U.S. FOOD AND DRUG ADMINISTRATION

ICCR PUBLIC MEETING

Wednesday, May 8, 2013

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U.S. Food and Drug Administration

University Station Building

Conference Room 3172

4300 River Road

College Park, Maryland 20740

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Capital Reporting Company

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Welcome and Overview of ICCR Process

DR. KATZ: We'll go ahead and get started. I hope you can all hear me. I'm Linda Katz. I'm the Director for the Office of Cosmetics and Colors, and I am also the lead from the FDA's delegation for ICCR. I am going to go through some logistic details, before I start to go through my presentation, just so everybody is clear on how this afternoon will move forward.

I will give a general overview, and following that, we have had requests from five speakers who are sitting at the table. They will each have 10 minutes to present the information that you have received in your packet. Following the end of the presentation, I will go ahead and close the meeting. The meeting is not set up as a dialogue. It's really just an opportunity to present Information. If you have any information or questions afterwards, you're welcome to present that to us as well.

Following the meeting itself, since we do have a

transcriptionist here, we will make a transcript available, which will be found in the docket. Probably it will take us, I would guess, a couple of months before it's up, but it will be available for everyone to look at within the docket.

As far as minor logistical issues, if people have cell phones, please turn them off or turn them to silence. It's a small room, and if they start ringing, it would be very distracting. If anyone needs to use the rest room, there are rest rooms down the hall to the right, and someone will escort you since you cannot walk through the building on your own. At the end of the meeting as well, we will escort you back downstairs. Those of you who have badges need to turn them in so that it's clear that you have departed the building.

And with that, I will go ahead and begin my presentation at this point in time, unless there is anything that I have forgotten.

(No audible response.)

DR. KATZ: Okay. So let me go ahead. I am going to sit down because I don't know if I am going to be in people's view standing up, and the room itself is small enough that you should at least hopefully be able to hear me if I am seated.

What I am going to do today is really just to talk about ICCR, which is the International Cooperation on Cosmetics Regulation. I'm going to go through and give a brief description of ICCR and its process. I'll do a summary of what happened last year, ICCR-6, and then give you a brief overview of what we anticipate as the upcoming issues for ICCR-7.

This really represents the beginning of FDA's international harmonization efforts. As you can see from this slide, they started back on October 11th of 1995. The goals at that time were fairly broad and overreaching, and they included the issues to try to promote trade, to promote a mutual understanding, and to try to harmonize in areas in which FDA could harmonize with other governments themselves.

Basically it was to facilitate the exchange

of scientific information, to have some transparency, and to accept certain standards that could be equivalent across the globe, and basically the bottom line was to avoid a lowering of harmonization, or as we called it, downward harmonization.

Now, when the harmonization effort was originally established by FDA, it really was established for drugs primarily. The other products that FDA regulated eventually came on board through the years, but it wasn't really until the late 1990s that there was a harmonization effort for cosmetics. That effort really started -- let me go back one more time -- with what we called CHIC.

For any of you who are sort of old-timers, you will probably remember CHIC, which was Cosmetic Harmonization International Cooperation. This was started as a quadrilateral organization, or quadrilateral group, very similar to ICCR, but really it was just an exchange of information. There was no real goal or anticipation that as a result of these meetings anything more than information would be exchanged.

As a result, in 2006, which was the last CHIC

meeting, the regulators got together and said CHIC isn't really working. You know, it's nice to get together and share information, but we need to do something a little bit more proactive in the international sphere. We decided that we needed to reestablish ourselves and thought it was better to reestablish ourself with a new name rather than use the old name so that it was clear that our goal and our mission was somewhat different.

The members were the same and they included Canada, the EU, Japan, and the U.S., the Food and Drug Administration (FDA). Our mission was to form a voluntary consensus model where we would try to work on items of mutual interest. Now, notice I don't use the word "harmonization" because we all agreed in our first meeting that we could not harmonize because all four countries regulated, or all four jurisdictions regulated, their products very differently, including what they would consider cosmetics and over-the-counter drugs. As an example, many products in the United States which are regulated as over-the-counter

drugs, such as sunscreens and anti-dandruff shampoo, are regulated elsewhere in the world as cosmetics. So as a result of that, we agreed that we could not really harmonize but we would try to work on items of mutual interest and to try to partner with our trade organization to see which topics might be of mutual interest throughout all of our jurisdictions. Again the reason why we didn't harmonize is because we all agreed that we could not change any one country's regulations.

