FOOD AND DRUG ADMINISTRATION

Good Manufacturing Practices for Cosmetic Products

Listening Session

DATE TAKEN: June 1st, 2023

TIME: 10:00 a.m. - 2:45 p.m.

PLACE: Via Zoom videoconference

NOTARY PUBLIC: Julianna Buser, Notary Public
State of Connecticut

A P P E A R A N C E S

Food and Drug Administration (FDA)

Dayle Lewis Cristinzio,

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Namandjé N. Bumpus,

Ph.D., Chief Scientist, FDA

DIRECTOR OFFICE OF COSMETICS AND COLORS, FDA

Linda M. Katz, M.D., M.P.H.

Open Public Comments:

Selina N Medina, Association of Food and Drug Officials (AFDO), SC

Veronica Ibarra, Cyan Labs S.A. de C.V., Mexico

Roger Larrauri Mora, Cosmetic Colors Schwan Cosmetics, Mexico

Nelson Webb, Procter & Gamble, OH

Steve Colwell, Empack Spraytech Inc., Canada

Lisa Wiseman, Port Jervis Laboratories, Inc., NY

Timothy King, Henkel, AZ

Sean Brown, Eternal Ink, LLC, CA

Don Frey, Independent Beauty Association, CA

A P P E A R A N C E S (CONT)

Shahn Anderson, Alliance of Professional Tattooists, MN

Allyn Shultis, Global Retailer & Manufacturer Alliance, Inc. (GRMA), PA

Gerald Renner, Cosmetics Europe - The Personal Care Association, Belgium

Leigh O'Donnell, The Handcrafted Soap & Cosmetic Guild, Inc., NY

Vivian Valenty, VB Cosmetics, Inc., AZ

Cynthia Johnson, Cindy J Cosmetic Labs, MD

Darlene Story, Lasting Impression, NJ

Anne-Marie Faiola, Bramble Berry, WA

Jamshaid Akbar Bhatti, SK JAMAL Private Limited, Pakistan

Todd MacLaughlan, Profounda Inc, FL

Jen Lee, Beautycounter, CA

Lillian Zhou, EWG, Washington, DC

Amira Adawe, The Beautywell Project, MN

Sudhir Sawarkar, Freyrs Solutions General Trading LLC, Dubai, United Arab Emirates

David Schmidt, AOAC International, MD

Linda Reinstein, Asbestos Disease Awareness Organization (ADAO), CA

Phoebe Fu, Reach24h Consulting Group China, China

A P P E A R A N C E S (CONT)

Dee Mashiah, The University of the District of Columbia, Washington DC

Craig Weiss, CPT Labs, NJ

Doug Farquhar, National Environmental Health Association (NEHA), CO

Danielle Palermo, Humane Society Legislative Fund, Washington DC

Donna Johnson, Indie Business Network, SC

Michael Pfeiffer, Pfeiffer Consulting GmbH + LLC, Germany

John Bailey, EAS Consulting Group, VA

Christopher Ho, Loreal, NJ

Don Ye, Estee Lauder Companies, NY

Tim Parrent, Mary Kay Inc., TX

Geoff Waby, Obelis USA LLC, OH

Caroline Bassoni, Cosmed Association, France

Alexandra Kowcz, Personal Care Products Council (PCPC), Washington, DC

Iain Moore, European Federation for Cosmetic Ingredients, Belgium

Brandi Reinbold, NSF International, MI

Matteo Zanotti Russo, Angel Consulting, PA

Megan Cox, Genie Supply, IN

Barbara Gant, Beauty of Holiness International, GA

A P P E A R A N C E S (CONT)

Katherine Montgomery, Forma Brands, NJ

Jodi Zimmerman, Smith & Nephew, TX

Robbie Walters, SoapEquipment.com, IN

P R O C E E D I N G S

MS. CRISTINZIO: Good morning. I see we've got a large group of people joining the webinar.

I'm Dayle Cristinzio, and I'm from the office of external affairs at FDA, and I will be moderating today's meeting.

Welcome to FDA's Good Manufacturing Practices for Cosmetic Products Listening Session.

Before we begin today's program, I want to go over a few housekeeping items. After opening remarks from FDA, we will proceed to several public comment segments. Presenters should follow slides to determine where we are in the speaking program.

This is a large public meeting, and we have made every effort to make sure it runs smoothly. However, unexpected issues do happen electronically, and so if they do, please bear with us as we will correct them as quickly as possible.

It is important to note that we made every effort to accommodate as many --

UNIDENTIFIED SPEAKER: He's trying to connect the conference room, but I'll take over.

MS. CRISTINZIO: Okay.

UNIDENTIFIED SPEAKER: My apologies. Okay, you can go

on. My apologies.

MS. CRISTINZIO: No problem.

It is important to note that we made every effort to accommodate as many attendees and public comments as possible. We have over 2,300 attendees on this webinar and have nearly 90 public speakers.

The transcript will be made available in the next few weeks in the docket and also this -- this is being recorded.

During this webinar all microphones, except for the presenters and my microphone, will be disabled, and the chat function will also be disabled.

At the appropriate time I'll introduce each speaker so that they can begin their presentations.

For the presenters, I remind you to please state your name and affiliation at the beginning of your presentation. I will not begin the three-minute timer until you have given your personal introduction, and then I ask you to honor your time limit to three minutes.

Slide presentations have been pre-loaded into this meeting slide deck. Please speak clearly and succinctly. You will let me know when to forward your slides as FDA will control the slides.

I also remind you to speak clearly and

succinctly -- sorry about that -- not only so you can be heard by others, but this also helps us in our ability to capture the appropriate transcript in an accurate manner. It also allows others to hear your presentation clearly.

I would also ask that each presenter submit their slides to the docket on your behalf rather than FDA's behalf. This completes the docket and allows you to have the input for the public comment.

I'd now like to turn today's program over to Dr. Namandje Bumpus, FDA's chief scientist for opening remarks.

DR. BUMPUS: Thank you Dayle for the overview, and thank you to all of you for joining us today on the Good Manufacturing Practices for Cosmetics Products listening session.

With the passage of the Modernization of Cosmetics Regulation Act of 2022, the FDA now has expanded authorities regarding cosmetics products. As part of this, we are to develop regulations to establish good manufacturing practices, or GMPs, for facilities that manufacture or process cosmetics.

Our GMP requirements will be intended to protect the public health and ensure cosmetic products are not adulterated.

It is imperative for us to hear from a broad group of experts including manufacturers, consumer organizations, and small cosmetics businesses to help inform our development of GMPs. So, we are thrilled to have you with us today.

In addition to our speakers from the United States, we have speakers from over ten countries joining us to provide insight on their relevant practices. By participating in today's listening session, you're helping us to continue our global dialog on FDA regulatory missions. Engagements with subject matter experts like yourselves help the FDA further our public health mission.

In a moment my colleague, Dr. Linda Katz, will give you more in-depth information on cosmetics GMPs.

We look forward to hearing your comments and thank you sincerely for being here today.

DR. KATZ: Welcome, and good morning again.

Today's listening session is regarding the Cosmetic good Manufacturing Practices. My next few sides will highlight the purpose of today's meeting and focus on the issues that will be addressed.

Next slide. As everyone knows, FDA's mission is to protect and promote the public health. The

purpose of today's meeting is a listening session to consult cosmetic manufacturers including smaller businesses, and contract manufacturers, consumer organizations, and other experts to inform the agency efforts to develop regulations to establish good manufacturing practices for facilities that manufacturer or process cosmetic products distributed in the United States.

Next slide. The Modernization of Cosmetics Regulation Act of 2022, or MoCRA, requires FDA to establish regulations on good manufacturing practices that are consistent to the extent practicable and appropriate with national and international standards. It also is to take into account the size and scope of a business, as well as the public health risks of cosmetics and to provide flexibility.

The deadlines that are listed as statutory dates for the proposed rule are by December 29th, 2024, and for the final rule by December 29, 2025.

Next slide. There are certain exemptions, and MoCRA does exempt certain small businesses; that is, a business with an average gross annual sales for the previous three-year period of less than $1 Million dollars from GMPs. Such exemptions, however, do not apply to the

manufacturers or facilities that manufacture the following cosmetic products: Products that regularly come into contact with the mucus membrane of the eye under customary or usual conditions of use. Products that are injected. Products that are intended for internal use, and products that are intended to alter the appearance for more than 24 hours under customary or usual conditions of use, and removal by the consumer is not part of such use.

Exemptions also exist for certain products and facilities that are subject to requirements for drugs and devices.

Next slide. In the next several slides I will talk about the topics for comment, and these are topics specifically that we're interested in related to good manufacturing practices.

First, identify any national or international standard; for example, International Organization for Standardization, ISO standard 22716:2007 and to the extent to which it would be practical for good manufacturing practice regulations for cosmetic products to be consistent with such standard.

Please include whether there are specific items in the standard, which are perceived to be

burdensome, or for which a less burdensome alternative exists that would protect the public health and ensure that cosmetic products are not adulterated.

Next slide. In addition, we're interested in hearing you describe what constitutes sufficient flexibility within good manufacturing practices for cosmetic products to ensure regulations are practical for all sizes and types of facilities. Again, taking into account the size and scope of the businesses engaged in the manufacture of cosmetic products and the risks to public health posed by cosmetic products.

Next slide. In addition, we are interested in having described what constitutes simplified good manufacturing practices requirements for cosmetic products for smaller businesses to ensure regulations do not impose undue economic hardship.

Also, describe appropriate compliance times for good manufacturing practice regulations.

Next slide. An additional topic is to what extent manufacturers of cosmetic products are already following a national or international standard for good manufacturing practices.

For manufacturers of cosmetic products that are

not currently following such a national or international standard, what would it cost to implement good manufacturing practices consistent with such a standard.

Next slide. In addition, provide reports or examples of adverse events or recalls associated with a cosmetic product that were linked to manufacturing practices. How would implementing good manufacturing practices impact the likelihood of a recall of cosmetic products? How would implementing good manufacturing practices impact the likelihood of consumers experiencing events from the use of cosmetic products, and how would these impacts differ by type of cosmetic products.

And now I will turn it over to our moderator to begin today's session.

MS. CRISTINZIO: Thank you so much, Dr. Katz, and Dr. Bumpus.

We are now going to move into our public comments segment. If a speaker is not present at the time that I call on them, I will try again to call on them at the end of each segment. And as a reminder, we encourage all presenters to submit your comments to the docket and to please be mindful of your three minute time limit.

Now, I'd like to introduce our first speaker who is Selina Medina from the Association of Food & Drug officials. Selina.

MS. MEDINA: Good morning. My name is Selina. Unfortunately, there was an error on my behalf when I signed up, and it was not for AFDO, but this is for speaking on behalf of my industry as an informed expert and a practitioner of tattooing for the last 22 years.

In the last eight years I've been involved with efforts of compliance, and we appreciate the efforts that the administration has done in order to unify and harmonize global standards.

There have been multiple nonprofit groups, foreign and domestic that have been putting a lot of effort into organizing and harmonizing standards for global safety efforts and human health impact.

We're excited from the tattoo industry to see that our industry is now being recognized as a prospective trade, but also as a profession.

We look forward to seeing cooperation with FDA in further industry efforts as we step forward into the future with the legitimization of the craft of tattooing. This concludes my statement.

MS. CRISTINZIO: Thank you so much, Selina.

Our next speaker is Sean Santiago from Developlus. Sean, are you -- are you with us?

Okay, it doesn't appear that Sean is ready to speak.

I'm going to move on to our next speaker and come back to him at the end.

Our next speaker is Chandelle Hermes and/or Victor Alonso from Bausch Health.

Not hearing anything from Chandelle or Victor -- it is early in the morning.

I'm going to move on to our next presenter. Sonu Panwar from Dabur India Limited.

Sonu.

Okay. Sonu, I believe you've been unmuted. Let's give Sonu another minute or so to try and figure this out.

Sonu, are you available to speak?

Okay. I'm going to move on and come back to Sonu at the end of the segment.

Next, we have on the docket for presentation is Veronica Ibarra from Cyan Labs.

MS. IBARRA: Good morning.

MS. CRISTINZIO: Good morning.

MS. IBARRA: Good morning, everyone. My name

is Veronica Ibarra I'm from Cyan Labs. Cyan Labs is a chemistry industry company based in Mexico -- Montara, Mexico and we are now a private label manufacture of skin care products. Some of those are cosmetics, some of those are holistic products. Should I do my question now?

MS. CRISTINZIO: Yes.

MS. IBARRA: Okay. Well, we are interested first to know when it will be ready -- the platform published to register for cosmetics. We -- right now we have this publishment number for us, OTC products for those services, manufactures. And when will the information -- well, we know that the day is December 19, this year, to register, but we do not know when the platform will be available.

The second question that I have is: When will it be published this year -- 21. With the difference now between cosmetics and OTC products. I mean, we have the CFR 21 with the actual one, the last one published, but will you let us know when it will be published; with the new information making this difference.

And, finally, we have read the MoCRA information that is available up to right now. And

if we are not manufacturing some products for some of the customers in U.S., but we are going to manufacture them six or eight months later, shall we also register right now for those ones or not?

Those will be our three questions.

MS. CRISTINZIO: Great, thank you so much, Veronica.

MS. IBARRA: Thank you.

MS. CRISTINZIO: Before we move on to our next speaker, I think we're having some technical issues recognizing names. I'm using the list of people who registered officially to call on people. If your Zoom name is not the same name as you registered with, our AV staff is not going to be able to recognize you and unmute you. So please take a minute to check to see that your name is correct. And you can do that by clicking on the participants button at the bottom of your window and clicking on your -- your icon or you're -- the double dot next to your name to change your name.

I'd now like to move to our next speaker. We have Roger Mora. Roger is from Cosmetic Colors. Roger, are you there?

MR. LARRAURI MORA: Can you hear me?

MS. CRISTINZIO: Yes. Thank you. Please proceed, Roger.

MR. LARRAURI MORA: Can you hear me?

MS. CRISTINZIO: Yes. We can hear you.

MR. LARRAURI MORA: Okay, thank you. My name is Ray Larrauri, I work in Cosmetic Colors. So the question is that -- for example, the company has been working with the ISO 22716, and we also have a registered VCRP for the FDA, voluntary register. And as well in Mexico, we have a couple of prices that were -- main health administering here in Mexico that they follow us, the GMP sold it.

So my comment is that all the companies have this certification for many years. This company has to be registered without problems. So MoCRA, I think, is a very good process to do it, but I think this will not -- let's say the problems to register. So the point is they have to to see if the company has all these registers, the company has to be very easy to registers. So --

MS. CRISTINZIO: We appear to be having some audio difficulties.

Roger, are you still there?

Roger, you are -- we are not able to hear you.

Okay, I'm going to --

MR. LARRAURI MORA: Yeah, can you hear me?

MS. CRISTINZIO: Yes, we can hear you now. Please proceed.

Roger, are you there?

Okay, I'm going to move on. Please be sure to submit your full comments to the docket. And I'm -- I really apologize for the technological problems.

I'd like to move on to our next speaker who is Diana Goana from BIOETICOS SAS.

Diana, are you present?

Okay, I'm going to move on to the next person.

Speaker number eight, Edwin Rios Arango from Laboratorio Naturex. Edwin.

Again, I'd like to make sure all of you have the correct name on the participant list so that our tech team can unmute you for your presentation.

Okay, I'm going to move on to our next speaker Nelson Webb from Proctor & Gamble. Nelson.

MR. WEBB: Hello, can you hear me?

MS. CRISTINZIO: Yes, thank you.

MR. WEBB: All right. Good morning. My name is Nelson Webb. I've been with Proctor & Gamble for 36 years, and today I'll be sharing my personal experiences working with FDA and industry.

As Procter & Gamble's QA external engagement leader, my job is collaboration. Everyday I have the opportunity to work with industry QA peers via associations such as the personal care products counsel and others. Whether commenting on draft guidance, or hosting conferences and webinars these interactions are critical to get industry and regulators on the same page.

Over the past few years I've had the opportunity to work with FDA officer -- office of surveillance on the quality metrics and quality management maturity programs.

Yes, those programs are for drugs, however, I believe we can learn from a couple of great examples of FDA and industry collaboration with those programs.

For quality metrics, my company participated in the FDA site visit program. This full day onsite experience at one of our manufacturing plants was a great vehicle to understand program objectives and for the office of surveillance to see our current oversight programs.

During the visit, we were able to roll up our sleeves and discuss which measures would be most valuable or least valuable, as well as understand

potential burden to industry.

We spent time discussing challenges with the data input portal and a path to improve the practical use of that tool.

I believe these numerous site visits also help to clear the industry to the office surveillance, the breadth of product types and manufacturing scenarios in the industry.

Moving on to quality management maturity. My company was one of seven firms participating in the finished dosage form QMM pilot program.

Once again, the office of surveillance engaged firms early in the planning of the pilot program and the assessments. Participating firms were encouraged to work together to interpret and provide feedback on the assessment tool and the process.

