

NWX-HHS FDA

**Moderator: Tammy Wirt
February 26, 2014
1:30 pm CT**

Coordinator: Welcome and thank you for standing by. At this time all participants are in listen only mode. During the question and answer session please press star 1 on your touchtone phone. Today's conference is being recorded. If anyone has any objections you may disconnect at this time.

And I would now like to go ahead and turn today's call over to Heather Howell. Ma'am, you may begin.

Heather Howell: Hello. I'm Heather Howell, the Deputy Director of CDRH's Office of Communication and Education.

Welcome to today's FDA webinar to discuss the final guidance document titled Request for Feedback on Medical Device Submission - the Pre-Submission Program and Meetings with Food and Drug Administration staff, also known as FDA's Q Submission Process.

The final guidance posted on Friday, February 14, 2014. We apologize for the delay in today's webinar. We have a lot of interest in this presentation so it

just took us quite a while to get everybody connected. But we are ready to begin.

And your presenters today are Dr. Soma Kalb, the Acting Director of the Office of Device Evaluation's IDE Program. And Ms. Elizabeth Hillebrenner of the Office of In Vitro Diagnostics and Radiological Health. Following the presentation we will open the call to your questions.

To assist with the Q&A portion of our call, we also have in the room with us, staff from the Center for Biologics Evaluation and Research or CBER and CDRH's Division of Small Manufacturers, Consumer and International Assistance.

The final slide of today's PowerPoint presentation includes contact information to assist with any questions that may not be addressed this afternoon.

Following today's presentation, the PowerPoint slides, audio recording of the webinar and a written transcript, will be posted to the CDRH's Learn Section of FDA.gov. You can find that Web site by visiting www.FDA.gov.

Click on Medical Devices and click on the CDRH Learn bullet in the middle of that page. Now I'll turn the call over to Soma.

Dr. Soma Kalb: Thank you. Good afternoon. My name is Soma Kalb and I'm the Acting Director of the IDE Program in the Office of Device Evaluation. Today I'm with Elizabeth Hillebrenner of the Office of In Vitro Diagnostics and Radiological Health.

We'll be discussing guidance for industry and FDA staff regarding the Q Submission Program at FDA. The guidance is formally called, Request for Feedback on Medical Device Submissions, the Pre-Submission Program and Meetings with FDA Staff.

The draft version was issued on July 13, 2012 and the final version was issued on February 18, 2014. This guidance covers many types of feedback. Beyond those preceding the submission of an IDE or other FDA submission. This guidance supersedes the 1999 Blue Book memo on the pre-IDE program.

Updates to this guidance in moving from the draft to final version, include broadening the scope to address all types of requests for feedback that are attractive Q-Submissions with an explanation of the tracking and logistics for Q-Submissions.

When the draft guidance was initially issued, the Q-Submission program was not yet fully developed or implemented in the FDA tracking system and the draft guidance did not include some types of meetings that are covered in the final guidance.

The final guidance provides the necessary detail to understand the different Q-Submission types, only one of which is the pre-submission. The final guidance also provides more detail on when to submit issue Q-Submission and policy clarification for meeting logistics.

The final guidance includes the refuse to accept checklist as an appendix to outline what FDA is looking for in the acceptance review. One of the updates to the guidance includes this helpful table that lists the different Q-Submission types.

It also indicates whether a meeting is associated with those types and gives a timeframe for receiving feedback on the Q-Submission. As you can see, pre-submission is one type of Q-Submission but there are several others.

These include informational meeting, study risk determination, agreement meeting, determination meeting, submission issue meeting and PMA Day 100 meeting. It is important to note that there are some types of inquiries that are not considered Q-Submission.

These include requests for feedback that are broad in scope, coming from a trade organization or other group. Q-Submissions should be submitted by those stakeholders that are planning a future medical device submission to FDA.

Q-Submissions are submitted to the document control center or DCC. Those submitted to CDRH should be sent to the address listed in the slide. For those - the address for the CEBR's document control can be obtained by contacting the CEBR contact listed at the end of the presentation.

As outlined in the eCopy program for medical device submissions guidance, one eCopy and one hard copy are required for Q-Submissions. The cover letter should clearly identify the (QSIP)type from the list of types that I showed in the previous slide.

The cover letter should give a sponsor contact information, the device name and any information specific to the (QSIP) types that Ms. Hillebrenner will discuss shortly.

With regard to follow on submissions to a given Q-Submission, amendments include additional information about an existing Q-Submission. These might

be slides, agenda updates, meeting minutes or meeting minute disagreement requests.

Supplements on the other hand, contain new requests for feedback on the same device and indication for an existing (QSIP).

Some examples might be where the original request for feedback was on the plan bench testing for a given device while supplement one might request feedback on the clinical investigational plan.

It is important to note that if the request for feedback is for device and indication that has changed significantly from a previous Q-Submission or the different type of feedback request, it will be considered a new Q-Submission and will be assigned a new number.

For example, if you had a pre-submission for a device where you were specifically requesting feedback but then wanted to have an informational meeting with FDA, that would be a new (QSIP)type.

Because informational meetings are different types of Q-Submissions, the informational meeting (QSIP) would receive a new number. It would not be a supplement to the previous Q-Submission.

The guidance describes the procedure for the acceptance review of the Q-Submission. Since the draft guidance was issued, we've been using a transitional acceptance review process where the clock was not stopped for those submissions that were missing important information.

In a few weeks we will be moving out of the transitional acceptance review procedures and following - and be following a more formalized process

whereby the review clock will stop if the submission is not acceptable. The acceptance review is not conducted for all Q-Submission types.

For agreement meetings, determination meetings, PMA Day 100 meetings and study risk determination requests, the Q-Submission is automatically accepted.

For other (QSIP) types the acceptance review is conducted within 14 days to determine whether the request qualifies as the specified type and if the submission is complete enough to proceed with the review and/or set up the meeting.

The checklist used by FDA staff is included as an appendix to the guidance. FDA will notify the sponsor of either acceptance or rejection of the submission. Both of these will come via email. The rejection email will list the information needed to make it complete.

If the file is rejected, the sponsor will submit the response as an amendment to the (QSIP). If the submission is then found to be complete, the review clock will start on the date of receipt of the submission that completed that Q-Submission.

I'll now turn it over to Ms. Hillebrenner, who will discuss each of the specific Q-Submissions.

Elizabeth Hillebrenner: Thanks Soma. First, we'll talk about the pre-submission which is definitely the most common type of Q-Submission we see at FDA. The definition of a pre-submission can actually be found in the MDUFMA 3 Commitment Letter.

It was during MDUFMA 3 that this program was developed together with industry.

A pre-submission is a formal written request from an applicant for feedback from FDA, provided either in the form of a formal written response or if requested by the sponsor, a meeting or teleconference, in which the feedback is documented in the meeting minutes.