This slide is really just a quick overview of where we've been in the last 7 years or 8 years. Basically the way that it's set up is that ICCR rotates on a yearly basis. The country who has the meeting plays the role of the executive secretariat for the year prior to the meeting. They will establish the agenda, they will establish all of the teleconferences that happen during the meeting; and they are responsible for the agenda and the final meeting and posting outcomes.

As you can see, we were responsible for ICCR-6, and Japan is responsible for ICCR-7, and we have

been rotating, as I said, on a yearly basis.

The way the work process goes is that we have an annual meeting and usually quarterly telecoms. More frequent telecoms are held if needed, but at least Quarterly. As I mentioned, we rotate among the four regions. From the U.S. perspective, we advertise the Public Meeting in the Federal Register: as a Public Meeting Notice and we announce when the meetings are going to happen. We've been holding open meetings prior to each ICCR meeting. They are usually held somewhere between a month and a half to two months before the meeting, again to get any input that any of our constituents might want to offer to us, or the hosting region who chairs the meeting, and the ICCR may charter working groups. You'll hear a little bit more about them as I go through.

The first day of the meeting is the Regulators Only Meeting. During that time we get together and talk about issues that we feel really are pertinent for regulators only and may have regulatory implications. The second day we meet with industry, so

it's an Industry-Regulator Meeting. And the third day is a Regulators Only Meeting again, where we will come back, go over what we've done, prepare a press statement, and make sure that we've adopted any outcomes that need to be put on our website so that everyone can see what we've done for the meeting and what our outcomes were for the year.

About 2 years ago, we started with a stakeholder, or open session that was held on the afternoon of the second day. The first time this was done was in the EU. We did it again last year, where we invited anybody to present any input that they would like. We did have speakers who presented some information to us which we have looked at, and, in fact, you'll see that some of it has impacted on our agenda for this upcoming year. In addition to that open session last year, we decided that we would have a session where we would invite regulators from and industry from other countries who had expressed an interest in seeing how our meetings were actually held and what we do. I'll talk a little bit more about that as I go into the outcomes of

ICCR-6.

This slide shows the agenda items and their broad categories: Alternatives to Animal Testing, Nanotechnology, Trace Impurities, In Silico Prediction Models, Endocrine Disruptors, and Allergens.

With regard to alternative test methods, we agreed that we would post the white paper, which is the last bullet point, the ICCR white paper "Applicability of Animal Testing and Regulation Frameworks within ICCR Regions," and that is available on our website. We also agreed that we would get regular updates from ICATM. ICATM is the International Cooperation on Alternative Test Methods. This is a group that actually formed out of ICCR which is now housed under the umbrella of the VAMs, ECVAM and ICCVAM in particular. This was designed in a way to help us so that we would understand which tests have been validated as alternative test methods and to give us more information on a regular basis.

We all agreed that we would get updates regularly on a semi-annual basis. Our updated table is attached to the reports and would be updated on

a yearly basis so that we would all know what tests have been validated, which tests are being worked on, and what tests need to go further.

For nanotechnology, we've actually had four working groups that have been formed. We just recently posted the document on "Characterization of Nanomaterials: Insolubility, Biopersistence, and Size Measurements in Complex Media," and that's been on our website just since last month.

There is another document that will probably be posted following the ICCR-7 meeting, which is the "Safety Approaches to Nanomaterials in Cosmetics." The only reason it hasn't posted yet is that it is still being reassessed and edited, but it hopefully will be posted soon.

We have formed workgroups as needed to deal with the issues of characterization and safety of materials as they arise. When the groups have answered their particular questions, they disband and another group is formed, as needed.

One of the other areas we've been working on for the last several years has been trace impurities,

and there are two documents which are being vetted now prior to being posted. One is on lead and one is 1,4-Dioxane, and we are hoping that those two will be available sometime later this year.

With regard to endocrine disruptors, this is a new topic for us, and this was actually brought as a request from one of our stakeholders. In ICCR-5 and again in ICCR-6, we were asked to look at some of the endocrine issues and to try to deal with endocrine disruption as a result of certain chemicals that might be found in cosmetics. A workgroup is being considered to deal with this further, but we will be having more discussion again at ICCR-7.

In addition, we formed a new working group for in silico prediction models. This is in a sense another way to look at alternative tests for animal testing. This working group has been established and has been working for at least the last 4 or 5 months. We're expecting an update from them at ICCR-7 to see how we need to go forward.

