... consistently -- performance of -- okay. I think many of you probably can relate to some of the experiences -- very close to my heart. In the sense that we really do not have all the tools that we need [indiscernible] compatible -- questions in the -- and questions on the website -- PowerPoint -- [indiscernible] diagnostic -- in terms of --

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Let's start with [indiscernible] here basically to take your input.

One of the --

Two -- that we are concerned about this morning -- what information and data are needed to demonstrate -- I am going to try to avoid the use of the word nanotechnology as much as possible, it's a word which probably doesn't have -- substantive meaning -- [indiscernible]

The second aspect which I am going to discuss this morning is -- under what circumstances particular products, status may change hoo -- [indiscernible] there was one -- now -- contains -- so-called -- nano-scale particles, from [indiscernible]

Kind of the thing we are talking about.

Okay, I think I am going to -- [indiscernible]

The third one comes from -- and so they -- question -- the first one is -- what states of nano materials -- should be identified, evaluated -- [indiscernible]

I don't think I want to -- these questions, so what I would like to do is -- let me -- think about -- comments you have, later for these questions.

[indiscernible] comment.

I think you can -- this morning. The FDA has a very [indiscernible], as you can see from the improved products, cosmetics, drugs. Not -- [indiscernible] what's possible nano scale -- minus 9 -- I think that's what we are talking about in this case, those kinds of particles.

[indiscernible] in this case has certain statistics, what kinds characteristics -- in terms of -- effectiveness -- trying to --

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Your questions -- definition -- want to see, where we are trying to get, those issues, do you think there's -- thinking about [indiscernible] different categories of -- materials, for some reason, how might we -- characteristics, relevant -- categories, having experience with that, issue, for example.

[indiscernible] use the word nano in a -- sense -- under which conditions we are concerned about -- product. Nano technology is -- chemistry, physics -- so -- trying to get your thinking, in terms of -- nano-scale materials, what properties are involved in understanding their characteristics that really are -- help us -- safety effectiveness.

Are we talking in terms of thin -- things like the nano scale -- or nano scale product -- [indiscernible]

Materials that whether it's about tissues about how they safety for other regards, anything you think is important. Goes into some detail about areas that need to field the greater [Indiscernible] Speak awe we're going to be able to start thinking about the approach sort of case-by-case evaluation because we don't have the type of understanding [Indiscernible: Speaker/Audio faint and unclear]

One obvious area might be [Indiscernible: Speaker/Audio faint and unclear] you're going to have to assume some data to tell people [Indiscernible: Speaker/Audio faint and unclear][Speaker too far away from the phone to hear clearly.]

One of the considerations that we talked about in respect to the non-scale materials [Indiscernible: Speaker/Audio faint and unclear] in terms of trying to understand the characteristics out in the field that helps the [Indiscernible: Speaker/Audio faint and unclear.]

I think one important thing would be the stability of thenano particles. [Indiscernible: Speaker/Audio faint and unclear]

I think the next question is not [Indiscernible: Speaker/Audio faint and unclear]

Are we still on 1A? [Indiscernible: Speaker/Audio faint and unclear]

I do work with that no EPA rolls and my view of 1A, I don't think we know enough yet to how to answer that question. That's a very broad question, that's what's written on the slide. I think the way that the agency should parse this out further is to consider the groupings of regulated products by EPA. What I mean by saying that a that no scale material or that no dates of technology and X-ray machine, might have the set up considerations for safety and other related things very different from [Indiscernible: Speaker/Audio faint and unclear] gets to the hazard profile as well as exposure and a lot of other things that it has already been thinking about and strikes me that similar considerations ought to be in the FDA world based on it's varying degrees of products of manufacturers. I think the profiles at risk and such should be considered for safety would be vastly different. MRI machine versus the stent versus a seed that is planted in someone's body. Clearly there are issues on the manufacturing side the fact that an MRI machine might have a that Nanotechology that is planted in the human body.

