Event ID: 1086061
Event Started: 9/8/2008 2:00:00 PM

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Good morning, again. I'm going to ask people to come back into the room and take their seats so we can go ahead and get started.

For the remainder of the session we have had questions from -- requests from two additional speakers. We will get started with the second request from Andrew Maynard, representing emerging nanotechnologies.

Thanks very much. Thank you. Do I have any way of changing the slides from here, or do I have to wave at somebody?

[Speaker/Audio Faint or Unclear]

Okay. First of all, thank you very much for holding this public meeting which I think will be beneficial to address some of the issues surrounding how we regulate some of these emerging technologies. I'm Andrew Maynard. We're trying to address some of the issues with nanotechnology. Just for your information we're a [Speaker/Audio Faint or Unclear], we've been trying to hard to look at the issues around the issues of nanotechnology and trying to help to work with government industries and chart a way forward. What I want to talk about this morning, very briefly is one of the projects we've been running for the last three years.

That is a project we started to look at where nanotechnologies are appearing in the marketplace. We started this a little over three years ago now. I thought it would be useful to start off and have a look at where cosmetics appear. If we could have the next slide, please.

This is a screen shot of the inventory at the moment. This is just some of the information we have. The inventory has -- inventory has a little over 800 products in it.
If you look at the products listed as cosmetics there's a little over 100. Manufacturers have identified them as cosmetics based on nanotechnology. The number of cosmetics products has been growing. If you look at the number of products that we have added since October of 2006 we've added [Indiscernible]. A final click on this slide.

If you look at the types they're wide ranging. Everything from anti-aging forms to hair care products. I want to talk about these products here.

First of all I have to give a number of caveats. First of all, you have to realize how we compile these data. We're relying solely on what the manufacturers put out into public

domain. It means that we're not sure if nano is being used in every case. We're relying on the manufactures.

I should also say this is web-based. Most of our searches are in the English language. If products are not available on the web or not available in English typically they've not been caught. I think it does give some insight into what is appearing in the market.

Next slide. This is a busy slide. I want to capture an idea of the types of the products out there, where they're intended to be used. You have the list of different types of uses of these products. Whether they're cleansing, conditioning, hair care, so on and so forth. You have the area of the body where they're intended to be used. Then the peaks are the numbers of products. You can see at the back right-hand side most of the products in the inventory are associated with skin and anti-aging products and conditioning products. There are a couple of products associated with hair care, to go on the hair and enhance the appearance of your hair.

It's more interesting getting into the types of materials that manufactures claim to be putting into these products. Let's go on to the next slide. I wanted to brake down the -- break down the ingredients. These are the products that come out. We have -- I'll say a bit about these in a second. We have the use of [Indiscernible] ingredients that will encapsulate products. We have a range of organic materials, which are hard to pin down more specifically. We have carbon-based compounds. And a large number of ingredients where we cannot identify what specific [Indiscernible] ingredients is. I should more about [Indiscernible] the nanocapsules. As you heard from the previous presentation there's a need to distinguish between those materials that are insoluble and those which are soluble. Of course, if you look at many of the organic ingredients these are things that will break up reasonably fast. You could argue whether they should be here or not. It's worth while to include them at this point. If you take one of these ingredient in many cases it's used for certain parts of the body. That means [Speaker/Audio Faint or Unclear] for enough time for it penetrate and do something. It's that aspect we need to ask a specific set of questions about. I think it's important to keep that category for the most. Move on to the next slide, please. You can break that down into the specific types of the materials that we have here. If you look at the right-hand side there are many cases of products where you are either looking at a mixture of materials or nanoscale ingredients are unclear or unspecified. Where you look where the materials are specified you can see clear trends here. The materials that are appearing most is large scale silver particles. Gold, silica, mica, I'll not read the rest you can. Here we can begin to get an idea of the sorts of -- sorts of non scale materials that we -- nanoscale materials we need to look at. Next slide, please. That's the background. That gives us some idea of what is appearing on the market, the types of materials, and the sorts of things we need to ask questions about. I want to talk more specifically about some of the challenges we face. Or some of the challenges that [Indiscernible] face. [Speaker/Audio Faint or Unclear]

Okay. The first challenge here is that if we nanosize an ingredient and add it to a cosmetic it may change the risk profile of that particular product. The research that's been carried out we know it could possibly change the risk profile in two ways. It can change

the exposure profile. It can change where the material goes and the potential dose. Let me give an example.