Another working group was recently established on allergens. This again is to look at

ingredients that are found in cosmetics. Since every country of the four that's here assesses allergens and it has warnings separately, it's a way for us to communicate to see what data went into acceptance of different warnings and how to pick the different ingredients to evaluate.

So this slide just summarizes what I've already said. This is a thorough process. We're looking for more transparency. Not only has this meeting gotten larger, but we also have had the session on the 1-1/2 day to talk with our stakeholders to give us more information. There will be a stakeholder session in Tokyo on Day Two that is planned.

In addition to that, we also last year, as I mentioned, invited representatives. Here are the countries where we had representatives last year, which were from Australia, Brazil, People's Republic of China, the Republic of South Korea, and Saudi Arabia. For this coming year, China and Brazil will be coming back to once again observe. And this year, as opposed to last year, we asked all of the observers to come and

explain how they regulate cosmetics. This year we're actually giving specific assignments for those countries who are coming back to help to give us additional information in the areas of our interests for the ICCR-7 meeting.

As I mentioned, Japan will hold this meeting. It's scheduled from July 8th through July 10th, and it should be 2013, I don't know what happened to the "3" at the end of the first bullet, but nonetheless, not 201 but 2013. Japan has taken care of the quarterly teleconferences. So far, the tentative agenda includes Alternatives to Animal Testing with its updates, the Nanotechnology, with its updates, updates about Trace Impurities, and further assignments in impurities to look at, and In Silico Models. There will be reports from the workgroups, the first report, and New Proposed Agenda Items, which would also include allergens and the endocrine disruptors and any other items, from our last teleconference, which is to be held in June, that need input from you or input that others have had from their stakeholders.

Public Comments

DR. KATZ: So with that, I would like to thank everyone for their attention. And then we will begin with going through with our presentations.

And our first presentation will be from Aryenish Birdie, from the Physicians Committee for Responsible Medicine.

MS. BIRDIE: Okay. Well, thank you so much for coming. My name is Aryenish Birdie, and I am speaking on animal testing and situating this issue in the global context. Today I am also representing People for the Ethical Treatment of Animals, and combined we have a membership of more than 3 million people worldwide and over 10,000 physician members.

So firstly I wanted to state that we support the invitation of Brazil and China as observers. We think that this is in the best interest of the citizens in their respective countries, and we think that this is a really great step forward.

So I wanted to start and say that 2013, even though we are not even halfway through, has been a game-changing year. As most people here know, the EU

has implemented a marketing ban on animal-tested cosmetics. As of January 1st, Israel has also implemented an import and testing ban for cosmetic products as well as household products. And India and Vietnam are taking strides amongst some other countries in moving in this direction. And I think it should be noted that this movement is largely coming because the global consumer is demanding it.

In the United States, there have been two independent polls that have showed public support for a ban on animal tests. One poll conducted in 2011 found that 72 percent of Americans oppose animal testing for cosmetic products, and in that same poll, 78 percent of Americans said that they support the development of alternatives to animal testing and think it's important.

Another poll this last year came out that reinforced these values, and that poll also showed that there is global consumer confidence growing in non-animal-tested cosmetics.

So because of all of this momentum in the United States and internationally, we have a few

recommendations for FDA to take.

So firstly, we realize that testing method harmonization isn't the goal here, but we believe that it is important for agencies within ICCR to harmonize their policy approaches on animal testing to take into account similar global desires of consumers around the world.

And so with this, here are some concrete positions.

One is to not accept any new data from animal tests. We believe this is the best way to maintain consumer protection and to minimize trade barriers.

And I think it should be noted that consumers have made it clear that ethics is important to them. They don't want animals dying for their cosmetics, and this should be a driving principle.

We also think that there are some successes to be learned and shared through this process and that are currently in the movement, and so implementing alternative methods into regulatory programs and training scientists, students, and regulators is just an idea of how we can continue to propel this movement

forward.

So I wanted to just briefly highlight a case study. Many of you may know that the COSMOS Project is a 5-year project largely funded by Cosmetics Europe and the European Commission, and it's looking to find non-animal solutions to the repeated dose toxicity test, and the main aim of COSMOS is to develop freely available tools and workflows to predict the safety to humans following the use of cosmetic ingredients, and it's a public- private partnership with the FDA providing a lot of data for the computational models to be built. And so between academia and industry and regulatory agencies, we just think this is a really great example, we really support this, and we are hoping to see similar collaborations with ICCR countries in this realm. We think that FDA can really take the lead in showing how non-animal development should be moving forward.