FDA, hosted a review after the pilot to gather feedback and a very open discussion and has continued to invite industry feedback via programs such as SBI workshops and targeted listening sessions with industry to understand the program benefits and objectives.

In fact, I have another one of those listening sessions this afternoon after the MoCRA Session.

The office of surveillance has also made

themselves available at numerable conferences and public forums to speak and answer questions on both quality metrics and quality management maturity.

I appreciate the efforts of the FDA MoCRA team to date and the office of chief scientist to openly communicate with industry.

I believe this continued collaboration will result in a GMP end product which delivers on consumer safety and confidence in a meaningful and systemic way.

In closing, I encourage you to consider further collaboration as I've discussed: Site visits, pilot programs, working sessions, engagement at industry conferences and more excellent events such as today's program are critical as we work together to shape the future of cosmetic good manufacturing practices. Thank you.

MS. CRISTINZIO: Thank you so much, Nelson.

Our next speaker is Steve Colwell from Empack Spraytech. Steve.

MR. COLWELL: Good morning. Can you hear me?

MS. CRISTINZIO: Yes.

MR. COLWELL: Thank you. Welcome.

First off, I'd like to thank the FDA for the opportunity to speak on behalf of my company. We

are a Canadian private label/contract manufacturer of cosmetics, consumer goods, and OTC topical products.

I would like to again build on questions that Veronica had submitted earlier from -- I'm sorry, I do not have her last name. But building upon her questions earlier.

I'm specifically today wanting to log questions regarding the information collection and how the registration process will go for a contract manufacturer, especially a foreign one, who is a contract manufacturer for multiple U.S. clients. i.e, we have one facility and we manufacture for many different U.S. cosmetic clients. The program so far we have seen is a registration of the products back to one facility; however, we are one facility manufacturing for multiple parties. And how that cost-linking can be done has not been demonstrated to us yet at this point.

As well Veronica had noted that we are also similarly, as a Canadian manufacturer, an FEI registered facility, for OTC products.

Again, so we are already in the FDA system as an OTC manufacturer. And furthermore, whether the cross-linking back in the cosmetic program and touch

base with the OTC program to have one registration number system, you know, facilitate that. Again, looking for the expanded language and logistics to do this process of the registration.

Again, I'd like to thank the FDA for the opportunity for presenting, and can -- just like to commend Nelson for the message he had as well.

Thank you, and good morning.

MS. CRISTINZIO: Thank you so much, Steve.

I'd like to turn to our next presenter Lisa Wiseman from Port Jervis Laboratories. Lisa.

MS. WISEMAN: Can you hear me?

MS. CRISTINZIO: Yes.

MS. WISEMAN: Hello, my name is Lisa Wiseman. I'm the senior manager of product integrity at Port Jervis Laboratories.

We are a New York facility that is a registered drug establishment and a contract manufacturer of both OTC and cosmetic products.

In general, our firm is highly supportive of actions which protect consumer safety through an established set of standards, which product owners and manufacturers would be expected to meet.

I would like to provide my view of how FDA could efficiently and effectively confirm the

ability for an international cosmetic manufacturer such as ourselves to meet acceptable standards of GMP performance.

Our site is audited to the ISO 22716:2007 standard through an accredited body. In this, I am familiar with the rigor of this certification process.

I would, therefore, suggest that this is an existing external assessment that FDA could leverage as a conditional requirement for a manufacturer of cosmetic products rather than the FDA having to perform their own audits, which would be a significant resource drain on the agency.

Also, since the ISO 22716:2007 standard is internationally recognized, this would be logical for the evaluation of sites like mine, which manufacture for both domestic and overseas markets.

I want to thank the FDA for providing the venue for soliciting input into this important matter. Thank you.

MS. CRISTINZIO: Thank you so much, Lisa.

Our next speaker is Paola Fantappie Dall'Orto. Sorry for the bad pronunciation.

Paola, are you here?

Paola, I believe our tech team unmuted you.

Okay. All right, well, I'll turn back to Paola as well as the other speakers who weren't available at the end of this session.

I'd now like to move on to Timothy King from Henkel, Arizona.

MR. KING: Can you hear me? Good morning.

MS. CRISTINZIO: Good morning, yes.

MR. KING: Thank you.

I have close to 40 years of experience in the industry, so I will be giving an industry perspective. I will not be representing a company or an association.

I request that the FDA utilizes cosmetic draft GMP guidance from 2013 to build upon as the national standard for cosmetic GMP regulations, as this standard has been in circulation for ten years. It represented the current thinking of the FDA at that time and has incorporated certain elements of ISO 22716, as appropriate, and is consistent with other established FDA regulations.

The FDA draft cosmetic guidance as viewed by some quality professionals, as more detailed and defined to prevent contamination mix-ups and errors than ISO 22716.

The verbiage in ISO 22716 has led to wider

tolerances of acceptable GMP standards in countries based on manufacturing sites and auditors interpretation of this certification.

Two examples of FDA cosmetic guidance that are more defined than ISO 22716 are water quality and raw materials, which emphasize verification of chemical, physical, and microbiological specifications to prevent cross contamination.

Further, the 2013 FDA draft guidance as a standard should be strengthened to add elements to improve GMP.

Hygienic design of manufacturing and packaging equipment to reduce the risk of cross contamination is one example. Verify chemical suppliers manufacturing quality systems that they are also of hygienic design appropriate to prevent contamination with microorganisms, chemicals, filth, or other extraneous materials.

Utilize principals of validation at a reduced documentation level to qualify manufacturing and packaging processes and expand upon documentation, data integrity, whether it be hard copy or electronic that it be truthful, reliable, and trustworthy.

As a point of reference, Health Canada has

recognized the personal care product counsel GMP QA cosmetic guidelines that could be utilized by the FDA to bolster the 2013 cosmetic guidance.

If the FDA developed more robust and defined cosmetic GMP regulations, this could be considered more burdensome to some companies who have not stayed current. However, the overall goal of ensuring the safety, purity, and quality of cosmetics is paramount to U.S. consumers and consumers around the world.

The average consumer who makes cosmetic purchases on the web, or views products at the retail level expects the cosmetic manufacturers, whether they are small, medium, or large global entities, meet an established standard to safely provide the intended benefits.

Overall, the FDA has historically set standards to protect consumers that were out in front of other countries standards and as such, encourage the FDA to use a strengthened version of the 2013 draft cosmetic guidance as the national standard. Thank you.

MS. CRISTINZIO: Thank you so much. That was exactly three minutes.

I'd now like to move to our next speaker, Sean

Brown from Eternal Ink.

MR. BROWN: Good morning. Can you hear me?

MS. CRISTINZIO: Yes.

MR. BROWN: Great, thank you.

Good morning. My name is Sean Brown, and I'm here representing Eternal Inc., a Tattoo pigment manufacturer.

I've been tattooing for the last 24 years, and I've been involved in manufacturing and tattoo regulations worldwide for over the last 15 years. And thanks again for allowing me to speak today.

While tattoo pigments share some similarities with other cosmetics, they are unique in their mode of application and their intended use; therefore, it is important to regulate tattoo pigments in a manner that reflects these differences and ensures their safety and effectiveness for consumers and professionals alike.

I urge the administration to consider these differences and continue to work with the tattoo industry experts while developing roles around MoCRA.

Furthermore, I ask the administration to fully consider the socioeconomic impact such rules may have.

Regardless of standards proposed by the FDA please draft clear guidelines. This makes it easier to understand and easier to comply with, thus, ensuring public safety. On top of clear guidelines, I ask that you give the industry adequate time to come into compliance.

Working together we have a chance to learn from worldwide successful regulations, and we have a chance to learn from those regulations with severe shortcomings such as the European REACH regulations.

Tattoo pigment manufacturers aren't running from regulation, in fact, we welcome it. While doing so, we ask that regulations are reasonable; that they're based on historical and scientific evidence, and that they are industry specific.

Furthermore, safety substantiation of good manufacturing processes are closely interconnected. Safety substantiation relies on reliable and consistent product manufacturing, which in turn depends on robust good manufacturing processes. Without sound GMPs, safety substantiation might not be accurate, and the safety of the product cannot be fully insured.

I would like to thank Dr. Katz and her team for her efforts in working with -- and to better

understand our industry and her willingness to work with industry experts.

We look forward to continue to work with the FDA on these regulations and more. Thank you.

MS. CRISTINZIO: Thank you so much, Sean.

Next, we have Don Frey from Independent Beauty Association. Don.

MR. FREY: Good morning, Dr. Katz. Can you hear me?

MS. CRISTINZIO: Yes.

MR. FREY: Good morning, everyone. My name is Don Frey. I'm president and CEO of the Independent Beauty Association.

Independent Beauty Association is a trade association that represents over 600 members of the beauty industry, primarily small to midsized companies.

Fundamentally, IBA is in support of incorporating most of the components of ISO 22716 as part of the FDA/GMP guidance. ISO 22716 is widely used as a benchmark standard for basic GMP compliance throughout the cosmetic industry.

It is recognized worldwide and was developed to promote a standard for documenting safety and ethical manufacturing practices among both small and

large companies.

The technical working group that developed ISO 22716 incorporated a broad panel of expert industry quality control and regulatory personnel, as well as select FDA representatives in the drafting of the ISO 22716 culminating in the 2007 version. It was officially recognized and endorsed by ICCR in 2007 soon after its publication.

Currently the ISO 22716 guidelines are accepted by all ICCR regulatory jurisdictions, including the U.S., Canada, Europe, Japan, Brazil, Israel, Korea and Chinese Taipei.

ISO 22716 provides clear and concise educational definitions for GMP control. Many, many, many, small and midsized, as well as startup companies, are looking for clear and concise guidance for their GMP compliance requirements, and ISO 22716 established these across 17 key elements of basic GMP.

Many GMP auditors are already trained and available to provide guidance for the service for the industry, and the draft GMP compliance was designed to incorporate nearly all the ISO 22716 elements. It addresses raw material controls already covered by color and other ingredient

safety requirements.

Fundamentally, it's most important that whatever FDA comply -- develops as GMP guidelines is not in conflict with ISO 22716, as it provides a balance guide for cosmetic GMPs without bracing more cumbersome language in 21 CFR guidance designed for dosage form and pharmaceutical drug products.

In summary, IBA supports the recommendation to incorporate the guidelines of ISO 22716 as basic requirements for the FDA's MoCRA GMP compliance requirement. This document is already published and could be easily adopted by both the FDA and the cosmetics industry. I also believe that small companies could benefit from extended compliance dates due to staffing and documentation issues with less burdensome -- which are less burdensome with regard to larger organizations.

Also, there should be some accommodation for raw material sampling so the certificates of analysis and color order appears -- standards could be used for establishing that rather requiring analysis of each raw material.

Thank you very much for this opportunity to provide comment.

MS. CRISTINZIO: Thank you so much, Don.

Next we have Shahn Anderson from the Alliance of Professional Tattooists.

MR. ANDERSON: Hello, can you hear me?

MS. CRISTINZIO: Yes.

MR. ANDERSON: My name is Shahn Anderson. I'm president of the Alliance of Professional Tattooists. The United States oldest and largest trade association nonprofit. I've been tattooing for 36 years, and I'm in my 16th year on the board of directors of that organization.

Thank you for the FDA for allowing us time to speak here.

I'd like to draw your attention to the impact that the modernization of Cosmetic Regulation Act could have on the tattoo industry. As you know, the act aims to improve the safety and efficacy of cosmetics including tattoo inks and products. While this is a noble goal, it could have serious implications for the tattoo industry, its artists and customers. The biggest concern for tattooers should be the socioeconomic impact and ensuring that these regulations do not impose undue economic hardship.

Inevitably, there will be price increases due to the amount of new testing required, upgrades to facilities to meet GMP requirements, and the

implementation of systems for recordkeeping and investigating adverse events.

The industry is already facing challenges with supply costs and those negative effects on small business owners. Moreover, these regulations could potentially hurt people who need medical tattoos for psychological benefits, areola restoration, and skin re-pigmentation to name a few. Additionally, the impact on marginalized minorities could be significant. These communities often rely on small businesses and may have limited access to safe tattooing options.

It is crucial, that any regulations put in place do not have a disproportionate impact on these communities and their ability to access quality products and procedures they trust.

Tattooing is an ancient craft being practiced by our species since before written history. There has been no major health crisis surrounding tattoos.

According to The American Cancer Society website, there is no direct evidence linking tattoos to an increased risk of cancer. Even the FDA website states it has received reports of adverse reactions associated with certain shades of ink marketed by a particular manufacturer, but reports

of allergic reactions to tattoo pigments have been rare.

Until more case studies and long-term studies can be collected there is simply insufficient data to list tattoo pigment as a potential risk. But instead, it has been a source of healing and expression for millions.

It is vital that we consider what impact this will have on the economy, on small businesses, on minorities and on people's recovery from terrible diseases like cancer and the pain of loss and grief.

I hope that this brings attention to the factors potentially unseen by this new law and to take them into account as we proceed.

Thank you for attention to this matter, and we look forward to working together to create regulations that promote safety while also considering the unique aspects of the tattoo industry, its practitioners, and customers.

Thank you very much for your time.

MS. CRISTINZIO: Thank you so much, Shahn.

Our next speaker is Allyn Shultis from the Global Retailer and Manufacturer Alliance.

MR. SHULTIS: Good morning, Dr. Katz.

MS. CRISTINZIO: Good morning.

MR. SHULTIS: I am Allyn Shultis, the executive director of the Global Retailer and Manufacturer Alliance, GRMA.

We are a member driven not-for-profit organization that as an independent certification program owner, focuses on the health and wellness categories including cosmetics, dietary supplements, and over-the-counter drugs.

GRMA is committed to promoting safety, quality, and trust throughout supply chains by designing solutions that satisfy manufacturer, regulator, retailer, quality requirements, and is accepted as an industry leader across those categories by a vast majority of industry stakeholders.

We believe that ISO 22716 provides a valuable foundation for cosmetics, it has wide acceptance internationally, as well as within use of the U.S. public standard NSF 455-3. However, while ISO 22716 forms a significant majority of the 4553 standard as identified as a normative reference, there are a few shortcomings that have already been identified -- that are related to the U.S. FDA cosmetic GMP guidance that has been included in the 4553. As an example, some of these elements that -- that are included cover finished product samples related to

retain samples that have the ability to be tested for adequacy for preservation and microbial contamination.

There has been a system for complaints, procedures, ability to investigate, report and follow-up on complaints alleging adverse events, as well as theoretical yield, versus actual yield comparison for production batches.

Additionally, with the ANSI joint committee process there's consistent review and oversight and -- I guess in a nonpartisan way. And the creation of the audit requirement guidelines to accompany the 4553 standards will be very helpful to manufacturers as it provides a richer understanding in detail around the clause-related requirements within the 4553, as well as ISO 22716.

Additionally, with the integrity of GRMA and the work and success of the NSF 4553 process through the joint committees, we believe a public private relationship with GRMA will provide the FDA valuable information for its public safety mission, and would appreciate an opportunity to discuss this at greater length in the future. Thank you.

MS. CRISTINZIO: Thank you so much, Allyn.

Next, we have Maxime Jacques from Cosmetics

Europe, the Personal Care Association.

Okay, I see that we -- we don't think we have Maxime here. We have a substitute speaker who is Dr. Renner. Dr. Renner, if you are online, please raise your hand so we can unmute you.

DR. RENNER: Okay, can -- can you hear me now?

MS. CRISTINZIO: Yes, thank you.

DR. RENNER: Okay, super, thank you very much. And apologies, Maxime Jacques is stranded at Istanbul airport coming back from a business trip. He asked me to step in for him.

Thank you very much for giving the opportunity to share our Cosmetic Europe and international experience.

MS. CRISTINZIO: It looks like we lost Dr. Renner.

DR. RENNER: Can you hear me again?

MS. CRISTINZIO: Yes.

DR. RENNER: Somehow I got muted again, sorry.

MS. CRISTINZIO: Okay, proceed.

MR. RENNER: I'll try again.

Thank you very much for the opportunity. Happy to share on behalf of Cosmetic Europe.

The experience that we have with GMPs in a regulatory context, in particularly, ISO 22716.

For those who don't know, Cosmetic Europe -- we are the EU trade association representing the interest of the European cosmetic and personal care industry. We represent about 8 percent of the European market, which is valued about 88B euros a year.

The first point that we would like to make is that ISO 22716, from a European perspective, has really proven suitable for cosmetics for over 15 years. ISO has gone through various periodic review cycles and the standard has lived up to the test of time. It's never been specifically challenged or fundamentally changed. So this is still a very good standard.

Most regions in the world, the biggest -- certainly, the biggest cosmetic markets have GMP standards, which are either directly linked or very much, if totally equivalent, to ISO 22716. The case for Japan, Brazil, South Korea, Asian, Middle East, Canada, most of the Latin American countries.