I should say this is here for illustrative purposes only. I know nothing at all about the actual safety of this product. This is a finishing polish. This is a hair care product. It uses nanoscale particles that penetrate the cracks of hair to give you better looking hair. The reason they're using this is because it can penetrate areas of hair that you cannot normally get to. I expect this is not a health or safety issue. You are dealing with dead cells here. One of the things that happens when you make ingredients at the nanoscale is they can get to places that are normally non-accessible. We have to ask what the consequences are. If you click again, and again.

And again, let me give you another example of that. Again, this is pearly illustrated. This is how [indiscernible] energizing cream. It is up on the slide because -- I put it up there for a specific reason. It is a product that uses old man of particles. If you look at the cream, it actually has a gold queue. In this specific case, this may not be a health and safety issue. I will say what I said that in a minute. It is gold because [indiscernible] you reduce it down to about five [indiscernible]. It changes its behavior radically. It changes from being in [indiscernible] to being highly effective metal. Now, that in change is where you have a significant change in behavior where chemistry stays the same period in this particular product, almost definitely that is not going to occur simply because you can see the be particles that is still exhibiting the behavior of gold.

So, I am not putting this product here to show that there are problems associated with it, but it does illustrate that it is easy to put ingredients in cosmetics at the national scale where you could hit the button and that chemistry remains the same. At this point I want to race here -- you can press the button again. Now technology has that potential to blur the lines between [indiscernible] lines three of the one to get into the issue of -- that has already been emphasized in this meeting. We do have the issue here, especially if you are looking at small outfits in tight end outlets that it is easier to include active [indiscernible] drugs and slipped under the radar of what is that cosmetic [indiscernible] drug? Let me give you a final an example to illustrate that.

This is a product from circuit stand pharmaceuticals. Again, I have no idea she -- I can tell you that this is not classified manufactured. I want to read out some of the information on this product is that they manufacture for us on the Web site. Informatio regarding one of the ingredients. This is what they claim to be the nanoscale entry in. Is something called the [indiscernible]. It is based on an essential. So, they said chromosomes in skin a chance. It contains the pure carbon cages to Lorraine's. They are natural carbons. That are up to 10 million times smaller than. [speaker/audio faint and unclear] [indiscernible] are also any form of natural carbon neutralized. Until 1995, it was believed that the body could not process any pure form of carbon. With the discovery of [indiscernible], we know how of carbon that is biologically active and pure. This is important for revitalizing in a symbol of the body. Now, I no [indiscernible], but as soon as you start talking about biological activity and penetrating deep into the [indiscernible

], you seem to be blurring the lines between something that is pure and cosmetic and something that has got and [inaudible] related products. So we have this issue. Scott.

Next one. A paper did the town just with based -- I just want to include by highlighting for things we need to close focus on. The first one is the issue of defining when material is used for [inaudible] purposes. This is something which has been raised a number of times in the last year or so. I think some [indiscernible] have already been raised with the idea of looking at [inaudible] behavior. It is a physical issue. I think that because it if you look at nanotechnology, there is temptation to use definitions of what is not technology and what is not that are based on encouraging use [inaudible] and new products. The issue is the definitions do not change or applied to regulations. Let me expand on that a little more. If you look at the definition of nanotechnology, say it comes from the National [indiscernible], is based on the idea of added value. That is [indiscernible] something that adds value to process. If you are looking at understanding [inaudible], if you are not interested in the added value. It is a content -- concept that has no place in looking impact. Instead, we need to look at a concept which is close to something you might call added risk. What has happened to an ingredient or product which is when to change its risk profile come to that difference between added value and added risk that needs to redefine what we are talking about here when it new materials including nanomaterial which is going to change that risk profile.