And then on a very different note, we were talking about preparing my slides for this, and we were thinking that in order to be the most effective and to make sure that a lot of these comments don't go into a

black box, for lack of a better phrase, for us to be as effective as possible, if we could have something to react to in this type of public format, it may help increase the efficacy. We want to know how to best support you, and so we have just a couple ideas that if we could see an agenda before -- I know that it's still in process, but if that proposed agenda that you just shared was available, then we could have made some points that could help really tailor into how you want to have the meeting at ICCR.

And that's about it. We want to know how to best support you, and we really appreciate your time. Thank you.

DR. KATZ: Thank you.

We'll go on then to our next speaker, Carl Geffken, from the Independent Cosmetic Manufacturers and Distributors.

MR. GEFFKEN: Well, thank you, Linda. I appreciate the opportunity to be here and to present comments on behalf of ICMAD.

(Setting up slides.)

MS. COOK: So, Carl, you would like your

comments displayed?

MR. GEFFKEN: That's fine. They don't have to be, but I thought that was protocol.

MS. COOK: Okay. Thank you.

MR. GEFFKEN: So thank you. Just for the record. And as far as breaks and so forth, we'll do the best we can.

DR. KATZ: Everyone has a copy.

MR. GEFFKEN: I think that's probably the easiest way anyway. Thank you very much.

My name is Carl Geffken, and I represent the Independent Cosmetic Manufacturers and Distributors. ICMAD, is a nonprofit organization, industry trade association, representing over 700 mostly small to medium size companies that manufacture or distribute cosmetic products, their components, materials, and services in the United States and worldwide markets. Recently we located to Deer Park, Illinois. ICMAD was founded in 1974 in Washington, D.C., to represent entrepreneurial cosmetic businesses, and while retaining that distinction, it has become a focused resource of programs that actively support both new

startup as well as established companies.

About 90 percent of our member companies are small but highly competitive businesses that compete globally for a share in our very creative cosmetic and skin care markets.

About half of our member companies have sales below $500,000 annually, while about 10 percent of our members have sales above $10 million per year. Six percent of our members are international and represent 18 different countries, although Canada is the most prevalent.

Our members are committed to the cosmetic consumer safety and in fact all have signed an ICMAD Code of Ethics when they joined.Participating companies are increasingly global in their market strategies, and because of their smaller size and competitive challenges, they have become uniquely aware of U.S. regulations and their differences in regulatory jurisdictions worldwide. ICMAD has an active EU assistance program to specifically help comply with the unique requirements of the European Cosmetic Regulation and its associated markets.

The Association also sponsored both an annual FDA Workshop and a Cosmetic Technical-Regulatory Forum amongst its other opportunities to provide ongoing regulatory assistance and to address the many technical and safety obligations for our segment of the industry. I assure you that the Association takes all compliance responsibilities with utmost concern.

Seven years ago, the FDA invited ICMAD to participate in the ICCR process to represent small business interests within the cosmetics industry sector. We continue to support all objectives and outcomes that foster a reduction in trade barriers and a leveling of the playing field to allow both business growth and improve service to consumers. As new and more challenging questions and concerns arise, demands for consumer safety substantiation increase in relevance as does the need for reconciliation of regulatory interpretations between different international jurisdictions.

From a historical perspective, in 2008, ICMAD sponsored a comprehensive consumer survey of over 2,300 individuals to better understand cosmetic ingredient

labeling interpretations, and we provided data to support broad, 80 percent, U.S. recognition of "aqua" as a potential equivalent to the INCI term "water." Our industry continues to experience the technical and economic burden of unique labeling differences when attempting to harmonize production for international sales, especially in the Canadian market. While the outcome of this issue has not yet been favorable for us, we continue to support any and all measures to align ingredient designations and other labeling differences among major regulatory jurisdictions.

With this in mind, ICMAD has been particularly interested in those topics which foster progress for improved approaches to product safety evaluation, a unified position on potential allergen labeling, a better understanding of endocrine disruption, and the methodology to discriminate between significant and inappropriate testing.

The current interest in nanomaterial characterization and the resolution of potential product safety concerns continues to captivate the public, so we hope that joint efforts already underway

will achieve a more fruitful consensus through joint collaboration between the four regulatory jurisdictions.

Finally, ICMAD supports the benefits to be gained from common characterization of safety for cosmetic ingredients and authorized substances. This is of particular importance for trace materials, especially those that have been well studied and where safe harbor limits can be established to build consumer confidence on a purely scientific basis. Significant progress has been made in the past 2 years, and we are hopeful that outcomes can be published soon and even further progress achieved on additional materials during ICCR-7.