Any more comments? We can move to the next question. This one is particularly useful. [Indiscernible: Speaker/Audio faint and unclear] when we talk about -- just to give you what we're trying to get from you here -- not the position of the materials, some deep chary ticks as much [Indiscernible: Speaker/Audio faint and unclear] but in terms of

trying to [Indiscernible] [Speaker unclear due to accent.] which are batch to batch that are usable. I think basically trying to get to an assessment of using the [Indiscernible: Speaker/Audio faint and unclear.]

Question two appears to be stands of technology [Indiscernible: Speaker/Audio faint and unclear] leave it up to the FDA in this regard.

Yes, I think [Indiscernible] On the spot here.

I can't speak for all but I can at least let you know that FDA and the national cancer institute have a [Indiscernible: Speaker/Audio faint and unclear.] development of standards and development of technology and new measurement capabilities. This focus is primarily on the chemical properties and materials. We're part of the picture. We don't work on a lot of the other issues but at least to a lesser degree. There are some additional less formal interactions right now with an FDA [Indiscernible: Speaker/Audio faint and unclear.] specked. They are photoed on specific problems. They're not necessarily broad. In the same powation, trying to figure out what needs to be done at best to develop standard materials. The answer is we're doing what you are asking us to do.

Let me give an example. It would take for life saving examples this is usually the code and [Indiscernible: Speaker/Audio faint and unclear] black boxes, we don't know what we're getting. Okay. On the other hand, yes, these are the truth of the [Indiscernible: Speaker/Audio faint and unclear.] commercial typo session. Who doesn't want [Indiscernible: Speaker/Audio faint and unclear] grade school tool. Used -- good tool, in time to characterize in that nature. The issue in this case is your experiences in different things we're trying to take in terms of what kinds of tools we use and the liability of that experience. Any other comments on this before I switch to the next question? [Indiscernible: Speaker/Audio faint and unclear] which is possible with respect to th[Indiscernible] S of the company. Wonder what's going on [Indiscernible: Speaker/Audio faint and unclear]

Rather than physical characterization I'm talking about toxicity or things likespeak not aware of what might be included there.

Standards [Indiscernible: Speaker/Audio faint and unclear.] recently been up to standards which is site toxicity test and both of those are specifically asked on the charts and those came out of the interaction between FDA and NCI and the national cancer institute. There are a number of others [Indiscernible: Speaker/Audio faint and unclear.]

Maybe he can raise issues or factors that you may be thinking ability because this is an opportunity for folks to tell us one of the things that questions you face, maybe have that experience. Interested to know in the industry seems to be subject, what were some of the questions that you're facing that we should take into account. What we're trying to do is hear from you so that we can develop guidance to help you. The questions you are asking yourselves internally you really want to ask them. Encourage to identify issues [Indiscernible: Speaker/Audio faint and unclear]

Okay. Let's move to question three. The question that focuses on the next steep, we have the material, you are trying to match it. Asking a very simple way are there any unique teetures of manufacture -- features of manufacturing materials?

Hopefully you can help us out for identifying the parameters that you are concerned about in the manufacturing. Unique charges in terms of the [Indiscernible: Speaker/Audio faint and unclear.]. The manufacturing in terms of number of products, number of used materials [Indiscernible: Speaker/Audio faint and unclear] control of the properties of these materials.

Question on some of the presentations I have heard in the past for some of these materials whether you could actually do functional toxicity testing on a batch. Can't rely on the physical characteristics of the material. Apparently if you can't see a difference, there is a difference has to do with functional testing.

A very big issue.

I think one of the things that we run into in our laboratory is that we often get different site samples and it's not always uniform. Another problem we run into is with bacteria, which bacteria's [Indiscernible: Speaker/Audio faint and unclear.] but you still have properties that cause biological affects. These are some of the problems we run into. I wonder if industry has run into this and what they're doing about it?

[Indiscernible: Speaker/Audio faint and unclear]

Questions here pop up if you are curious about the answer. We don't have answers to them all right now. [Indiscernible: Speaker/Audio faint and unclear.] the issues for approval timing. Agency getting a clear seasonsable issue of trying to anticipate and facilitate [Indiscernible: Speaker/Audio faint and unclear.]