More recently, China also developed its own GMP standard, which is, nevertheless, very, very close to ISO 22716. So for this reason, we believe, and we support, that the statement of the International Cooperation on Cosmetic Regulation, ICCR, which

already -- I think in 2008 or 2009 -- recognized and recommended ISO 22716 as a key standard for the manufacturing of cosmetic products.

We would say from a U.S. perspective -- we'd like to emphasize that adoption of this standard would mean that U.S. companies will be able to in one -- prove compliance with GMP for the U.S. market but at the same time for all major markets in the world. And on the country going for a divergent different standard in the U.S., it would mean that U.S. manufacturers would have to duplicate their GMP efforts in terms of compliance demonstration to do something for the U.S. market and demonstrate something even if only slightly different for other markets. And that's not just an administrative burden, but it would mean real additional costs and real barriers to business growth.

One of the good features that the success of ISO 22716 is linked to the fact that it's developed in a way that it can be easily implemented, easily translated to all sizes of companies and a whole range of cosmetic products, it is a very flexible standard. I mean, it describes the principles, it describes the objectives that must be followed and also the general approaches by which

they can be met, but it doesn't go into an undue detail, which is then one size fits all, this is only one specific way by which GMPs can be achieved regards of the size of your company just take as an example a young start --

MS. CRISTINZIO: You are at your three-minute mark.

DR. RENNER: Okay, so then I will stop and just say -- to emphasize again that it is a transferable standard that works for big and small companies alike and it can be applied to all cosmetic product types.

Thank you for your attention.

MS. CRISTINZIO: Thank you so much.

I'd like to now move to our next speaker. Leigh O'Donnell from The Handcrafted Soap & Cosmetic Guild.

MS. O'DONNELL: Yes, can you hear me?

MS. CRISTINZIO: Yes.

MS. O'DONNELL: Okay, thank you.

Good morning. My name is Leigh O'Donnell, and I'm the executive director of the nonprofit trade Association, the Handcrafted Soap & Cosmetic Guild or HSCG.

We represent over 400,000 businesses making and selling handcrafted soap and cosmetics in the United States. Many of the small businesses we represent fall within the 1M annual gross revenue exemption to GMP regulations and are unlikely by intent or circumstance to surpass the exemption cap in the future. However, there's still an appreciable percentage of small businesses with unique needs making and selling handcrafted soap and cosmetics that have grown their businesses to the point where they will be subject to GMP regulations promulgated under MoCRA.

Here are a few of the potentially burdensome or impossible regulations that could adversely affect the small business as we represent. The Good Manufacturing Practice Guidelines inspection checklist for cosmetics; number five production, Part D states that weighing and measuring of raw materials is checked by a second person. Many small businesses in the cosmetic industry are one person owned entity or have limited staff. Having a requirement that mandates a second person must check and verify any weights or measures would be overly burdensome and devastating to the industry.

The ISO 22716 standard Section 4.2, types of

area states separate or defined areas should be provided for storage production, quality control, washing and toilets.

In many small businesses space is at a premium and is used for various activities as needed. Creating and maintaining separate spaces for each type of activity, except, of course, washing and toilets could be difficult or impossible for a small business.

Providing an option to protect against confusion or cross contamination in multi-used spaces might be an effective alternative. Small business generally do not have on-premises testing facilities. The FDA draft GMP guidelines require that raw materials are sampled and tested for conformance with specifications.

Small businesses rely on certificates of analysis from their suppliers and visual inspection. To mandate in-house testing of all incoming materials would be a virtually impossible requirement to meet. Some suitable accommodation for small businesses would be needed.

Retaining samples of finished products are required by all existing GMP guidelines. Retaining a sample is a simple task for a large company

producing large batches of a single product. This requirement would be difficult to impossible for small businesses that make very small batches due to cost and space constraints.

In creating new GMP regulations for the cosmetic industry in the United States, careful consideration must be given to the smallest producers in the industry. The HSCG hopes to see FDA create simple, easy to understand GMP guidelines for small businesses to ensure this industry can grow and thrive.

We are willing to assist the agency in whatever way they can in creating GMPs for small businesses.

Thank you for allowing me to present this statement on behalf of the handcrafted industry, and thank you to the FDA for seeking this feedback.

MS. CRISTINZIO: Thank you so much Leigh.

Our next speaker, Sharonda Newsome from Happy Farm Botanicals. Sharonda, could you please raise your hand so our AV support can find you. It doesn't look like you're present.

Okay, I'm going to move on to our next speaker. I have Nina Khizani from GS Beauty. Nina, Nina, you've been unmuted. Nina, are you there?

I -- I also want to let you know you can email

us at, MoCRAGMP@fda.hhs.gov if you have questions or technical issues.

I believe Nina, you need to unmute on your end, we've unmuted you here. Nina, I will come back to you and hopefully we can work out the technical issues before then.

In the interest of time, I'm going move on.

Our next speaker is Vivian Valenty from VB Cosmetics, Vivian.

MS. VALENTY: Good morning. My name is Vivian Valenty. I've been a chemist for 59 years and a president of VB Cosmetics who manufactured Nail Polish and manicure and pedicure products for over 30 years.

As a cosmetics manufacturer, our company strongly believes in providing safe products to our customers and is -- patient about compliance with FDA regulations.

Our biggest challenge with the regulations is not their existence, but the lack of specificity. The terminology used in the regulations need to be fully defined for everyone to understand. The lack of clarity could lead to multiple interpretations, which then requires the need for legal resolution. This situation could lead to an

unequal justice of the outcome that depends on the proficiency of the legal team and the company's available resources to defend itself. For instance, companies demonstrate the safety of their products by showing the absence of known toxic compounds through chemical analysis. The regulations need to state the analytical methodology to be employed and the maximum allowed concentration value for the compound based on toxicology studies.

If there are uncertainties, then they need to be stated in the regulations. In good faith a cosmetics company will claim that the product is free of the toxic compound based on the results from a laboratory conducting its analysis using a method with a detection limit of parts per million.

A second laboratory using highly sophisticated instrumentation capable of detecting substances to parts per trillion might detect the toxic compound. The key question is, what is the allowable concentration of this toxic compound which does no harm to the human body?

The cost of sophisticated analysis is expensive. Each cosmetic product consists of multiple raw materials and its raw material may have 5, 10, 20 or more discrete chemical compounds. Its

batch of every raw material must be analyzed to avoid using it if contaminated since the source and timing of the contamination may be unknown.

The analysis for specific toxic compounds or family of similar compounds in a mixture of chemically diverse other compounds requires definition of the sample preparation method and analytical methodology to be employed.

With increasing activity of law firms engaging in class action lawsuits, the cosmetic company could inadvertently be the victim of a costly legal challenge because of the failure of the lawmakers to provide specific terminologies that will not be subject to interpretations when they craft the Bill before sending it to Congress and passing it as law.

In closing, please think through the details of each requirement and how small, medium, and large manufacturing companies may fulfill its compliance obligation without incurring undue hardship.

When the manufacturer of cosmetic products does its due diligence to comply, the lawsuit shields it from costly losses.

Thank you so much for giving me this opportunity to present my thoughts.

MS. CRISTINZIO: Thank you so much

Vivian.

Our next speaker is Cynthia Johnson from Cindy J Cosmetic Labs.

MS. JOHNSON: Hello. Can you hear me?

MS. CRISTINZIO: Yes.

MS. JOHNSON: Perfect. Hi, everyone. My name is Cynthia Johnson. I am the founder and CEO of Cindy J Cosmetic Labs here in Baltimore, Maryland. I have a contract laboratory to help small businesses like myself create their own custom formulation in the hair care and skin care industry.

My comments are very similar to Sean Brown, Don Frey and also Leigh O'Donnell.

Some of our core values here in Cindy J is community and accessibility. And it seems like from the information that was given, a lot of the bigger companies, bigger manufacturers and also bigger laboratories seem to benefit more than our smaller businesses. Smaller businesses in particular already have limited resources. And it seems like with these new changes there are even more resources that small businesses have to acquire. And I do ask that the FDA work with small businesses on these certifications guidelines and grace periods.

I know we talked a little bit from

Leigh O'Donnell as far as a material handling, hiring more personnel, maybe even getting into more robust technology to help minimize that human error.

But all and all I do ask that FDA work with our small businesses. Especially our small contract laboratories and manufacturers with these guidelines and also grace periods.

Thank you very much for giving me the opportunity to speak. And everyone, please enjoy the rest of your day.

MS. CRISTINZIO: Thank you so much, Cynthia.

Now, I'd like to return to the beginning of the segment as promised. I want to go back through the names of the people who registered to speak who were not available when I called on them earlier.

Thank you so much for pulling the slide up. I'd like to try and recognize speaker number two. Sean Santiago, from Developlus. And again, if you're present, please raise your hand.

Okay, I'm going to move on to the next one, number three, Chandelle Hermes or/and Victor Alonso from Bausch Health.

Okay moving on to the next speaker, number four Sonu Panwar, who's from Dabur India Limited.

Our AV team is telling me we don't have you on

the line or don't believe you're there.

Moving on to speaker Number 7, Diana Goana from BIOETICOS SAS. Diana, are you with us? If you are, please raise your hand.

Okay, going to move on. Number 8, Edwin Rios Arango from Laboratorio Naturex, and again, apologize for the bad pronunciation. Edwin, are you with us?

Okay onto the next slide, we have speaker Number 12 that wasn't with us earlier. Paola Patricia from Unique SA. Paola, are you with us? Please raise your hand.

Okay it doesn't seem she is here. Paola, you were asked to unmute if you'd like to speak, please unmute yourself.

I apologize for any of these tech -- technical difficulties. Paola, are you able to unmute yourself?

Okay. I'm going to move on to our next speaker. Number 20 was Sharonda Newsome. Sharonda, are you on with us? Please raise your hand, and it looks like we don't see you on.

Moving on to the next slide, our last speaker from the segment that wasn't able to speak earlier was Nina Khizani from GS Beauty. Nina, are you

there?

Okay. It looks like none of these speakers who registered are able to present today.

I just like to remind everyone that everyone is welcome to submit comments to the docket. So if you were unable to unmute or had technical problems, we apologize. But know that your comments will definitely be viewed.

I see that Nina is online but needs to unmute herself if she would like to present, Nina.

Okay. Well, it looks like that is the end of our first segment of public comment.

We're going to take a few minute break and come back in five minutes to resume the presentation. Thank you so much.

(Off the record at 11:14 a.m.)

(On the record at 11:17 a.m.).

MS. CRISTINZIO: Good morning again. My name is Dayle Cristinzio, I'm from FDA, and I'm the moderator for today's session.

Welcome if you're just joining us for the Good Manufacturing Practices for Cosmetic Products Listening Session. We just completed segment one, and we're now going to begin segment two for the open public comment.

Next slide, please, great. And as a reminder, I'm going to ask everyone to be mindful of the three minute time limit. I will jump in and I also apologize for any names I mispronounce.

The first person we have up, in segment two. I'm just waiting for this slide to advance again, thank you, is Darlene Story. Darlene is from Lasting Impression. Darlene if you are present, can you please raise your hand so that we can unmute you. And it looks like she just dropped off of the meeting, oh, there she is, I see her.

MS. STORY: Okay. Can you hear me?

MS. CRISTINZIO: Yes.

MS. STORY: Hi, my name is Darlene Story representing Lasting Impression in Englewood, New Jersey, and we manufacture products under our name, and we also act as contract manufacturers.

Most of our comments were already addressed as a contract manufacturer.

We already implement most international GMPs, and we encourage others to do the same. That is why we think the MoCRA Act is so beneficial.

But, we do have concerns for the little guy. Much of our contract manufacturing is for small companies under private label, and some do refilling

of our bulk packaging.

So, to reiterate what Cynthia Johnson just said, we ask that you please take into account, specific regulations for different levels of production so it is easy to understand for these smaller companies with adequate time for them to implement this.

I thank you and I thank you for your time, and I greatly appreciate it.

MS. CRISTINZIO: Thank you so much, Darlene.

I'd like to move to our next speaker, Steven Rosenfeld from the F.C. Sturtevant Company.

Steven. Steven, if you're present, please raise your hand. Doesn't look like we're seeing you on the list of participants currently. I'll come back to you at the end of this segment.

Our next speaker is Karen Marquez from the Soap Products Cosmetics Company. It doesn't appear that Karen is present with us just yet.

Our next speaker is Stephanie Porter from About Face by Stephanie Face, and I believe we did hear from her that she may not be able to present. So we'll just give her a second in case she's here with us.

Okay, onto our next speaker, number 28. I'm going to wait for the slide to advance. There we

go.

Jamilah Rasheed by Shea by 'J' Jamilah, are you present? Please raise your hand for recognition.

Okay, moving on to the next speaker. Speaker Number 29, Khathu Phungo from The University Of Northwest South Africa.

Khathu are you here? Kathu, if you're with us, please raise your hand. And I apologize if I'm mispronouncing your name.

Okay. We're moving on to our next speaker. And again, I'll come back to these at the end of this segment.

Our next speaker number 30, is Desiree Saputo from Golden Lab, LLC.

Desiree are you with us?

Okay, at number 31, our next speaker is Anne-Marie Faiola from Bramble Berry Washington. Anne-Marie, are you with us to give public comment?

MS. FAIOLA: I am. Can you hear me?

MS. CRISTINZIO: Yes. Thank you.

MS. FAIOLA: Thank you for allowing me the opportunity to speak.

My name is Anne-Marie Faiola. I'm the CEO of Bramble Berry of Washington State based personal care product supply company serving the small

businesses of the hand-crafted industry. Product safety, consumer choice, and ingredient quality are what drive many into the hand-crafted industry.

Like other colleagues in the hand-crafted industry, we promote adherence to existing good manufacturing practices and educate and train members of our community in ensuring safe production environment and processes.

We utilize the existing FDA draft guideline informed by ISO 22716 standards to advise our members and customers on how to adhere to good manufacturing processes. But, not all of the existing draft guidance practices apply to the home based small manufacturer environment and those differences should be identified and accommodated as the FDA seeks to update GMPs in compliance with the passage of the modernization of Cosmetics Regulation Act of 2022.

Standards identified in the draft guidance regarding documentation, records keeping, buildings and facilities, equipment, personnel, materials, and production are the ones that small businesses can generally apply with modifications for scale.

GMP standards need to provide flexibility and exempt small businesses from requirements associated

with laboratory controls, internal audit procedures, including weight and measurement controls, and staffing requirements that are not applicable to small business.

Our approach to educating and training places an emphasis on safe handling and treatment of ingredients and ensuring products are safe and free from adulterations. As the FDA develops new approaches to GMPs, we encourage the agency to be outcome focused in applying any new standards rather than strictly process focused. Adding multiple additional steps or costs associated with the adoption of new GMP standards will harm small business without producing better results.

Documentation and record keeping requirements for small business should consist of procedures that a sole practitioner can adhere to. Many small businesses are manufacturing in a home environment, so accommodations for size and scale need to be acknowledged when developing and applying GMP practices. This is particularly relevant when considering GMPs related to facilities, equipment, materials, handling and production.

One person filling a soap mold by hand represents a fundamentally different scale of risk

than an industrial filling station. These differences need to be taken into account in creating GMP standards going forward.

Regarding adverse events, I've been in the hand craft business for nearly 25 years. I'm not aware of any adverse events or recalls associated with manufacturing processes utilized in the home or small business environment.

Our research indicates the FDA has taken enforcement action regarding small businesses, including for manufacturing practices, misleading claims, adulterated cosmetics, and unsanitary conditions. So this isn't to say that adverse events or recalls associated with manufacturing have occurred in the hand-crafted sector, but that I haven't encountered them.

Promotion of GMPs and adherence to safe standards is appropriate. It promotes safe work environment, safe products, and provides competence to consumers. But in developing and applying GMP standards going forward, the FDA should acknowledge and apply these standards in a way that works for small business.

Thank you for allowing me to speak today and the work you're doing.

MS. CRISTINZIO: Thank you so much more, Ann-Marie.

Our next speaker is speaker number 32. Jamshaid Akbar Bhatti from SK JAMAL Private Limited. Jamshaid, are you with us? And if you are with us, please raise your hand so our AV support team can unmute you.

Okay, I'm going to move on to our next speaker. Speaker number 33, Todd Maclaughlan from Profounda Incorporated. There you are, great thank you, Todd.

MR. MACLAUGHLAN: Hi, thanks so much for having this meeting. We appreciate that. A lot of the points that I wanted to raise have been raised already so I won't go over them. I just wanted to raise -- maybe three different things.

First of all, Profounda is a company that we have a drug business. We make our own products in the cosmetic industry. We also act as a contract manufacturer as well, and we also manufacture supplement products for others and ourselves.

I guess in terms of the -- the clarity I'd like from the FDA with regard GMP and cosmetics as it relates to process controls for manufacturing. So since we sort of do both drugs and cosmetics, there's different GMP standards. When you say GMP

means different things.

