U.S. FOOD AND DRUG ADMINISTRATION

PUBLIC MEETING

PREPARATION FOR THE 2015 INTERNATIONAL COOPERATION ON COSMETICS REGULATION (ICCR) MEETING

Thursday, September 10, 2015

Location:

Center for Food Safety and Applied Nutrition

5100 Paint Branch Parkway

Wiley Auditorium

College Park, Maryland 20740

Reported by: Natalia Thomas

Capital Reporting Company

S P E A K E R S

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P R O C E E D I N G S

DR. KATZ: Okay. I guess we'll go ahead and we'll get started.

It's now five after 2:00. It seems that we're a small group in a big room. And what I might suggest is that if people want to come down a little bit, it might make it a little bit cozier and friendlier as we go ahead and get started.

While I'm hoping that -- we do have one person who has requested to speak who does not appear to be here, I'll just go ahead and give some general introductory remarks and then I'll start with the presentations themselves.

For those of you who may not know me, I am Linda Katz. I'm the Director for the Office of Cosmetics and Colors here at the Food and Drug Administration and I'm also the lead for the FDA in ICCR.

Today's meeting is a public meeting which we do every year in preparation for the ICCR meetings. This is our way to find out from constituents and others who might have an interest

in cosmetics, any interesting ideas or thoughts that they might have or would like us to bring with us to our annual meeting. So that's the purpose of this meeting this time of the year.

For some very -- housekeeping purposes, if anyone needs to use a restroom, the restrooms are up the stairs and over to the side. Someone will escort you. And there are some people here from FDA in the back who will go ahead and bring you there and bring you back to the room if that needs to happen.

For those of you who may have cell phones that are on, please put them to silence because for those who may be speaking and in fact, it may only be me, it's a little disconcerting when the cell phones kind of go off particularly in this big room with -- where things will vibrate and echo.

And this meeting itself is being recorded. There will be a transcription available probably several months down the line and you'll be able to find it when it is available in the

docket itself.

And with that, let me just ask the question, John, do you know if there's anybody who is waiting to register before I start?

(Brief pause.)

DR. KATZ: Okay. And if not, then I'll go ahead and get started with my presentation.

(Brief pause.)

DR. KATZ: Okay. We'll just wait for the one extra person since again, we're a small group. And as soon as that person walks into the room, I will go ahead and get started with the presentation.

(Short recess.)

DR. KATZ: All right. Well, let me go ahead and get started then.

As I mentioned before, I am Linda Katz, I'm the Director for the Office of Cosmetics and Colors here at the FDA. And the time that I have this afternoon, what I'm going to do is to really outline a little bit the ICCR process. As you could see from the first slide, ICCR stands for

International Cooperation on Cosmetics Regulation.

I will talk a little bit about what our outcomes were at last year's meeting, ICCR 8, and go through the upcoming issues for ICCR 9.

So let me give a -- start back with a little bit of historical reference. Basically, prior to the 1990's or in the 1990's, the FDA set about a policy on international harmonization. And the policy was set up really to look at ways that we could harmonize and work with our counterparts throughout the world.

And many of the overreaching goals were to include the ability to facilitate trade and promote mutual understanding, to facilitate the exchange of scientific and regulatory knowledge -- with the foreign government officials. That is to allow transparency to the extent permitted by laws of each of the different lands. To accept equivalent standards, compliant activities -- look at compliance activities and enforcement programs of other countries and if such programs met our FDA level of public health protection, we would

work to adopt them whenever possible. But the primary goal was to avoid the lowering of public health protections afforded by U.S. law. In other words, to avoid downward harmonization.

So let me go back a little bit. Before we have ICCR, in keeping with the harmonization processes, we had what was called CHIC. And CHIC was a way that we established a cosmetic -- it was originally set up to establish cosmetic harmonization between four governing regions and those were the United States, Canada, Japan and the European Commission. The same four primary stakeholders or the steering committee that I'll talk about in the ICCR process.

CHIC itself was established really more as an information exchange. It really wasn't set up in a way to really do anything, but really just to talk about how the different jurisdictions regulated differently.