A pre-submission takes place when FDA's feedback on specific questions, is necessary to guide product development and/or application prep. So this would be prior to an intended submission of an IDE or marketing application.

A request for a pre-submission should include specific questions regarding review issues relevant to a planned IDE or marketing application. So this could be questions regarding pre-clinical or clinical testing protocols or data requirements.

And our guidance document does include some examples of both - both positive examples of things that we think would be productive questions for a pre-submission meeting or a teleconference, as well as some examples of questions that might not be so productive.

A pre-sub is intended to be specific to the questions posed. So FDA will prepare for the meeting or teleconference or written feedback, based on the questions you write in your submission.

However, as other things come up during our discussion or during our internal preparations that we think will help you, we will certainly offer you that additional feedback as well.

A pre-sub is generally meant to be a onetime process per topic. It's not intended to be iterative. But it could be utilized multiple times for different topics on the same device.

As Soma mentioned, you might have one discussion about bench testing and then one discussion about a clinical trial design, both for the same device. But it's not intended to have multiple conversations about the same type of testing.

If significant changes are made to a proposal in response to our feedback, then it might be appropriate to bring a subject matter back up for additional discussion. Okay. A pre-sub is not intended to be a mechanism for FDA to design your nonclinical tests or clinical study protocols.

We simply don't have the resources to do this type of consulting work. It's not for us to design these things though we're happy to give you feedback on your proposals. A pre-sub is not a phone call or email regarding questions that can be readily answered by the lead reviewer.

If there's a minor process question that you would typically just pick up the phone and call a reviewer in the branch that you typically work with, you can still do that. Pre-submissions are not necessary for inter - or not appropriate for interactive review of an active submission.

So when we have an IDE or a marketing application open and we have questions for you that we want to work with you interactively on, we will still email you or call you and ask you those questions. We're not going to make you send in a pre-sub to have that type of interaction.

We will track that interaction with the marketing application or IDE. A pre-sub is not a request for designation, a 513G or an appeal. A pre-sub is not a

determination or agreement meeting although such meetings are also tracked as (QSIP)s. And a pre-sub is not a meeting that is informational only.

For information - informational meetings are - when sponsors just want to present an overview of a product area or a particular device and FDA is in listening mode only. These are not pre-submissions but they are (QSIP)s. So when should you consider submitting a pre-submission?

These are voluntary but they are highly encouraged. We especially encourage them prior to initiating long term or expensive preclinical studies.

We certainly don't want you going out and conducting a two year animal study only to find out after the fact, that the study design was flawed and didn't produce meaningful data. So before a study like that would be a good time to come talk to us.

We recommend talking to us before planning a clinical study that does not require an IDE. This would be studies that are either conducted outside the US entirely that are exempt from the IDE requirements or are non-significant risk and therefore exempt from an IDE application.

It would be a good idea in those cases, to get some feedback to make sure that the clinical study is going to answer the questions you're hoping it'll answer for you. We recommend pre-submissions before submission of an IDE, to discuss any nonclinical data or clinical study design issues.

We think that having this interaction before the IDE could lead to a more successful IDE outcome.

We recommend pre-submissions before a submission of any marketing application to apprise the team on specifics of device and clinical study, if there have been changes since the initiation of an IDE.

To obtain feedback on preferred data presentation - this is especially important for PMAs, especially with the statistical data.

The pre-submission process gives an opportunity for sponsor statisticians to sit in the room with FDA statisticians and speak their language directly to one another and make sure that both parties understand what needs to come into submission and how it should be presented to optimize the review process.

It's also helpful just to gain insight into potential hurdles for approval or clearance so that companies know, especially for a big submission, just how do set their expectations in terms of what's going to happen during the FDA review process.

Pre-submissions are very strongly encouraged when you're preparing a submission for a new device that does not clearly fall within an established regulatory pathway.

We can talk about the indications and what pathway might be appropriate for that particular device based on the indication you select. Next slide. So there's also some IVD specific considerations for when to submit a pre-sub.

We recommend you come to us before conducting clinical, nonclinical or analytical studies or submitting a marketing application for a new IVD that is a multiplex device, capable of simultaneously testing a large number of (analyte)s, contains new technology, new intended use, new (analyte)s, new

clinical questions, complex data or statistical questions and - or uses a predicate or reference method that is unclear or uncertain.

And just to give you a brief overview of what the pre-sub process entails since this is such a common pathway to follow - first, the sponsor submits their pre-submission to the document control center. FDA will conduct the acceptance review that Soma described, within the first two weeks.

If a meeting or a teleconference is requested, FDA will work with a sponsor to schedule that meeting or teleconference within the following week after acceptance.

So our target is within one week of determining acceptance of your pre-submission that we will contact you and offer you one or more potential meeting dates where our team can be available to meet with you.

We will also, if you have requested a meeting or teleconference, provide you advanced feedback in writing, via email, at least three business days prior to the meeting or teleconference. Then we provide our feedback within the time range of 75 to 90 days. We're shooting for 75.

The guidance document has been updated to indicate that this is the range that we are shooting for. So that would be either holding the meeting or teleconference by this timeframe or if you have just - only requested written feedback, sending you that email within this timeframe.

And then if we do have a meeting or teleconference, it's the sponsor's responsibility as outlined in the MDUFMA 3 Commitment Letter, to provide a draft of the meeting minutes to FDA for review. We ask that you send these to the document control center.

I realize that the draft guidance asked that you send them to the lead reviewer. The final version of the guidance has been updated to reflect our policy which has always been to send it to the document control center so that we can track them.

So these minutes will get logged in as an amendment to your pre-sub. We will review them within two weeks. And either determine if they are acceptable and let you know, or provide you with revisions or edits.

And FDA's edits will - edited version that we send you will be the official version unless you submit a meeting minutes disagreement amendment.

The feedback on the FDA provides on a pre-sub will represent FDA's best advice based on the information provided.

This was discussed extensively during the MDUFMA 3 negotiations and FDA committed in MDUFMA 3, to stand behind our feedback unless information and subsequent submissions is not consistent with the pre-sub.

So if you've changed your indications for use or made a significant design change then our previous feedback might not still hold. Another situation is if data and the subsequent submission raises important new issues related to safety and effectiveness.

And feedback given previously does not adequately address important new issues materially relevant to determination of safety and effectiveness that have emerged since the time of the pre-sub. So the last case is when the practice of medicine has changed.

There's new scientific information available that we have to take into our bigger picture consideration. And if the new information does impact safety and effectiveness then our feedback may change.

In going from the draft to the final version of the guidance, we have updated this section of the guidance to provide a little bit more clarity.

We indicated, for example, FDA may modify previous feedback if new findings and scientific findings emerge that indicate there is a new risk or increased frequency of a known risk that affects the prior advice or if there is a new public health concern that affects the prior advice.