So as much clarity as that the FDA can provide in terms of how we can stay compliant on the cosmetic side, especially as it relates to formulation control. There's a lot of times we get people coming in with the formulation as an idea and not necessarily as vetted it might be for other products that I'm familiar with.

The second thing is the activity that the FDA takes with regard to developing regulations also affects the state level as well. We're one of the few states that actually regulate or inspect for cosmetics manufacturing as well in the state of Florida, and I think we need to make sure that there's not an undue burden on small companies by having different standards between what the state does and what the federal government does with regard to inspection and licensing. Right now, we're required to have licensing for multiple -- for drugs, for supplements, for -- for cosmetics as well as for contract manufacturing. There's a lot of different things that have multiple layers to our complex --

The third point I'd like to make is just the FDA obviously should -- should do enforcement. I

think it's good for all of us as U.S. citizens, but the same time, looking to the FDA to give as much support to help companies like ourselves get better in terms of what we're doing and others.

So -- that ends my comments, and thank you for your time.

MS. CRISTINZIO: Thank you so much, Todd.

Our next speaker, number 34, is Nan Qin. And again, I apologize for the bad pronunciation, from Natural Immunogenics. Nan are you present? Doesn't appear that the speaker is with us. Oh, actually, our AV team is saying you are unmuted. I think you need to unmute yourself on your end Nan, in order to speak. Nan, give you one more minute or second here to see if you can unmute yourself. It appears that you look fully unmuted. You might be having some problems with your audio. And I apologize in advance for any of our technical issues we may be having.

Again. I'll -- I'll return to you after we finish the list of speakers to see if you're able to get your audio to work.

I'm going to move on to our next speaker, number 35, Melissa Gomez from Laboratorios Rety De Colombia. And again, sorry for the bad

pronunciation.

Can you move the slide ahead, thank you. Melissa are you here? It doesn't appear that we have Melissa on the line.

I'm going to move on to our next speaker, number 36, Jen Lee from Beautycounter.

MS. LEE: Hello. Thank you for having me here. My name is Jen Lee, and I'm the chief impact officer at Beautycounter, a clean beauty brand. Beautycounter is pleased to be here today, and we thank you for this opportunity to speak.

Our company's mission is to get safer products in the hands of everyone, and we believe that advocating for more health protective regulations is an important part of delivering on that mission.

With various third-party certification and awards for a comprehensive approach to safety we've prohibited around over 2800 ingredients from our products.

We diligently screen each ingredient used in our formulas against 23 health and environmental end points using the best available science to help us formulate products using safer alternatives to convention. Our hope is that the FDA will encourage and incentivize contract manufacturers of

all sizes to obtain ISO 22716 certification as it currently represents the gold standard for the industry.

At Beautycounter, we work with many contract manufacturers, and while some of our CM's already are ISO 22716 certified, it remains a voluntary standard. We spend a significant number of resources to conduct audits of our manufacturers to ensure that they adhere to GMPs, however they should not fall on brands to do so, regardless of whether specific items in the standard require more efforts than others, we believe that to protect public health, all manufacturers should adhere to the ISO 22716 standard.

Our estimate is that it would take between 12 to 18 months for manufacturers to become compliant and we believe remediation efforts when brands find gaps or issues during an audit can be more timely and costly.

To ensure smaller businesses are able to become ISO 22716 compliant, we encourage the FDA to provide educational sessions on GMP requirements, best practices and access to technical experts with experience and compliance.

In addition, we believe that the GMP rule should

include an emphasis on water quality. Manufactures should be encouraged to install effective validated water filtration systems as defined in the rule and be provided with access to experts on water management. Since water is the highest level ingredient in most cosmetic products, we believe that emphasizing the importance of water quality would significantly enhance product quality and safety and reduce the likelihood of adverse events. A water system that is properly qualified and validated enhances the microbiological quality of products and controls against trace contaminants and environmental toxins.

Although it's currently not the case, consumers should be able to go into a store and trust that the cosmetics that they purchase are held to high quality standards.

Our hope is that incorporating these changes to GMP guidelines will provide protection and guarantee to consumers that the products they purchase are held to high quality standards.

Thank you for your time.

MS. CRISTINZIO: Thank you so much, Jen.

We're now going to move on to speaker number 37, Lillian Zhou from the Environmental

Working Group.

MS. ZHOU: Hi, good morning everyone. My name is Lillian Zhou and I'm the law fellow for the environmental working group, which is a National Environmental Health Organization.

EWG supports quick implementation of mandatory GMPs, and we're grateful that Congress directed the FDA to finalize GMPs by December 2025.

We recently found that the number of cosmetics related adverse events reported to the FDA has significantly increased over the last 2 decades. Specifically, we found that in 2000 consumers reported fewer than 500 cosmetics related adverse events to the FDA. Over the next 2 decades, that yearly rate grew over six fold, with over 3200 cosmetics related adverse events reported in 2019. Over 30,000 cosmetics related adverse events have been reported since 2010.

One explanation for the rising number of adverse events could be the increase in cosmetics imports in recent years and the high rate of adulteration and mis branding among imported products. In 2016, 20 percent of imported products that the FDA tested had adverse findings primarily due to illegal color additives and microbial

contamination.

Stronger production and laboratory controls can make manufacturers ensure their products are safe before they hit U.S. shelves.

There's also a rising number of high profile consumer concerns related to cosmetics, such as asbestos and cosmetics made with Talc --

Asbestos contamination points to the need for stronger testing of raw materials and mandatory testing methods based on the latest science. And in addition to raw material testing, we think it's critical that GMPs require final product testing to address toxic chemicals that are inadvertently introduced throughout production.

Consumers can be better protected from contaminants such as 1,4-Dioxane and PFAS if manufacturers are required to test for these toxics, not only during source material checks and processing, but in finished products.

In the case of PFAS, PFAS can come in through contaminated water and some PFAS are intentionally added are known to break down into other PFAS in the final product.

To ensure the safety of products and that consumers are getting exactly what they see on the

product label, final product testing should be a critical component of any strategy to address toxic contaminants.

And finally, GMPs should address the need for manufacturers to maintain thorough control records.

Thorough record keeping is necessary to ensure integrity and provide necessary documentation to FDA where the need for records inspection arises, such as in the case of adverse events and recalls.

And to conclude, consumers are using multiple products every day and should be able to trust that their products contain exactly what is stated on the label.

Strengthening production controls, raw material and final product testing and record keeping is necessary to keep people safe.

Thanks for your time.

MS. CRISTINZIO: Thank you so much, Lillian.

Our next speaker, number 38 is Amira Adawe from The Beautywell Project.

MS. ADAWE: Hi everyone, can you hear me?

MS. CRISTINZIO: Yes.

MS. ADAWE: Yes, hi. Good morning. My name is Amira Adawe. I'm the executive director of the Beautywell Project, a nonprofit organization that's

based in Minnesota, but we work all over the United States, and my work focuses on addressing chemical exposures from cosmetics and OTC products like skin lighting products, which are also classified as cosmetics and some of them can be addressed.

So over the years we have been, you know, working with communities that are disproportionally impacted by toxic chemicals in cosmetics, predominantly communities of color. And so I am really glad to see that FDA is hosting this important listening session. And so I just want to highlight a couple of things.

One of the things is that throughout our work in communities that we have seen is the false and mislabeled cosmetics when they're imported into the United States. So what happens a lot of times is repackaging. Larger industries of cosmetics contract with smaller retailers, smaller business owners, and then what they do is that they repackage products, and then they relabel. And so some of these labels do not indicate the actual ingredients of the cosmetic, especially if they contain toxic chemicals. And so we have tested many products -- many cosmetic products that contain heavy metals which are very

toxic that yet are never indicated in the label.

And so it's very important for FDA to create standards and regulations that equally apply to larger industries as well as smaller business owners who are manufacturing cosmetics, whether in their homes or a small manufacturer because that will help to eliminate some of these issues.

The other thing that I want to highlight is that language, simplifying all of these regulatory languages that FDA will come up with, all of these standards, language that FDA will come up with to actually simplify so it makes people to understand and comply with regulations and that applies to everybody, whether it's a -- large industry or a -- smaller owned business industry. Especially those that English is not their first language and are in the cosmetic industry. So simplifying language is very important for one safety, but also overall to comply with the standards that FDA and regulations that FDA will come up with.

So I want again to stress that it's very important we have come a very long way in the United States to this stage that we're at today to regulate cosmetics and come up with important -- and

so I want to emphasize that the FDA thinking about centering this around health and safety and environmental protection instead of just the economic well-being. Yes, the economic is important, but the health and safety is so important because we have been dealing with communities that just disproportionately impacted by toxic chemicals from cosmetics, and so thank you so much for giving me this space and listening to my voice. Thank you.

MS. CRISTINZIO: Thank you so much Amira.

Our next speaker, number 39 is Sudhir Sawarkar from Freyrs Solutions General Trading.

DR. SAWARKAR: Yeah, hi. Can you hear me?

MS. CRISTINZIO: Yes, we can hear you.

DR. SAWARKAR: So good morning to all. This is Dr. Sudhir, I am a global player in regulatory consultancy and healthcare.

I would like to express my sincere appreciation for the practice state taken towards the implementation of the modernization of cosmetics that MoCRA, with the robust global Good Manufacturing Practices.

The commendable approach reflects the strong commitment to ensuring consumer safety and product

quality while aligning practices with the global cosmetic standards.

The implementation of GMP in the cosmetic industry represents a significant positive development as it aligns with the global standards and best practices. By harmonizing regulation with other countries it becomes easier to facilitate international trade and promote the consistent product quality across the border.

Given the interconnected world, the nature of the world where the cosmetic products are manufactured and distributed and consumed worldwide this harmonization is very vital, is of vital importance.

GMP compliance plays the crucial role in fostering innovation within the industry by establishing high standards and emphasizing the quality control. Major manufacturers are motivated to continuously improve their processes and develop a safe and more effective cosmetic product.

This communicates the notion that not only benefits the consumer by providing them with the superior options, but also prepares the industry towards as a whole.

Moreover, the implementation of GMPs in the cosmetic

industry will announce the transparency and accountability. Clear guidelines for production labeling, and testing, enables consumers to make more informed decision about the product they purchase and use regular audits. Inspection will ensure ongoing compliance. Thereby maintaining the consumer trust and confidence in the marketplace.

I have some queries regarding the inspection and the audit of the cosmetic product outside the U.S.A., which are going to be challenging.

How would be the inspection conducted going forward for the manufacturer or private label manufacturer outside the U.S.A.? Will that be risk-based or will that be a prerequisite to get the market authorization in the U.S.?

Once again, I expressed my gratitude to the US FDA for taking these important steps toward implementing MoCRA with the strong GMP practices.

Your efforts will contribute to a safer more transparent and globally harmonized cosmetic -- fix industry.

I eagerly anticipate witnessing the positive impact this will have on the quality of products and the wellbeing of the consumer. Thank you very much.

MS. CRISTINZIO: Thank you so much.

Moving on to our next speaker, number 40.

David Schmidt from AOAC International. David, if you're with us, please raise your hand so we can unmute you.

Just recognizing we are running ahead of schedule, and I will definitely come back to those who were not available when I called on them at the end of this segment.

Okay. I'll move on to number 41, Linda Reinstein from Asbestos Disease Awareness Organization.

MS. REINSTEIN: Great. Can you hear me?

MS. CRISTINZIO: Yes.

MS. REINSTEIN: Perfect.

Thank you for the opportunity to address this esteemed panel today. My name is Linda Reinstein, and I am the co-founder of the Asbestos Disease Awareness Organization, ADAO an independent nonprofit.

Asbestos has become my life because of the life it has taken. Asbestos made me a widow and took my daughter's father and I proudly represent tens of thousands of families like mine harmed by preventable illness that is caused by toxic products.

Now for 20 years ADAO been dedicated to

preventing asbestos exposure to eliminate all Asbestos-caused disease. And I'm honored to join nearly a 100 people today from 20 countries all seeing and raising concerns about cosmetic safety.

Let's be clear the FDA cosmetic act that was passed in 1938 has only banned 11 ingredients and asbestos is not one of them. I spoke at the 2020 FDA meeting on testing methods for asbestos in talcum cosmetic containing products, and it was clear, there is a great divide between industry and public health organizations.

We want to make certain that people on this call understand the jurisdictional differences that FDA does have, the jurisdiction over personal care products and cosmetics, and of course EPA has it over chemicals, but both are focused -- should be focused on risk management.

Well, today we're directing our comments on GMPs. I want to use asbestos as an example of toxic cosmetic contamination and the risk management failures with four facts.

Asbestos is a known human carcinogen. There is no safe level of exposure, each year nearly 40,000 Americans die from preventable asbestos-caused Diseases, and without a ban, imports and use will

continue.

Now highlighting the importance of standardized testing and transparency enforcement is key. Fifteen years ago ADAO did product testing in 2007. Our testing confirmed five consumer products were contaminated with asbestos, one was even a child's toy.

In response, the industry attempted to mount a defense based on low level testing protocols in hopes of negating results, sadly this response is not uncommon.

Now while testing is -- is necessary and prudent, it won't eliminate toxic exposure, so preventing materials first-hand is important.

Looking at the FDA's proactive approach we applaud you for the testing you have done and how transparent you have been.

We're also, as a group, calling on Congress to pass the Alan Reinstein Ban Asbestos Now Act.

Regulatory failures have shown the risks of asbestos cannot be managed and testing is nearly impossible.

That concludes my three minutes, and I'll put longer comments into the docket. Thank you.

MS. CRISTINZIO: Thank you so much Linda, and

that's a great reminder. We do have the docket open for anyone to insert their public comments.

I'm going to move on now to our next speaker, number 42.

Phoebe Fu from Reach24H Consulting Group in China.

MS. FU: Hello.

MS. CRISTINZIO: Hi.

MS. FU: I well, this is Phoebe Fu. I'm a regulatory consultant from Reach24H Consulting Group, China.

Basically, we are a company that based in China and have branches in the U.S.A., South Korea, and Japan, and also we have cooperation with companies around the world. I would like to look at the GMPs from two angles.

First. We have a lot of U.S. companies who want to enter the Chinese market. As we all know, the Chinese market has a very strict GMP standard, and that is a lot of American companies, they find it very difficult because a few states like New Jersey and California have the state GMPs, so they can help their companies in this state to enter Chinese market very quickly without the animal tests. Before other companies -- if they don't have the large

associations like PCPC, GMPs, they couldn't enter the Chinese market or they have to do the animal tests, which is very unacceptable for them. So I think if the FDA could ask whether it's the federal government or state government that can do the GMP, it would definitely help the U.S. companies enter the Chinese market, which has a very strict GMP standard.

And on the other hand, a lot of Chinese enterprises want to enter the U.S. market and so we -- every Chinese cosmetic enterprises has the certificate from the government directly, which is very good but we also need to notice that the category of, or a definition of cosmetics is very different because in China some soap or toothpaste or like a mouthwash, they are not considered as the cosmetic. So it would be difficult for the FDA to define the GMP from many other countries as well.

So this is my opinion, I hope FDA can take these two things into consideration and help both American companies and the Chinese companies to get through -- go to each other’s country most smoothly. That can definitely help. Thank you for your attention.

MS. CRISTINZIO: Thank you so much, Phoebe.

Moving on to our next speaker number 43.

Dee Mashiah from the University of The District

Of Columbia, Washington, DC.

MS. MASHIAH: Yes hello, can you hear me?

MS. CRISTINZIO: Yes.

MS. MASHIAH: Yes. Thank you good morning, everyone.

My name is Dee -- Mashiah, and I'm here today as an advocate for small businesses as a scientist, as a Doctor of Public Health and as a supporter of the UDC Pass Program at The University of the District Of Columbia.

I am committed to making a positive impact in my community. I'm also an entrepreneur and the owner of D-Spot, Inc. It's a DC and Maryland company, and I specialize in manufacturing high quality hair care and cosmetics.

My brands Jane Bulan and -- Organicky have customers in the U.S. and around the world.

But, however today I want to address a critical issue affecting many small business owners, including myself. As a scientist, I understand the importance of regulations and quality control within industries but I respectfully urge the FDA, our supervisor authority to consider the challenges faced by local businesses when it comes to product registration. When it comes to certification

fees, I think it's essential that these procedures and these fees are, you know, all the process of approval, that they're going to be reasonable and affordable for small entrepreneurs. For instance if a person starting a home base lotion business, I don't think it should be an overwhelming experience because of, you know, excessive fees that they can't afford or complex requirements that the average person cannot handle.

So I think we need a system that fosters and supports the dreams and inspiration of individuals, you know, people that are locally and they wish to pursue their entrepreneur spirits, well while ensuring, of course, consumer safety and quality control. So I'm taking an example, the UDC Pass Program. It's a resource for individuals to overcome economic challenges and build a brighter future through education. This is a part of the TENA Program and the university, and it gives guidance and resources to aspiring entrepreneurs from the DC area.