The ICCR process has achieved some clear success in its support and recognition of the ISO 22716 Standard for Cosmetic Good Manufacturing Practice. This success alone has demonstrated the benefit of collaborative discussions where experience is shared between industry and the regulators to meet and resolve a longstanding void. Compliance with GMP is a basic foundation for manufacturing and helps to assure

product safety and trust for our consumers worldwide. We hope that all four regulatory jurisdictions will soon be in a position to jointly publish recognition of this minimum expectation for basic GMP compliance.

In conclusion, ICMAD is committed to continued participation and support of the ICCR process, and we look forward to the upcoming ICCR-7 Industry Caucus during the joint meeting of regulators in Japan. ICMAD is also on record in its support for an open process, timely publication of official ICCR outcomes, and a wider international outreach to include new jurisdictions where market significance and broader engagement would be beneficial on that global basis.

Thank you for the opportunity to provide comments today during this FDA public hearing, and thank you for your attention.

DR. KATZ: Thank you, Carl.

Our next speaker is Francine Lamoriello, from the Personal Care Products Council.

MS. LAMORIELLO: Thank you, Linda.

Good afternoon, everyone. My name is Francine Lamoriello, and I am Executive Vice President

of Global Strategies for the Personal Care Products Council. Thank you for the invitation to join you this afternoon.

On behalf of our industry, I am pleased to once again take this opportunity to emphasize our industry's support for the ICCR process. We would like to express appreciation to FDA and the other participating regulators from Europe, Japan, and Canada for their participation and support of the ICCR process. We believe the ICCR has been a beneficial forum for the exchange of information and regulatory alignment between important markets for cosmetics and personal care products.

The Personal Care Products Council is the leading national trade association representing the global cosmetic and personal care products industry. Founded in 1894, our more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the United States.

Our members represent some of the most well-known and trusted brands and product categories in the

world. We also represent many medium and smaller sized companies as part of our membership. In fact, two-thirds of Council member companies have annual sales of under $5 million.

For more than 100 years, regulators and policymakers have relied on our organization to deliver honest, credible, and accurate scientific and technical information about cosmetics and personal care products. We take this responsibility very seriously, and we are pleased to represent our industry in the International Cooperation on Cosmetics Regulation.

The cosmetics and personal care products industry is a truly global industry, dependent on open markets and transparent, consistent regulatory environments around the world. Our member companies continually strive to uphold and surpass the most stringent standards and regulatory processes worldwide and to provide consumers with safe, innovative, and high quality cosmetic and personal care products, the ingredients for which are globally sourced.

International trade is a critical component to the success of our industry, and significantly

contributes to our ability to expand manufacturing and employment, as well as to support other industries such as advertising, packaging, and transportation. The globalization of our industry promotes continual technological innovation, which contributes significantly to the application of scientific advancements and benefits consumers around the world. For all of these reasons, the Personal Care Products Council is actively engaged in international efforts to align global regulatory standards for consumer products, to eliminate trade barriers, and to ensure a level playing field for our member companies while at the same time reinforcing consumer confidence in product safety. Initiatives such as the Trans-Pacific Partnership, the proposed Transatlantic Trade and Investment Partnership, and other international trade, regulatory fora, and scientific exchanges support these objectives.

The stated mission of ICCR, "to maintain the highest level of global consumer protection, while minimizing barriers to international trade," underscores the important role of FDA and other

regulators in a global environment.

We believe that the ICCR can serve as an important forum for alignment of regulations, policies, and guidelines affecting our industry and as a source for other countries looking to model their regulatory approaches around such common guidelines.

As the ICCR is now completing its seventh cycle, it is important to acknowledge the important decisions that have been taken by regulators in the process already, including support for a common standard for cosmetic Good Manufacturing Practices; a common definition of nanotechnology as it pertains to cosmetic products; principles of cosmetic products safety assessment; and promotion of validated methods for alternatives to animal testing.

We believe the ICCR has an especially important role in considering common science-based policies for the treatment of trace substances which can sometimes be found in cosmetic products and ingredients, many of them arising from natural sources.

For example, over the past several years, the ICCR Traces Working Group, which consists of scientists

and regulatory experts from the four ICCR jurisdictions, including regulators, recommended Principles of Handling Trace Materials, and this was endorsed by the ICCR.The ICCR Traces Working Group has also developed recommendations for the management of lead in cosmetics and 1,4-Dioxane, and this past year have been working on recommendations regarding trace levels of mercury, which will be presented to the ICCR-7 meeting in Tokyo in July.

