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UNITED STATES FOOD AND DRUG ADMINISTRATION

PREPARATION FOR THE 2018 INTERNATIONAL COOPERATION ON
COSMETICS REGULATION (ICCR-12) MEETING

Thursday, June 7, 2018

2:05 p.m.

Food and Drug Administration

Wiley Auditorium

5001 Campus Dr.

College Park, MD 20740

Reported by: Natalia Thomas

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A P P E A R A N C E S

LINDA KATZ, DIR. OF OFFICE OF COSMETICS AND COLORS

DAVID STEINBERG, STEINBERG AND ASSOCIATES

DEBORAH CAMPBELL, AMERICAN COSMETIC MANUFACTURERS ASSO.

JANET VARNELL, ESQ. VARNELL & WARWICK

JAY ANSELL, VP, PERSONAL CARE PRODUCTS COUNCIL

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1 P R O C E E D I N G

2 DR. KATZ: For those of you are here, we're
3 just waiting a few minutes to see if some of the
4 additional people who said they were going to attend will
5 show up. Okay, good afternoon. Can everyone hear me?
6 I'd like to take this opportunity to welcome everyone to
7 our public meeting in Preparation for the
8 2018 International Cooperation on Cosmetics Regulation,
9 or also known as ICCR-12, meeting that we're having
10 in Tokyo next month.

11 Before I get started with my presentation, I
12 just want to go over some general housekeeping rules. If
13 anybody has any electronic devices that make sounds,
14 please either silence them or turn them off now so that
15 people won't be distracted during their talks. If you
16 need to leave the room for any reason, please exit
17 towards the back and someone will escort you to wherever
18 you need to go. At the end of the meeting I'll come back
19 and make some final comments.

20 The way we'll work things is that I will start
21 off with the introduction and it will be followed up by
22 public comments. The first one will be from David

1 Steinberg from Steinberg and Associates, the second from
2 Deborah Campbell at the American Cosmetic Manufacturers
3 Association, the third will be Janet Varnell at Varnell &
4 Warwick, and the fourth will be Jay Ansell at the
5 Personal Care Products Council.

6 I won't introduce each of you, but after the
7 speaker before you speaks, if you could just come and
8 plan to start your talk after they finish up, that
9 would be helpful. As I said, I'll finish up at the end.

10 So let me begin and welcome you to our meeting
11 in preparation for ICCR. In the time that I will be
12 speaking, what I'll do is describe the ICCR and its
13 process, do a summary of outcomes from ICCR-11 which
14 was held in Brazil last year, and talk about some
15 upcoming issues for ICCR-12.

16 So for those of you who have been here before,
17 this is an old slide, but it really puts perspective onto
18 why ICCR was eventually established. We look back into
19 October 11, 1995 when the FDA policy was established on
20 international harmonization. This policy was designed
21 with the goals to

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1 facilitate international trade, to promote mutual
2 understanding, to facilitate exchange of scientific and
3 regulatory data, to talk about further ways that we
4 could be transparent to the extent permitted by law, to
5 accept equivalent standards, compliance activities, and
6 enforcement programs of other countries, again, if those
7 are applicable to the FDA's level of public health
8 protection. Finally, one of the major criteria was to
9 avoid a lowering of public health protections. In other
10 words, to avoid downward harmonization.

11 So initially CHIC was that entity that was
12 established in the cosmetic realm. For those of you who
13 have been around for a long time, people will remember
14 CHIC, the Cosmetic Harmonization and International
15 Cooperation. The first meeting was held in April of
16 1999 in Brussels, Belgium and the participants were
17 Canada, the EU, Japan, and the United States.

18 The goals at that time, in keeping with the
19 1995 policy, was to talk about international regulatory
20 schemes to seek areas of
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1 commonality for development of regulatory alignment,
2 and to develop a memorandum of cooperation. CHIC met
3 three times. Its last meeting was in Canada in 2005.
4 The reason why CHIC was disbanded was that the
5 occurrence of the meetings were so infrequent that as a
6 group we decided we needed something that would occur or
7 meet on a more regular basis and where we could really
8 try to accomplish the goals that were set out.

