as a recall or enhancements?

Ron Brown: So I want to make sure that I clearly understand your question. When you're saying there's new used cases are you saying that - I want to stop here and just turn to a certain segment of the guidance document to ensure that I'm following your question. And really what we're talking about here is differentiating violative devices from non-violative devices.

And so on page 6 of the guidance document one of the things this point out is - and it sounds like what you're referring to here, is an increase in overall failure rate, increase in a single failure mode rate or an indication of a new failure mode. It may suggest a failure as a device to perform as represented. And those are some things that - it sounds like in your examples that you may be eluding to and if I'm not in the right area of concern can you please let me know right now? That's kind of like what you're referring to?

Weiping Zhong: I think when you said the new used cases I think you're right. Could it be a new failure mode? I think it's a good answer. Thank you very much.

Ron Brown: All right, you're welcome.

Coordinator: Once again to ask a question press star 1 and record your name and company. And our next question comes from (Lawrence Pitchiano) of Johnson & Johnson. Sir your line is open.

(Lawrence Pitchiano): Thanks very much for the presentation today and excellent question and answer session. My question has to do with the first set of examples with regard to IVD performance change and consideration for pre-market notification that'd be a submission. So in the latter case example where the enhancement was made from 95 to 98% sensitivity there was a specific comment there to consider the need for a notification, some kind of submission.

Now with regard to the violativ edevice that was being restored from 90 to 95 are we still going under prior guidance which is if you're restoring the product to its original state? And so in the case of an IVD if it was a reformulation or a tweak in the algorithm to restore the sensitivity that wouldn't require a submission or is that same thing changed since the issuance of this guidance?

(Ian Fletcher): My name is (Ian Pilcher) and I'm a consumer safety officer in OIR for In Vitro diagnostics. There are kind-of two parts to your question and there are two different criterias to whether you get a new 510K. Since you're just restoring it to clear performance there's no performance change and based on that, you wouldn't require 510K. It's going to depend on what change you're making. If it is a must then you have to look at the other half and are you changing your product, your technology in a significant way.

If it's a minor change to an algorithm, algorithms are touchy so we're going to kind of not touchy. They're difficult because it depends on how they're used and what role they play in the device that if you were changing a buffer or making some minor change like that it wouldn't require a 510K. If you were making a larger change to this essay of the device or the reagent, the instrument or the reagent, that may require a 510K. So you'd have walk through that guidance and determine whether or not a new submission is required.

(Lawrence Pitchiano): Okay thank you. I appreciate it.

(Ian Fletcher): You're welcome.

Coordinator: And our next question comes from Earle Canty of Intuitive Surgical. Your line is open.

Earle Canty: Thank you very much for the opportunity to ask this question. The example is you have a device in the market. You have no reports of serious injury. The device meets specifications and it's acceptable from your risk management process. You identify and develop some enhancements to that. The enhancements reduce risk. We'd argue that that's an enhancement and not a recall. Would you concur with that assessment?

Ron Brown: Based on what you're saying and to do a quick summary of what you're saying is you have a device that isn't (violative). You're looking at making some changes in the device that aren't as a result of the device being violative for any risk of being previous identify. And the changes were actually are going to - changes are going to improve the device's safety of performance is what - it sounds like you're saying.

Earle Canty: That's correct. Risks were identified but they were deemed acceptable. And so the change is further reducing the likelihood of that risk.

Ron Brown: And it sounds like it's within the realm of what we've listed on - in the enhancement definition on page 11 when you were just talking about a change to improve device's safety performance. It's not a change to remedy a violation of the Food, Drug and Cosmetic Act.

Earle Canty: Thank you very much.

Ron Brown: You're welcome.

Coordinator: Once again to ask a question press star 1 and record your name and company. And our next question comes from (Ashley Davis) of (Turmo) DCT. Your line is open.

(Ashley Davis): Thank you. When considering software bug fixes when does the agency consider its software bug fixed to be an enhancement and can any bug fix being applied to a device currently in distribution as well as to further production be considered an enhancement?

Ron Brown: Thank you for that question. Again can I ask you to - let's go back to the first question. That might make it easier and better for the audience for me to - when I go to respond to make sure I identify exactly what you're asking. I think the first question you were talking about there was a software correction that needed to be made.