So I think basically recognizing the hardship that people face, minority owned enterprises, women own enterprises.

We want to ask the FDA to implement

measures to address challenges for those specific individuals and promote a more inclusive environment.

We can help people, you know, make their dreams come true and support the community, thank you. Thank you all for your time and attention.

MS. CRISTINZIO: Thank you so much Dee.

Our next speaker, number 44 is Craig Weiss from CPT Labs.

MR. WEISS: Can you hear me?

MS. CRISTINZIO: Yes.

MR. WEISS: Good. I'd like to thank the FDA for hosting this listening session on this very important topic.

I am Craig Weiss, President of the Consumer Product Testing Company. We are a third-party quality laboratory that's been in business since 1975. We've been primarily in FDA-regulated areas, including cosmetics, medical devices and pharmaceuticals. So, I've had to become well versed in many GMPs.

I would urge the agency to, oh, and I'm also -- I am an independent beauty association board member and I share the technical regulatory committee. So I'd like to endorse the comments of Don Frey and I

also would hope that the agency would accept the ISO 22716 document as a starting point for this GMP. It's an international document and has world-wide acceptance and therefore would make export much, much easier.

I would also request that when GMPs have issued, that guidance for both inspectors and businesses would be issued because much of even the ISO document has language in it that is very drug like and can be easily misinterpreted by both business and inspectors and I thank you for your time.

MS. CRISTINZIO: Thank you so much.

Our next speaker, number 45 is Doug Farquhar from the National Environmental Health Association.

MR. FARQUHAR: Thank you very much.

Again. I'm Doug Farquhar with the National Environmental Health Assoc.

We represent over 7000 governmental private academic and uniform service sector environmental health professionals in the U.S., its territory and as internationally as well.

NEHA first released its body art model code in 1998 to assist the development of standardized regulations and inspection practices for body art facilities. We have continued to update that code

and, in fact, we anticipate an update this year.

NEHA body art committee who oversees the update of the code is comprised of both industry and regulators to ensure that the code reflects the current science and protects the health and safety of both consumers and practitioners.

We are very interested in the activities that FDA is seeking today, and we want to make sure that this effort to address inks and pigments will reflect the latest science and will provide an excellent guidance for all members of the body art community to engage in.

Body art's primarily regulated by the state, local tribal and territorial public agencies, primarily the local public health agencies.

With so many people, one in five adults in the U.S. having a tattoo, this necessitates the need for a public health oversight by these agencies over the industry. Body art standards and regulations advanced by these agencies continue to struggle to keep up with the evolving trends within the art of tattooing.

The requirements to ensure safe tattooing vary greatly among each one of the agencies as to his training and guidance. The lack of a national

public health guidance to promote safe tattooing, including safe ink's, places this burden of safe tattooing on the local agencies.

NEHA supports FDA research into safe inks and to ensure body -- our practitioners are using the safest, most effective practices involving the art of tattooing, both the regulators and the profession operating body art facilities must be aware and must be knowledgeable about these changes to the industry and regulations to the industry must reflect those changes.

Body art is a rapidly growing industry. Research and guidance on inks and pigments, as well as on the various tattooing practices enables the body art practitioners to perform these activities safely and the environmental health professionals to relate them effectively.

NEHA supports the development of cosmetic good manufacturing practices, both the guidance and regulations. We support FDA on this initiative and look forward to working with the agency in making sure that the best and most common, most effective regulations are put into place to make sure that the industry arrives and thrives.

With that I'm going to say thank you.

MS. CRISTINZIO: Thank you so much Doug.

Our next speaker, number 46 is Danielle Palermo from the Humane Society Legislative Fund.

MS. PALERMO: Hello. Can you hear me?

MS. CRISTINZIO: Yes. wonderful.

MS. PALERMO: Wonderful, thank you so much for the opportunity to comment today.

My name is Danielle Palermo, and I'm commenting on behalf of The Humane Society of the United States and The Humane Society Legislative Fund.

Modernization of Cosmetics Regulation Act of 2022 or MoCRA requires the FDA to issue new rules on Good Manufacturing Practices or GMPs. MoCRA also included a sense of Congress, which states that animal testing should be phased out, with the exception of appropriate allowances.

We believe that the humane cosmetic act serves as a model for those allowances, which includes limited exceptions to the prohibition on animal testing done for the following purposes:

1. To address a specific human health concern, as determined by the secretary of health and human services.

2. To satisfy for in testing requirements.

3. For testing required on ingredients for

non-cosmetic purposes.

And 4. For products regulated as drugs by the FDA.

To attain the sense of Congress, it should be established as part of the GMP regulations under development that cosmetics must be manufactured or produced without the use of new animal testing, unless a manufacturer can show that the limited exceptions such as those in the after mentioned provisions from the humane cosmetic act are applicable.

MoCRA amends the food drug and cosmetic act to state that if a product has been manufactured or processed under conditions that do not meet good manufacturing requirements, then a product is considered as an adulterated product.

Cosmetic products produced or manufactured using animal testing should not be considered to meet GMP requirements and should be deemed as adulterated products. The GMP regulations limiting the use of new animal testing should be applicable to all businesses as the FDCA or Food Drug and Cosmetic Act does not require animal testing for cosmetics.

Currently, ten states and 42 countries have

passed laws to end or limit cosmetic animal testing, there's also strong industry support for this. The personal care products council, the trade association representing 90% of the U.S. cosmetic industry has endorsed the Humane Cosmetic Act, as well as nearly 400 companies who have individually endorsed the Humane Cosmetic Act.

We urge the FDA to take this opportunity to address the sense of Congress that animal testing for cosmetics should be phased out, by requiring companies who manufacture or sell their products within the United States to not use new animal tests.

The FDA will provide the regulatory alignment that company's desire while ensuring cosmetic safety assessments are utilizing modern non-animal approaches that provide more human relevant information.

Thank you very much for your time today.

MS. CRISTINZIO: Thank you so much, Danielle.

Next speaker, number 47 is, Rafael De Oliveira from Trinny, London. Raphael if you're with us, please raise your hand so our AV team can unmute you. It doesn't appear that Rafael is with us. I'll return to you when I go back through the list,

in case you're on.

I'd like to move to speaker, number 48, Hossam Mohammad from Vision Perfumes and Incense Manufacturing. Can you move to the next slide, please. Thank you. Hossam, are you with us today?

And we're running very far ahead of schedule. So, some of these folks might not have anticipated me calling on them so early. And I apologize for that. It doesn't look like Hossam is logged on.

And it also doesn't appear that our next speaker number 49, Robbie Walters, is logged on.

But I'll call on him just the same just in case they're logged in under a different name. While Robbie Walters from SoapEquipment.Com are you with us?

Okay. Moving on to number 50, Donna Johnson from Indie Business Network.

MS. JOHNSON: Yes hi, good afternoon. Thank you so much.

My name is Donna Maria Coles Johnson. I'm the founder of the Indie Business Network an entrepreneur training company, founded in 2000 to represent and assist artisan makers of consumer products such as soaps, cosmetics, perfumes, and so forth.

In our quarter century of serving we have observed the robust and tremendous growth of our thousands of members nationwide who now serve consumers who are overall thrilled with the fact that they now have so many choices when it comes to their personal care products.

Our members are committed to making and selling safe cosmetics, and they pride themselves on doing so. Our constituents and members are very small businesses. Some may call them micro-businesses and the vast majority of them are women owned. Many of them are minority owned businesses, and many of them are also family-owned businesses using their vendors to even train their children in the ways of business and entrepreneurship.

They support their local communities by selling their products at pop-up shops, small retail stores and spas, farmers markets and more. Many of them run their businesses from their homes until they're grown enough to lease a space in their local areas.

I have several examples that I'd like to share just briefly. Many of these companies have been members of the Indie Business Network for over 10 years. One, for example, started a small business in her home, grew to sell her products on Etsy.com,

then to her own website, and now owns four retail stores in the state of New Jersey.

Another one, also is in New Jersey, started her small business in her home and is now training other people to own and manage their own businesses and also sells her products, private label, to a nationwide hotel chain.

A minority own business in Baltimore whose spouse has recently joined her business also sells her products on a website and also private label to a hospital chain, she sells her shampoos and her conditioner products.

So this is just a small sampling of what some of our members are doing. So to get to some of the points that you raise for comment requests, I'd like to address flexibility, simplicity, and economics.

In order to thrive, small and microbusinesses require flexibility. It is so critical that the FDA consider an actual need for regulation before implementation of any rule that embrace actual accommodations due to manpower, cost, paperwork, and space constraints, that are unique to small and home based businesses.

Simplicity is also important in the sense that there be ample time for small companies to

understand and implement new requirements.

In addition, economic considerations must be consistently and adequately and practically considered as any new regulations are considered for implementation.

Thank you so much for the opportunity to share with you today. I look forward to continuing to work together to craft regulations that promote and support both safe products and the continued robust growth of the small businesses that are the very engine of the U.S. economy.

MS. CRISTINZIO: Thank you so much, Donna.

Our next speaker is speaker number 51, Michael Pfeiffer from Pfeiffer Consulting, GmbH.

MR. PFEIFFER: Yeah, hello. Can you hear me.

MS. CRISTINZIO: Yes.

MR. PFEIFFER: Okay. Yes hello. Good day, ladies and gentlemen. Thank you to FDA for the organization of this very informative event and for the opportunity to speak on the important topic of GMP for cosmetics, and ISO 22716.

My name is Michael Pfeiffer and I'm the founder, owner, and managing director of five consulting in Germany and prior consulting LLC in the United States.

Since 1994 we have been supporting the customer industry in different areas, including GMPs for cosmetics, and we have been supporting U.S. companies in the implementation of the EU requirements for now 13 years, with ISO 22716 playing a central role. Now the focus on the implementation of the GMP ISO 22716. Back in 1994 I had the privilege of being one of the pioneers among cosmetic's GMP auditors in Europe.

Today, based on our extensive experience of now 29 years of cosmetic GMPs, which includes more than 8000 GMP audits and hundreds of implementation of standards worldwide. I can recommend the ISO 22716 as valuable, proven and relevant tool with a clear conscience. Whether you're a small company or global player, this standard provides a flexibility and interpretation range for successful implementation in the companies.

Adopting this standard will make it easier for companies, especially small and mid to medium size companies, to operate on a global scale of applying a uniform standard.

Therefore, I propose daily implementation of ISO 22716 be included in the requirements of MoCRA.

I'm happy to be available for further

discussion on the topic of cosmetic GMPs.

Let's work together to -- harmonize and efficient regulatory landscape for the cosmetic industry.

Thank you very much. And have a nice and successful afternoon. Bye, bye from Germany.

MS. CRISTINZIO: Thank you so much, Michael.

Next is speaker number 52, Nozomi Brown Uqora, Inc., Nozomi. If you are with us, please raise your hand so we can unmute you.

Okay looks like Nozomi dropped off the list at the last minute. So I'm going to move on to our last speaker of the segment, Scarlett Perez Olea. Thank you. Scarlett, are you on the line with us? Can you please raise your hand.

Also, recognizing that we are running about 45 minutes ahead of schedule, so I'm hoping that some of the people we missed earlier in the segment have joined.

Okay. Doesn't look like Scarlett is with us. So, as promised, I'm going to go back to the beginning of segment two, to speakers number 25 and who were not present when I called on them the first time.

Just waiting for our AV team to move the slides

back. Perfect. Thank you so much.

First speaker I'm going to call on that was not present earlier is Steven Rosenfeld. Steven, are on the line?

Okay, the next one I'm going to call on is Karen Marquez from Soap Products, Cosmetics. Not hearing anything from Karen.

Moving on to our next speaker, number 27, Stephanie Porter, from About Face by Stephanie Face. Not hearing anything from Stephanie.

Moving on to speaker number 28, Jamilah Rasheed. Shea by J. Are you on the line with us?

And given that we have a lot of time if you were in segment one and missed your chance to speak, you may also raise your hand and I will recognize you to speak at this time.

I'm going to move on to speaker, number 29, Khathu Phungo from the University of Northwest South Africa. Please raise your hand if you're up on the line.

Not hearing anything from Khathu.

I'm going to move on to number 30, Desiree Saputo. Desiree, are you on the line with us?

Okay. Moving on to speaker number 32, Jamshaid Bhatti. Many of these people calling from very far away. It might be just missing the time zone change.

All right. I'm going to move on to our next speaker who we missed out on earlier in the session. Number 34, Nan Qin from Natural Immunogenics and I believe Nan was on earlier. Nan, please raise your hand if you are on.

Okay. And I'm also hearing that Jamshaid number 32, might be on, great.

MR. BHATTI: Yes, yes. I'm here. Good morning to you all, how are you, hello --

MS. CRISTINZIO: Great. Please proceed. Thank you.

MR. BHATTI: Hello.

MS. CRISTINZIO: We can hear you, please proceed.

MR. BHATTI: Hello, the U.S. Food & Drug Administration experts and professionals from different characters of life saying to you good morning in the U.S., and goodnight here in Pakistan.

Thank you, Dayle, for giving me the opportunity to express my views here. You're handling this webinar as a moderator very smartly, and I much

appreciate it.

Well, I am Jamshaid Akbar Bhatti, CEO SK JAMAL Private Limited, Pakistan, feeling tremendous honors to be in the public meeting Good Manufacturing Practices for cosmetic products listening session Zoom webinar.

As we are all industry stakeholders already concerned to follow fully all good manufacturing practices for cosmetic products, but now we're facing new challenges like COVID, climate change, and other related issues, which really -- effect directly and more closely to our industry, people, environment, and areas. They are, of course, sensitive by nature and are great important. . .

MS. CRISTINZIO: Jamshaid, I think we lost you.

Are you still there?

I think we might have bad connection.

Just a reminder, our docket is open until July 3rd. So anyone who wishes to submit comments to the docket or missed their chance to speak as a speaker, we will definitely be accepting and considering your comments then.

Moving on to the next speaker who we missed out on in the second segment, number 35, Melissa Gomez. Melissa, are you on the line with us?

Okay. It doesn't appear she's with us.

I'm going to move on to our next speaker, number 30, sorry -- number 40. David Schmidt, who I know has a different screen name; listed as Robin. David, please raise your hand so we can recall you.

MR. SCHMIDT: Yes, can you hear me?

MS. CRISTINZIO: Yes, thank you.

MR. SCHMIDT: Okay, thank you.

My name is Dave Schmidt, and I'm executive director of AOAC International. AOAC promotes methods development, validation, and quality measurement in the analytical sciences. Established in 1884, AOAC today is renowned for its compendium of methods, official methods of analysis of AOAC, international.

AOAC reviews and approves methods that have undergone rigorous systematic scientific scrutiny to ensure that they are highly credible and defensible.

AOAC methods are referenced and used by industry, research organizations, testing laboratories, academic institutions and regulatory agencies, including the FDA.

Adherence to GMPs minimizes the risk of adulteration or misbranding of cosmetics. Good manufacturing practices must include following established methods for cosmetic products as they

are sampled and tested.

AOAC methods help ensure conformance with laboratory quality processes that prevent contamination, whether from hazardous microorganisms or chemical toxins. For decades AOAC has offered cosmetic methods as part of its official methods of analysis of AOAC international for use by cosmetic manufacturers and laboratories. For example, AOAC methods on the efficacy of preservation of non-eye area water missile cosmetic and toiletry formulations and gas chromatography for water and ethanol alcohol and cosmetics.

Other AOAC methods such as those related to heavy metals and PFAS may also impact cosmetics.

As FDA considers regulations to establish GMPs for facilities that manufacture or process cosmetic products, AOAC urges the agency to reference the usage of methods and technically equivalent standards in rule making and guidance documents.

Thank you for your time and consideration of these remarks.

MS. CRISTINZIO: Thank you so much, David and thanks for hanging with us through these technical issues. We're really glad we are able to recognize you to speak.

Our next speaker is number 47, Rafael De Oliveira. Rafael, are you with us?

Okay. I think I'm going to move on to number 48, Hossam Mohammad, from Vision Perfumes and Incense Manufacturing. Hossam, if you're on the line, please raise your hand, so we can recognize you.

Okay. Moving on to speaker number 49, Robbie Walters from SoapEquipment.com. Doesn't appear Robbie is with us either.

Okay. We are going to keep moving on.

We have Nozomi Brown, number 52.

And the last speaker in this segment that we are going to try and recognize is Scarlett Perez Olea number 53. Scarlett, if you're with us, please raise your hand.

It looks like Nozomi is on. We have given you, we have unmuted your mike. Maybe you need to unmute yourself. Just giving Nozomi another few seconds to see if we can get their mike unmuted.

MS. BROWN: Hello.

MS. CRISTINZIO: Hi, we can hear you.

MS. BROWN: Hi, yeah. Sorry about that. I've actually canceled my comment, I'm sorry -- like it was only a couple of days before this meeting but, yeah, no comment from me at this time, I just wanted

to listening to everybody's input.