9 Rather than continue the same name which we
10 thought might not be a positive thing, ICCR was
11 developed. It was established in 2006 with its first
12 meeting in 2007. The initial members were the same
13 members as from CHIC, which were Canada, the EU, Japan,
14 and the United States. And in 2014, Brazil was added to
15 the ICCR steering committee.

16 The first things that we did were to establish
17 terms of reference using the voluntary consensus model
18 and it was modeled after ICH, VICH, and GHTF. We
19 decided we would invite our industry partners, which was
20 slightly different from the other international groups
21 at the time.

22

1 This slide is here for reference to let you
2 know where we've been over the last 12 years or so. As
3 you can see, we meet pretty much the same time every year
4 with a few minor exceptions, and this year's meeting will
5 be held in Tokyo on July 10th through 12th.

6 So what is the ICCR work process? What does it
7 look like? Well, we meet once a year and we rotate in
8 the five regions so that the region who's in charge of
9 the meeting, is responsible as being the secretariat for
10 that year. We have an annual meeting and interim
11 teleconferences. Usually we talk to each other
12 quarterly, and ICCR may also establish subsidiary working
13 groups to deal with specific issues that have arisen or
14 topics that have come up.

15 In the United States, we hold a public meeting
16 prior to the annual meeting, to obtain comments. Not all
17 of the jurisdictions do the same thing.

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So the structure for the meeting itself.

1 The first day is a regulators-only meeting; the second
2 day is regulators plus industry; and the third day is a
3 regulators-only meeting. On the third day, we go over
4 the outcomes, we develop a press statement, and we
5 develop other statements that we will put on our
6 website.

7 We also have a stakeholder session on day
8 two, and this allows stakeholders usually from a
9 particular region to come and present topics of
10 interest that they think ICCR might want to hear about
11 and might be able to develop to put into our agenda in
12 future years. The outcomes of the ICCR meeting are
13 posted on our website and I have the website
14 information here. I will show you a slide at the end
15 again with this website info.

16 For those of you who've been around for a
17 while you'll know that our website has changed. The
18 deliverables and accepted documents are posted on the
19 website.

20 So for ICCR-11, which met in 2017 in Brazil,
21 the agenda items were microbiology standards,
22 integrated strategies for safety assessment of cosmetic

1 ingredients, cosmetic product preservation, allergens,
2 industry presentations, updates from observing
3 regulators, and stakeholder presentations. The following
4 slides will summarize what the outcomes were.

5 For the microbiology standards, ICCR adopted,
6 and this is the title of the document, the "Review of ISO
7 Microbiological Standards - Guidance for Cosmetic
8 Preservation and Product Protection." This report was
9 adopted, as well as the review of ISO standards embedded
10 in ISO 17516 report, and both were published and posted
11 on our website.

12 For integrated strategies for safety
13 assessment of cosmetic ingredients, ICCR adopted the
14 "Integrated Strategies for Safety Assessment of Cosmetic
15 Ingredients, Part 1," and that report is also on our
16 website.

17 For cosmetic product preservation, the ICCR
18 agreed to develop new terms of reference since the
19 previous terms of reference was no longer applicable,
20 because the process, that it was related to, was
21 completed.

22 For allergens, a similar situation. ICCR

1 agreed to develop a new terms of reference since the
2 previous documents had been posted on the website.

3 With regard to industry presentations, we
4 heard a presentation on e-commerce and cadmium levels in
5 cosmetic finished products. A proposal is pending from
6 industry regarding those presentations.

7 From observing regulators, we heard updates
8 with regard to cosmetic regulations from
9 representatives from Argentina, Chile, Columbia, South
10 Korea, South Africa, and Taiwan. We also heard from
11 stakeholders who made presentations on animal testing
12 alternatives and talked about products whose claims and
13 uses may not be compatible with cosmetic regulatory
14 frameworks.

15 The ICCR Steering Committee is reviewing some
16 of the proposals for consistency with ICCR objectives
17 and the scope of work that's deemed by the terms of
18 reference. Other new work items may also be submitted
19 to ICCR at any time.

20 As I mentioned, ICCR-12 will be held in Tokyo.
21 We've been holding quarterly teleconferences to discuss
22 the outcomes of the work

1 group meetings and where they are at this point in
2 time. Our last quarterly teleconference will be held
3 later this month.