Further, FDA intends to work with the sponsor to address any new issues raised by the change, taking into consideration the stage of development where possible. The next type of Q-Submission is informational meeting.

The purpose of an informational meeting is for sponsors to share information with FDA. They may be appropriate for providing an overview of ongoing device development when there are multiple submissions planned within the next year or so.

This will help familiarize the review team about a new device with significant differences in technology from currently available devices. There's no expectation of FDA feedback. FDA is going to be in listening mode during informational meetings.

We will not be having pre-meetings to prepare responses for questions because the whole purpose of the informational meeting is just for us to learn from you about what your plans may be. The team may ask questions or other - offer other suggestions if appropriate if they come up.

We're not going to hold back any feedback we might have for you but we're not going to - in an informational meeting, we're not going to have planned responses to questions. These meetings are granted as resources allow. And we target scheduling them within 90 days.

Please ensure, if you would like a meeting, an informational meeting, that your package contains sufficient background information to allow us to identify the appropriate attendees. So we want to know if we need to include an animal study expert, a statistician.

We need to know enough about what you plan to discuss with us so that we could have the appropriate review team available.

And the same meeting minutes procedure that we use for pre-submissions whereby the sponsors provide the draft as an amendment to the DCC, should be followed for informational meetings as well.

In this case the minutes may be much briefer because FDA is only in listening mode and not necessarily providing any feedback. The next type of Q-Submission is a study risk determination request.

So FDA is available to help sponsor the clinical investigations and/or IRBs in making a risk determination. You are not required to come to us for a risk determination but we are here and willing to provide this if this is something that you request.

The policy here has remained unchanged. What we have done now is in the (QSIP) guidance, because we are now tracking these as Q-Submissions, we have referenced the existing information sheet guidance for the policy and

explained that the administrative procedures, now involve submission of a (QSIP) with a written request for a study determination.

And then we will respond to you with a formal letter. So the only new thing here is that these requests are getting Q numbers. Next I'll talk about both agreement and determination meetings. These meetings were instituted under (FDAMA) as early collaboration meetings.

And that is what the existing guidance document is titled. Again, the policy here is remaining unchanged. What is different is that these things are now being given Q numbers.

So in our guidance document, we have referenced the existing guidance document and explained that we're giving Q numbers and targeting 30 days for the meetings and that the minutes follow the same process of the sponsor drafting and sending draft minutes as an amendment to a (QSIP).

Next we have submission issue meetings and we'll spend a little bit more time on these. We had a lot of comments to the docket on submission issue meetings.

We've had a lot of questions outside of that, internally and externally, regarding when is a submission issue meeting appropriate and inappropriate. So we've added a lot of information to the guidance to provide additional clarification here.

These types of meetings are appropriate for sponsor requests for an in person meeting to discuss a planned approach to responding to deficiencies.

So what that means is if you had a 510K or a PMA or an IDE or any submission under review and it got put on hold, with a deficiency letter, and you want to make sure that you know that your approach to responding to that deficiency letter, is going to be in the right ballpark where you want FDA's feedback on some aspect of that response before you actually send it to the DCC for your - before you send in a 510K supplement or a PMA amendment.

And you want a meeting to discussion that feedback, that's called a submission issue meeting. Also, if you want a teleconference that involves management participation to discuss your planned responses, that would be a submission issue meeting.

If you want feedback on a planned approach that - to responding to deficiencies that requires in depth preparation by the review team and management just purely due to the nature of the questions, then that would require a submission issue.

So for example, if you want feedback on plans to submit a justification for not providing information requested, that would likely require submission of a (QSIP) because in order to respond to that to provide you with such feedback, we would have to involve management and the whole review team.

Any time the question is significant in nature and requires management involvement, we're going to ask you to send in a submission issue meeting request or (QSIP) request. We could provide feedback in writing if that's how you would prefer it.

The next slide talks about when submission issue meetings are not generally appropriate. So these are not needed for brief clarification questions that can be readily addressed by the lead reviewer.

These types of clarification questions are simply documented in the review record associated with the parent submission. Submission issue meetings are not necessarily for teleconferences for which you don't need participation of the manager or consultant.

Again, these can be documented in the review record associated with the parent submission. Submission issue meetings are not appropriate for feedback on a proposed protocol prior to conducting a major study to address a deficiency.

If you want feedback on a whole protocol to allow the review team adequate time to review that protocol, we request that you send in a pre-submission so that the whole team could take the time to review that protocol and give you the feedback you need.

Submission issue meetings are not appropriate for pre-review of planned responses. It is our general policy that we don't pre-review your planned responses. This information rather, should be reviewed as a formal response to the deficiency letter.

So this would be sending in just - sending in your 510K supplement or your PMA amendment or your IDE amendment with that information. Submission issue meetings are also not necessary or appropriate for interactive review.

Interactive review takes place when the file is under review, not when it's on hold. And that can continue as is and documented in the review record associated with the parent submission.

Okay, and the last type of Q-Submission is the PMA Day 100 meeting. This is another case where the policy hasn't changed. We still reference the existing guidance on PMA Day 100 meetings. The purpose of such meetings is to discuss the status of a PMA review.

What's new is that these are being tracked as Q-Submissions. We are linking them to the PMA in our databases. What you need to know is that if you're requesting a PMA Day 100 meeting within your original submission, we will automatically log in the (QSIP) when you log in your original PMA.

However, according to (unintelligible) you have up to 70 days to request the PMA Day 100 meeting. So if you want to do so later in the PMA review process, you must send in that request as a (QSIP) to the DCC.

We will try to provide our - any outstanding PMA deficiencies to you at least ten days in advance of this meeting. This syncs up nicely with our PMA substantive interaction goal of 90 days.

So within 90 days of the - of receipt of the PMA, you should be getting a major deficiency letter or a notification that will proceed interactively. And then ten days later, roughly, you might have a PMA Day 100 meeting if you so choose.

And again here, the meeting minutes will be tracked as amendments to the (QSIP) and to follow the same policies. Now I'm going to turn it over to Soma, who will discuss general tips for successful meetings with FDA.

Dr. Soma Kalb: Thank you Elizabeth. In all the types of Q-Submissions and meetings with FDA we have several recommended best practices to ensure that your meetings are successful.

We recommend that you follow the suggested logistics for meetings with CDRA and CBER staff as provided in section 4 of the guidance. In order to facilitate scheduling, please provide several options for possible meeting dates.

And as Elizabeth noted, FDA will contact you within seven days of acceptance of your Q-Submission, to start scheduling.

In order for the meeting to meet your objectives, include focused questions in your submission, keeping in mind the timeframe of review and the expected duration of a teleconference which is - or meeting, which is typically an hour.