Move onto the next one. [Indiscernible: Speaker/Audio faint and unclear] particles become smaller [Indiscernible: Speaker/Audio faint and unclear] if they want to sort of particles start to be stable. I think for many, many techniques that play with one of them is at this point [Indiscernible: Speaker/Audio faint and unclear] what are some of the considerations that need to be available in the operation processing and storage so that contain a nano scale parts. Get a different batch, [Indiscernible: Speaker/Audio faint and unclear.] we don't know those kinds of considerations.

So the question as [Indiscernible: Speaker/Audio faint and unclear] are there particular preparation practices and [Indiscernible: Speaker/Audio faint and unclear] because all the people show of hands, do you think the answer is yes.

[Indiscernible: Speaker/Audio faint and unclear] does anybody think the answer is no?

Okay. So we're just trying to say for those who either raise their hands, what might be some of the things that might be linked to cause the product to [Indiscernible: Speaker/Audio faint and unclear] anyway, we don't have the answers to the questions because they are framed in yes or no. [Indiscernible: Speaker/Audiofaint and unclear.]

[APPLAUSE]

I just wanted to point out that without some question help from industry, we're going to have to come up with some sort of an approach on guidances and everything and it helps that we have some industry in the past on a lot of things we've worked on has made these guidances and regulations a heck of a lot more useful to both industries and the government so I hope we can get a little bit of discussion going here.

I think I can mention a few things that I am aware of. Maintain this version of the nano particles that are intended to be aggregation that you mentioned already, perhaps exceptional closer to the ox dated [Indiscernible: Speaker/Audio faint and unclear]that's what I can think of off the top of my head.

Just to go beyond the materials. [Indiscernible [Indiscernible] [Speaker unclear due to accent.]

Are products that contain raw materials. My point is that we should consider the interaction of the materials with the other materials that's important. That may affect deeingliation. [Indiscernible: Speaker/Audiofaint and unclear] the interaction of the materials with the other materials [Indiscernible: Speaker/Audio faint and unclear.] in terms of trying to keep particles. That would be important to find out including processes such as [Indiscernible: Speaker/Audio faint and unclear.] quality of these particles [Indiscernible: Speaker/Audio faint and unclear.]

Some ideas for guidance so the question of the [Indiscernible: Speaker/Audio faint and unclear] talk about a little bit about the guidance as --

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Good morning everybody. We are here trying to gather information so we can make comments and remarks about the type of evaluating medical December vices. Much of this is being done on a case-by-case basis. Put that out in guidance to make that possible. Comment about what guidance -- we're going to ask for pertinent information. Guidances coming out in the future, I would encourage you to look at the specific guidance as it comes out that they be applicable to Nanotechology or that no materials test methods -- if you don't have any comments now, I would encourage you to follow our guidance process. As we put guidance out, feel free to comment on those guidance and look at how we're using that information today. If you don't use it's -- think it's comment or if you do think it's appropriate comment. We'll use that information now when we update.

Thank you. Let's move onto the next one. [Indiscernible: Speaker/Audio faint and unclear.]

When it's related to [Indiscernible] [Speaker unclear due to accent.] particles of determination. Kind of a comment we're looking for in a case like this here related to different position techniques.

One of the things we've seen in diagnostics [Indiscernible: Speaker/Audio faint and unclear] multiple analyzes [Indiscernible: Speaker/Audio faint and unclear] and while they seem to work pretty well, we're not aware contactually of the exposure of the user that has any particular down the road health affects. Laboratory technician use antibodies, you don't know if that has any affects. We'd also like to know a little more about the [Indiscernible] Quality. You might be able to get that by reading the notes or not. But sometimes where we don't get all of that information in an application and guidance we might actually want to ask for evidence that different things aren't overlapping in respect to quality.

[Indiscernible: Speaker/Audio faint and unclear][Unable to understand speaker clearly due to distance and accent.] We may have been [Indiscernible: Speaker/Audio faint and unclear] distribution then the [Indiscernible: Speaker/Audio faint and unclear]small particles that can cause the limiting [Indiscernible: Speaker/Audio faint and unclear]

An issue we face is if you are not forming the particle and use particles from the distributor that someone has mentioned already at what point does that no seem to be that no to a conglomeration makes it into making [Indiscernible: Speaker/Audio faint and unclear] what point does it seem to be nano and claim at that point you are really nano?