(Ashley Davis): My question really was when does the agency consider its software bug fixed to be an enhancement?

Ron Brown: So we do have - give me one second please. I want to make sure I can point you in the right direction. I know we do have an example in the guidance document that talks about software. Thank you. We do have an example in the guidance document on page 6 where it talks about medical device software.

And basically I think you're challenging the fact that we have an example that talks about what we consider the software change to being a recall and are

there examples of software fixes where it could be considered an enhancement.

I'd say that there probably are if they're within the realm of the device not being violative because there may be some instant changes you're going to make based upon user request that may be minor things like we have an example where the device has changed and the display on the device was changed to make it easier for the end user to see the information being displayed. So there are some changes that I think will fit into that realm. However I can't give you any examples right now off the top of my head.

(Ashley Davis): Okay thank you. My second part of that question is can any bug fix being applied to the device is currently in distribution as well as to future production be considered an enhancement? So it's already out in the field as well as still in-house.

Ron Brown: I'm sorry. Can you repeat that question?

(Ashley Davis): Can any bug fix being applied to devices currently in distribution as well as to future production be considered as an enhancement?

Ron Brown: So if you're making a change to newly produced products as well as products out on the market that aren't violative and it fits within that definition of an enhancement then the answer is yes.

(Ashley Davis): Okay thank you very much.

Coordinator: Our next question comes from Mr. Tom Shafer of Stryker Endoscopy. Your line is open.

Woman: Hello. Thank you for taking our question. I've got a question on stock recovery. We (unintelligible) of the definition of stock recovery you talked about marketed but the example that you guys have given in the guidance document talks about distributing product from the non-conforming (unintelligible). So is that - would that be the guidance going forward on stock recovery? We haven't - that we have marketed the product but we haven't distributed it. Would that be considered stock recovery?

Ron Brown: So the key point for a stock recovery is that no portion of the product has been released. Everything is still under the firm's control. So if the devices are still under your control then it would fit into the realm of a stock recovery.

Woman: Correct. But my question is that we have marketed the device but the device that's not in our control is not (violative). But based on this issue during manufacturing only that lot was affected, not everything that's out in the market and all of that lot which was non-conforming or had the issue was still in our control and we decided to fix that lot. Would that fall under stock recovery?

Ron Brown: So thank you for that question. So I think I have a good idea of what you're saying. So basically the products that were previously distributed weren't (violative). You discovered a problem in manufacturing with the lot that hasn't been released. And so what you want to know is since it's still under your control would that be considered a stock recovery.

Woman: Correct.

Ron Brown: Okay. So that sounds like its well within the realm of a stock recovery. But I think FDA does want you to ensure that these devices have been distributed

wouldn't have to worry about the same issue of concern being identified with the products - the same products that are part of the stock recovery.

Woman: All right. Thank you. I actually have another question on software modification. So like I said we do have - started looking at the example that's in the guidance document.

Let's say we have, you know, an issue in the field, and we're getting complaints about it but that failure mode has been identified in our risk document and is well within the entry that we're seeing. It was going to occur in the field but we still decided to take an action and upgrade our software to reduce the (unintelligible) mode. Would that be considered enhancement or a recall if we did decide to do anything with the product that was on the market?

Ron Brown: So the basic question is would this be - would your device be considered violative if it's still within your expectation of failure mode in rate, correct?

Woman: Correct.

Ron Brown: Well if it's still within the realm of what's the expected for your failure mode in rate it sounds like the device may not be considered (violative). However, FDA also caution firms that sometimes when they do look at what they've had as parameters from the point of design and they've been distributing the product for several years they need to go back and make sure they're re-evaluating that because there are some significant single failure modes that FDA would be very concerned about. So that's something that I'd caution, that sometimes when firms are doing the trend analysis they may say for the month we've had ten failures.

However you had three failures so very significant and they were very high risk to the patient. And you haven't had - and you may have ten for this month and you may have one for January, two for February and you average them out and you're well within your parameters of what you'd consider average failure mode.

So that's something that I think you should really take some time and consider when you're evaluating what'd be considered accessible as far as failure mode and rate and you're doing your trend analysis.

Woman: All right. Thank you so much. That answered my questions.

Coordinator: And our next question comes from either (Rachel Weiss) or (Cathy Park) of (Michael Ford) Orthopedics. Your line is open.