Provide your agenda in advance so that all attendees are aware of the meeting objectives. And be sure to bring the right experts to the meeting. It's also important to have the appropriate FDA staff at your meeting.

It is helpful and appropriate to indicate to FDA in your submission, if you believe someone with specific expertise should attend.

Although FDA intends that the feedback the agency provides in a pre-sub will not change, as Elizabeth mentioned, if the feedback given previously does not adequately address new issues that may have emerged since that feedback was provided, FDA's advice may change.

FDA will not provide definitive guarantees on the feedback. Importantly, FDA will not make approval decisions in a pre-submission meeting. Also as Elizabeth mentioned, please don't expect FDA to have iterative meetings on the same topic.

The goal of the pre-submission program is to provide one time advice on a given topic. Please design your submissions to make forward progress with this in mind. FDA will prepare to ensure that the meeting is productive.

As any new information that comes in during the review will need to be evaluated by the review team, we recommend that you do not provide new information close to the time of the meeting.

Any new information, may need to be considered a supplement to the (QSIP) in order to get the review that it deserves.

Some additional helpful hints include limiting the presentation of the information that's in the pre-meeting materials to a start of the allotted time for your meeting, in order to allow adequate time for discussion.

It's helpful also if you bring a dedicated attendee to take detailed notes so that you can provide accurate meeting minutes and to summarize action items at the close of the meeting and ask for clarification if needed.

With regard to meeting minutes, the new guidance outlines the existing policy, the draft minutes from the sponsor, should be submitted to the document control center within 15 days. It is helpful to submit the minutes soon after the meeting, while the discussion is still fresh in our minds.

Note that the minutes document what transpired during the meeting in summary form. They shouldn't be a transcript and they should not provide new responses to issues raised during the meeting or follow up requests for feedback. These should be submitted as (QSIP) supplements.

The FDA review team will review and edit the minutes and if necessary, well they'll edit them if necessary, within 30 days of receipt. If edits are needed, the FDA sends the revisions to the sponsor by email.

After 15 days the FDA-edited version of the minutes become final unless the sponsor submits a meeting minutes disagreement amendment to the document control identifying the issues with the FDA-edits.

The minutes disagreement should refer to disagreement regarding what was said and agreed upon during the meeting, not disagreement with the feedback that was provided.

At - if a meeting minutes disagreement amendment is submitted, FDA will arrange a teleconference to discuss those minutes. And at the conclusion of the teleconference, FDA will either revise the minutes to reflect resolution or note that the parties agree to disagree.

The minutes that were revised by FDA based on the telecon are considered final. This concludes our presentation on the pre-submissions and meetings with FDA guidance. We will now have a question and answer session.

However, if you have any questions in the future, they can be directed to the contacts that are listed on the screen.

Heather Howell: Thank you Soma and Elizabeth. Operator, we will now take questions as they come into the queue.

Coordinator: Thank you. We will now begin the question and answer session. If you would like to ask a question over the phone please press star 1. Please unmute your

phone and record your name. Your name is required to introduce your question.

Again, if you would like to ask a question over the phone please press star 1. To withdraw your question press star 2. One moment please for the first question over the phone. I do have a question. (Hyung Kim), your line is open.

(Hyung Kim): Yes. I have two questions. The first question is, is there any connection between pre-sub and 510K submission?

So in other words, if you - we establish the (unintelligible) through this pre-submission with FDA and that if we followed that protocol (unintelligible) as we agreed in the pre-sub than the original problem in the 510K review.

So in other words, can we submit the 510K, we may mention about the (QSIP) number or as the review can note a connection between them, something like that?

Dr. Soma Kalb: Yes. If you have conducted a pre-sub or if you have submitted and received feedback in a pre-sub prior to your 510K submission it is absolutely appropriate and you should reference that pre-submission in your 510K submission.

Elizabeth Hillebrenner: In fact that's part of the 510K RTA checklist is to include that information.

(Hyung Kim): Yeah. So there are really no any new issue including the 510K review? Is that right?

Elizabeth Hillebrenner: I'm sorry. We're going to get the volume turned up here in a second. Could you - just give us one second and then I'll ask you to repeat the question. Okay. Can you repeat it again?

(Hyung Kim): Okay. So if we (unintelligible) - completely follow the protocol to agree with FDA during the pre-sub then there will be no new issues will be - no...

Elizabeth Hillebrenner: It's not guaranteed. No. Because we don't know what the data are going to be. If we're talking about the protocol or the pre-sub, we can give you feedback that we think this is going to be a good study to do and that it might likely support a 510K.

But without knowing the outcome of the actual testing we can't tell you for sure that it's going to support the 510K.

(Hyung Kim): Okay.

Dr. Soma Kalb: And particular...

(Hyung Kim): My second question is during the 510K review, the deficiency indicated by FDA's reviewer, if we do not agree with this deficiency, then do I - can I submit the submission meeting to the - for the (unintelligible)? Is that...

Elizabeth Hillebrenner: If you'd like a meeting to discuss the deficiency and your approach to responding to it, yes. It might be that we ask you to for A, B and C and you think X, Y and Z might support it. And then you want to get our feedback before you actually respond to the 510K.

That would be appropriate to have a submission issue (QSIP) where we talk about whether alternate types of responses would address the underlying question that FDA had during its review.

(Hyung Kim): Okay. Thank you.

Heather Howell: Thank you. We'll take the next call.

Coordinator: Thank you. The next question comes from (Heather Nigrell). Your line is open.

(Heather Nigrell): Thank you. I have a question regarding the timeline for the review. It was stated earlier that FDA has 75 to 90 days to provide feedback and I'm wondering is that 75 to 90 days in addition or beyond the 21 days for the initial contact to set up a meeting?

Or is it the goal of FDA to provide feedback within 75 to 90 days from the time the document control center receives the submission?

Dr. Soma Kalb: Right. Our target of providing feedback within 75 days, that's relative to the receipt of the complete submission. So let's say that you received feedback that we accepted your review, on day 14. So it would be what is that? Sixty one days after that would be...

Elizabeth Hillebrenner: Roughly yeah.

Dr. Soma Kalb: ...the beginning of the target. So between 75 and 90 days from receipt of the submission, the complete submission.

Elizabeth Hillebrenner: But that's just a target. There is no MDUFMA performance goal associated with any of these submission types.

(Heather Nigrell): Okay. Thank you.

Coordinator: Thank you. The next question comes from (Rama Tiagi) from (Janet Graff)'s line. Your line is open.

(Rama Tiagi): Thank you for taking the call. And it's a good - a very good presentation. I have a question regarding that which I think I've got the answer but I just want to confirm, because the whole presentation was talking about IDE and PMA, since it was not mentioning 510K.

So I wanted to know that if this applies to 510K also and we can make the Q-Submission for that. So I'm pretty sure the answer - that was my one first question. Okay? And that all the regulations will be applied to it.