4 With regard to the agenda, you'll see some
5 continuing themes that we're going to continue to talk
6 about integrated strategies for safety assessment of
7 cosmetic ingredients. We'll also continue to talk about
8 cosmetic product preservation, allergens, analytic test
9 methods, and communications will be somewhat new, as
10 well as any new proposed agenda items that may come up
11 during the course of that meeting.

12 This slide is really put here more for
13 reference and it lists our website so that you can find
14 the information that I've described in that website.
15 You also can see who the regulators are from each of
16 the different regions.

17 So thank you for your attention and now I'd
18 like to welcome David Steinberg to give his
19 presentation.

20 MR. STEINBERG: Just a very short speech. I
21 have three suggestions. One, we've heard before many
22 times and the whole purpose of this is when we're

1 talking about harmonizing or agreeing or doing things
2 the same, it keeps coming up. And the whole concept
3 behind it is to try having simpler, more uniform
4 ingredient labeling for cosmetics, that there's a
5 finite amount of space, and there are certain things
6 because of different issues way before ICCR started,
7 before CHIC. This goes back when I was born in Europe
8 back in the '80s when we started doing ingredient
9 labeling.

10 So the first one I'm going to talk for about
11 one second, and that's water. The rest of the world
12 uses the word aqua. We did studies. They were
13 presented, I think it was 10 or 12 years ago, where
14 American consumers know that water and aqua are the
15 same thing. So why can't we just all have, and agree
16 to have aqua as the INCI name or the ingredient name
17 for water? It's something I think we really need to
18 consider.

19 The second one is more difficult and this one
20 is there's certain definitions which really need to be
21 defined. They sound simple, but they're not. What I
22 would like to recommend is a working

1 group from the five member countries of ICCR to come up
2 with realistic, uniform definitions of what a leave-on
3 cosmetic is or what a rinse-off cosmetic is. If you
4 think that's a simple statement, I'm going to give you a
5 real simple explanation. Some people have heard this
6 'cause I've said this before.

7 My wife came home from a hard day at work and
8 she needed to relax. So she filled the bathtub up with
9 warm water, took a bottle of bubble bath, which was
10 preserved with methylchloroisothiazolinone and
11 methylisothiazolinone preservative, dumped some in and
12 soaked for 20 minutes. When she was done, she got out
13 of the tub. She dried herself off. She never rinsed
14 off. Is that a leave-on product or a rinse-off
15 product?

16 Then she decided she needed a face mask. So
17 she took a jar of this black clay, again preserved with
18 the methylchloroisothiazolinone and
19 methylisothiazolinone mixture, put it on her face and
20 about a minute later washed it off with soap and water.
21 Is that a leave-on or a rinse-off? Well, the answer is
22 we don't know.

1 And maybe we have with more and more
2 restrictions on the use of ingredients from both Europe
3 and from Canada as to these can be used for leave-on or
4 for rinse-off, I think it would make sense to have a
5 committee formed, a working group as ICCR does, to
6 define these.

7 The last one is something which is far more
8 complex and that's country of origin. This is something
9 that again means different things in different countries
10 and we really should have the same working group sit down
11 and try coming up with a uniform definition understanding
12 that there might be little questions in certain countries
13 as to what they mean by country of origin.

14 That leaves me to the last topic, which I will
15 scare you on. That's good. I'm going to try teaching
16 you some chemistry. The FDA has approved the color years
17 ago called yellow 10. Original name was
18 D&C yellow 10. It's a mixture of the sodium salts of a
19 mono- and disulfonic acid and you can see the long
20 chemical name. I'm not going to go through it.

21
22 It is principally mono-substituted, which is

1 about 75%, if I remember correctly, from the Code of
2 Federal Regulations. Europe calls this by the CI
3 number, which is their way of determining nomenclature,
4 and it's called the Colour Index 47005. This is
5 principally a disodium substitution. Japan uses their
6 nomenclature system, which is Ki203, and theirs, again,
7 is principally disodium.

8 Now I'm going to teach chemistry very quickly.
9 Push the right button. About 55 years ago I took
10 inorganic physical chemistry and one of the things we
11 learned, and it was equilibrium reactions and stuff I
12 always forget 'cause I didn't like it. But if you take
13 one mole of sodium hydroxide and one mole of a weak acid,
14 and you racked them, you form a salt. When you take that
15 and you put it in water, the pH is around nine or ten
16 because you have a strong base and a weak acid.

