

Preparation for the 2015 ICCR Meeting 09-10-2015

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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

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1 S P E A K E R S

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3 Linda M. Katz, MD

4 Director

5 Office of Cosmetics and Colors

6 Center for Food Safety and Applied Nutrition, FDA

7

8 David C. Steinberg, FRAPS

9 Steinberg & Associates, Inc.

10

11 Rosemary Cook, MBA

12 Office of Cosmetics and Colors

13 Center for Food Safety and Applied Nutrition, FDA

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1 P R O C E E D I N G S

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

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

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

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

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

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

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

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

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

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1 docket itself.

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

5 (Brief pause.)

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

8 (Brief pause.)

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

14 (Short recess.)

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

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

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1 International Cooperation on Cosmetics Regulation.

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

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

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

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

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

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

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

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

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

15 So our first meeting of ICCR was in
16 2007. The members at that time were Canada, EU,
17 Japan, the U.S. and later in July of 2014, Brazil
18 joined the steering committee. We set up a terms
19 of reference and that was a voluntary consensus
20 model in which we all agreed that that would be
21 the way to go forward.

22 We looked at the precedence from ICH,

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

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

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

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1 on a quarterly basis. More if needed.

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

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

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

22 On the second day we have our regulators

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

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

14 ICCR 8 was held in Ottawa last year and
15 I'll kind of go through the agenda and the items -
16 - the outcomes from that meeting. It was a busy
17 meeting as you can see. We talked about the ICCR
18 8 year in review, ICCR web, governance, allergens,
19 in silico, quantitative structure-activity
20 relationship or QSAR models, alternatives to
21 animal testing, trace impurities, microbial
22 contaminants and we got the update from observing

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1 regulators.

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

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

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

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

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

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

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

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

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

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

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

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

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1 cosmetic product. The documents on mercury and
2 1,4-dioxane are still undergoing final review.

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

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

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

22 The ICCR steering committee reviewed the

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

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

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

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

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

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

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

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

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

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1 Second thing is, please forgive all of
2 my typo mistakes. I hunt and peck. I type with
3 two fingers. I was able to type five books, over
4 100 columns on cosmetic regulations, countless
5 numbers of papers and chapters in books and things
6 like that, and I got older I noticed that my mind
7 thinks and sees one thing and I type something
8 else. So it's September not what's up there.

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

11 (Brief pause.)

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

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

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

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

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

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

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1 seems to ignore that.

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

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

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

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

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

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

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

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

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1 The INCI name may also be used in the
2 United States on the provision that the alcohol
3 meets the regulations as defined in the alcohol,
4 Tobacco and Trade Bureau -- they changed the name
5 several times -- and is represented and listed in
6 27CFR in Section 20 and 21. We have specific
7 spelled out rules.

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

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

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

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

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

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

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

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

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

4 The most popular one for years and years
5 and years was SD alcohol-40. Now it's down to 139
6 registrations. I can remember looking at these
7 numbers probably 20 years ago it was probably over
8 1200.

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

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

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

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

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

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

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

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

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

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

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

1 is ridiculous.

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

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

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

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

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

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

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

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1 that's insoluble.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 24 hours later they said, oh, the blue
16 dye is something that's totally prohibited in
17 every cosmetic that has a positive list and every
18 country usually does have a positive list of
19 colors. So we were putting unapproved colorants
20 on our face and our hair. Those were the major
21 applications. Some nail polish.

22 So we really are hiding things and I

1 believe in transparency. So let's have solutions.

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

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

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

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

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

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

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

22 Tin oxide is an approved colorant in the

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

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

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

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

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

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

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

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

21 DR. KATZ: Thank you, David.

22 And we have one other comment that

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1 Rosemary Cook will read.

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

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

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

13 This comment is for the public record.
14 Jean Publi.

15 Thank you.

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

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

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

8 Thank you very much and thank you again
9 for coming.

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

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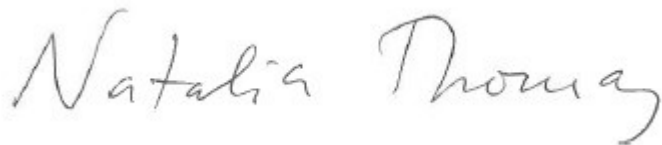
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