And the second question I have that I want to confirm that if the 510K for the IVD is it the Q-Submission is going to be given to - still to the DCC? Or somewhere else? Or CBR?

Dr. Soma Kalb: Yeah. So the Q-Submission program and the pre-submissions apply for all different types of FDA submissions - IDEs, CMAs, HDEs, 510Ks. And all submissions, whether they're going to OIR or ODE to come in through the document control center.

(Rama Tiagi): Thank you.

Dr. Soma Kalb: You're welcome. Next question please.

Coordinator: Thank you. The next question comes from (Maryann Bruzinski). Your line is open.

(Maryann Bruzinski): Hi, yes. Thank you. I had a question regarding slide - it's either 25 or 26, regarding the submission issue meeting. The first one says in person and the second one is a telecon with management participation. I'm trying to understand the difference with those.

Is it when you have an in person meeting you're not going to have management present? And a telecon, management will be present.

Elizabeth Hillebrenner: Sorry for that confusion. No. In person will have a management present, a manager present. All in person meetings have managers present. So...

(Maryann Bruzinski): That was my experience. I just wasn't sure.

Elizabeth Hillebrenner: Yeah.

(Maryann Bruzinski): Okay. And then telecon also a manager present or you request the manager present?

Elizabeth Hillebrenner: So, you know, teleconferences can go either way obviously. If you request a manager present then it would definitely need a submission issue (QSIP).

If you don't request the manager present but because of the nature of your questions you're asking something really complicated or proposing something really novel, to address a deficiency and the reviewer needs to include their manager, then it would need a submission issue (QSIP).

(Maryann Bruzinski): Okay. Thank you.

Dr. Soma Kalb: Next question please.

Coordinator: Thank you. The next question comes from (Chris Scavoto). Your line is open.

(Chris Scavoto): The question - first, thank you. The question is for submitting a human factors protocol just to simply have a review of the protocol and make sure it's in alignment with current expectations. What is the process for that on the pre-sub?

Dr. Soma Kalb: I think if you have a targeted question around that protocol it would be appropriate for a Q submit - a pre-submission.

If that is a particular protocol and test report that you plan to provide to support a future marketing application or IDE application then it's definitely something that's within the scope of the pre-sub program.

(Chris Scavoto): Okay. Thank you.

Dr. Soma Kalb: You're welcome. Next question please.

Coordinator: Thank you. The next question come from (Larry Lufley) from (Kimberly Garcia)'s line. Your line is open.

(Larry Lufley): Hi. I just have a quick question. Could you tell me the difference, by definition, between the pre-submission for an IDE and a pre-IDE?

Elizabeth Hillebrenner: Well so the pre-IDEs were initially developed to provide feedback prior to submission of an IDE. However, that program over time, grew to include a lot more than just that. There was a lot of flexibility associated with it.

So we would log in basically - we used it as a catchall for logging in any type of request for feedback so that we could get tracking numbers associated with those - with the request for feedback. So the program just sort of ballooned.

And it was used for all types of feedback - feedback with four or 510K, PMA, anything you can think of. So in MDUFMA 3 industry had a desire to have a more structured pre-submission process. And in doing that, in developing that program in the commitment letter, decided to rename it what it really was.

It's used for - as a pre-submission for any type of submission, not just IDEs. So beginning on - in October of 2012 when MDUFMA 3 was implemented, we stopped logging in requests for feedback as pre-IDEs.

And started logging in Q-Submissions and specifically if it met the definition of a pre-submission it would be a pre-sub Q - a pre-sub type of a (QSIP).

Dr. Soma Kalb: And so there are currently no new pre-IDEs anymore. There are no files that are given numbers that begin - I mean assignment numbers that begin with the letter I. Any type of pre-submission, whether it's for an IDE or a PMA or an HDE or anything, is given a Q number.

(Larry Lufley): Okay. Thank you.

Dr. Soma Kalb: Next question please.

Coordinator: Thank you. The next question comes from (Rhonda Howah). Your line is open.

(Rhonda Howah): Hi. I was wondering if you could elaborate more on the agreement and determination meetings. Is a pre-sub required before you can request one of those meetings or can you go straight to a meeting just to get initial feedback before submitting a pre-sub?

Dr. Soma Kalb: So agreement and determination meetings have very specific purposes. And it's not necessary - if you want to go that route that is something that's different from a pre-submission.

A pre-submission allows for more dialog and interaction and has different timelines from the agreement and determination meeting.

If you refer to the guidance that Elizabeth outlined, called Early Collaboration Meetings Under the SCA Modernization Act, Final Guidance for Industry and for CDRH Staff, which was issued in 2001, that provides more specific information about agreement and determination meeting.

But they have more specific procedures, different timelines and less opportunity for interactive discussion that's allowed under the pre-sub program.

(Rhonda Howah): Okay. Thank you.

Coordinator: Thank you. The next question comes from (Donna Tassic). Your line is open.

(Donna Tassic): Yes, hi. I just wanted to ask - following up on the first question in the question and answer session, regarding giving information in a submission, about a

pre-submission discussion. Which section should we give that in? Is it the other or where should we put all those previous communications?

Elizabeth Hillebrenner: In the 510K. We recommend the cover letter and/or the voluntary cover sheet form 3514.

(Donna Tassic): Okay. So not in the other section?

Elizabeth Hillebrenner: I'm sorry? In what other section?

(Donna Tassic): Not in the other folder of the 510K, other, the last section?

Elizabeth Hillebrenner: Oh.

Dr. Soma Kalb: Section 21.

((Crosstalk))

Elizabeth Hillebrenner: I think that if you have it in the cover letter that's a safe place to put it.

(Donna Tassic): Okay.

Elizabeth Hillebrenner: If you need to discuss it in detail and reference it into its own section, that's acceptable as well.

(Donna Tassic): Okay. Thank you.

Elizabeth Hillebrenner: Thank you.

Coordinator: One moment for the next question. The next question comes from (Robin Fatzinger). Your line is open.

(Robin Fatzinger): Hi. Thank you. So we have a question and kind of a concern, something that has come up in the past when we were looking for feedback on a deficiency for a 510K.

And could still be a concern now with the (QSIP), is if there is some question about say, some additional testing that the agency is asking for and we request a meeting to discuss that deficiency.

If that meeting doesn't end up - and the 510K is on hold, if that meeting doesn't occur until 90 days or later, into the process, you only have 180 days on hold. And then you might not have enough time to do the testing that's requested.

So has that - was that brought up in the comments at all? Or is that something that FDA has considered?

Elizabeth Hillebrenner: So for submission issue meetings, our target is to schedule these within 21 days. And that is part of the reason. So the concept behind this is that we shouldn't have a lot to do to prepare because we already reviewed the 510K or whatever it is.