If it [Indiscernible: Speaker/Audio faint and unclear.] does it go back to nano?

Comment from the previous question. Purity's arguments a question comes from [Indiscernible: Speaker/Audio faint and unclear] interact with and vested interest in this and it seems to me we're still too early in a stage to answer the question to a degree for [Indiscernible: Speaker/Audio faint and unclear] we're striving to address these issues and the con didn't of your issue also matters -- content -- not thinking too much about how is it going to behave [Indiscernible: Speaker/Audio faint and unclear] what are we talking about? The state of the material to the distributor or is it going to be the case when it's introduced into the system. It can be scanned, biological fluid, plasma or whatever. The answers seems to be it differences widely on the media that's done. Other things in them beside other [Indiscernible: Speaker/Audio faint and unclear] physical characterization techniques that are listed right now. A lot of what we're focusing on is how to apply the technique to the biological [Indiscernible: Speaker/Audio faint and unclear] I wanted to add that comment.

You make a good point [Indiscernible: Speaker/Audio faint and unclear] characterize [Indiscernible: Speaker/Audio faint and unclear.]ty--ty solving -- [Indiscernible: Speaker/Audio faint and unclear.]

My impression on this is there's not a basic knowledge of all this. Kind of crunched sometimes to [Indiscernible: Speaker/Audio faint and unclear] I guess I would say that while this is about process, somebody needs to go to the [Indiscernible: Speaker/Audio faint and unclear] panel to get a PMA, at least get some inputs PMAs, FDA, GMA, private sector that's not vested in a way that's going to allow them to be accountable. Are these going to be stamped accurately to get an application that's going on. Who years -- two years ago [Indiscernible: Speaker/Audio faint and unclear] argued against approving the reclassification of radio logical equipment based on the question of replicated by different equipment. Very interesting behavior. I think the industry is probably going to be very reluctant to get into anything a lot of medical December vices. Not sure how all -- devices. Secondly, when FDA lacks expertise probably staff people who understanding [Indiscernible: Speaker/Audio faint and unclear]

[Indiscernible] [Speaker unclear due to accent.] in fact, we had to withdraw one of these materials because of separation issues. I can understand now some of those issues. Let's go to the next question.

[Indiscernible] [Speaker unclear due to accent.] talking until now, characterization of materials having gone through medical discussions things come back to you [Indiscernible] [Speaker unclear due to accent.] that's what this one is here for.

The second goal of this meeting, the separate example, I can give you correctly [Indiscernible] [Speaker unclear due to accent.] initially it was containing to say large particles micron phase and now someone decide by putting these particles inside the matrix hopefully get a better packaging, performance [Indiscernible: Speaker/Audio faint [Indiscernible] [Speaker unclear due to accent.] .

Certainly want the same thing. Technological differences between the device own the new device. I guess it would be a question whether [Indiscernible: Speaker/Audio faint and unclear.] technological difference and the answer were as it is, the next question is, are data required? But actually it addresses the technological difference. I think we're going to go back to the questions you were asking before. What data do we want to see and then is there an effectiveness issue. You need to determine whether it's equivalent or not. Start asking if there's a technological difference?

I think the big area technological difference, I think hopefully you have some comments on that one.

Difference in the technological category, that means that [Indiscernible] [Speaker unclear due to accent.] practice safely and effectively. What are the questions and the questions you have to say if there are methods to evaluate -- address the safety and effectiveness of these questions, then you say the manufacturer has [Indiscernible] [Speaker unclear due to accent.] then substantially [Indiscernible: Speaker/Audio faint and unclear]

Question does the only -- think about guidance, a simple piece of guidance the absence of specific information to the assumption is that the materials [Indiscernible: Speaker/Audio faint and unclear] one question I have [Indiscernible] [Speaker unclear due to accent.] help for say prediction and of that situation you walk into, want to answer that kind of thing. Give you the level of knowledge in the materials or not?

Anyone in favor?

Anyone in --

[Indiscernible] [Speaker unclear due to accent and distance from the phone.]