MS. CRISTINZIO: Okay. Thank you so much Nozomi for turning in today.

We are definitely running ahead schedule of schedule. We are 30 minutes ahead. I know there were a number of people who were not able to present during the first segment. I'm just going to give those who missed their opportunity to provide live public comments in the first and/or second segment to please raise your hand, so our AV team can recognize you and unmute your line.

We definitely want to give everyone opportunity to be recognized who signed up to speak.

I see you Jamshaid, do you want to complete your comments? You were only about halfway through.

MR. BHATTI: Yeah, of course. Thank you for giving me the opportunity again. I'm Jamshaid Akbar Bhatti from Pakistan. I was just extending the situation especially between the change -- COVID issues and climate change that we must be very specific and scientific -- clotting products is and the quality of the product, especially in the developing countries and in them and in all the specialist parties like FDA or other scientific research, recognize and certain avoided parties

linked together, so that we have regular sessions for offering counseling for good manufacturing practices for the industry and attacking them to follow strictly all these good practice manufacturing.

Thank you so much for your all and giving the opportunity there. Okay.

MS. CRISTINZIO: Thank you so much for your persevering through technical issues. We really appreciate you joining us today.

MR. BHATTI: It was really honor one for me -- and team and all the respected colleagues from the world here. Thank you from Pakistan and we hope you have some regular sessions for our region here because you see that many complaints from Pakistan like to having some certification or constant or some sorry type of expert views, but they're facing some problems here, approaching the search mission and the FDA is providing wonderful forum for such inspections, guidelines and stations there and we were happy for being your active team industry member here for such type of regular adamant thank you so much, and I wish all the members here, all the speakers here a good time, good learning and goods session. Thank you so much.

MS. CRISTINZIO: Thank you so much Jamshaid.

It's really important part of our regulatory process to hear from our stakeholders and receive public comment.

I'm just going to pause one more moment just to see if there's anyone else who was in segment one or two that was not available to speak when I called on them.

Please raise your hand our AV team can recognize you. And while we wait for that to happen, I just want to remind everyone our docket is open for comments until July 3rd. The docket can be found at www.regulations.gov and the docket number is FDA-2023-N as in Nancy -1466. And again, the docket is open until July 3rd for comment.

Not seeing anyone with their hand raised from segment one or two that signed up to speak. I think I'm going to conclude the first half of this listening session. Since we are so far ahead and I don't want to miss out on people who know that they're supposed to speak after our lunch break. I am going to take an extended break so that we stay on our projected schedule.

We're going to break until 1:15 p.m., and we will begin our next open public comment segment with

presentations that have slide decks.

Again, we'll begin again for the third segment at 1:15.

Hope everyone gets a little break and see you after lunch. Thank you.

(Off the record at 12:31 p.m.)

(On the record at 1:14 p.m.)

MS. CRISTINZIO: I want to remind everyone who has signed up to speak that I will show the slides so you can see where you are in order and if you are a speaker who is presenting a PowerPoint presentation we are the ones that control your slide deck, so you will need to prompt us to move the slide forward. And as I did in the beginning session and the first half of the session, if you miss your slot, I will come back to you at the end of the segment to see if I can recognize you to speak. We want to make sure that we get as many public speakers on the record as possible today.

So with that, I'm going to go to our third segment. This is open public comment presentations with slides. I'm going to ask you to, if you are on this list, to raise your hand when we are nearing you on the list so that our AV team can recognize you and unmute you.

First on deck, we have John Bailey from EAS Consulting Group.

MR. BAILEY: Can you hear me?

MS. CRISTINZIO: Yes.

MR. BAILEY: Thank you very much. Okay thank you. My name is John Bailey, and I'm currently consulting with EAS Consulting Group.

Next side, please. Just my background, I've -- had spent more than 30 years at The Food and Drug Administration, serving as the first director of The Office of Cosmetics and Colors when it was initially conformed. And then after that, the director of the Office of Applied Research and Safety Assessment.

After retiring from FDA I spent ten years at the Personal Care Products Council, first as director of Cosmetic Chemistry and then after that as senior vice president for science. And after retiring from PCPC, I've been working as an independent consultant, mostly helping small companies understand cosmetic regulations.

Next slide, please. Just to show a little bit about MoCRA this is a list of the elements, most of them and GMPs by regulation are going to be a big part of it. So, I'm very happy that you're having this listing session. It's important to understand

fully what that entails for the industry.

Next side, please. And this, just for time orientation. The GMPs don't really kick in until about the beginning of 2026, but there has to be -- there's a lot that has to happen between now and then for FDA to issue the regulations. So it's important to know where you are on the scheme of things as MoCRA continues to roll out.

Next slide, please. And I think it's really important to understand what exactly GMPs mean from the perspective of FDA and FDA is instructed by the law to establish a regulation that sets up the standards for good manufacturing practice. And it's really important to understand that this is intended to protect the public health and make sure cosmetics are not adulterated. This allows FDA to inspect records, there is a guidance or instruction to provide simplified GMPs and to hold this listening session. So I think that's a very good thing.

I'll just add here that GMP regulations are just that, they're regulations. Their interpretation of the law, and a GMP violation during inspection could cause your products to be adulterated. So it's really important to understand that.

Next slide, please. So what are the key characteristics of cosmetic GMPs. I think we've heard a lot of that in the presentations this morning. One size does not fit all products and companies. There are larger companies, some sophisticated, some not. Flexibility in this situation is really important. As we heard earlier, this is opportunity to achieve international alignment while advancing safety, product safety.

I think one thing that we haven't heard much about is the adoption or acceptance of third party auditing for cosmetics, I think that will help FDA and the industry a lot.

A reasonable ruler must be applied, in other words, cosmetics are not drugs or foods. They are in fact the safest products that are regulated by FDA, and that should be kept in mind. There are existing models that can be considered, there's no need to reinvent the wheel.

Next slide, please.

MS. CRISTINZIO: And just reminding you. You reached your three-minute limit, John. Wrap up --

MR. BAILEY: I'm sorry, there are three guidances that ISO 22716 that you've heard about.

Next slide -- and I'll go very quickly here.

We do -- okay, I -- I highly recommend that ISO 22716 be adopted. FDA inspectors will have to be trained to understand cosmetic GMPs. I don't think there are very many in the field. And FDA should accept third party inspection certified auditors and implementation will be a learning experience for everyone. So sorry, I went over. Thank you very much for the opportunity speak.

MS. CRISTINZIO: Thank you so much John. Not a problem. Please make sure to submit your written comments to the docket.

MR. BAILEY: Yes, thank you.

MS. CRISTINZIO: Thank you.

Next speaker, number 55, we have Christopher Ho, from Loreal. Christopher, if you're on the line, can you please raise your hand so or AV team can prompt you to unmute?

MR. HO: Hello. Can you hear me?

MS. CRISTINZIO: Yes, we can.

MR. HO: Excellent. Thank you, so good afternoon. And thank you for the opportunity to speak and to give input on this very important topic.

My name is Christopher Ho. I work for Loreal and I'm a member of PCPC quality assurance committee.

However, today I'll be speaking on behalf of PCPC quality assurance committee, the GMP working group, and specifically, regarding sufficient, flexibility within the upcoming GMP regulations.

To frame the talking points, I'll be taking into consideration that consumers are indifferent about the facility type, size or scope of the business. Consumers really expect and demand safe cosmetic products at all times. So from the GMP working groups point of view, the recommendation is that consumer and product safety should be paramount, and therefore GMP rules should be the same regardless of the facility type, size or scope of the business.

Should there be any consideration for flexibility, it should be based on a holistic risk based approach with appropriate mitigation plans, taken into account that the inherent risk of the product types. So, for example, whether it's a micro sensitive product or not and the intended use of the product?

Possible areas for consideration could be the usage. Next slide, please. Possible areas of consideration could be the usage of digital and paper records as long as it can be demonstrated that

they are equivalent.

Second consideration could be for sampling and testing frequency so it could be based on historical data or possibly capability studies to help determine the frequency and having control measures in place to avoid adulteration, which is key.

A third consideration could be for water quality. So, for example, the use of drinkable water source has determined by a regulatory authority that meets minimum world health organization requirements.

The fourth and final consideration is the possibility of using existing infrastructure and equipment. So, for example, not having to have separate areas for all the activities or having to completely redesigned infrastructure, but instead focus on mitigation of the risk itself.

In summary, GMP rules should be the same for all regardless of the facility type, size or scope of the business. However, should flexibility be considered, it should be based on the inherent risk of the product type and the final intended use of the product. Thank you.

MS. CRISTINZIO: Thank you so much.

Our next speaker, number 56 is, Don Ye from

Estee Lauder.

MR. YE: Hi, Dayle, can you hear me?

MS. CRISTINZIO: Yes.

MR. YE: Okay. Can we go to the next slide, please. I just have one slide for talking point.

Okay, thank you.

I greatly appreciate the opportunity to comment on the future state of the U.S. cosmetics GMP.

My name is Don Ye from Estee Lauder Companies, and I'm speaking today as an industry representative from the GMP working group.

In the absence of the regulated U.S. cosmetic GMP standard, the cosmetic industry has been utilizing A variety of GMP tools, available both domestically and internationally.

Based on an industry member survey the ISO 22716:2007, good manufacturing practices and ANSI 4553 good manufacturing practices for cosmetics U.S. are most utilized. Both standards have the same core quality systems and they vary in part due to the updates to keep current.

What existing standards, ISO and ANSI provide an opportunity for faster and more efficient adoption -- by companies, experience, education and expertise is readily available due to the maturity

of the standards, that's facilitating implementation and compliance. As demonstrated through an industry survey, many companies already have systems in place and are certified for ISO or ANSI. With ISO and ANSI certificates, the companies are able to sustain business continuity, both internationally and domestically.

Both ISO and ANSI are accredited and recognized. ISO 22716 is accepted internationally by both regulatory bodies and industry, and ISO does provide an opportunity for hominization. With an existing standard, FDA may consider a regulatory scheme similar to that implemented for food with the Voluntary Qualified Importer Program, VQIP. For cosmetics, the food model would need revision to reflect the lower inherit public health risk level of cosmetics. As in VQIP, the model of FDA accredited third party certification program could be utilized for the cosmetics program.

The third-party certification could also provide an opportunity for an enforcement scheme that is flexible to support both the forecast inspection and risk base schedule.

With FDA accreditation, there's also an opportunity for FDA cosmetic certificate which the

industry has been requesting for the purpose of global registration opportunities.

An alternative to the existing standard is a GMP model consisting of high-level principal based GMP regulations, utilizing public forms and guidance documents to propagate more specific requirements and involving expectations, similar to in line with CGMPs, however the potential uniqueness of this model is likely to implicate additional layers of education, training, implementation to what most companies already have.

With all new regulations there are intended and unintended consequences. The use of GMP standard will be the least burdensome in most cases, however, even with existing cosmetic standard, there are unintended impacts due to enforcement activities and cost, such a certification.

Recognizing the new paragon for cosmetic regulation, industry has a preference for balance and challenges and opportunities with foremost intention for consumer safety and quality. Thank you.

MS. CRISTINZIO: Thank you so much. Don.

Our next presenter is Tim Parrent from Mary Kay.

MR. PARRENT: Thank you, and hello. My name is

Tom Parrent, I lead the corporate quality function at Mary Kay. We're responsible for global governance and compliance, supplier quality management and culture quality. I also serve as an industry SME on the NSF joint committee on GMPs for cosmetics, which developed ANSI 455-3 and I'm a member of the ISO 22716 technical advisory group. I also serve as a vice chair of personal care products council quality assurance committee.

On behalf of Mary Kay and the cosmetic and personal care industry, I'm pleased to provide the following comments.

Next slide. Mary Kay is committed to providing safe quality products for independent consultants and their customers. Every year we spend millions of dollars and conduct hundreds of thousands of tests including clinical studies with independent dermatologists, ophthalmologists, and other medical experts, to ensure product safety, quality and performance.

However, having a safe and effective form is only part of the equation. Mary Kay supports good manufacturing practices for cosmetics. We believe all cosmetic manufacturers should follow GMPs to assist in manufacturing high quality products

expected by consumers and minimize any risk to public health based on manufacturing.

We also recognize the benefits of engagement and collaboration, offer assistance to work with FDA to develop GMPs for cosmetics. Using a current standard as a framework for FDA GMP regulations would provide a faster and more efficient approach for adoption of cosmetic GMPs. These standards themselves are published resources, such as training and consulting that are accessible to help with implementation, but maybe the biggest benefit of using a recognized standard, it would allow cosmetic GMPs to evolve and remain current without having to update through rulemaking as these standards are open at regular intervals for review and updates.

Using ANSI 455-3, or ISO 22716 would be a practical approach to consider for implementing cosmetic GMPs. Neither standard is perfect, but both provide a solid framework for cosmetic GMPs.

Educate and collaborate before you regulate is a preferred way to implement cosmetic GMPs. In the educate before you regulate approach similar FDA tactical implementing FSMA is a good example to how to engage industry with educational tools before regulating. A collaborate before you initiate

approach like FDA is doing as they're developing standard quality metrics, and quality management training programs are good examples of collaboration between the agency and the industry and have been beneficial to both parties.

PCPC members have also benefited from the collaboration with FDA during PCPC annual GMP workshops which are tailored specifically for industry covering topics such as data integrity, method verification to investigations and inspection readiness.

Speaking of inspections, inspections should be based on risk, including inspection history and inspection outcomes. Inspection products should be given to sites never audited or sites with unfavorable inspection outcomes.

In closing, we welcome updates -- to engage with FDA and cosmetic GMPs and provide feedback on any standards or approaches under consideration.

Once a decision is made we request FDA identify the standard or alternative approach to stakeholders as soon as possible.

Thank you for the opportunity to speak and listening to this comment.

MS. CRISTINZIO: Thank you so much, Tim.

Next we have Geoff Waby from Obelis.

MR. WABY: Hello.

MS. CRISTINZIO: Hi Geoff.

MR. WABY: Hello -- can I start from the next slide, please. Yeah, oh, sorry. Go on back one slide, please. I'm sorry. That's it, that's the one.

Hello. So, good afternoon, Dayle. So my name is Geoff Waby, and thank you to Dr. Bumpus and Dr. Katz for this opportunity.

Could you go onto the next slide now please.

So Obelis is 35--years old, it's based in Brussels, Belgium and focuses on enabling companies around the world to comply with cosmetics regulations in key markets, including the European Union, the UK, Switzerland and now the U.S.

Obelis co-founded the European responsible person association and is an active participant on European commission working groups on cosmetic regulations.

Next slide, please. The FDA asked for comments on existing practical international standards, as we've heard ISO 22716 is the most widely accepted standard. It was created by an international working group. To maintain their ISO certification,

manufacturers are inspected regularly. A third of cosmetics on sale in the U.S. are imported. GMP compliance needs to be actively inspected across the world for comprehensive U.S. consumer protection.

As for flexibility to cover companies of different size and scope, the existing FDA drug model is good. Consumers deserve the same level of protection for all products regardless of the size or location of the company that made them.

Drug GMP regulations are the same for all companies. To differentiate between small and large facilities, more detail is provided either by guidance or by applying simple practical factors. One very basic example, records have to be complete, accurate, traceable to specific batches of product. How you do that depends on whether you used paper or computers.

The FDA will need to build a cosmetics inspection arm. To avoid imposing undue economic hardship, if the GMP regulations are unique to the U.S., inspections may be focused more heavily on domestic manufacturers, putting them at competitive disadvantage as they spend to get compliant, while importers are left relatively uninspected.

Next slide, please. The time to comply depends

on the choice of GMP regulations. If the FDA aligns with ISO 22716, many companies are certified today. The FDA may want to review the inspection reports by the relevant accreditation body for those sites and we'll have to decide how to address certification inspections after the FDA regulations are finalized.

So adoption of ISO does raise many questions, but it may be a more economically and practical way to protect U.S. consumers versus deploying FDA inspectors globally to inspect against the U.S. only GMP regulation.

Next slide, please. The Food Safety Modernization Act was a good example of FDA combining with industry academia to create training on the new regulations. And I note that the training will be for newly created FDA inspectors as well as cosmetics manufacturers across the world.

The first compliance cycle should concentrate on understanding the requirements and having a plan. Using a risk assessment process, both product category and the site history. For example, in OTC drug inspections should be used to set compliance priorities between the sites.

Thank you once again for this opportunity to speak. Thank you.

MS. CRISTINZIO: Thank you so much, Geoff. You were right at three minutes.

MR. WABY: Thank you.

MS. CRISTINZIO: Next presenter is Caroline Bassoni from Cosmed Association.

MS. BASSONI: Yeah. Can you hear me?

MS. CRISTINZIO: Yes.

MS. BASSONI: So good afternoon everyone. My name is Caroline Bassoni. I'm the regulatory affairs director of Cosmed.