Woman: That's MicroPort Orthopedics and thank you for taking our question. I understand under the guidelines as it's stated now that we don't have to submit an 806 for an enhancement. If our company decides that we all agree this falls under an enhancement what evidence do we need to maintain that we've made that decision? Where would we keep it and how long or do we even need to do it?

Ron Brown: Hopefully so. I'd say - I'm sorry. So I think that the basic question is do you need to maintain some documentation and that's yes because when FDA investigators come out they'll be looking at your records and they'll be looking at things where you decide if this was or wasn't a recall, whether or not something was reportable for an 806 and if you have justifications in that reporting and whether or not like you're saying if it's an enhancement how are you identifying that this doesn't fit within the realm of being a recall.

Woman: So is that captured on an 806 form or can each company create their own type of documentation?

Ron Brown: So at this state we don't have any standard format for documenting this information. It's not captured for 806 because we're saying that it's exempt from 806 reporting. So that's something that firms will have to ensure that they document as they would all of their decisions.

Woman: Okay. Thank you very much.

Woman: Do we want to - no. I think the rest of our questions have been answered previously but thank you.

Coordinator: Once again to ask a question press star 1, record your name and company. And our next question is a follow up question from Jeff Secunda of AdvaMed. Your line is open.

Jeff Secunda: Thanks for taking this follow up. This is in regards to changes to the label or labeling in a situation where a company becomes aware that customers are using the products incorrectly despite adequate instructions. And they send a letter to customers saying basically read the instructions. They tell you what you have to do. That's one scenario.

The other is where the company provides additional information in a letter, additional information that wasn't in the instructions for use but is simply to use the term an enhancement of the information that the customer could use. Are those enhancements or are they considered to be recalls?

Ron Brown: Okay thank you for the question. I want to just stop here and just to make sure I identify each scenario separately. So the first scenario, it sounds like you're

saying that devices not (violative), what you're doing is sending out a form of communication reiterating to customers that you have concerns that they're not following the instructions for use and maybe using the device off the label.

In that case then you - then firms are within the right to just issue that communication. And generally that's in the realm of what we'd consider a safety alert where there's no violation. Firms are basically reiterating what's already in their labeling.

Jeff Secunda: Okay.

Ron Brown: And if you don't mind could you go through the second scenario again?

Jeff Secunda: Sure. The second scenario is where the company provides additional information to support the state methods already in the IFUs. So the company wouldn't consider the labeling to be inadequate or violative but it's to help the customer better understand a certain issue so this additional information not just reiterating existing information.

Ron Brown: I hesitate to give you a blanket answer of this sounding like an enhancement because I have to be honest, the example is a little vague to me in what information is being added to the IFU. Anytime you make changes to the IFU FDA is concerned that there's possible relabeling which fits into the realm of what'd be considered a correction.

So I think you have to evaluate what - how significant those changes are but I'd say that at this point in time this would be another opportunity to point out that if you have questions like this and you're looking at making these types of changes I'd refer you to dDICE as I mentioned earlier. Their information is

on this last slide and they can help you in trying to - to get into maybe some specifics of what the changes you're intending to make.

Jeff Secunda: Right. I understand the difficulty in - especially in the second scenario. Does FDA have any plans to have additional guidance so that companies would know when a safety alert is -- if you will -- an enhancement and when it crosses the line into a correction?

Ron Brown: At this point in time, we don't have anything we're working on as far as guidance document or anything that's for a safety alert but that's something that we'll definitely take back as an identified concern of an area that's of interest. We have - that concern has been expressed before and I'm glad you shared that so we can make sure that we need to maybe take a look at going back and adding some more emphasis possibly in this area.

Jeff Secunda: Okay. Thank you very much.

Coordinator: Our next question comes from (Patricia Lee) of Thermo Fisher Scientific. Your line is open.

(Patricia Lee): Hello. Once you determine you need to go down the path of recall for a violative product what's considered the date's initiation for the recall, the date you send the letter out or the date a customer receives the notification?

Ron Brown: So - I'm sorry. Could you repeat your question?

(Patricia Lee): Once you decide that you need to initiate a recall is the initiation date the date you send out the letter or is the date the customer receives the notification?

Ron Brown: So the basic answer to your question is when you send out the letter to notify the customers, that is a point in time where it'd be considered you're initiating a recall.