I don't think it's different [Indiscernible: Speaker/Audio faint and unclear] what question -- new questions are -- perhaps it would be a good idea to put out guidance that these are the questions we want answered so people don't come to us unprepared if we decide to change this technology.

This used to be a serious question it's very helpful to us. This is where the issue of guidance we're trying to focus on [Indiscernible] [Speaker unclear due to accent.]

I just wanted to follow up on this Mansfield's comments from a regulatory process standpoint, sitting here not being an expert in nano materials, I can't answer the first part of the question, what data information should be considered, but when I look at the regulatory process [Indiscernible: Speaker/Audio faint and unclear] I think the existing 510K pree tee would address this paradigm and to follow up on the comment from my perspective. I think the key issue to be addressed is whether it's a change to contain -- to implement or include nano devices or some other change, should be evaluated on the basis of that determination as to whether the nature and significance of the change creates a shift in the regulatory status of the product. I do believe the existing 510K and the 510K paradigm adequately at least based on the publicly available information at this point, addresses this sort of change in technology for 510K product. So I think the potential of added information becomes available or more detailed questions related to particular nano materials but fundamental question as to whether it's safety efficacy change for something that creates a different regulatory status has to be evaluated. What I don't think should be considered at this point for that reason, I was pleased to hear the comments from FDA right now. I don't think moving to a no know material are included or a priority should create a situation where the 510K status is automatically discarded.

Thank you for the comment. Appreciate that.

[Indiscernible: Speaker/Audio faint and unclear]

I agree that the existing guideline [Indiscernible: Speaker/Audio faint and unclear] the question I was reforring to is, what -- questions that [Indiscernible: Speaker/Audio faint and unclear]

Thanks. I hope my comments weren't interpreted as me misunderstanding you. We are in agreement that the 510K process can address the technological shift moving to technical device, moving to contain nano materials. That's how I interpreted your comments. I was just trying to reinforce those.

Thank you. [Indiscernible: Speaker/Audio faint and unclear] example of the material changes from the micron size to the nano particle size. That is a very significant change especially since the new material we have just said, a [Indiscernible: Speaker/Audio faint and unclear.] penetrate mainly themselves and so these questions come up with new compared to the old material so [Indiscernible: Speaker/Audio faint and unclear]

I just wanted to point out that the class parent devices you may want to go through the desix making process, if you add nano materials trigger to limitations of exceptions that you may come in with a 510K. Get a determination from the agency from the final process if you find yourself in that situation and you are unsure.

Just mentioned the [Indiscernible: Speaker/Audio faint and unclear.] what I was talking about is class two material [Indiscernible: Speaker/Audio faint and unclear] I don't know what trial of the product she was referring to. What classified by. [Indiscernible: Speaker/Audio faint and unclear] to the old materials so new materials will be classified as class three.

It is not equivalent [Indiscernible: Speaker/Audio faint and unclear] and then yougo through a sequence of [Indiscernible: Speaker/Audio faint and unclear] let me clarify for 510 processment class one and class two [Indiscernible: Speaker/Audio faint and unclear] the devices that can be evaluated by controls and standards, I need a three month approval. Those products contain materials automatically, they have to go through a [Indiscernible: Speaker/Audio faint and unclear] process, really extensive evaluation [Indiscernible: Speaker/Audio faint and unclear]

We question that occurs to me, how does FDA use nano materials in a category A510 application for [Indiscernible: Speaker/Audio faint and unclear.] still in the PA category. That's already been replicated it seems like a little bit of concern that if you are doing the first 510K of the PMA get more scrutiny.

I'll try to address. But I'll try.

I want to get us back on track here. The purpose of this meeting [Indiscernible: Speaker/Audio faint and unclear]

This is not a one on one discussion. We're trying to get input. Okay. One second. I think the billions of dollars going in there, there's no doubt we'd have technology earlier. Use by the public but [Indiscernible: Speaker/Audio faint and unclear.] are trying to comply with the integrations. Again, the way technology existed to seeks some of your comments, it does see an impact on the [Indiscernible] System migration is a [Indiscernible: Speaker/Audio faint and unclear.] of materials.