Okay, move to the next one.

Cosmed is a French trade association created in Tutislama [phonetic] with more than one thousand members mainly small, and medium size cosmetic companies.

Cosmed is deeply engaged in the European development of the regulatory framework, especially through our representation as SME United acting as a direct tech headquarter in the cosmetic working groups of the European Commission.

Okay, move to the next one. So as we got to GMP for cosmetics, which we advocate as best in class model for ISO 22716.

So first we standout is already recognized and implemented as the official one under a number of

regulations including in Europe and the cosmetic product regulation. But also in many international countries such as Canada, Brazil, Japan, Israel and -- and much more. And as well as that is officially endorsed by ICCR. So here such -- among international standard -- on top would also facilitate international trade with a common framework.

And, finally, it would simplify the magnus of quality in companies with only one standard to apply.

Can move to the next one.

So in Europe this ISO standard has a longer history of practice for cosmetics, has existed since 2007 and included in the cosmetic product regulation since 2009. This system has proven to be effective and to end in every step of production and at all levels of supply chain and leading to better quality products. It also supports the management of in-market quality issues such as deviation, complaints, and recalls. Those are key benefits that fits to all product types and all company sizes and complexities.

And finally, it is important to note that ISO 22716 is not only super quality principles, but also

contributes to company's competitiveness.

Next one please.

So finally, we want to share our European experience with cosmetic SMEs. So, yes, clearly ISO 22716 implementation is possible and it can be successful for SMEs. However, specific consideration and support needs to be provided to them. Key element has needs for more transition time to allow them to put in place proper GMP processes. They would need, as well, education with -- another essential aspect is support. To note as well that most SMEs are not used to inspection, and would need to dedicate its support to get prepared to phase them in.

So in conclusion, cosmetic support ISO 22716 has relevant model for GMP for cosmetic products.

And we want to thank again FDA for their opportunity to contribute to this public observation today.

MS. CRISTINZIO: Great, thank you so much, Caroline.

Our next speaker, number 60 Alexandra Kowcz from the Personal Care Products Council.

MS. KOWCZ: Thanks, Dayle.

And I'd like to start with the next slide

please. Next one.

Good afternoon. My name is Alex Kowcz, and I'm currently the chief scientist of the Personal Care Products Council. PCPC is one of the most well-established trade organizations in Washington, D.C. founded in 1894. Our member companies consist of small, medium, and large size entities that manufacture, distribute, and supply the vast majority of cosmetics and personal care products in the United States.

Our companies are global and are committed to providing safe, innovative products that enhance the quality of life for all of us. PCPC and our member companies are pleased to offer our support to work with the FDA to develop good manufacturing practices for cosmetic products.

Through the work of the association’s quality committee over the past 40 years we have published industry best practices for GMPs, called the quality assurance guidelines, and stand ready to assist the FDA with the development of cosmetic, GMP regulations.

For the successful implementation of cosmetic GMPs, one of our key messages is to recommend that the agency consider a collaborate, educate,

regulated approach, before enforcing cosmetic GMPs. To that end, we offer the following remarks in response to the topics.

Next. As you've heard from previous speakers, two cosmetic GMP standards to consider are ISO 22716 and ANSI 4553.

It is noteworthy that the ISO standard has broad international acceptance, as you've heard today, and has been adopted by numerous countries, which in effect, promotes the global marketing of cosmetic products.

Incorporating a recognized standard into FDA GMP regulations would be less burdensome and offer the following key benefits. Adoption of an existing standard will allow caused GMPs to evolve without having to update GMPs through rulemaking. Training is already available. Many companies have systems in place to adhere to this. An alternative to the adoption of an existing standard would be to have high level principal based GMP regulations, more specific requirements and involving expectations could be propagated through public forms and guidance documents to reflect current GMPs.

Next. Regarding the topic of flexibility within GMPs. The requirement for consumer safety

and product quality should be the same irrespective of facility type and size. Consumers don't care where a product is made. They do care about the quality of the product.

In our opinion, size does not matter. All cosmetic manufacturer should follow GMPs to assist in manufacturing high quality products expected by the consumers and to minimize any risk to public health.

Consumer safety and product quality should be the goal for all sites. However, GMPs should also be flexible and allow for the consideration of risk based on the product type and manufacturing process and controls.

The assessment of risk should be holistic and consider the production facility, the equipment, the processes, specifications, the testing, product formulation and intended use.

To allow for flexibility with implementing GMPs, consideration should be given to the usage of existing infrastructure and equipment, the usage of digital and paper records, where they are equivalent. Appropriate sampling and testing frequency, appropriate water source quality.

Next. Regarding the topic of simplified GMP

requirements. GMP should be the same for all businesses since final cosmetic products to consumers should meet the same safety and quality requirements.

All businesses making cosmetic products should have established procedures for ensuring GMPs are followed, including appropriate water quality with regard to the type of product.

Simplified approaches can be implied to assure GMPs. For example, allowances should be built in for size and various organizational structure to cover the quality responsibilities where the number of employees is limited. Sufficient time should also be given for businesses to develop systems and comply with requirements.

Next.

MS. CRISTINZIO: Actually, Alex overtime can you please wrap up.

MS. KOWCZ: Sure. In response to the topic of appropriate as I stated before, the collaborate, educate, regulated approach is the best framework. We encourage collaboration with industry to better understand the range of capabilities within our sector. And then proposed that there should be an educational year while the regulations are rolled

out industry wide.

Thank you very much for this opportunity and for listening to our important feedback.

MS. CRISTINZIO: Thank you so much Alex.

MS.KOWCZ: Thanks, Dayle.

MR. CRISTINZIO: And our next speaker is Iain Moore from the European Federation for Cosmetic Ingredients.

MR. MOORE: Good afternoon. I hope you can hear me.

MS. CRISTINZIO: Yes, we can.

MR. MOORE: Yes. Thank you very much, indeed for the opportunity to speak. I did send in some slides, and I'm not seeing those, but yes they're there now, thank you.

Next slide, please. My name is Iain Moore and I'm the chair of the GMP committee working group for EFfCI the Europe Federation for Cosmetic Ingredients, and we represent over 140 industry members across Europe with six national associations and 17 organizations indirect membership. And we've -- engaged globally with cosmetic trade associations around the world, including colleagues from PCPC and cosmetics Europe who've spoken previously today and also – CAFCI in China. And we

also host and deliver the EFfCI GMP certification program for cosmetic ingredients, which has got more than 250 suppliers of cosmetic ingredient suppliers registered with that certification process, including 38 in the United States.

Our job here is very much to ensure the safety of cosmetic ingredients and thereby the safety of cosmetics to ensure consumer safety.

Next slide, please. In terms of our requests to the FDA, it's really to ensure that the cosmetic ingredients are not included within the scope of the GMP. The fundamental here that we've learned is the cosmetic ingredients are made by chemical synthesis, and so they have different threats to consumer safety than those in cosmetic manufacture and the detailed rules of GMP for cosmetics are not suitable to control those threats posed by cosmetic ingredients.

There's one reason why we developed the EFfCI GMP certification scheme for cosmetic ingredients. Because in Europe, as we've heard, they wanted a GMP for cosmetics some time ago, and cosmetic ingredients were previously included in scope, and that was going to cause a lot of complications for cosmetic ingredient manufacturers. So that's why I -- I request

is to keep the GMP for cosmetics just to cosmetics and not to cosmetic ingredients.

Next slide, please. The other factor is, again, this kind of crossover with drug product manufacturing. There's a lot of discussion about this, at what point does it a cosmetic become a cosmetic? At what point does a cosmetic ingredient stop being a cosmetic ingredient, and we would advocate that there's allowance that if a material is made and supplied as a cosmetic ingredient, even if itself is a mixture of cosmetic ingredients, that it's still a cosmetic ingredient. It's not some sort of intermediate cosmetic and therefore subject to FDA rules on cosmetic and cosmetic GMPs.

The key thing here is to try and keep things simple and to do a risk-based approach that others have advocated to ensure consumer safety. So this, again, is -- is covered in scope with the EFfCI GMP certification program and that we can make blends or mixtures of cosmetic ingredients which we can supply to cosmetic manufacturers to facilitate the manufacture and provide that with a high degree of assurance and quality.

So thank you very much indeed, for the opportunity to speak with you today and hope the

rest of the day goes well. Thank you.

MS. CRISTINZIO: Thank you so much Iain for joining us from Belgium.

Our next speaker, number 62 is, Brandi Reinbold from NSF International.

MS. REINBOLD: Good afternoon Dayle, can you hear me?

MS. CRISTINZIO: Yes, we can.

MS. REINBOLD: Great. So, I am Brandi Reinbold commenting on behalf of NSF International. As a public health not for profit with a mission to protect human health, NSF has more than 75 years of experience developing an American national standards and I appreciate the opportunity to discuss NSF ANSI 455-3, which is the American National Standard for cosmetics GMPs.

Next slide please. ANSI 455-3 was developed in 2018 in partnership with the GRA a consortium of retailers and manufacturers to address the need to comply with ISO 22716 international standard globally and with FDA GMP guidance domestically. The result is an ANSI credited standard that includes both the ISO 22716 and FDA guidance within its scope. And unlike ISO it provides a platform for national participation and control.

Standards designated as American national standards follow ANSI essential requirements for due process, including openness, balance, and consensus.

Changes via the ANSI process, ensure one interest does not overpower others and changes are more quickly inactive compared to regulation as new public health threats identified or practices advanced or become absolute.

The standard includes a guidance document to convey details on typical GMP compliance in a flexible way to accommodate a variety of manufacturer processes and situations. It also includes a section on audit practices to be used by certification bodies who can certify against the GMP requirements.

Next slide, please. There is a long history of use of consensus standards and related conformity assessment activities by federal agencies.

The benefits include being more cost effective in time than developing a government unique standard, enabling the agency to take advantage of the expertise of the private sector, and aligning regulation with industry best practices.

An accredited third-party certification can also be leveraged to enable regulators to make risk-based

enforcement decisions with limited resources.

The benefits to the regulators are also benefits to the regulated parties. Additional benefits to the regulated parties include the ongoing opportunity to participate in the standard setting process, and perhaps the most important benefit of the practice is the furtherance of public interest by the effect of improving the GMPs over time.

A major limitation is the legal requirement to include a version. It is burdensome for the FDA to revise this reference. Due to the continuous management practices of NSF as a standard writing body, NSF and ANSI 455-3 is the only public standard which can still easily be modified to meet any rulemaking criteria prior to the compliance deadline.

NSF ANSI 455-3 is the existing GMP standard with the greatest utility to maximize benefits and minimize limitations of such a reference. It has the versatile and national control needed to meet current and future needs of U.S. consumers, manufacturers of all sizes and regulators, domestically and globally.

Thank you for this opportunity to provide

comments.

MS. CRISTINZIO: Thank you so much, Brandi.

Our final speaker presenting slides today is Matteo Zanotti Russo from Angel Consulting.

MR. RUSSO: Yes. Could hear me?

MS. CRISTINZIO: Yes.

MR. RUSSO: Yes, good afternoon. My name is Zanotti Russo -- but well, thank you for giving the opportunity to speak, to tell you about my experience, to share with you all my -- my consideration about GMP.

Well, I'm CEO of the Angel Consulting, we are our company and bold and regulation and compliance. We are a subsidiary as -- Europe and UK and the United States with the aim to help the international level about the cosmetic revelation.

So I lead different teams of experts in my company. Some of them are involved – in GMPs and others safety assessment, and then in there so basically, we have a long experience even from our European presence in three main pillars that are introduced with MoCRA.

One of these is GMPs, well, GMPs I heard about From most of the other speakers that the proposal, the most reasonable proposal is to start from

ISO 22716, I agree with this.

So, please next slide. I basically agree with the idea of the approach based on ISO 22716.

Please, the next slide. The lid can move, okay. But -- well another expert before told something I read that we don't need to reinvent the wheel. It's true, but ISO 22716 was invented kind of 16 years ago. So I wonder if the -- the chance to improve. And then I see two main issues can be improved. And then shortly pick one is the link between good manufacturing practices and safety assessment and safety substantiation. Because in most cases they are not linked --

Please, the next slide. They are not well linked and -- sorry --

Next slide, please okay. Because we're not talk fact practice or a tool to replicate as the control that the safety assessors approved in the ideal products into the real life.

Next slide, please. And then an example and which the control of the specific batch can in part into the safety assessment, and then there is an interaction.

Next slide again. There is an interaction, and

then this is a purchase, and then I suggest to move it to improve the GMP. And then the last issue and in my opinion, is missing and can be improved.

The next slide, please. Is concerning the risk assessment, risk analysis is missing. So I don't consider what can happen. So the -- count ISO 22716 this is good, but that nothing about what is the consequences if there's something wrong that is coming in other kind of ISO like 3485 or HCCP or IF8PC.

So I suggest basically -- sir, ISO 22716 is good starting point because it was developed 16-years ago. We have a lot of experience that can be available for improving and then has to be a starting point to improve. I suggest to move in this direction.

Thank you so much for your attention.

MS. CRISTINZIO: Thank you, so much, Matteo.

We're now going to move to the next portion of our presentations. These are oral comments without slide ducks that are three minutes each. Just waiting for our next slide. There we go.

Our first presenter in this segment is Sophie Chen from Magnolia Cosmetics Co. We have

Sophie on the line, if you're on the line, please raise your hand. Doesn't it look like Sophie is here.

As I have done in previous segments, I'll come back after the end and see if we can capture anyone who wasn't available when I called on them.

Moving on to the next person, 65, is David Manley from Plexus Worldwide okay. Not hearing anything from David Manley.

Going to move on. I've been told that our next presenter, Prerna is not presenting due to a scheduling conflict.

So I'm moving on to number 67. I'm going to unfortunately pronounce this name wrong, but I'm going to say Mr. Yontei, if you're on the line from Nigeria, we'd love to hear from you. You're here, please raise your hand so our AV team can unmute you.

Okay. Moving on to number 68, we have Thiago Garaveli from Brazil. Thiago if you're on the line, please raise your hand.

Okay. I'm moving on to our next person on the list, number 69, Tatiana Guzman Zapata.

Recognizing it's difficult for some of our international participants with time changes and

such. I believe that's probably why we're having so many absences.

I'm going to move on to number 70. We have speaker 70, who is Maria Isabel Herrera from Syam Cosmetics in Colombia.

Okay. Not hearing from Maria.

Going to move on to speaker number 71, Noemi Rodriguez Barrera, also from Colombia. Please raise your hand and let us know you're here.

I'm going to move on to speaker number 72. The name I'm also not going to try to pronounce because it won't -- it won't be good, Mr. Mekkaoui from Morocco are you on the line?

Okay I'm going to move on to speaker number 73, Aline Oliveira. Aline, are you on the line with us today?

Apologies if I'm mispronouncing these names.

I think I'm going to move on to speaker number 74. We have Carolina Dias from Honma Industria Cosmetica in Brazil. You're on the line, please raise your hand so our AV team can help you unmute. Not hearing anything from Carolina.

Moving on to speaker number 75, Mariane Tavares Fagundes from Masterline do Brazil.

And just to reminder as we wait to see if any

of our presenters are raised their hands. Anyone on this presentation or in the public can submit comments to our docket. So if you're not able to speak today we still love to hear from you.

Not hearing from Mariane our speaker number 75.

I'm going to move on to speaker number 76, Raphael Alvis, Unibell Sac, Peru.

Okay, not hearing from Raphael.

Moving on to speaker number 77, Nelsy Ospino from Colombia. Yes. If you're here, please raise your hand so we can unmute you.

Okay, and moving on to our last speaker of this segment, number 78, Charmain Bosch from Production & R&D from South Africa. I believe Chairman is on the line and we have prompted you to unmute, if you'd like to speak, we have time for you. Charmain, we'd love to hear from you if you can unmute yourself.

Okay as promised I'm going to go back to the beginning of this segment without slides just to pull up the names one more time to see if anyone who is listed is on the line and would like to present starting at number 64, Sophie Chen. And if any of you are here, please raise your hands our AV team can unmute you.

David Manley, this whole -- this whole list

here was not available.

Prerna, Yontei, Thiago, Tatiana, Maria, Noemi, Mekkaoui, Aline please let us know if you're available.

And going to the next slide for the rest of the segment through number 76 or 78, actually.

Carolina, Mariane, Raphael, Nelsy and Char main, if any of you are available to speak, we'd love to hear from you.

Okay I believe that brings us to the end of this segment. We are again, very much ahead of schedule because we had so many presenters not show up.

I am going to decline the break that we have scheduled, that we're originally going to schedule at 2:30 to 2:35 since we still have a lot of time left and want to be mindful of our -- our FDA principals time and everyone's time on the line.

I'm going to proceed to the next segment of open pop public comment.

We proceed to speaker number 79 on our list, Soad Alhasan from Turkey. Soad if you're on the line, we'd love to hear from you.