17 This is no different when we have a
18 disubstituted product. Yes, yellow 10 is chemically
19 different than CI material from Europe and from Japan.
20 Until you put them in water, and that's how we use them,
21 these are water soluble dyes. When we put them

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1 in water, they come to an equilibrium, and guess what.
2 They're the same thing.

3 So if you start with the disubstitution here,
4 it comes back to this level, and if you start with a
5 monosubstitution here, guess what. It goes back to the
6 same level and it all depends on the pH of your
7 finished product.

8 So what I am suggesting is not changing
9 anyone's specifications. That's ridiculous. What I'm
10 saying is allowing a harmonized label and the
11 harmonized label would allow you to say yellow 10, then
12 CI 47005, or the reverse like they do in Europe, CI
13 47005, yellow 10, because that's what's in the
14 cosmetic, not the name of what was started, but what
15 actually appears when you make the cosmetic.

16 So there are my suggestions and I hope they
17 have a successful meeting and I thank you for your
18 time.

19 MS. CAMPBELL: Good afternoon. My name is
20 Deborah Campbell and I am President of ACMA, the
21 American Cosmetic Manufacturers Association. ACMA is a
22 nonprofit trade association of cosmetic manufacturers

1 and distributors located in the heart of Washington,
2 DC. We are a relatively new cosmetic trade association
3 founded in 2011 and we have already developed a strong
4 base of well-respected members.

5 US companies that manufacture and/or
6 distribute cosmetic products in the US are eligible for
7 membership in ACMA. Our members include new and
8 established brand owners, manufacturers, distributors,
9 ingredient suppliers, and retailers all supplying the
10 American market. They are composed mostly of small to
11 medium size entrepreneurial companies interested in
12 breaking into the global market.

13 We continue to build our association and look
14 forward to expanding our membership in the future. We
15 represent the interest of American companies that wish
16 to export their American and personal care products,
17 and we support these companies with a broad array of
18 services and resources. ACMA charges no annual fee for
19 membership. Our services are funded by processing
20 documents for our members at minimal fees.

21 Our mission is to support cosmetic
22 manufacturers and distributors to expand into the

1 international marketplace by focusing on international
2 regulations. ACMA's goals are twofold. One, to
3 provide assistance to cosmetic companies to understand
4 expert regulations, and two, developing partnership
5 with the FDA to provide guidance on requirements of the
6 international cosmetic market for our members, which
7 brings me to the subject of my talk today, breaking
8 into the global market.

9 Many of our members already export some
10 products to Europe and other countries. We are, we are
11 dedicated to helping our members expand and thrive, not
12 only survive in the international marketplace. There
13 are many things to consider when marketing cosmetics
14 abroad.

15 The major consideration is that the standards
16 of composition and manufacture of the receiving country
17 can vary very much from US standards, or sometimes not
18 that much. Products that are manufactured and sold
19 freely in the US may not have been manufactured or
20 produced according to the required standards of the
21 importing country or may contain ingredients banned,
22 banned by these other countries.

1 For this reason, the accepted practice of
2 requiring a Certificate of Free Sale as it now exists
3 may be inappropriate. For instance, according to the
4 Official Journal of European Union 2009, Annex 2, there
5 are greater than 1,000 listed substances that are
6 prohibited to be used in the manufacture or production
7 of cosmetics. According to the FDA website, there are
8 11 ingredients prohibited from being used in the
9 cosmetics in the US; although, it is against the law to
10 use any ingredient that makes the cosmetic harmful when
11 used as intended.

12 The accepted industry practice of requiring a
13 CFS for US products being exported to Europe may be
14 insufficient 'cause there is no indication of the
15 ingredients used in the manufacture of the products
16 listed on the certificate.

17 To solve this matter, we propose that the CFS
18 as it now exists should be updated to include a
19 statement that the composition of the listed product
20 complies with European standards. Companies must also
21 ensure that their products have been manufactured within
22 the regulations of the receiving country, which

1 brings us to the Good Manufacturing Practice
2 Certificate, or GMP. Many new cosmetic exporters face
3 difficulty obtaining a GMP for their products because
4 they're not manufacturers. They develop their product
5 composition and packaging and contact a large
6 manufacturer to produce their product and package it
7 for them, making it market-ready.