The acceptance of an aligned position in the areas of traces helps to ensure the application of sound science, both within ICCR as well as non-ICCR members, that is useful for both regulatory authorities and the global industry. Therefore, we hope that the ICCR regulators will endorse these and the other ICCR recommendations and implement all ICCR decisions as guidances or other regulatory measures as appropriate.

The invitation to six other countries to participate in last year's "Global Regulators Forum," hosted by the FDA, was an important step in including other partners in the global regulatory alignment effort.

Our industry fully supports the formal expansion of ICCR to countries such as China, Brazil, Korea, Australia, and other interested countries that would both contribute and benefit from this important work.

We understand that the expansion of ICCR to other members means that our efforts must become even more efficient and that the ICCR processes and procedures become even more effective. We look forward to working with FDA and other regulators to enhance the ICCR process in the months and years ahead.

Thank you very much.

DR. KATZ: Thank you.

Our next speaker is Dr. Nick Palmer, from Cruelty Free International.

DR. PALMER: Thank you. Thank you very much. I am very grateful to the Food and Drug Administration for organizing this event and letting us take part, and to everyone here for their interest.

I am very aware of the limited time, so just very briefly an introduction on Cruelty Free International. Some of you may not know it's the

leading organization focused specifically on the ending of animal testing for product testing on a global basis, and that's focused initially on cosmetics. We hope later on to move to other household products.

MS. COOK: I think we're going to have to do this manually for you because it's not the usual format for PowerPoint.

DR. PALMER: Okay. It's working now. I just pressed it too hard. It was a bit more sensitive than I realized.

We have offices in Boston, London, Singapore, and we have partnerships with organizations in all the major cosmetic markets, specifically India, Korea, Vietnam, Brazil, and Australasia. Because of the time limit, I won't go through the individual country positions, but if there is anyone interested here in them, I'm happy to talk after the meeting.

So the European Union, as you'll be aware, has recently introduced a ban on animal testing for cosmetic purposes. This slide is perhaps interesting as it shows the process that took place. Way back in 2004, the European Union banned all finished product

testing for cosmetics on animals, and during 2004 to 2009 they had the rolling process of phasing out animal testing on ingredients as soon as alternatives were validated.

In 2009, there was a ban on the testing of ingredients within the European Union but not yet for imports, and this year the process was completed with a ban on imports on cosmetic ingredients or products which had been tested primarily for the purpose of animals (sic) -- primarily for the purpose of cosmetics.

Now, we'll skip a couple of national pictures and come specifically to the issues that arise. Now, Cruelty Free International would obviously be delighted, and so I think would many of the others here, if there was simply a decision at the ICCR that all of the participating members wanted to move towards the same kind of global ban. Realistically, we realize that isn't going to happen, and we wanted to focus honestly on the three issues which come up all the time when the ban is discussed.

The first is the interaction with REACH and

with other testing environments. What is a company supposed to do if it's got an ingredient which is used both in cosmetics and for other purposes? In some cases, the manufacturer may not even know initially whether its main market is cosmetics or something else. And there are various positions on this. The one on the left is what we would like, which says if the ingredient has been tested on animals, you can't use it for cosmetics. The middle position would be that you cannot use the animal tests to prove safety, but you can do other tests to prove safety. So the fact that you've done animal tests doesn't actually rule it out. And then the third position would simply be if you've done the test, you can use the data so long as you've initially done it due to some separate testing regime. The European Commission position, somewhere between Number 1 and Number 2, that products cannot be marketed if their ingredient has been tested primarily for cosmetic purposes.

The second issue, innovation. One of the concerns of industry, we understand, is that the introduction of the ban could impede the introduction

of exciting new ingredients which would develop the market. We understand with Cosmetics Europe only 3 to 5 percent of new cosmetics each year actually have new ingredients, so that just sets the proportions, and a significant number of those have already been proved safe by using non-animal methods or under alternative testing regimes like REACH.

The balance we struck here is between the consumer demand, which all over the world reflects the same wish to move away from animal testing that was referred to in the first presentation, with the need for innovation, which is very important to the industry. And I think it's fair to say in Europe the drive for non- animal alternatives are very much spurred by the impeding ban. Industry just felt, well, if we're going to have this ban, we better get on with it, and I've spoken to many of the leading figures in industry, and they acknowledge that was a major factor. Ultimately, we do have here a political decision, how far are we willing to respond to consumers who are particularly concerned about animal testing?