CHIC met every year, year and a half or so or whenever it was convenient. And again, at the time of the last CHIC meeting which would have

been in 2006, we basically decided that it was time to form something new and that's when we established ICCR.

And ICCR was established in 2006 as a way to go forward to actually sit and try to come up with substantive ideas of things that we could try to harmonize or -- I loosely say harmonize, but really more to cooperate with. That we all agreed was that whatever issues we decided to discuss would be issues that would not necessarily cause any one jurisdiction to change their regulations because we all agreed that even though we all knew what cosmetics were, we all regulated cosmetics a little differently.

So our first meeting of ICCR was in 2007. The members at that time were Canada, EU, Japan, the U.S. and later in July of 2014, Brazil joined the steering committee. We set up a terms of reference and that was a voluntary consensus model in which we all agreed that that would be the way to go forward.

We looked at the precedence from ICH,

VICH, GHTF as ways to kind of model what it is that we could do. But in addition to that, we became a little bit more broader reaching and included input from industry trade associations as partners.

This slide really just -- it shows the locations of where we've been since ICCR has been in existence. As you can see, the first ICCR meeting was held in Brussels in 2007 and we've completed at least two rounds through and we're now beginning our third round with ICCR 9 that will be held again in Brussels on November 4th through 6th.

ICCR itself has the following process and we've been fairly consistent since its initiation. And that is, we have an annual meeting and interim telephone conferences. We all agreed that it was important to have at least one face-to-face meeting a year and logistics really precluded us from getting together more frequently than that. Well, we agree that we needed to stay in touch and we usually do these teleconferences

on a quarterly basis. More if needed.

The meeting venue, as you can see from the previous slide, rotates amongst the four regions and soon to be the five regions. That the notice of the meetings and draft guidelines are announced publicly for stakeholder comments. And for the U.S., that would be -- our announcements are put in the Federal Register.

The hosting country also is the region's chair for the ICCR meeting and takes on the role of the secretariat. So this year, the secretariat for ICCR has been Europe. ICCR also has -- may charter subsidiary working groups as needed to get the work processes done.

With regard to the actual structure itself, on the first day, it's a regulators only meeting. And this gives the regulators time to talk about items that we feel are really more relevant for regulators and ways to go forward and to hear about any problems that may have occurred recently within each jurisdiction.

On the second day we have our regulators

and industry meeting. And that last session of that day we usually have about one to two hours, depending upon stakeholder interest, for stakeholders to present to us information of concern or interest to them.

On the third day we have the regulator meeting and we adopt -- with adoptions of the meeting outcomes at the close. And those meeting outcomes previously had been posted to each individual website, but now that we have an ICCR website as I've put up on here, those outcomes are posted there so that all can see it. And again, it's a way to increase our transparency.

ICCR 8 was held in Ottawa last year and I'll kind of go through the agenda and the items -- - the outcomes from that meeting. It was a busy meeting as you can see. We talked about the ICCR 8 year in review, ICCR web, governance, allergens, in silico, quantitative structure-activity relationship or QSAR models, alternatives to animal testing, trace impurities, microbial contaminants and we got the update from observing

regulators.

The outcomes are as follows. With regard to the ICCR 8 year review, this group presented their views and perspectives of what happened over the preceding eight years. Part of the reason why they decided to do this was because it was at the end of the second go round of cycles. As I mentioned, we're now beginning our third round.

The regulators and industry agreed that the ICCR is important to continue and to maintain the goals of the highest level for safety for cosmetics while minimizing the barriers to trade.

We announced that our ICCR website was available and that, as I mentioned before, the reason for this website was to improve the transparency of the ICCR process until our stakeholders and others know what is of interest to us and what documents we have worked on during the course of the year and haven't been agreed to.

One caveat I will mention is that even if a document gets posted and we've agreed to it

as the regulators at the meeting, it does not hold any actual regulatory stance. Meaning that we don't approve them, but we agree that this is the best science and the best information for us to go forward and to take that information back to our own respective jurisdictions.