We wrote the questions so we've done our prep. And we don't need that whole, you know, 90 days to get ready for the meeting. And it's also best to have it when it's still fresh in our minds.

And then it also gives you the feedback you need right away, so that you can still proceed to address the deficiency within, you know, the remaining 160 days on your hold clock.

(Robin Fatzinger): Okay. I think maybe we misunderstood that. So that meeting should happen within 21 days?

Elizabeth Hillebrenner: That is our target. Now sometimes sponsors ask for the meeting to be 60 days later. And if that's what the sponsor requests then we'll do that. But we will try to schedule it within three weeks.

(Robin Fatzinger): Okay. And does - that's usually a teleconference, I presume?

Elizabeth Hillebrenner: Yes.

(Robin Fatzinger): Okay. If you wanted to have it face to face that might be more challenging to do in a short...

Elizabeth Hillebrenner: Yeah. The logistics. Exactly.

(Robin Fatzinger): Okay, great. Thank you.

Coordinator: Thank you. The next question comes from (Lissa Egan). Your line is open.

(Lissa Egan): Hi. You had mentioned that within one week of determining a meeting or not, FDA will offer one or more meeting dates. And I was curious, what would you recommend as the next steps if the lead reviewer has not made contact within that week timeframe?

Elizabeth Hillebrenner: So you would have the lead reviewer's name from the acceptance email...

(Lissa Egan): Yes, I do.

Elizabeth Hillebrenner: ...that you got by around day 14ish. And after a week you could contact them to follow up.

(Lissa Egan): Okay. Thank you.

Coordinator: One moment for the next question. The next question comes from (Cheryl Clayman). Your line is open. Hello (Cheryl), please check your mute button.

(Cheryl Clayman): Hello?

Coordinator: Your line is open. Thank you.

(Cheryl Clayman): Thank you. Sorry guys. The question that we have is if we were submitting a letter for priority review status, does that change any of the timeline for the (QSIP) process?

Dr. Soma Kalb: I don't believe it does. That is something that we could follow up on but I don't believe it does.

(Cheryl Clayman): Okay.

Dr. Soma Kalb: I don't think it has any bearing on these Q-Submission timelines.

(Cheryl Clayman): Okay. Thank you.

Heather Howell: Next question please.

Coordinator: The next question comes from (Dave Petrich) from (Angela Tucker)'s line.
Your line is open.

(Dave Petrich): Hi. Thank you for the presentation. I have a question about the scope of the final guidance document. And as an earlier caller mentioned, the pre-IDE program is replaced by a pre-sub and that includes CBER as well.

So my question is does the final pre-sub guidance apply to CBER products that are subject to an IND as well? And if not, is there a similar document?

(Cheryl Cochman): If the - this is (Cheryl Cochman) from CBER. If the IND is for an in vitro diagnostic device, then yes, the pre-sub guidance apply. If the IND is for a non-device biological then it does not apply. So...

(Dave Petrich): Okay.

(Cheryl Cochman): ...there's a very specific dividing line with respect to INDs and BLA. They must be...

(Dave Petrich): Okay.

(Cheryl Cochman): ...for an IBD.

(Dave Petrich): Okay. So a biological IBD under an IND would apply?

(Cheryl Cochman): Yes.

(Dave Petrich): This guidance would apply? Okay. Thank you so much. I really appreciate it.

(Cheryl Cochman): You're welcome.

Coordinator: Thank you. The next question comes from (Rosina Robinson). Your line is open.

(Rosina Robinson): Thank you. The question I have relates to how the (QSIP) program relates to the pre-de novo submission kind of interaction. Hello?

Dr. Soma Kalb: That might be beyond the scope of this call. You can - right, you can send it into CDRH Questions and we can try to address it that way.

(Rosina Robinson): Thank you.

Coordinator: Thank you. The next question comes from (Paul Dryden). Your line is open.

(Paul Dryden): Yes. The previous caller just asked my question. It had to do with timelines on pre-de novo submissions. And I just heard that it was outside the scope of this conversation. So...

Dr. Soma Kalb: Okay.

(Paul Dryden): ...I understand the response.

Coordinator: Thank you.

Dr. Soma Kalb: Thank you.

Coordinator: As a reminder, if you'd like to ask a question over the phone, please press star 1. To withdraw your question press star 2. One moment please for the next question over the phone. The next question is from (Judy Dunlap). Your line is open.

(Judy Dunlap): Hi. I have an easy question. I'm just wondering if there are any fees associated with these meetings or pre-sub.

Dr. Soma Kalb: No, there aren't.

(Judy Dunlap): Okay. Thank you.

Dr. Soma Kalb: You're welcome. We can take the next question.

Coordinator: Thank you. The next question comes from (Gonaj Mulini). Your line is open. (Gonaj), your line is open.

(Gonaj Mulini): Okay. My question is for the pre-sub. The lead reviewer for the pre-sub usually will that end up being the lead reviewer for the marketing application too?

Dr. Soma Kalb: Not necessarily, although it makes good sense that they would, you know, that a reviewing branch would try to have the same lead reviewer. But that can't be guaranteed and there's no assurance that it will be.

(Gonaj Mulini): Okay. Thank you.

Coordinator: Thank you. The next question comes from (Linda Kria). Your line is open.

(Linda Kria): Hi. I just have a question regarding - we submitted a 510K and before we could send in our additional information for the deficiencies we received a closed out - closeout report.

And my question was we - there was a consensus standard that was in transition and - until I guess the end of this last year it was okay but come this year the standards I guess to the third edition.

So my question is, is that a question that I can have the reviewer from the 510K answer or does this have to go through the pre-sub or does it go through the submission issue meeting? If we have - we want to resubmit this product with obviously answering all the deficiencies.

But we also wanted to know if we can submit with the previous IEC standard since it was submitted before it expired. Or do we have to comply to the current standard? So that was my question. So I didn't know if we had to send that through pre-sub.

Elizabeth Hillebrenner: We have a 510K expert with us. Just one second.

(Linda Kria): Okay.

(Katimar Rojjan): Hi. This is (Katimar Rojjan). If your submission was...

(Linda Kria): Hi.

(Katimar Rojjan): Hi. If your submission was submitted before the expiration of that (unintelligible) standard, it (unintelligible) continue finishing your submission with that version.

(Linda Kria): Okay. So but we still have to - after the closeout it would be considered a new submission though?

(Katimar Rojjan): By closeout you mean - we see...

(Linda Kria): The final closeout report. So that would be - that would mean basically an NSC, correct?

(Katimar Rojjan): Was the file deleted?

(Linda Kria): I'm sorry?

(Katimar Rojjan): Was the file deleted?

(Linda Kria): I can't hear what you're saying.

(Katimar Rojjan): Was the file deleted?

Dr. Soma Kalb: We're not clear what you mean by a closeout report.

(Linda Kria): Let's see. Let me look at the title of their response.