The third problem is China. That industry

has at least superficially a real dilemma here. If they want to sell something in China, they know the product will be tested on animals, and if they want to sell it in Europe, they can't test it on animals. So what are they supposed to do? China is aware of the issue because they won't be able to export to Europe ultimately, they don't want to be pushed around and told what to do, but they are moving, they've got the draft guideline on the 3T3 NRU alternative validation. They're working intensely with IIVS, I see Dr. Brian Jones back in the room here, spends I think much of his time in China instead of with his wife, and she appreciates the sacrifice I hope, and there is I understand a 5-year plan to introduce most of the OECD Test Guidelines for Alternatives to Animal Testing, and intensive training programs are underway. And China's industry is concerned about the potential impacts on future export ambitions, so they are moving also in this direction.

Now, I'll skip the science bits because I'm again happy to talk again after the meeting with anyone interested.

Our message really for the ICCR is in the light of this tremendous movement across the globe and the concern about animal testing, which is visible among consumers in each country, it would be very helpful both to consumers and to industry if there was some kind of roadmap, so even if they're not going to implement this ban right away, in the same way as in Europe, people could see the dimensions, they're moving in that direction, what the likely time scale was. If industry knows that, it will shape the development of alternatives, and if consumers know it, they will see that the regulatory bodies are responding to their concerns.

And specifically there are three issues which we hope the meeting in July will look at.

Firstly, is there any reason at all to allow animal testing on finished products? It has practically died out. It hasn't happened in Europe for nearly 10 years now. Most of the companies that we talk to say that they really don't have an interest in doing this, they don't feel it's necessary for safety, and they would be quite happy to live with a ban on

animal testing of finished products, and that would probably -- because not much is going on, the actual number of animal tests reduced that way would be pretty limited, but it would show the regulators responding to consumers by actually putting a stop to that.

The second point would be even if we can't do it overnight, can a deadline be set when the regulators expect to end all their animal testing for cosmetic purposes so that industry has both a target but also certainty? So it's just important to industry to know where they stand.

And thirdly, where an alternative has been validated either in the U.S. or in Japan or in Canada, shouldn't the regulators say that the animal tests for that particular endpoint should end immediately? Because it just makes life difficult for industry if they've got this uncertainty of when they are going to be required to phase the things out, and if the alternative is available, they would like the confidence that it would be accepted in all the regulatory regions, and it's reasonable then again as a response to consumers, the alternative is there, it's

no longer necessary to do the animal tests, shouldn't the regulators then say, all right, it's time to stop?

Contact details right at the back. I'm here until tomorrow evening. I'm happy to talk with anyone interested. And otherwise, please get in touch. Thank you for listening.

DR. KATZ: Thank you.

And our final speaker is Annie Ugurlayan, from the National Advertising Division.

MS. UGURLAYAN: Good afternoon. Thank you to the FDA for the opportunity to participate in today's public hearing. My name is Annie Ugurlayan, and I am a senior staff attorney at the National Advertising Division. The National Advertising Division is the investigative arm of the Advertising Self-Regulatory Council, or the ASRC, and is administered by the Council of Better Business Bureaus.

The ASRC establishes the policies and procedures for advertising industry self-regulation, including the NAD, the Children's Advertising Review Unit, the National Advertising Review Board, the Electronic Retailing Self- Regulation Program, and the

Online Interest-Based Advertising Accountability Program.

The NAD monitors and evaluates truth and accuracy in national advertising in any medium, whether directed to consumers ages 12 and over, businesses, or other service professionals.The NAD initiates cases as a result of its own monitoring in response to formal competitor complaints filed through a "challenge" process and from consumer complaints and complaints by the local Better Business Bureaus.

Although the NAD's self-monitoring efforts are limited due to resource constraints, most cases are initiated by competitors, it routinely monitors advertising. The review process, though voluntary and informal, follows a detailed set of procedures available on NAD's website. All decisions are made public. The failure to participate in the NAD process or failure to implement NAD-recommended changes at the conclusion of the process results in automatic public referral to the appropriate federal or state regulatory agency. As discussed below, cosmetics advertising has been an important area of focus in NAD's self-

monitoring efforts, and the NAD issues approximately five decisions involving cosmetic products each year.

The benefits of effective self-regulation are manifold, from speedily resolving complaints, to creating high standards of truth and accuracy, to increasing public trust in the credibility of advertising, to enabling consumers to make better purchasing decisions, and to the promotion of fair competition. Government regulators, such as the Federal Trade Commission and the states attorneys general, can, as a result, devote their limited resources to investigate advertisers who deliberately engage in deception or endanger the health, safety, or financial well-being of the public. The self-regulatory system is bolstered by the long-time support of the FTC.