With regard to governance, the regulators provided an update on the ICCR expansion criteria and process and Brazil joined ICCR as part of the steering committee at the end of that meeting. And so this will be their first meeting where they attend as the member of the steering committee as opposed to an observer country.

With regard to allergens, we set up a terms of reference and a report was posted. This was

Allergens and Cosmetics and Personal Care Products: Comparison of Jurisdictional Regulations and Approaches. What we've done over the course of the year is to look at that further and to see where there are differences amongst the

jurisdictions and where there could be continued interest to go forward in the subsequent years.

With regard to our in silico and QSAR models, the in silico approaches for safety assessment of cosmetic ingredients was accepted and posted. And this working committee has also agreed to continue forward to look at other modelling and look for certain specific models that might be relevant again for looking at cosmetic safety.

For alternative test methods, the regulators received an update on the International Cooperation on Alternative Test Methods Activities, ICATM. And that this again, we created an annex to the original report that would be updated on a semiannual basis. And the updates include any new methods that have been currently accepted as being valid to go forward.

With regard to the trace issues, the document on lead was accepted and posted and this document talks about the maximum level of ten parts per million that should be strived for in a

cosmetic product. The documents on mercury and 1,4-dioxane are still undergoing final review.

With regard to updates from observing regulators, ANVISA presented their updates on cosmetic regulation and innovations in Brazil from the previous year.

And finally, for the involvement of interested parties in ICCR, the regulators finalized the criteria to allow interim parties to submit detailed proposals for work items for ICCR members for consideration. The interested parties include new regulators, our international trade associations that are associated with the new regulators, NGO's, and academia.

In addition, we went ahead and had, as participants, both Brazil and representatives from the People's Republic of China and the open public session for stakeholders had presentations made on nanotechnology, cosmetic product safety, alternatives to animal testing and endocrine disruptors.

The ICCR steering committee reviewed the

proposals for consistencies with objectives in the scope of the terms of references of ICCR and any other work items that might be submitted were also discussed as to what to do with them during the course of the interim year before the next ICCR meeting.

So that brings us up to ICCR 9. And as I mentioned earlier, this will be held -- Europe is the host. EU. And it will be held in Brussels on November 4th through 6th. We have had our interim telephone calls and the last of our quarterly calls occurred earlier this month.

The agenda looks fairly similar to last year because we're finishing up on some of the additional items that we had started. So we're going back to revisit governance, we're looking at allergens to proceed and look forward to see how we might want to proceed with regard to specific allergens or recommendations for labeling and things along those lines.

We're also looking again at alternatives to animal testing to see which new tests have been

validated in the course of the past year. We're going to get the update on our trace impurities particularly for mercury and 1,4-dioxane.

We'll hear from the in silico -- or the QSAR modelling group about the activities that they proposed and have done over the last year and where they propose to go for the future. We'll talk about cosmetic preservation which is a new topic for ICCR and any new proposed agenda items that might come in as a result of this meeting or other sources will also be raised.

So with that, I will conclude my remarks and I will now turn the microphone over to our first speaker. And our first requested speaker is David Steinberg from Steinberg and Associates.

MR. STEINBERG: Thank you very much. I have a couple comments to make before I give you my actual presentation.

First, I'm sorry I was late. Blame Amtrak and Metro. They were just taking forever. The Amtrak train was a half hour late out of New York City and they don't tell you anything.

Second thing is, please forgive all of my typo mistakes. I hunt and peck. I type with two fingers. I was able to type five books, over 100 columns on cosmetic regulations, countless numbers of papers and chapters in books and things like that, and I got older I noticed that my mind thinks and sees one thing and I type something else. So it's September not what's up there.

The second thing is my disclaimer. If I can move this forward. Which button do I push?

(Brief pause.)

MR. STEINBERG: Okay. Let's go back.

I am here for myself. I am not representing any trade association, any government, any cosmetic company, any manufacturer of any raw materials or anything like that. These are strictly the warped ideas that came from my brain. I'll be talking about two of them today. On Tuesday I spent twelve terrible hours trying to fly four hours and I came up with a third one, but I'll wait until next year unless you beg me and then I'll tell you what my other brain child is.