Moving on from that. If you are going to identify where things might need to be behaving in a different way because [inaudible], we need clear trigger points so that we can begin questioning about how they can be regulated. And it is unclear get what trigger points they are going to be for these nanomaterial. If you look at the discussions going on for the past figures and publications up there, there are some things which are likely to be more useful than others. We are one to be looking at trigger points that are related to the size of ingredients. We have no [indiscernible] with limits. If you make something smaller and to do it because you are one to change the behavior of the product, how is that when to change the risk profile? Similarly, there are going to be trigger points, new questions associated with changing the shape of ingredients, tinting their surface country, whether that is adding something, changing their charge in different media, and a number of other things. It could mean trigger points like changing the certain areas of material. [inaudible] change functionality. Also, a lot of these things -- a quick point is that if you introduce something at the nanoscale, that should mean you ask questions about how [inaudible]. Next point.

That leads on to the question of how much information we have to begin to formulate to address these trigger points and how much information is still lacking. Clearly here, there is a lot of information lacking here. We need more research. FDA needs more clear research to address some of these issues and come up with [inaudible]. This also requires [inaudible] this is a process that has are restarted. And then the final points here. It is a fairly clear point. We are all struggling with how we can make the best use of nanotechnology, whether it is looking at cosmetics, drugs, other applications. We are all to a certain extent trying to work out what is a product and what is a process. The boy to

make progress is to be [inaudible] about what works and what doesn't work, what questions we need to be asking.
[applause]

Before we go on, are there any specific questions? Do need to come to the microphone and identify yourself.

I just want to repeat the question -- [speaker/audio faint and unclear]

The proxy have put on the web, have any of them been looked at chemically to verify that the -- have any been removed because they were not bound not to have nano? Does anyone want to verify that?

Not to my knowledge. We have [inaudible]. But the added, other products out there, no, to my knowledge, no one has [inaudible]. [speaker/audio faint and unclear]
I wonder if someone commits either Andrew or someone from the FDA, what is the definition of [indiscernible] so we can better understand the problem?
I will go ahead and do that and [inaudible] which does define the difference. A cosmetic is anything that is -- This is not the exact definition verbatim, but it is unreasonable that you do put onto alternate the invisible. It is something to make some look better. A drug has a function claim and it is intended to treat [indiscernible] or to prevent [indiscernible] from happening. In other words, when we give someone a drug, we are trying to prevent or treat some kind of a disorder in a major [indiscernible] function claim.

[speaker/audio faint and unclear]

We are not getting into the discussion Perce of what the FTE eight defines a different way. If this -- it depends on how you define aging. In some cases it is cosmetic and some cases it is a drug for did it is the drug itself. It is clear that if you are really trying to market a product to treat something to prevent something and make something better, do are technically a drug and you should be regulated as a drug. Now, one other thing I will say is that there are drug cosmetics. You do have companies and products were you have drug claims in cosmetic claims. And then in the manufacture it is obligated to market their product following the regulatory necessities [inaudible] so that you are obligated to make sure that the [inaudible] of that drug as well as [inaudible]

[speaker/audio faint and unclear]

Again, this would depend on what your drug is. Some drug cosmetics would be new jobs and it would be pre approval. Some fall under the monogram. Therefore, we again have to have [inaudible]. Okay. I guess since it looks like there are no other questions, we will go on to our next speaker, which is Carolyn Cairns from the Consumers Union.

Thank you. I don't have a power point today. I am reading from the comments. My name is Carolyn Cairns. I am Program leader from the technical division of Consumers Union,

which is the [indiscernible]. We appreciate the opportunity to comment once again on the needs for FDA report -- regulate materials as unique substances, which may pose different [indiscernible] than their larger counterparts. It has been two years since the FDA published on these issues in over a year since the past reports. In the meantime, Andrews presentation pointed out, many new products continue to reach store shelves with [indiscernible] materials. We hope FTE will use the information from this meeting today and continue action to regulate these materials. Like others before, I am going to speak today about both "we do know and what we don't know and need to know to come out with now engineered materials to ensure that they are safe. We think that the delay in regulating prior to market approval and market sifted -- safety testing is just for during the late in the development of the critical analytical tools that are needed to characterize the present talk to city and state of [indiscernible] already out there. Consumers Union has been investigating and assemble and consumer products for several years. Our comments are based on our own research and test of several nano products, particularly sunscreen. It is this a flea -- it is one to be a lot of comments on my sunscreen pertain equally to cosmetics. A recommendation about the type of analytical data that FDA should be demanding for these materials and Commerce can be summarized in four basic points, which are very similar to what and represented. First, that nano materials should be. New across the board, and we don't think they should be considered generally recognized.