For cosmetics advertising featuring anti-aging claims, nearly all of the cases are self-initiated, or monitoring, cases. NAD has reviewed over 50 cosmetics cases since 1987, and more than 60 percent of those cases occurred within the last 10 years. During this time, some manufacturers have made very

strong performance claims promising dramatic reductions in wrinkles and other unwanted signs of aging, and in other instances posturing their products as equivalent to, or substitutes for, surgical procedures. Attached is our Cosmetics Case Digest, which provides summaries of our cases over the last 3 years.

NAD decisions have provided guidance to cosmetics advertisers on a variety of issues including, but not limited to, the following: to avoid likening the results obtained by topical cosmetics products to invasive medical procedures; to avoid overstating the efficacy of their cosmetics products by ensuring that all messages reasonably conveyed by the advertisement, which may be different from the messages that the advertiser intended to convey, are properly supported by competent and reliable scientific testing that elicits statistically significant and consumer meaningful results; ensuring that performance claims based on self- assessments from consumer use testing mirror the wording of the specific questions upon which the claims are based to avoid overstating product performance; advising that in the absence of testing on

the actual product, claims about the benefits of certain ingredients may be appropriate provided there are reliable studies that link the ingredient to a claimed product benefit, that the amount tested was the same amount as is found in the product, and that the claims accurately reflect the studies' results; to ensure that photographs and product demonstrations which depict product performance accurately reflect what consumers can reasonably expect to achieve when using the product as directed; and finally, to advise that disclosures cannot cure an otherwise inaccurate claim, but they can be appropriate in instances where the claim is accurate provided they are clear, conspicuous and in close proximity to the claims they are qualifying.

"Natural" and "organic" claims are increasingly prevalent in cosmetics advertising in response to increased consumer demand for such products. When evaluating such claims, NAD will, as always, look at the challenged claims in the context of the advertising at issue to determine the messages that are conveyed. In the absence of any defined standard

by the FDA of "natural" or "organic," NAD considers industry usage, consumer expectation, and any testing or other scientific evidence that relate to the source and the amount of each ingredient in the product. NAD tries, whenever possible, to harmonize its decisions with any relevant regulatory authority, but in the absence of regulatory guidance, seeks to ensure that these terms are used consistently with consumer understanding.

In conclusion, NAD's goal in its cosmetics cases is to ensure that advertising claims are truthful, accurate, and substantiated by competent and reliable evidence before they are disseminated. Cosmetics advertising claims have been an active and important part of NAD's monitoring efforts and will be a continued focus in the future. This product area has evolved enormously over the years, and NAD's decisions seek to ensure that claims about a product mirror the testing conducted on the product. Because under its procedures the NAD can receive both the views of the advertiser and the challenger to assist review of the substantiation offered in support of an advertising

claim, NAD has encouraged increased competitor challenges in this product area. The more information NAD has about the underlying science, the more informed decisions it can make. The NAD process upholds standards that enhance the credibility of brands, encourages product innovation, and improves consumer confidence in advertising.

It is our hope that the ICCR meeting will consider the important role of advertising self-regulation in the area of cosmetics and that its determinations will advance the mission of advertising self-regulation especially by encouraging cosmetic industry support and participation in self-regulation as an important complement to FDA oversight. This will help ensure that consumers receive truthful and accurate advertising messages.

Thank you.

DR. KATZ: Thank you.

Adjourn

DR. KATZ: And with that, we have reached the end of our meeting at this point in time since there were no other requests to speak during the

timeframe that we were accepting speakers. So with that, I would like to thank everyone for coming. If you have any additional information that you would like to make sure that reaches us before the ICCR meeting in July, feel free to contact me directly or Rosemary Cook. Her contact information was available on the Federal Register Notice, and we will be glad to take that information along with us to the meeting.

Thank you very much for coming.

(Whereupon, at 3:02 p.m., the ICCR Public Meeting was adjourned.)

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I, NATALIA THOMAS, the Court Reporter before whom the foregoing proceeding was taken, do hereby certify that the proceeding was recorded by me; that the proceeding was thereafter reduced to typewriting under my direction; that said transcript is a true and accurate record of the proceeding; that I am neither related to nor employed by any of the parties to this proceeding; and, further, that I have no financial interest in this proceeding.

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