8 We advise our new companies using this
9 strategy to request a Good Manufacture Practice
10 Certificate from that manufacturer. With this GMP
11 certificate for their product, they can reissue the GMP
12 certificate under their own company name based upon
13 what the US manufacturer produced for them.

14 Another way we are assisting our members to
15 break into the global market is by encouraging them to
16 participate in our new Customer Connect registered
17 distributor program. This program brings
18 manufacturers, distributors, and importers together for
19 mutual benefit. ACMA members manufacture some of the
20 finest cosmetic and personal care products available in
21 the US today and are already exporting these American
22 made products to a number of foreign countries. Our

1 members have the merchandise and expert experience that
2 international cosmetic distributors and importers are
3 looking for in a partner.

4 This innovative program is a forum where
5 contacts can be made and developed into long lasting
6 business relationships. Our members participating in
7 the Customer Connect program make their contact and
8 product information available for interested
9 distributors or importers.

10 Distributor and importer information is
11 available to all ACMA members interested in locating an
12 export partner. Manufacturers are always looking for
13 new markets and partners to help them develop a
14 foothold in the, foothold in the international
15 marketplace.

16 ACMA is in the process of developing other
17 programs and providing more resources to assist our
18 members to expand their businesses. ACMA is dedicated
19 to help our members break into the global market while
20 ensuring that they produce safe products compliant with
21 all existing regulations of the United States and the
22 importing countries.

1 Thank you for allowing ACMA to participate
2 today and be part of this planning meeting. Thank you.

3 MS. VARNELL: It's a pleasure to be here.
4 Thank you for letting me come. I know the last thing
5 anybody wants to do is listen to lawyers, but I have,
6 I'm in good company here with other lawyers. But my
7 name is Janet Varnell. I'm a private practitioner and
8 I come to you from Florida, and I want to talk about
9 post market surveillance in the hopes that it will
10 assist you in preparation for the ICCR meeting.

11 I'm going to begin by saying, asking you who
12 is Jessica Deetz and why do you care who Jessica Deetz
13 is? Jessica Deetz is a stay-at-home mom in Indiana.
14 She has two young children, a little boy who's nine and
15 a little girl who is two.

16 Jessica saw posts on Facebook by her friends
17 who were marketing their hair care products and said
18 that these hair care products could regrow your hair
19 and that they were so safe they could be used for
20 things like pregnant women to lower hormonal levels to
21 help with hair loss. They also said they had a safe
22 junior line that was good for children that are ages

1 one to nine.

2 Since it's sold via a multilevel marketing
3 company, she purchased the products from her friend.
4 She paid more than \$300 and after a few months using
5 them on both herself and her children, Jessica realized
6 that she was experiencing hair loss and other adverse
7 reactions. Worse yet, her son had horrible head sores
8 on his head and had begun to develop bald patches,
9 which he ultimately was ridiculed about when he went to
10 school.

11 Then she goes into her daughter's crib and
12 finds lumps of matted hair falling out of her two-year-
13 old daughter's head to the point that the child lost
14 over half of the hair on her head.

15 So I've come to ask you all that, to pay
16 attention to people like Jessica Deetz and the
17 thousands of other consumers who are experiencing
18 serious reactions, not only to Monat products, but
19 others. And I think that if we had properly working,
20 working mechanisms for better post market surveillance,
21 then we would be able to do a better job to help people
22 like Jessica Deetz and all of the other thousands of

1 consumers that I end up running into.

2 Everyone here is either in industry or working
3 for the FDA and then ultimately you all are going to
4 have this opportunity to work with the ICCR. This is a
5 real legitimate plea. I've come to you all the way
6 from Florida, flew up here just because by chance if
7 there's somebody here who can have an impact on the,
8 the tools that we use to try to monitor what's going on
9 with people.

10 For instance, like the FDA complaint system,
11 we need to do something that will promote big
12 consumers' use of those mechanisms and track that data
13 a little bit better because it's, as a lawyer I can
14 tell you that it's damn near impossible to help these
15 people.