Dr. Soma Kalb: Yeah. You might want to contact your review team for these questions. They seem pretty file...

(Linda Kria): Okay.

Dr. Soma Kalb: ...specific.

(Linda Kria): All right. All right, no, I wasn't sure if I had to schedule a pre-sub meeting or a submission issue meeting. That's why I had kind of given you a background.

Elizabeth Hillebrenner: Yeah, I would - contact your lead reviewer to ask him or her their advice on what type of submission to submit. Or how best to proceed.

(Linda Kria): Okay. All right. Great. Thank you.

Coordinator: Thank you. The next question comes from (Kenta Karasaki). Your line is open.

(Kenta Karasaki): Thank you very much. I have a question. What company has a couple of applications of the 510K so far and the under review by reviewer? And can I start - is it possible to set up the pre-sub and the submission issue meetings even the currently ongoing reviewing? Is that correct?

Elizabeth Hillebrenner: The submission is under review?

(Kenta Karasaki): Correct.

Elizabeth Hillebrenner: Right. No. Submission issue meetings are for when the file - if the file goes on hold then you may request a submission issue meeting to discuss deficiencies that put the file on hold.

(Kenta Karasaki): I see. I see. How about pre-submission process?

Elizabeth Hillebrenner: Pre-submission is for before you send it in. So once the file is here and under review, the FDA needs to take their time to actually review it. And we're not having sponsor initiated interactions while it's here and under review.

We might contact you with an interactive review request for additional information. But when it's here and on our clock, we're focusing on doing our part of doing that review.

(Kenta Karasaki): I see. For example, we see the deficiency better then we can try to set up the submission issue meeting. Then we can discuss.

Elizabeth Hillebrenner: If you think it's necessary. Yes.

(Kenta Karasaki): Okay. Thank you very much.

Elizabeth Hillebrenner: It's not required.

(Kenta Karasaki): Yeah. It's required. Yes.

Coordinator: Thank you. The next question comes from (Tanya Porter). Your line is open.

(Tanya Porter): Thank you. I have a question just basically on the submission issue meetings. So if you're issued a deficiency letter and you request a submission issue meeting, do you also need to write back to them and say, you know, if you're not going to have the review within the 45 days of responding to that deficiency letter to ask for an extension or is that automatically given to you?

Dr. Soma Kalb: The - there isn't any link between the (QSIP) submission issue meeting and whatever submission that you are having the submission issue meeting for. So if you need...

(Tanya Porter): Okay.

Dr. Soma Kalb: ...additional time you would need to submit an extension request.

(Tanya Porter): Okay. All right. Thank you very much.

Coordinator: Thank you. The next question comes from (Charlemagne Tua-Edwards) from (Catherine Leed)'s line. Your line is open.

(Charlemagne Tua-Edwards): My question already got answered. Thank you.

Coordinator: Thank you. The next question comes from (Julie Baker). Your line is open.

(Mana Hati): Hi. This is (Mana Hati). I was wondering if there is any meeting type here defined where we can get some help in classifying our product, if it is not exactly fitting into one of the (unintelligible).

Elizabeth Hillebrenner: So that wouldn't be a Q-Submission. That would be a 513G submission which is a separate pathway. We don't have any of those experts in the room here but you could - if you need help with how to do a 513G request for classification, I would suggest contacting (Dismika).

(Mana Hati): Right. Thank you so much.

Coordinator: Thank you. The next question comes from (Georgeanne Brown). Your line is open.

(Georgeanne Brown): Hi. If everything has to go to document control center does that mean it has to be in electronic form as well?

Elizabeth Hillebrenner: For Q-Submission?

Dr. Soma Kalb: Yeah.

Elizabeth Hillebrenner: Yes.

Dr. Soma Kalb: For Q-Submissions, yes. You should follow the eCopy guidance and it provides information on - for all the different FDA submission types of CRA submission types. What...

(Georgeanne Brown): Okay. I just wanted to be sure this counted. Thank you very much.

Dr. Soma Kalb: It does.

Coordinator: Thank you. The next question comes from (Michael Piasenza). Your line is open.

(Michael Piasenza): Thank you. Good afternoon and thanks for taking my question. If a special 510K is submitted on a change to illegally market the device where we own the 510K, and the FDA reviewer suggests that a traditional 510K be submitted instead, would the pre-sub process then be appropriate to discuss suggested options on how to proceed? Hello?

Dr. Soma Kalb: Sorry. Sorry. We're trying to figure out how to answer your question.

(Michael Piasenza): Okay.

Dr. Soma Kalb: So I think that we don't have the exact answer for that. If you can send your question to CDRHQuestions@FDA.HHS.gov we can...

(Michael Piasenza): Sure. Sure.

Dr. Soma Kalb: ...get your answer to you.

(Michael Piasenza): Okay. Will do. Thank you very much.

Dr. Soma Kalb: You're welcome.

Coordinator: Thank you. The next question comes from (Belinda Jackson). Your line is open.

(Belinda Jackson):Hi. For all the submission types, are they just - I was just wondering if they were business days or including weekends.

Dr. Soma Kalb: Calendar days, not business days.

(Belinda Jackson):Perfect. Thanks. So next question please.

Coordinator: Thank you. The next question comes from (Diane Kiernan). Your line is open.

(Diane Kiernan): Hi. Thanks so much for taking my call. We talked earlier (unintelligible) regulated by CDRH as well as CBER. And we focused in on in vitro diagnostic products. But there are other medical devices that are reviewed by CBER.

My question is does this guidance apply to devices regulated by CBER as well?

(Cheryl Cochman): Yes. This is (Cheryl Cochman) again. This guidance does apply to all devices regulated by CBER. The previous question was with respect to INDs and BLAs. It - the guidance applies to those INDs and BLAs that are for in vitro diagnostics.

So you would not likely have a BLA or an IND for something that is not also a device unless it's an IBD. Does that help?

(Diane Kiernan): Yes and no. I guess the question I'm - there is also a different eSubmission process which I know is outside the scope of this discussion so I'll save that for another time. But there's another - there is something other than eCopy where you can submit a submission to CBER.

And I'm assuming that also applies to 510Ks as well, since I have you on the line (Cheryl). So it isn't just eCopy for 510Ks, for devices regulated by CBER. If there's any submission process can we use that as well?

(Cheryl Cochman): That's - that is a very complex question because CDRH and CBER have different eSubmission initiatives. I would suggest that you follow up with - do you have a review team that you normally work with?

(Diane Kiernan): Yes.

(Cheryl Cochman): I would follow up with your review team.

(Diane Kiernan): Sounds good. Thanks so much for answering my question (Cheryl).

(Cheryl Cochman): Sure.

Coordinator: Thank you. The next question comes from (Velata Doj). Your line is open.