I just have a question that sort of covers this, basically boils down to the fact that how do manufacturers know that they're not using a nano material? This goes back to all this saying because eventually they're going to have to know that I think, with the guidance going out.

The problem with a lot of nano materials that we never worried about. I would think with design control and process validation [Indiscernible: Speaker/Audio faint and unclear] would in fact cover the manufacturer of nano particles. Some of the questions that would have to ask is be unique to the nano scales material but I don't think you need to generate new questions that are quality systems levels in order to get at that. Because the quality system is very broad. You need to do what you need to do to show your product intends to do. From my mind, there's nothing that needs to be added to that system of technology.

A question for the audience, the QSR regs are adequate to pass on the scenarios that [Indiscernible: Speaker/Audio faint and unclear.] in terms of what you have to do to validate [Indiscernible: Speaker/Audio faint and unclear.]

I think [Indiscernible] [Speaker unclear due to accent.] lead to discussion in this area.

The top of the focus of the issues is the [Indiscernible: Speaker/Audio faint and unclear] pass it onto the industry, interested in trying to move along in technology, for the materials in the certain that we're always trying to get past a market that are effective phase fives. New questions where can flow down review process because we don't know enough to review it as sufficiently or [Indiscernible: Speaker/Audio faint and unclear] first step of that process trying to facilitate in our own industry or who should be looking at and why. [Indiscernible: Speaker/Audio faint and unclear] that is almost to try to help practice what are the practice. [Indiscernible: Speaker/Audio faint and unclear] what statutory definition do you satisfy. If you are [Indiscernible: Speaker/Audio faint and unclear] what's part of the process that you're trying to achieve. These are questions that we try to work through as an agency with a product. We all have come to this office [Indiscernible: Speaker/Audio faint and unclear.] early onto facilitate the thinks. That's what this question is about, do you have any true sense of what we should be thinking about in regards to classification. [Indiscernible: Speaker/Audio faint and unclear] chemical actions think about ha this does [Indiscernible: Speaker/Audio faint and unclear.] destination it's helpful to be thinking of this early on. Formal conversations would be helpful. If you have any additions [Indiscernible: Speaker/Audio faint and unclear.]

I was interested in knowing by show of hands how many here are interested in working on or interested in combination products of [Indiscernible: Speaker/Audio faint and unclear.]

Combination of products, as I mentioned [Indiscernible] [Speaker unclear [Indiscernible: Speaker/Audio faint and unclear] part of nano materials are concerned what I have seen so far is the [Indiscernible: Speaker/Audio faint and unclear] actually when I asked carbonizationcharacterization [Indiscernible: Speaker/Audiofaint and unclear]

I couple of hands come up. A related question interested in that topic, been thinking about these questions, kind of pondering internally about where you're going to go [Indiscernible: Speaker/Audio faint and unclear] that's not an issue through it all.

Just a general comment to a specific question, from my perspective, I think the hospital approach to classification based on the primary vote of action, defined in relation to the intended use clinical indication, other pew Dick product should still be applicable. I think we're seeing from my perspective where inclusion of nano material or change to incorporate a nano material is just another potential technological change of the product. But I think the general approach to classification of a combination product would still be applicable based on the primary action.

[Indiscernible] [Speaker unclear due to accent.] doesn't change by adding [Indiscernible: Speaker/Audio faint and unclear] provide reduced bacterial [Indiscernible: Speaker/Audio faint and so that the added benefit of similar products assume that additional some of our product might actually [Indiscernible] [Speaker unclear due to accent.] required clinical trials for sure in a [Indiscernible] [Speaker unclear due to accent.] nano materials on similar products.

[Indiscernible:Speaker/Audio faint and unclear] might metabolize to achieve this purpose. That's part of the conversation I heard about cans to excel [Indiscernible: Speaker/Audio faint and unclear] purpose of the nano scale material [Indiscernible: Speaker/Audio faint and unclear]

Okay. I think some of you for a variety of reasons don't want to make comments, but [Indiscernible: Speaker/Audio faint and unclear.] until please to provide comments and identify the issues that are [Indiscernible: Speaker/Audio faint and unclear] helpful for us to move forward in this direction.