So my suggestions have to do with two specific things and they have a common thread. And the first thing is safety and the second thing is transparency. And of course, the third thing is harmonization. Okay?

So the first thing I want to talk to you about is alcohol. And I have had this discussion with the other part of the FDA better known as CDER or Brand X or I don't know -- their friends over there.

The CDER regulations on alcohol are in conflict with each other so it causes confusion. But I wanted to talk to the confusion we have here in the cosmetic industry.

Alcohol. The word alcohol alone -- not cetyl alcohol, not fatty alcohol, just the word alcohol when used as an ingredient declaration is ethyl alcohol chemically or ethanol. Okay? It has a CAS number. It has an EINECS number. It specifically describes alcohol that is pure or the only thing that's with it is water or aqua or O. We'll go through that -- details, but everyone

seems to ignore that.

It is drinkable, it is undenatured which means we're not adding anything to it that makes it unfit to drink. It goes by many names. My favorite is martinis or scotch. Okay?

And when we label our product as alcohol, we are saying it is undenatured. This leads to an area that I don't know anything about. I don't want to know anything about and that is the taxation of alcohol for ingested use. That's a money enhancing -- revenue enhancing product.

Okay. We add denaturants to alcohol to make it unfit to drink. Everyone understands this. It recognizes the fact that alcohol has other uses besides getting smashed. It has uses that are in cosmetics, we use them in many different formulations and we make them so they're unfit to be consumed.

If you try drinking denatured alcohol you will get sick. That does not stop teenagers. It does not stop them. This is a health issue which is why I have this as my first suggestion.

Okay. The European Union, when they were formed, when it was the European Common Market before it was the European Union, they recognized that each one of their member states, and in those dates I think there were eight, had different rules for denaturing alcohol. They agreed to have a mutual respect of each country's denatured alcohol.

So if you have an alcohol that's denatured according to the British specification, that will be acceptable in France or Germany or Italy and now they're up to 28 countries and they still do this.

To label this, they came up with the word Alcohol Denat. And Denat. is the abbreviation for denatured. Okay?

Now, the INCI dictionary states that Alcohol Denat. is ethyl alcohol, okay, that is denatured with one or more denaturing agents in accordance with the national legislation of each of the European community countries. All of the EU member states recognize this.

The INCI name may also be used in the United States on the provision that the alcohol meets the regulations as defined in the alcohol, Tobacco and Trade Bureau -- they changed the name several times -- and is represented and listed in 27CFR in Section 20 and 21. We have specific spelled out rules.

I know this is hard to read. You just need to go to the 21CFR and go to the -- 27CFR and you will find these exact things.

They have all of these different grades and this is just the ones that I've listed here that are permitted in products that we are interested in and they listed different ones. Bath brush preparations, colognes, hair and scalp, lotions, creams, all the different toilet -- and you see all the different ones.

And the way we labeled them was SD alcohol and then after the word alcohol the number and if it's the number with a dash and a letter that -- so you saw on your label SD alcohol-40. And we knew what it was. That meant that you were

using alcohol that met the FDA -- the alcohol, Tobacco and Firearms regulations.

This is something I put together just for everyone's information. What alcohols do we really use in the United States? It is one thing to have that huge list here of all of these different alcohols, but do we use them? And the answer is no. We use a little SD alcohol-1, you can see it has a grand total of two reporting to the FDA under their voluntary cosmetic notification process.

The denaturant is principally methanol which raises some very serious questions. It certainly is a health question. If you drink denatured alcohol that's denatured with methanol, we have problems. We have problems.

We have 3A which is isopropyl. That I've just seen in a couple formulations that were sent to me. I was rather surprised.

You really have to skip down until we get to 39C. And 39C, it is denatured with diethyl phthalate. This is probably the favorite denatured

alcohol for fragrances. But under today's environmental climate, it contains a phthalate. Oh, my God, what are we going to do?

The most popular one for years and years and years was SD alcohol-40. Now it's down to 139 registrations. I can remember looking at these numbers probably 20 years ago it was probably over 1200.