(Velata Doj): Hi. If we received a written feedback for a pre-sub and we want to discuss it further with the reviewer, can we request a teleconference and are there any timelines around this request?

Dr. Soma Kalb: You can request a follow up teleconference. That would be best handled by submitting a supplement to the pre-sub so that you can assure that you have focused questions in mind and that the appropriate FDA staff will be available and you can provide an agenda for that teleconference.

((Crosstalk))

(Velata Doj): ...timelines for the FDA to respond?

Dr. Soma Kalb: It's the same as for the original. Supplements have the same review timeline as the original pre-submission which is 75 to 90 days is our target.

(Velata Doj): Okay. Thank you.

Dr. Soma Kalb: You're welcome.

Coordinator: Thank you. The next question comes from (Vincent Arguri). Your line is open.

(Vincent Arguri): Hi guys. I was wondering, will the finalized (QSIP) meeting minutes become part of the public record once the device is approved? And if so, where can it be obtained?

Dr. Soma Kalb: No. These are not - these do not become part of the public record. They become part of the FDA record.

(Vincent Arguri): Okay.

Dr. Soma Kalb: Does that answer your question?

(Vincent Arguri): It does.

Dr. Soma Kalb: Okay. Next question please.

Coordinator: Our next question comes from (Jeff Morgan). Your line is open.

(Jeff Morgan): Hello. This has been very informative and I really appreciate the time everyone's taking. My question is basically two parts. The first part is a little bit more convoluted.

I have a client that has a device that is 510K cleared and an accessory to that device which is not that I can find at least, found in a product code, is going to be modified because it's more comfortable for the patient, not because of NBRs, etc.

My question - the first part is, is this something that then needs to be communicated to the FDA in any way? Or is just design documentation, design control and any modification testing, etc. in the design file, sufficient for this non-cleared accessory?

Dr. Soma Kalb: Just one minute. Your question, we believe, is outside the scope of this discussion on the (QSIP) program. You can submit it to CDRH questions and we'll...

(Jeff Morgan): Okay.

Dr. Soma Kalb: ...be able to get your answer. Or to (Dismika).

(Jeff Morgan): Okay. Yeah. I did (Dismika) and it was kind of unclear because I was made aware that at least from publication from the FDA that the guidance for industry on deciding when to submit a 510K for a change to an existing device, was withdrawn.

And yet the - (Dismika)'s response still said that they're still using that guidance. And I'm unclear as to what we do in these cases, where we get conflicting information.

Dr. Soma Kalb: Okay. We understand your question. If you can send it to CDRH Questions we'll...

(Jeff Morgan): Okay. I'll do that.

Dr. Soma Kalb: ...specifically...

(Jeff Morgan): Okay.

Dr. Soma Kalb: ...covered by our 510K staff.

(Jeff Morgan): Okay. Thank you.

Coordinator: The next question comes from (Debbie Brown). Your line is open.

(Debbie Brown): Hello. You indicated that the review for completeness of the pre-sub is going to be more rigorous now. And I'm wondering where that review occurs. Is that going to be occurring in the document control group or at the branch or exactly which group is doing that review for completeness?

Dr. Soma Kalb: The reviewing branch that will be doing the acceptance review.

(Debbie Brown): All right. Thank you so much.

Dr. Soma Kalb: You're welcome. And there is a...

Coordinator: Thank you.

Dr. Soma Kalb: A checklist is at the end of the guidance which shows what we're looking for.

(Debbie Brown): Thank you.

Dr. Soma Kalb: You're welcome.

Coordinator: Thank you. The next question comes from (Amy Walback). Your line is open.

(Amy Walback): Hi. Thank you for the presentation. Just a clarifying question - my understanding from the presentation is that if we request a pre-sub teleconference that feedback will be provided in writing in advance of the meeting. Is that - I just wanted to confirm that that is true.

In which case, if the feedback is, you know, all inclusive and there's no additional comments, is it possible to just then either cancel that teleconference request?

Dr. Soma Kalb: Yes. You can. That is definitely an option if you find that the email feedback provides you with all the answers that you need. It's certainly an option to cancel the meeting.

Elizabeth Hillebrenner: We've had that happen several times actually. And no one minds the extra hour in their day. So...

(Amy Walback): Yeah. It seems like that would be the best approach then, would be to always request the teleconference rather than just email feedback and then you have the option of having that interactive review with FDA or discussion rather than having to submit an additional pre-sub to request the teleconference. Is that fair to say?

Dr. Soma Kalb: That sounds like a good strategy to me.

(Amy Walback): Okay. Thank you.

Coordinator: The next question comes from (Melissa Robinson). Your line is open.
(Melissa Robinson), your line is open.

(Melissa Robinson): Oh yes. I'm sorry. I was on mute. Yes. With the acceptance review it's - is it 14 days once you submit the application for it to be accepted?

Dr. Soma Kalb: It's 14 days from - we're just checking if it's 14 or 15 days from...

Elizabeth Hillebrenner: Fourteen.

Dr. Soma Kalb: Yeah. Fourteen calendar days of receipt of the submission by our document control.

Elizabeth Hillebrenner: And I know it's different than RTA for 510Ks and PMAs are 15 days? It comes from the MDUFMA 3 commitment letter that it says 14 for pre-sub and 15 for the other types.

(Melissa Robinson): Okay. So even if you had a (QSIP) that's a submission issue, it would still go through the 14 days then it would have the 21 days for the meeting to occur? Or is that going to be in...

Elizabeth Hillebrenner: Good question. Technically we do have up to 14 days to do the RTA. But in reality, we're going to be looking at it much quicker. It's - and if you look at the checklist in the attachment it's very short.

(Melissa Robinson): Yes. I saw that. Yeah.

Elizabeth Hillebrenner: So...

(Melissa Robinson): Okay.

Elizabeth Hillebrenner: ...in order to get the meeting on the books and everything, we'd be looking at it quicker.

(Melissa Robinson): Okay. But if it wasn't a - it was just a regular pre-sub then it's the 14 days plus the potentially 75 to 90 days?

Dr. Soma Kalb: No. Including - the 14 days are included in the 75 to 90 days.

(Melissa Robinson): Okay, great. All right. Thank you very much.

Dr. Soma Kalb: You're welcome.

Coordinator: And right now I'm showing no further questions.

Heather Howell: Okay. All right, well thank you and thank you for your questions and for your participation in our webinar this afternoon. This concludes today's presentation. For further questions, please refer to the contact information that is included in the slides.

I remind you that these slides will be available on the CDRH Learn Web site, along with the recording of today's webinar. A written transcript will also be available at that site but may not appear until early next week.

So on behalf of CDRH, I thank our presenters and our listeners. Have a wonderful afternoon.

Coordinator: Thank you so much for participating in today's conference call. You may disconnect your lines at this time. Thank you and have a great day.

END