>We think all nanomaterials should be characterized to features known and [indiscernible] such as size, chart, state, shape. Using [indiscernible]. I think a number of other speakers have pointed to this today. I am going to talk a little more about that. We need to build products, a specific risk analysis features to assess the direct and indirect impact [indiscernible] in which they are used in putting their interaction with other ingredients. Finally, where results of product specific exposure [indiscernible] all developed, we need to insure that they accurately reflect the true condition in which products will be used. [inaudible] are to achieve a very wide range of changes and chemical specific property, the biological impact which will be you need to specific changes made and behavior and state of those materials and products in which they are used. I think that is really important. We have heard a lot about that today, all the different features that can change in formulation, and that is something that we think is really important. I think they really do not warrant FDA on a case by case basis. Therefore, FDA is to require assessments for all engineered nanomaterial. We have said before that the company's need to disclose to the FDA and public funding [indiscernible] at the nano scale. We do know that the size and quality can't really change toxicity. The world and society have featured some of the [indiscernible] hon. The tremendous increase, for example, [inaudible] can greatly increase reactivity and therefore toxicity thereby calling in the traditional mass and sensible approach. Therefore, we need to -- need these materials Pete to be disclosed and regulated. Researchers at the University of Oregon and Oregon State University and many others have made some progress in developing databases to begin to develop rudimentary toxicity constraint. Far from being predicted, these databases and tools are still being developed. They are really not sufficient to draw out universal conclusions about structure activity relationships. Given the number of variables that can be altered in the development of use of nanomaterial it is

hard to [inaudible] at this time. I think really particularly that is widely need to go much more slowly and really look at the individual ingredients in the forms that they are used before they enter the market. Further tests characterizing spier 11 may not predict their activity and product formulation. That is why we think of its such that FDA should consider each new use as it's own separate entity.

>Nano materials related to contaminants and impurities May at that and is tenable as well as I can outside using sunscreens can be using -- it can be coated with aluminum or silica. These differences can affect reactivity [inaudible] and active as well operated the recent finding that is involved can degrade metal surface coating it raises many questions about the reactive nature of many, not just this type of nanomaterial, but others like it. Some nanomaterial can change forms. For example, from the annotated from the invisible. Change charge also raises questions about their stability and how we then can make any assumptions about their safety in different forms.

Product Security is another concern. It is hard to see how right now these differences are accounted for, if at all, it in product specifications. Certainly, on the labors all that consumers are -- labels, all the consumers are seeing are [indiscernible] as well in the case of cosmetics, the Clinton critics predicted one manufacturer may be using an aluminum cage around the [indiscernible], for example. Another may be using a different form. All that is one to affect the, you know, how well they work as well as their toxicity and file availability. So, that is why we think it is particularly important to emphasize the need for full characterization, to really know exactly what we are dealing with. And from the [indiscernible] for technical difficulty for -- We do that kind of testing to ensure purity, particularly if the contamination or variation in the forms doesn't significantly affect cross functionality. The FDA and assembled to not include requirements to disclose critical characteristics. As I said, particularly [inaudible] markets if testing. You have the same problems. We have seen potentially misleading terms like Micron nice. They are not defined, but yet there are widely used in a lot of products for did leading sunscreen brands, for example, have found the nanoparticles in every mineral based sunscreen product we have tested. [inaudible] other than a few cases. As interest presentation point out that same problem is -- [inaudible].