Why the decline? The decline is that the denatured denaturant in SD-40 is brucine and brucine is prohibited in the European Union. So if you're going to harmonize your product, you can't do SD-40. Or do you?

Okay. Let's go to the major one that we're using right now and that is SD-40B which is basically a mixture of tertiary butyl alcohol and denatonium benzoate.

I see formulations constantly coming in from Europe claiming Alcohol Denat., which is correct and it's legal and it's coming from England and their favorite denaturant is -- is exactly this, but they don't put the tertiary

butyl alcohol in it. So in reality, they're not in compliance with the U.S.

regulations, but they're in compliance with the European regulations.

And nothing happens because they label it Alcohol Denat. There's no transparency, there's no disclosure about what's happening. You can see that most companies are now hiding what they're actually using by labeling and registering it as Alcohol Denat. 4,600 hits on this. So we're not having transparency.

We really need to deal with this and it's easy to say we have a problem. How do you deal with it? And I have a solution. Because otherwise I think it's too easy to say, here are the problems, someone else go solve it. We call those people politicians. I want to give solutions to the problem.

There are two reasons why I think you need to disclose the denaturants. First, we want to see if they're allowed here and the second thing is the medical or safety issue.

When someone drinks denatured alcohol and is rushed to the emergency room, the product is labeled SD alcohol-40, the medical people know exactly how to treat it. If it's labeled Alcohol Denat, they use just the generic way to treat alcohol poisoning which may or may not be appropriate. It's time for disclosure and I think this is just as true in Canada and just as true in Europe and Japan and Brazil.

Okay. Here is Alcohol Denat. This is just going over what I have already said. There's no reason to go any further with it. But I do have this really strange problem with the European Union and some of their for hire representative persons.

The RP's are constantly saying that you have to list on your ingredient listing of your product all of the trace amounts of anything and everything. Any mixture that you put into a cosmetic down to the fourth decimal place. It has to go on the label which is silly. But they absolutely refuse to put the denaturants in. That

is ridiculous.

I want to know what the denaturant is in my alcohol that is being used more than I care that they have got .0001 percent propylene glycol which was used as a partial solvent in one tenth of a percent of some stupid plant extract that I put in for marketing purposes. That's not disclosure. This is important. Knowing what the denaturant is.

So here's the solution. We'll keep exactly where we are right now. If you use the word alcohol in your ingredient labeling, that is pure alcohol, it is not denatured. If you are using denatured alcohol, just put in parenthesis right next to it what the denaturants are.

Full disclosure. It's simple. It's not going to cause major legislation anywhere to adopt this, it gives you transparency. Really. Let's do it.

Okay. The second one is one in which the history is just as important as to what is happening. And that is the section of cosmetic

ingredient labeling that is called "may contains". In Europe they use the plus/minus symbol. In Canada you also have -- use the French translation. I don't know what Brazil -- Brazil has gone to English so I don't need to worry about their ingredient labeling, but I would have no idea what it would be in Portuguese.

Okay. The FDA, when we came out with ingredient labeling, recognized that even though a certified batch by the FDA is supposed to be the same thing, there are different shades that occur because of the way these dyes are manufactured. And it's not the dyes we think about. It is the lakes. Okay?

Dyes we can deal with. Lakes are used principally in colored cosmetics such as lipsticks, some liquid makeups, but rarely, a lot of eye shadows and nail polish. And we need pigments, not dyes for this. So we convert them to the lake. And if you don't know basic chemistry, a lake is simply a way to take a soluble dye and make it a pigment. Something

that's insoluble.

And so the FDA recognized that if you wanted to come up with the exact same shade of lipstick and you're using red 6 or as we used to call it, D&C red number 6, aluminum lake. We'll go through the whole thing. Now it's just red 6 lake. You were allowed to add a little bit of other permitted colors so they got the exact same shade. And those minor additions that you may or may not be putting into your product have the exact same shade were called "may contains" and that's where we listed them.