(Patricia Lee): Okay thank you.

Coordinator: And I show no further questions at this time.

Ron Brown: Can I just - just one last point, that last question. I also want - would you like to consider that for recall initiation there's some other areas of concern that I'd like to share that were not mentioned in your question. So additionally if, within your firm, at the point of time when you decide and whoever has the authority to make the final decision of whether or not to recall, once that takes place that's when we'd consider one example of recall initiation.

A second example is as you've mentioned, when you issue the letter. A third example would be if you actually take an action of removing a device a performance in former correction. So I just want to make sure that we give you a little bit more information that may be helpful when you're trying to decide when a recall has initiated and especially when you're trying to meet the ten working days requirements for 806 report.

Coordinator: And (Ms. Lee) if you need to have a follow up.

(Patricia Lee): No thank you.

Coordinator: All right. We do have one other question from Kevin Randall of ComplianceAcuity. Your line is open.

Kevin Randall: Yes, thank you for taking my question and taking the time to answer and put the guidance document together and discuss this difficult (process). So over the preamble to FDA's quality system regulation in part 820 the FDA says that user error is considered to be a non-conformity. I'm wondering when user errors then trigger the threshold of being violative or making the product (violative).

Ron Brown: So I'd have to hesitate at this point in time because I - this is outside - I'm sorry. Your question is outside the scope of the guidance and I'm not prepared to answer that question.

Kevin Randall: Well maybe I can rephrase it. If we have discovered user error in the marketplace what should we be doing to decide if that constitutes a (violative), makes the product violative such that we'd need to do a recall?

Ron Brown: So user error - there's a couple of things to consider when we start talking about user error. And one of the things that you'll see in the guidance document also talks about labeling concerns and whether or not it's adequate. So when we start talking about user error and when I go out and do presentations with the firms we get into some discussions of root cause evaluation.

So when you're doing a root cause evaluation I caution that sometimes people get into the realm of user error and it's usually identifiable as a root cause but I'd caution and say maybe take a deeper dive to ensure that there may not be some other concerns that may be the true cause whether it's inadequate labeling, whether it's even within the main - on the manufacturing plant floor where you have your SOPs are inadequate.

There are so many things that may come into play when you start talking about user error so there's the intentional - unintentional mistakes and with device labeling. So those are some things that you may want to refer to when you're considering user error.

Kevin Randall: Okay thank you.

Coordinator: Our next question comes from Greg Levine of Ropes & Gray. Your line is open.

Gregory Levine: Yes hello. Thank you very much for the program. I'm trying to understand the scope of FDA's assertion that identifying a new failure mode is a recall.

So if you have a problem that you find post market and that wasn't readily foreseen pre-market when you did your risk analysis you issue a communication to users to inform them of this issue and how they might protect the patients against this problem and let's say that perhaps it wasn't foreseeable because it only affects only a small sub-population of the users.

So you've issued these in a notice like a safety notice and this isn't information that's already in the IFU. Its new information for the users and it is reduced in the risk to health at least in this particular sub-population. Is that a recall in FDA's view and if so why is that a recall because I think - and also assume the company never made any specific assertions or promoted the product for use in this particular sub-population so something that wasn't initially foreseen. So could you address whether that type of circumstance would be a recall?

Ron Brown: So you added a lot of variables in that examples that make this question a little bit difficult to answer especially at the end where you alluded to all label use.

Gregory Levine: Okay, sorry. I didn't mean to allude to all labels. I was just trying to say that the manufacturer never specifically promoted the device as particularly useful in a given sub-population, the sub-population for which the failure mode was later identified. So it was just that it was intended for a general population and then later post-market they identified that there is a problem with the device in a particular sub-population.

Ron Brown: There's two parts to this question that does - that I want to address. So the first part was you mentioned that FDA sees a failure in a single failure mode at every instance as a recall and that's not true. I just want to make sure that you understand that this is something we want you to evaluate when you're trying to make your decision.

We don't think that every time that there's a single failure or a new single failure mode that fits with the requirement of a recall. And the second thing is there are some intricacies in your example that will require more delving into to be able to make a determination whether or not your device is violative because based on your example it's hard for me to discern whether or not it's violative.