This is the nano secure questions [Indiscernible] [Speaker unclear due to accent.] publishing this case. Focusing on how to prevent certain materials the batches process. [Indiscernible: Speaker/Audiofaint and unclear.] okay. What we tried to do this morning was to seek your comments on three specific issues. One was the process of writing a guidance, what are your comments in that and then time to look at the ability to change if it were to contain [Indiscernible] [Speaker unclear due to accent.] issues. What we're doing until October collecting your comments from the [Indiscernible] Meeting and summarizing these and coming forward with that with what recommendations -- subsequent actions are going to be. At this stage, I think we are in the process of providing top guidance. Your comments will be very helpful. Or you can submit through contacts that are here and others in the center. Please do so. This is very helpful, trying to

come forward, here current knowledge. Before we disburse, I wanted to get your thoughts on the variety of reasons we come to meeting, want to take the . One of these -- [Indiscernible] [Speaker unclear due to accent.] falls in that category a show of hands please. Just to get information and how that [Indiscernible] [Speaker unclear due to accent.] show of hands on that. Is it possible that we may -- my top question here, is it possible that when you thought about the questions, to get your feedback, any indication of that. Okay.

I actually have two comments. I thought the question at the very beginning of the site and where the [Indiscernible] [Speaker unclear due to accent.] especially from parts of enforcement. I think you have [Indiscernible: Speaker/Audio faint and unclear] it's two very different materials. Manufacturers differently, behaves differently. A different way and of course [Indiscernible: Speaker/Audio faint and unclear] application as well. The second was I was wondering is I hear talk about nano materials and nano particles, was the particles and the material made of [Indiscernible: Speaker/Audio faint and unclear.] it's also what is in there, right? I mean is there -- the different from the particle that you need from parts of the elements rather than [Indiscernible: Speaker/Audio faint and unclear.] how are you going to check that? Is there a plan for some sort of internal analysis of these materials [Indiscernible: Speaker/Audio faint and unclear] building blocks. I don't know, should [Indiscernible: Speaker/Audio faint and unclear] is there any remaining discussions on them? Not just some [Indiscernible: Speaker/Audio faint and unclear]

Anybody else want to comment on this?

Just out of curiosity before I respond to this, which is a very good point, how many have a background of materials engineering? One of the funsmental principles of materials engineering is properties, structures. The discussion surrounding the technology and adding to your products tends to focus on the structure, size, but the properties that people are concerned with, when you have nano engineered products that are made of one material versus another material there's -- one may have properties that are biologically significant. If you have a very specific definition of what is not Nanotechology then something that has a significant impact, they fall outside of that definition. It's important to keep focused on the point that all these rules and regulations to make sure that what dose of market is safe and effective and it's a challenge, as you can see. On how to make sure that end point is reached and that -- mainly things like this to discuss those thing from the practical standpoint from what folks in industry and packaging help curves that process. What are the materials that have a significant biological property. But may have a very significant impact on processability. That kind of feedback I know is very welcome within the industry.

Comments that you'd like to offer?

[Indiscernible: Speaker/Audio faint and unclear]side charge but also what [Indiscernible: Speaker/Audio faint and unclear] the structure, the composition and how does [Indiscernible: Speaker/Audio faint and unclear] because as you go down the size,

it's not the size level that matters because as the structure for example, for any [Indiscernible: Speaker/Audio faint and unclear] that you otherwise see as the [Indiscernible: Speaker/Audio faint and unclear] change. So as you go down the size, you can agree that [Indiscernible: Speaker/Audio faint and unclear] so the problems doesn't change. You need to find the structure, what has gone into the [Indiscernible: Speaker/Audio faint and unclear.] and anything you'll find the finished product. What I know [Indiscernible: Speaker/Audio faint and unclear.] but when it is in nano form, the properties remaining where the [Indiscernible: Speaker/Audio faint and unclear]

Okay. Folks, thank you for taking time this morning to participate in this discussion and again, we welcome your comments for the public process and get directly in touch with us. Thank you.

This concludes the part of the vital discussion.

The captioner is now disconnecting. If you need further assistance, please contact Caption Colorado, 800-590-4197. Thank you.

[event concluded]