In for a nickel, in for a thousand dollars, industry came back very shortly thereafter and said, if we have a common base of lipsticks. Why can't we just list all of the colors as may contains and that way we don't have to spend as much time on labeling and things like this? And that became what was acceptable and what is done.

Even though I have some real issues as to whether this is really the purpose of may

contains, but this is what is happening now. And as other countries have adopted ingredient labeling, they are allowing all of the colors to be listed as long as the base is constant as may contains.

Well, what we knew in 19 -- in the 70's changed. And it changed dramatically. There were two separate areas in which we changed what we were putting into our products to give them color. The first is what I call the major chemical changes. We started coating pigments and we coated them with all sorts of wonderful different things which gave us better slip, better feel, better coverage, better stability. It's endless. Okay?

The second branch were what we used to call interference pigments, but since that's prohibited, now we give them other names. But these were the pearlescent pigments that when light struck them they gave us this wonderful pearl effect.

Now, I'm not going to argue and I'm not

going to talk about whether titanated mica is a new colorant or not. The FDA has been dealing with that or trying to deal with it for years. The manufacturers say no, it's strictly a mixture. So it's heated to 800 degrees Celsius. You can't separate them. Okay. I'm not going to deal with that.

But what we have come up with, and it's been in the past ten to fifteen years, is a lot more new technology. And we have to have a way to deal with this. And we're not. We're ignoring it. No transparency.

We did something -- this was a major concern with the FDA in the -- around 1985. We did something. We borrowed it from Broadway. When you had actors and actresses in the heavy light in the Broadway shows, one of the problems was when they had the big lights on them, they really didn't look that good and normal theater make up wasn't answering the problem. And I don't know who thought of this, but they took the glitter that we used to play with when we were in first

grade. You know, that fancy stuff that we would paste and on have a picture of Santa Claus so we would take red glitter and white glitter and yellow glitter and we'd glue it on. They took that glitter.

What was the glitter? The glitter was polyethylene terephthalate. A thin sheet. A color. Usually it was a dye, followed by another sheet of polyethylene terephthalate and then it was heat sealed. Then it was chopped up. And I mean chopped up. And that was one of the reasons why it adhered to Broadway theater skin. Because of all of the jagged edges.

In 1985 the FDA had major issues because we started using this glitter in cosmetics. And this glitter, because of the jagged edges, if you get it in your eye, you got to see a doctor to try removing it. Don't try removing it yourself, you'll scratch your cornea. It's still exists today.

The issue surfaced around five years ago and I believe the country was England and it was

from the retail level. A store there went to a major cosmetic company and said, polyethylene terephthalate is not a color. Polyethylene terephthalate is basically colorless. Why is this stuff green or blue or gold? What dyes do you have in there? We don't know. What do you mean you don't know? Well, we buy it from the supplier and he's not going to tell us.

These are color additives, people. And the store final said, okay. It's real simple. You have 24 hours to tell us what dye is in that composite called polyethylene terephthalate or we're throwing all of your products out of the store.

24 hours later they said, oh, the blue dye is something that's totally prohibited in every cosmetic that has a positive list and every country usually does have a positive list of colors. So we were putting unapproved colorants on our face and our hair. Those were the major applications. Some nail polish.

So we really are hiding things and I

believe in transparency. So let's have solutions.

So here are some of the things that have happened. Companies have come up with being more creative. They have their ingredient listing and they have the normal ingredients -- we'll take a nail polish base for example. And it has the normal ingredients there. And then they have a may contains list of colorants and then a may also contain list of all of the things that come with the colorant.

Let's start as simple as titanium dioxide. You cannot buy pure titanium dioxide. All titanium dioxide is treated. How many of you know what the treatment is that's given to most pigment grade titanium dioxide? I'll venture to guess no one in this room knows. It's a trade secret. But it's also known if you want to do enough homework. Okay?

And so depending on what you're using the titanium dioxide -- our biggest use in applying it to the skin is as a white pigment and the most common coating is aluminum stearate. You

ever see that in the ingredient list? No. Should we? Absolutely.