It sounds like your IFU is correct and it sounds like the patient population. Here's where it gets tricky when you get for general population but you say it's not intended population. So that to me is it gets a little confusing when you say it's for the general population because that means that includes everyone. So when you say that was intended for that population that statement is a little contradictory to me.

So that statement alone makes me - gives the appearance that the device may be considered violative because you did have that in your IFU and it was

indicated by your firm and your labeling that it's okay for users to - for that population to utilize that device and that should've been I think considered in your risk evaluation. And that's something that we may consider it a recall because you're going out and you're doing a formal correction to reduce the risk to health.

Gregory Levine: I apologize, thanks. I was probably a little unclear on that point and I may have thrown you. I don't mean a general population as in everyone in the universe. I mean that the device is cleared for a - a device has an intended use. That intended use doesn't specify particular ages or particular types of patients with particular conditions and so on. It just says it's useful for patients who have particular disease or condition in general. If you have this disease or condition the device is useful for you.

Post market what you learn is that a small subset of patients who have particular characteristics, that there's a - the device doesn't perform optimally in those patients. And so there's a - I think our (arguably) a new failure mode you've identified a failure mode you didn't enforce initially when you did your risk analysis. I think you answered my question when you said - you may have answered my question when you said not every identification of a new failure mode is a recall because one I think could potentially read the guidance to suggest that.

You're saying that's not the case but I didn't mean to suggest that there was something off label about the promotion or use of the device. It's all on label. The issue is post market you identify a problem in a given subpopulation and then you put out information to tell users, tell the physicians if you have patients who have these attributes you should be aware of this issue.

Ron Brown: So I - if this situation were presented to me with more specific information, it sounds to me like on the surface that you are performing some form of correction to reduce the risk to health and it sounds like your device may be considered (violative).

So I'd say that if you weren't sure in this situation I'd definitely caution you to reach out to your local district office. And if you're not familiar with that person we do have that information on slide 22 so you can access that information and I'm not eluding to this is something that you may have an actual scenario but this is something that you may want to reach out to them directly if this type of situation does occur.

Gregory Levine: Thank you.

Coordinator: Our next question comes from (Cathy Park) of MicroPort Orthopedics. Your line is open.

(Cathy Park): Thank you. We have another question involving the enhancement portion. This enhancement only concerns the final device. Say we were to change something in the process, a different machine, a better machine but the final design and product was the same. That wouldn't fall under an enhancement, correct?

Ron Brown: So enhancement definition, it does talk about changes to make the device easier to manufacture. Is this the case that you're alluding to in your question?

(Cathy Park): Easier to - not necessarily, like I said a new machine. Easier to manufacture, I'd interpret that we cut a step out or we done something to the product to make easier to assemble which to me would mean you'd have to change the

prints, etc so no. I'm talking about if we just changed the manufacturing machine for instance.

Ron Brown: So the device is still performing as represented.

(Cathy Park): Correct.

Ron Brown: It's still manufactured the correct specifications.

(Cathy Park): Correct.

Ron Brown: So your basic question is whether or not this would be an enhancement. I don't think is really an enhancement question. I think this is what other regular obligations you need to consider because the device is not (violative). So you're not making the change to the actual device. You're talking about manufacturing process changes where it may move in more in the direction of possibly 820 considerations.

(Cathy Park): Yes, perfect. Okay thank you.

Coordinator: Our next question comes from (Kara Shapiro) of Johnson & Johnson. Your line is open.

(Kara Shapiro): Hello. I have a question about if we had a case where we had products that was distributed and was acceptable for our internal risk documentation and then we had some product that had not been distributed and was held for an investigation for some other reason but for the product that was still under our control. If we sound that it was acceptable for our documentation but had a higher potential or poor potential performance. And in an effort to be as conservative as possible we wanted to scrap that product.

Even though both these groups, what was in our control and what had already been distributed met the same requirement, would scrapping the product that hadn't been distributed put us in need of recalling or otherwise affecting the products that was in the field?

Ron Brown: Okay so the basic premise of your question sounds like it's along the lines of what we discussed earlier regarding a stock recovery because you have some devices that are in your stock and you identified that wait a minute, these devices may not be performing as represented so you want to take action on those. And you want to know whether FDA would expect you to take action on the other devices that are out or have been distributed.

(Kara Shapiro): That's correct.

Ron Brown: And the answer is yes because these devices should be considered if they're manufactured at the same time. They should all have the same actions taken. Customers should be notified and you should take action to remove the devices from the market.