16 Their claims are small. Even when, even in
17 the case of Jessica Deetz. This is not a case that
18 most lawyers could ever take to court. It's only going
19 to be successful if it's a class action. I've been a
20 consumer protection lawyer for over 20 years and I'm here
21 to tell you I may have been able to bring, bring the Wen
22 hair care settlement to, together last year,

1 but it is no easy row to hoe and these cases should not
2 ever happen and they should never be tried in our court
3 system. This is something that we can get the
4 manufacturers to do a better job on and get the FDA and
5 the other ICCR members to do a better job of policing.

6 So let's talk just for a second about the
7 feedback that I've gotten from these thousands of
8 consumers 'cause I've specifically asked them. I want
9 to know how we're actually accomplishing this post
10 market surveillance. You know, you get it from three
11 sources, right? You get it from physicians. You get
12 it from consumers. And you get it from the company,
13 the manufacturers themselves.

14 So I only really know very much about what I
15 find in the records of the manufacturers and what I
16 find when I see the records that are handed over from
17 the FDA at some point, but I really know what the
18 experience of a consumer is who's trying to give
19 information back to regulators, whether it's like, for
20 instance, with Monat, which is also sold in Canada, the
21 UK, two of our other partners in the ICCR, as well as
22 here in the US. I know that, that they give me

1 feedback that when they try to make the claim or a
2 complaint, the, the system is too onerous.

3 If we truly, whether you're a manufacturer or
4 you're a regulator, if you truly do want to know what's
5 going on with the product in the market, scientifically
6 we know you have to try to gather that data about what's
7 going on in the market. What whether there's an unusual
8 number of adverse reactions.

9 So I find from my folks that when they go to
10 make a complaint, they are asked questions that they
11 don't, that are very intimidating and they don't know how
12 to answer. They're frequently asked questions that they
13 don't have an answer to like you're not allowed to
14 register this complaint unless you can tell what batch
15 number or, you know, specific items on pikes that they
16 may not have retained the product to enter the
17 information.

18 So they don't know it, but can't they at least
19 say, hey, I only know this? I used a shampoo. It was
20 this general type and it was made by Monat. Why can't
21 they just tell you that so that at least you will know,

22

1 hey, we have maybe 250 very unscientific reports, but
2 we have 250 additional people where we have very little
3 information that are complaining about, about having
4 severe adverse reactions.

5 You want that information. If you don't have
6 it, if the manufacturer doesn't have it, they can't do
7 anything to prevent it in the future. So the first
8 element being simplify the complaint process. The
9 second is I implore you to talk with ICCR and here at
10 the FDA to consider better communication with the
11 clients.

12 You know, I don't have very many industry reps
13 here, but I'm glad to have you here because you're
14 certainly in a position with the manufacturers to talk
15 about the importance of communicating with your
16 customers. If you have a tremendous number of people
17 complaining, it can be a curse, I know, but it can also
18 be a blessing.

19 It's also a resource for you to find out
20 what's wrong, identify it quickly, deal with it. I
21 know, I noticed a firm-generated recall of shampoo just
22 this past week by Paul Mitchell. I applaud that when I

1 see that. I don't know how on earth Paul Mitchell knew
2 to do that or how much, who brought pressure to bear on
3 it, or whether it was all, it's Paul Mitchell's culture
4 that they decided we're going to deal with this problem
5 of a contaminate in our shampoo or not. I don't know,
6 but that is a stark contrast to what I see.

7 But there are real victims and I can't help
8 most of them. I need for you all to find a way to
9 capture what people are trying to tell you. They don't
10 feel like they can tell you what's going on. They
11 don't feel like they're listened to and they're not
12 feeling like you communicate with them about what's
13 going on. And if all the FDA does and if all ICCR does
14 is send an e-mail back that says we are continuing to
15 gather information, that's something.

16 But I am sick and tired of having people
17 parade across my e-mail or call me on the phone and
18 tell me tragic stories and I cannot help them. There's
19 just no way for me to bring a lawsuit for everybody who
20 has a small amount of harm, but I'm seeing it by the
21 thousands.

22 So you have to do something to get those

1 complaint processes in your post market surveillance to
2 do a better job of that and capture that data. Thank
3 you.

4 DR. ANSELL: Good afternoon. My name's Jay
5 Ansell and I'm vice president for cosmetic programs at
6 the Personal Care Products Council. I'd like to thank
7 FDA for holding this meeting and showing its interest in
8 soliciting the viewpoints on the ICCR process from its
9 stakeholders.