So I decide, what are all of these other things that we are buying that we're not disclosing and I started to make a list. Okay? And the first one that same to mind immediately was mica because mica causes problems. Mica is a permitted colorant in the United States so therefore we can put it in the may contains. We're not violating any of the FDA regulations or guidelines.

Mica is not a permitted colorant in the European Union. It is a permitted cosmetic ingredient. It has a CI number. That does not mean it is permitted as a colorant in the European Union for cosmetics. And they have taken regulatory action against companies who have listed mica with its CI number because that indicates it's an approved colorant.

So we have a conflict we can't harmonize. We've got to do something about this.

Tin oxide is an approved colorant in the

European Union. In the United States it's a cosmetic ingredient. It's not a colorant. Where is tin oxide showing up? Some of these new interference pigments. It gives a white cast background. It gives you better brilliance in what you're using.

So I started looking at some of the others. And I'm not going to list them. I got about this far as you can see and I stopped. Why? Because this was about ten, maybe eight percent of all of the different additives that we are now putting on pigments for cosmetic purposes. It's an astronomical list.

So let's have a solution. Here's the problem. What do we do? And the answer is just what I did with Alcohol Denat. We will put the color. Titanium dioxide. Europe wants the CI number so we put it up there. CI77891. And our coating is aluminum stearate.

So right next to it we're going to add aluminum stearate. We're going to have iron oxides. This time we're using CI77492. And it's

coated with dimethicone so it has better smoothing properties when you put it on your face.

Blue number 1. Here we go. We discovered one of the interesting polyethylene terephthalate glitters. It's just as good using blue 1 which is an FDA approved certified color. So what is the colorant? It should be labeled blue 1, (polyethylene terephthalate). That's the carrier, that's not the colorant. We have a solution.

That's what I wanted to say. I hope ICCR at some points looks at this. It has several advantages. First, it's simple. Second, it doesn't require major legislation. Third, it allows for total transparency on what we're doing. So therefore, I think it's a good idea.

And I'll be glad to answer any questions. And if you really bug me and you have the time, I'll tell you what my third suggestion is. But I don't want to tell until next year.

DR. KATZ: Thank you, David.

And we have one other comment that

Rosemary Cook will read.

MS. COOK: Good afternoon. This is a public comment in response to the Federal Register notice, submitted by Jean Publi.

I do not want animals used for cosmetic testing anymore. No dogs, cats, cows, goats, guinea pigs, et cetera. It's time to stop abusing animals for animal testing.

I also do not want lowering of American test standards to meet international lower standards. The profiteers would just love to get lower standards.

This comment is for the public record. Jean Publi.

Thank you.

DR. KATZ: And with that ends the actual requests for speaking at today's meeting.

I want to thank everyone for coming. If you have any particular comments or suggestions that you could like to make for ICCR, you're welcome to do so into the docket. And we will take that with us to the ICCR meeting in Brussels.

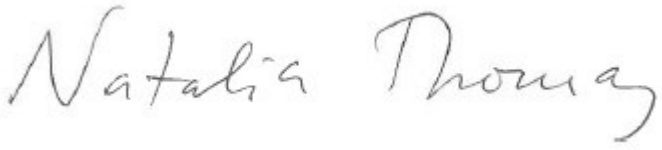
In addition, I would like to thank the following people for their help at this meeting. And it's in no particular order, but I'd like to thank Juanita Yates, Adrien Choice, Nolan Chase, Rob Collins, Tiona Shackleford, Beth Myers, Donnie Lowther, John Misock and Rosemary Cook for all of their help in having this meeting today.

Thank you very much and thank you again for coming.

(Whereupon, the FDA Public Meeting for Preparation for the 2015 International Cooperation on Cosmetics Regulation (ICCR) Meeting concluded at 2:47 p.m.)

CERTIFICATE OF NOTARY PUBLIC

I, NATALIA THOMAS, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.



NATALIA THOMAS
Notary Public in and for
the State of Maryland

My commission expires: 11/30/2018

Notary Registration No.: 7623755

CERTIFICATE OF TRANSCRIBER

I, ALICIA GREENLAND, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of this action.

September 23, 2015 — ALICIA GREENLAND