(Kara Shapiro): Okay and that's even if they're all meeting our internal documentation meaning our internal acceptable risk levels.

Ron Brown: So I think what we're talking about here is a couple of things. Basically firms, they have products that release in the market. They have products that they may have in this document but they also generally - some firms maintain additional products for additional testing to ensure that the products on the market are still meeting specifications. And so sometimes that's when some of these things are detected.

They continue doing their internal testing products that would fail. And in those cases sometimes new issues are identified that may not have been discovered in the product release testing. So yes, we do expect or, yes, we expect firms to take actions to ensure that the violative products are removed from the market.

(Kara Shapiro): All right, thank you.

Coordinator: Our next question and apologies for the pronunciation is (Anya Silmer) of Trigger Medical. Your line is open.

(Anya Silmer): Good afternoon and on page 6 of the guideline there - it's distinctive that failure to perform (unintelligible) will generally constitute a medical device recall. And my question is then how would (unintelligible) specification is defined if this is covering only the specifications given to the customer and in the (accordance) of international (unintelligible) or if this includes all internal manufacturer specifications.

Ron Brown: I'm sorry. Could you repeat your question because I want to make sure I understand. It almost sounds like there are two parts to your question.

(Anya Silmer): Okay. On page six of the regulation it's stated that the presented specifications that failure to perform according to (unintelligible) specifications would generally constitute a medical device recall. My question is regarding the definition of represented specification, does this include only specification (unintelligible) to a customer and according to international regulations or if this is also applicable to internal device manufacturer specifications which may be in the level above the required specification?

Ron Brown: So I think the basic question is - what we're talking about here is what we mean by the represented specifications. And so the represented specifications are going to go back to what are the specifications that you have identified in your IFU. You have identified in your pre-marked review anything that you've identified as what are the specifications for your device.

So when you send your device in for pre-marked review you're identifying specifications and you're identifying how the device is expected to perform. So when it falls outside those parameters that's when you'll want to consider whether or not your device is (violative). Does that help answer your question?

(Anya Silmer): Okay thank you for that.

Coordinator: Our next question comes from (Laura Lee Mylicon) of Medtronic. This is our last question. Your line is open.

Man: Hello this is (unintelligible) early but the question is in 806.2 in the definition of correction it was the term point of use. In your guidance the point of use term has been removed. I want to understand the implication of that change. If we apply the term point of use it may imply that we do design changes on upstream and future products but don't change products that are existing in the field. Then that could be considered not a correction. Is that correct interpretation?

Ron Brown: So basic answer to your question is - and I want to make sure I summarize things correctly. I think the basic answer to your question is if you make a change to your device and you only make changes in devices that haven't been distributed and you're going to make - you're not going to do any correction or removals to devices that have been distributed. Is that within the

realm of what we consider acceptable or would it fall into the realm of reportable correction. Is that what you're asking?

Man: A correction, could be a (unintelligible) or not a (unintelligible), yes.

Ron Brown: Yes so the basic concern is, and you're asking why the definition from the guidance document - the 806 definition isn't referenced, the part 7 definition is referenced because the basic expectation is, if you have violative products on the market, FDA does expect you to address those violative products.

Man: Okay. So the point of use definition needs to be included when we define a correction or not?

Ron Brown: The point of use definition wasn't included in the guidance document and that was - it would refer to the definition in part 7 to outline our clear expectations.

Man: Okay thank you.

Coordinator: That concludes our question and answer session. And I'll turn the call back over to the moderator for the close.

Irene Aihie: Thank you. We do apologize as we've run out of time during today's Q&A portion of today's presentation. If you have any further questions please send them to [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov). Again this is Irene Aihie and we appreciate your participation and thoughtful questions.

Today's presentation along with the slide presentation will be available on the CDRH Learn section of [fda.gov](http://fda.gov) and also at [www.fda.gov/cdrhwebinar](http://www.fda.gov/cdrhwebinar) by Friday November 14 under the tab "past webinars and stakeholder calls 2014". If you have additional questions about the guidance please use the

contact information provided at the end of the slide presentation. As always we appreciate your feedback. Again thank you for participating and this concludes today's webinar.

Coordinator: That concludes today's conference. Thank you for your participation. All participants may now disconnect.

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