Finally, [indiscernible] have the potential to adversely indirect with other ingredients in the same product or products used correctly. FDA is aware of the research findings that indicate mineral based sunscreens, for example, which less -- likely contain nanoscale of [indiscernible]. The nature of the properties of National materialist depends on how they are changing from their counterparts. We talked about this quite a bit. The increase in surface area that is created when a material is reduced to our critic to the nanoscale often has staked -- shape, size, type, structure. [inaudible] smaller particles can immune -- or directly enter cells in the nuclear attic area and reach parts of the body of the conventional skill. [indiscernible] cannot. Finally, the other concerns about the use of engineered nanomaterial it relates to the end of the product life. We have seen accumulation of conventional pharmaceuticals and [indiscernible] in drinking water in environmental media. There is no reason to suspect that [indiscernible] would be any different. Considering new products coming into the marketplace, FDA should evaluate

these downstream effects as well. Our test of nanoscale of sunscreen says that formula varies greatly. Some with unreasonable performed well and others did not. None provided greater you be a or you BB protection than the other sunscreen than our tests. I think again making generalizations about an ingredient that may, in fact, be very different from product formulation to product formulation from a manufacturer to manufacturer is went to be very difficult. Many consumers have expressed concerns about the safety of engineered nanomaterial and products because they have different properties. It is a material [indiscernible]. Finally, as I said, FDA should bill and mandate the [inaudible] in points not likely to be expected or conventional any size materials. Consider requiring a battery of tests that include those that -- [speaker/audio faint and unclear] That is my presentation predict any questions?
[applause]

At this point, we are close to the noon hour. We have one of two options, which is which can go ahead and see if everybody from the floor wishes to seek or take our lunch break for about an hour per it would come back here about 1:00 or 1:15 at this point in time, the afternoon session doesn't seem like it will be that long, but I would like to go through some of the questions. At this time, why don't we just go ahead and do the break for lunch and plan to be back here about 1:15 and we will get started again.

[Public Meeting on Nanotechnology on break for lunch until 1:15 Eastern] the.
Good afternoon. I am one to ask everyone to take their seats. You need to do something to get the microphones back on? Good afternoon and I guess we will go ahead and called the session to order. I gave all little bit longer for lunch time, thinking perhaps -- what is that?

[speaker/audio faint and unclear]

So we need just to wait. Okay. For the technical difficulties. We will start in just a sec.

1. All right. We will go ahead and get started trade we were waiting for our transcription service to come back on line so that we can continue to transcribe for the record on at this afternoon's session. I would like to welcome everyone back after lunch. At this point in time, I don't have anybody else that has requested any [inaudible]. So, what I am going to do is [inaudible] that were published by the [indiscernible] for the break out session of cosmetics. What I would like to do is read each questioned individually and see if there is anyone who has anything that this -- they would wish to say or comment for the record straight answer any questions or provide any additional information. What I would request is that we would come around with the microphone. Please identify who you are and who you are all represented -- representing. So that we get that in a transcription. We will have that information. So, let me begin with breakout question one. What characteristics or types of nanoscale materials would be important to specify when considering potential risks of cosmetic products?

[speaker/audio faint and unclear] I think regarding your question what we intend to do is to [inaudible] comments by October 24th. We will not [inaudible] answer at this time. Is there anyone from the audience who otherwise like to comment on the question? Or have any additional information there to respond?

If not, then I will go through the second question: If your company markets a cosmetic product with nanoscale particles, what function do they perform, at what concentration are they used, and how stable are they in the formulation?

Any comments? Then I will continue on. What, if any, additional studies are done for a product containing nanoscale particles to prove that this type of formulation is safe? What differences in safety or absorption have you observed between products formulated with nanoscale particles versus those that are formulated with [macroparticles] non-nanoscale materials?

The next question is, Are safety assessments being done at the bulk ingredient level or final formulation or both? How do these assessments differ? Any discussion? Comments?

And the last question is, What is the effect on bioavailability of making larger particles nanoscale? Would you expect to see increased absorption/toxicity? Any discussion? All right. Well, if not, then I guess I will probably end this session. We plan to review the information, I would encourage all of you who are in the audience, if you do have information you would like to share, do so in written form and so that could be submitted to the docket by October 24th in addition, we hope to use this information to help us with creation of guidance that will help us and help you develop products that will be safe to be marketed for consumers for cosmetic use. With that, then I will end the session and invite all of you to attend one of the other two on going sessions. The drug session is in the room in the [inaudible], and the food section is in the room all the way over to my left. Thank you very much for coming and coming back after lunch.

1:30 Eastern Time Zone, captioner is advised that this particular event has concluded for the day. Please visit events 108-6059 and 108-6058 for continued captions, thank you.

[Event Concluded]