10 Briefly, the Personal Care Products Council is
11 the leading national trade association representing the
12 global cosmetic and personal care products industry.
13 Founded in 1894, our more than 600 members include
14 manufacturers, distributors, and suppliers of a vast
15 majority of the finished personal care products
16 marketed in the United States. While our members
17 represent some of the most well-known products in the
18 world, we also include many medium and small size
19 company as part of our membership.

20 For the 125 years, regulators and policies,
21 makers have relied on our organization to deliver
22 honest, credible, and accurate scientific information

1 about cosmetic and personal care products. We take this
2 responsibility very seriously. We're pleased to
3 represent our industry in the International Cooperation
4 on Cosmetics Regulation initiative.

5 Cosmetic and personal care products industry is
6 a truly global industry dependent on open markets and
7 transparent and consistent regulatory environments around
8 the world. Our member companies continually strive to
9 exceed the most stringent regulatory and product
10 integrity standards worldwide and to provide consumers
11 with safe, innovative, and high-quality cosmetics that
12 they have come to expect with ingredients that are
13 imported from around the world.

14 We understand international harmonization is a
15 critical component to the success of our industry and
16 significantly contributes to our ability to expand
17 manufacturing and employment, as well as to provide other
18 industries, such as advertising, packaging, and
19 transportation.

20 The globalization of our industry also promotes
21 continual technological innovation which contributes
22 significantly to the application of these

1 scientific advancements benefiting consumers around the
2 world.

3 For all these reasons, the Personal Care
4 Products Council is actively engaged in international
5 efforts to align global safety and regulatory standards
6 for consumer products to eliminate trade barriers and
7 to assure a level playing field for member companies
8 while at the same time reenforcing consumer confidence
9 in product safety.

10 Now the stated mission of ICCR, to maintain
11 the highest level of global consumer protection while
12 minimizing barriers to international trade, underscores
13 the important role of FDA and the other regulatory,
14 regulators in a global environment. We believe that
15 the ICCR serves as an important forum for alignment of
16 regulation, policy, and guidelines affecting our
17 industry, and as a resource for other companies,
18 countries looking to align their regulatory approaches
19 around common guidelines.

20 We're very encouraged that ICCR's dedicated
21 website, which was formally launched in 2014, will
22 continue to serve as the important vehicle for the

1 public and private sector to review the results of ICCR
2 work.

3 We're looking forward to the results of the
4 ICCR-12 meeting, especially endorsement of a report on
5 applications of an integrated strategy for safety
6 assessment of cosmetic ingredients, as well as
7 endorsement of the ISO analytical methods, and
8 continuing work items in the areas of preservation,
9 assessment of allergies, and many of the other topics.

10 Further, the important work undertaken by ICCR
11 has been recognized by industry and regulators in other
12 countries who have reviewed the ICCR documents and have
13 expressed interest in participating in the meetings.

14 We're particularly pleased this year to welcome
15 representatives from Columbia, Israel, Korea, South
16 Africa, Taiwan, and Thailand to participate in ICCR-12 as
17 observers.

18 Our industry fully supports the participation
19 of other countries in the ICCR process. We're also
20 interested in exploring other avenues to promote the work
21 of ICCR globally and to continue the synergies between
22 ICCR and other forum such as ISO. As

1 international trade on cosmetics and personal care
2 products continues to expand, achieving the goal of
3 global regulatory alignment becomes more critical. We
4 look forward to working with FDA and the other
5 regulators to enhance the ICCR process in the months
6 and years ahead. Thank you.

7 DR. KATZ: Thank you all for your
8 presentations and comments and for making the trip here
9 to tell us what you think. The information that you
10 provided I will bring back with me to ICCR-12 in Tokyo.
11 I would also, before I finish up, would like to thank
12 several people from my staff and others in the FDA for
13 helping us today. Jonathan Hicks, who helped to
14 organize this meeting, as well as Kate Thrieschman and
15 John Gasper, who you may have met when you walked into
16 the building, and Juanita Yates, who was at the welcome
17 desk.

18 So with that, I'd like to conclude this
19 meeting. Again, thank you for coming.

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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

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CERTIFICATE OF TRANSCRIBER

I, Penny Knight, 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.

June 19, 2018

DATE

Penny Knight

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