Moving to our next speaker. We have Megan Cox from Jeanie Supply. Megan please raise your hand so

we can unmute you.

MS. COX: Hello. Can you hear me?

MS. CRISTINZIO: Yes, we can.

MS. COX: Okay. Thank you so much. In this session we've heard from many large manufacturers who are urging the FDA to stick with third party certifications they already have and apply the same rule to all companies across the board. But I'd like to offer a different perspective.

My name is Megan Cox, and I'm the president and founder of Genie Supply the beauty lab for entrepreneurs.

We opened our lab in 2018 when we recognize that the Indy -- beauty segment was growing rapidly but the domestic market lacked the manufacturing infrastructure to support small batch beauty manufacturing.

After interviewing dozens of beauty founders, we realized that due mostly to a lack of options, these brands were mostly manufacturing their products in their own kitchens. As a small batch manufacturer are large batches are what other manufacturers might consider a pilot run, the founders we support are 90% women and over 50% people of color. We believe that the work we do in providing a safe, clean and

reliable space to bring underrepresented group's ideas to market is extremely important for both diversified and innovation in the marketplace. Without safe spaces like ours innovation may continue on, but it will happen in much less safe environments for consumers.

We can all agree that cosmetic safety regulations are long overdue overall. But today I want to urge more careful consideration of the burden that these new regulations could impose on small batch manufacturers like ourselves. While we are voluntarily FDA registered and currently follow GMPs as drafted by the FDA in 2013, mandating a third-party audit or continuous third party audits would cause undue financial burden. We would gladly undergo audits conducted by the FDA themselves if the fees were waived or assessed on a sliding scale. According to the SBA a small business is one with revenue between one and $40M. The exemption proposed in MoCRA identifies a small business as one with $1M or less in revenue, which in 2023 is much too small.

Manufacturing is a low margin industry. A small manufacturer like ourselves need to manufacture at least an extra $300,000 of cosmetics

per year, just a break even on the ISO auditing fees.

One million dollars in revenue for beauty brand is much different than $1M in revenue for contractor manufacturer, or 1M per year on revenue to a beauty brand can mean 750 to $900,000 in gross profit and potentially a similar net income.

One million per year in revenue to a manufacturer can mean as little as 250,000 in gross profit, and potentially even a net negative income.

Manufacturers already work with low margins, and mandating third party ISO auditing will most certainly cause undue financial burden, significantly damping innovation.

I would urge the committee to reconsider the definition of a small business when it comes to contract manufacturers.

My recommendation is anywhere from five to ten million in annual average revenue, the point at which manufacturers become profitable and truly attractive for merger or acquisition opportunities, and at which they may have up to 1M in gross profit. Otherwise, I recommend looking at the volume produced per year, square footage of the facility or other indicators for additional petition exemption.

In conclusion, we are fully supportive of the proposed changes that will result in increased and consistent safety for end consumers. However, we want to urge careful consideration of the impact that these changes might have on both innovation and the manufacturing and the beauty space, particularly by historically underrepresented in an under funded group, and to create ample exemptions and flexibility to allow innovation to continue seamlessly.

For my final two cents mandating testing requirements to prove the safety of cosmetics, requiring testing submission or specifying recall standards will make a much larger impact with less financial burden across the board.

Thank you for the opportunity to provide comments today.

MS. CRISTINZIO: Thank you so much Megan.

And thank you to all of our speakers for their flexibility as we moved ahead since we are running ahead of schedule.

Next on our list, it's speaker number 81, Carrisa Lallatin from Adventures in Soap. Carrisa, if you're on the line, please raise your hand. Moving on to our next speaker. Speaker number 82,

Barbara Gant, of Gant Beauty of Holiness International.

MS. GANT: Hi, yes, this is Barbara. How are you?

MS. CRISTINZIO: Good, thank you for joining us.

MS. GANT: Yes. Thank you for having me. I just want to say thank you so much with small business. I'm situated here in Acworth, Georgia, and we like to say we're bringing holiness to the beauty industry.

We make body butters and body oils, and we are looking to expand internationally. We're excited about the opportunity to learn about the international standards that are being presented today, and we basically just wanted to introduce ourselves and say hello and let you guys know we're definitely taking notes and jotting down names so that we can hopefully reach out to connect in the future.

We can be reached at beautyofholinessinternational.com, all of that spelled out or bgantatbeautyofholinessinternational.com.

Thanks so much.

MS. CRISTINZIO: Thank you so much for joining us, Barbara.

Our next speaker, number 83, is Victor Almeida from Flora Brazil. Victor, if you're on the line with us, please raise your hand so we can unmute you. Not hearing from Victor.

I'm going to move on to speaker, number 84, Isabel Cristina. I'm going to butcher the last name, so I'm not going to try, but from Brazil. Isabel, are you here with us today? I'm not hearing from Isabel.

Moving on to our next speaker on the list, speaker number 85, Bhaskar Mandi from Sun Pharmaceuticals Industries in India.

And, again, I know we're running way ahead of schedule. So if you have missed your spot and you're joining us late, please raise your hand so we can find you and unmute you to speak. Not hearing from Bhaskar.

Going to move on to speaker number 86, Anusha from IM Pro Makeup in New York. Anusha, are you with us? It looks like we have a few people who have raised their hands but have different names. I'm going to -- I'm going to ask our AV team to maybe unmute the first one and see where we can, if

we can acknowledge, get them up and running.

Okay. I'm going to move on, but if you do want to speak and miss your spot. I will come back to you at the end of this segment.

And move onto speaker number 87, Katherine Montgomery from Forma Brands.

MS. MONTGOMERY: I can you hear me?

MS. CRISTINZIO: Yes.

MS. MONTGOMERY: Hi, thank you very much for the opportunity. My name is Katherine Montgomery. I'm the VP of regulatory and testing at Forma Brands. We are a brand based in the United States with operations in the U.S., Canada, EU, UK, Australia, and New Zealand. I am here today to reconfirm what Don had presented from the IBA association. Basically, we believe strongly that the FDA should base their next GMP compliance largely based on the ISO 22716. A significant portion of the U.S and international cosmetic manufacturers currently adhere much of the ISO 22716 and also to the FDA draft guidance, which was published in June of 2013.

I think it is important to understand that cosmetics have a long history of safe use in the U.S. and are generally considered a low-risk product and

so that it makes sense to use a GMP compliance standard that's already largely being used across the world. And as it has already been said by several other participants today, the IOS 22716 is recognized by the EU, UK, Canada, Australia, and many other major countries within the world and by continuing to adopt to the IOS 22716, it would allow better abilities to trade with these countries and to allow cosmetic companies large or small to get their goods in other locations.

That's all my comments for today. So thank you much.

MS. CRISTINZIO: Thank you so much, Katherine.

Moving on to our next speaker, number 87 or 88, Laurel Arrigona from Smith & Nephew in Texas. I think we might have --

Yeah, sorry.

MS. ZIMMERMAN: Hi, can you hear me?

MS. CRISTINZIO: I think we might have Jodi Zimmerman, is a substitute speaker for this comment, go right ahead.

MS. ZIMMERMAN: Yes, that is correct. Well hello and good afternoon and thank you so much for allowing me the opportunity to speak today.

My name is Jodi Zimmerman. I've been a

registered environmental health specialist for about 13 years now. Today I am representing the Association of Food & Drug Officials and the AFDO Body Art Committee as a co-chair of the AFDO Body Art Committee. The Body Art Committee was formed in 2016 to provide a means for discourse between regulator, state and federal and the regulated body art community.

AFDO was organized in 1896 with the goal of harmonizing regulation of consumer products. In 1938 AFDO supported adoption of the modern FD&C Act, which includes the addition of cosmetics. AFDO has supported the adoption of GMPs for all classes of regulated products that promote safety following risk based scientific -- operated practices that are reasonable for the regulated industry to implement. AFDO supports adoption of cosmetic regulations closely aligned with ISO 22716 cosmetics, good manufacturing practices and guidelines.

AFDO has the following suggestions concerning cosmetic GMP regulations. Specify requirements to maintain safety substantiation data. It is recommended that FDA specify parameters around which safety substantiation data should be organized. For finished products AFDO suggests the following

information be used for safety substantiation.

1. Supplier suitability.

2. Ingredient safety.

3. Packaging safety.

And 4. Four processing safety.

For each category, safety should be defined in terms of microbiological, chemical/mineral and physical/particulate parameter. Based on these safety facts, acceptance criteria can then be defined and used to support GMPs to support GMPs that are incorporated by a firm. GMP should not be implemented without acceptance criteria.

AFDO suggests that the FDA establish through GMP rule making process the type of data required to establish acceptance criteria. Having such guidance will help create a level playing field for all manufacturers. Thank you.

MS. CRISTINZIO: Thank you so much.

Moving on to our next speaker number 89, Akram Shah from Amson Vaccine and Pharmaceutical in Pakistan, Akram Shah, if you're here, please raise your hand so that we can unmute you.

Okay. I'm going to move on to our next speaker number 90, Carlos Bisio from Fastforward Trading Company.

Okay. Moving on to our next speaker, number 91, Jocelyn Jang from SOPY in Korea.

And again, acknowledging we are very far ahead of schedule. So some of these folks might not have dialed in quite yet, and then I'm going to go to our last speaker on the list.

Number 92, Aline de Lima Silva from De Sirius Cosmeticos in Brazil.

Okay I'm going to acknowledge that we are -- we are running very far ahead of schedule, and I want to make sure we have a chance to hear from as many people as possible. So at this time, I'm going to take a brief break and resume again at 2:35 in hopes that we can catch some of those in the last segment who believed they were going to speak after 2:35 this afternoon. So for now, we'll take a few minute break. We'll be back at 2:35. Thank you so much.

(A short recess is taken.)

MS. CRISTINZIO: Good afternoon, and welcome back. I'm Dayle Cristinzio. I've been moderating today's session and as a reminder, this meeting is recorded. This meeting will also be transcribed and a transcript will be posted as soon as possible. A number of you have asked in the chart where that will be posted, and it will be on our

www.regulations.gov site.

For those of you who are just joining us, we are running way ahead of schedule and have gone through the entire list of speakers who have signed up today, but there are a number of people who missed their slots and I'd like to give everyone a chance, given that we are so far ahead, to be recognized and present. If you have signed up to speak and you missed your slot, please raise your hand.

I think Robbie Water or Walters was on earlier and suggested he misses his slot. We're happy to hear from you if you're still there. Great. Thanks.

MR. WALTERS: Hi, so I'm Robbie Walters. I am the owner of SoapEquipment.com. We make machinery and equipment for the handmade or small batch soap and cosmetic market.

We're the largest equipment supplier to this end of the market in the world. We sell to every country. We sell to all continents except Antarctica and every country not on the BIS sanctions list.

And one of the things that I wanted to bring up, we, you know, definitely welcome regulation and

standardization in this space, but there really are two market segments that I don't think have been kind of clearly enough defined. So the small batch and handmade manufacturers that to my typical customer has about $100,000 in revenue. They're about 30,000 of those companies in the United States. There's a lot of them in you know, Africa, and the Middle East and the manufacturing methods that they're using to make their products are fundamentally different than what, you know, an Estee Lauder or Loreal would use. They're using natural oils, kind of traditional manufacturing processes in very small batches and, you know, as we know, with all of our customers, we've never had any safety or regulatory risks. So we do understand the need to, you know, standardize the regulation and make it, you know, easier for people to have clarity on what is going to be required of them. But out of all the manufacturers in the United States, the small batch manufacturers, we have designed seven of the ten largest factories. And of those factories, every single one of them would probably have to spend more on regulatory compliance than they actually have on physical machinery in their plant.

And, again, if you're you know, one of these

large publicly traded companies, this is not you know, going to affect you, but you can see the effect of this. If you were to walk into a Whole Foods or a Kroger or a Trader Joe's in the United States, you're going to see dozens, if not hundreds of -- of companies represented in those stores who are small local businesses. You know, a 100,000, 500,000-1,000,000-2,000,000 in revenue. If you were to go into the same thing in Europe you -- you see a little bit, you know, less of that. And so there's a very strong, vibrant small manufacturer market in the United States that exists because, you know, they're making relatively safe products and it's easy to get in the industry and, you know, we supply them with equipment and I -- I would just caution, a you know very, you know, strict implementation of this on the small end of the market for reference of our, you know, tens of thousands of customers. We only have three customers who are larger than the census definition of a small business, that's $40M in revenue. And for those customers, they are definitely going to have no problem complying with, you know, whatever regulations are put in place.

But on the smaller end, you're a $100,000 dollar revenue, $500,000, 1M of revenue, if they

have to, you know, do have oil samples for five years. Oil tends to go rancid. Does that mean they're going to need to install refrigeration?

If they have to have, you know fairly, you know, complex reporting requirement. Most of these businesses do not have the institutional capability to do that, and they will get better over time. And, you know, this regulation and standardization will definitely give them a target to where they can improve that as they grow.

But if the sales thresholds are kept too low I -- I think it could really limit the growth of the market in the United States, Africa, and in The Middle East.

The soap and cosmetics market is much more competitive than it is in Europe because the barriers to enter are lower because you can get with a relatively safe product and you can fairly easily get it into a grocery store. And you just don't have too much of that in areas where it's very strictly regulated. And I think if you were to compare more strictly regulated areas to less strictly regulated areas you're not going to see a massive difference in safety or product recall.

So I -- I would just encourage the FDA to, you

know, look at the census definition of a small business, because at the very small end of the market, which, you know, hasn't been, you know, hasn't had as much speakers on this call. Very strict enforcement of this with strict testing, strict regulatory requirements, strict recordkeeping the -- they're just not going to be able to afford to do it. And most of my customers would really, really struggle with the implementation of this as written.

Again, my big customers who are making $50-$60M dollars a year, which is very few customers, they're going to have no issue at all doing this. And I -- I think it'll be a great thing for them, but I -- I would encourage you know, following closer to the census definition of a small business and if you are going to put the threshold lower than that, potentially doing that over time so that the market will have time to adapt because most of my customers don't have you know, just don't have the capacity to do this right now. Again, they can get better at it going forward, but I would definitely encourage raising the revenue threshold, if that's it is at all possible and properly segment in between the publicly traded companies with hundreds and millions

of dollars in profit and, you know, the $2M sales company that know, makes their product locally and just got into a Whole Foods because that's a lot of our customers, and they are really going to struggle to follow a strict implementation of this. So thanks.

MS. CRISTINZIO: Thank you so much Robbie and thanks for the flexibility to come on a little late.

Just acknowledging we are running ahead of schedule and asking our AV team to pull up the slide that would've started at number 79 for our 2:35 segment again. We have a number of speakers from other countries, and I want to make sure we give a chance to everyone who signed up to speak and just putting up the names to acknowledge. If any of you are on the line and want to speak, please raise your hand so that our team can recognize you to speak. Just going to give everyone one more moment.

We had over 92 presenters signed up to speak today, and all of the presentations were really helpful, and I really appreciate everyone's flexibility as we are running ahead of schedule.

Okay. Hearing from no one in the audience that they have missed their opportunity to speak. I would like to wrap up today's session by turning the

program over to Dr. Linda Katz for closing remarks.

DR. KATZ: Thank you and I want to thank everyone again who presented today and for those who listened throughout the whole day today to the different presentations.

We appreciate your comments and remarks, and we look forward to hearing from all of you in the future.

As a reminder, as we have as on the slide, comments are due to the docket with a deadline of July 3, 2023, and if you have written comments to submit, please submit them to docket number FDA 2023-N- 1466.

Please follow all of the instructions for submitting comments described in the federal register notice. The comments should be submitted electronically on https://www.regulations.gov to the docket number again, FDA 2023-N-1466.

Written or paper submissions can be submitted as follows: To mail/hand delivery/career.

Dockets management staff HFA 305, Food and Drug Administration, 5630 Fisher's Lane room 1061, Rockville Maryland, 20852.

Next slide. In addition, there will be a transcript available. And the transcript of the

listening session will be posted at https://www.regulations.gov as soon as it is available.

In addition, some related resources are listed here to refer back to the federal register notice for the public meeting; the Modernization of Cosmetics Regulations Act of 2022 and again, the draft guidance for industry cosmetic good manufacturing practices, which posted in June 2013.

If you have any additional questions, feel free to contact us at 240-402-1130, and that's the office of cosmetics and colors general number.

And emails with questions can also be sent to us at MoCRAGMPmeeting@fda.hhs.gov.

Next slide, and with that, we will adjourn today's meeting. And, again, I thank you for your participation. Goodbye.

(The following meeting concluded at 2:46 p.m.)

CERTIFICATE OF REPORTER

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I, JULIANNA BUSER, hereby certify that the foregoing proceedings were taken before me at the time and place therein designated, and that the foregoing pages, are a true and correct record of the foregoing proceedings.

I further certify that I am not a relative, employee, attorney or counsel of any of the parties nor am I a relative or employee of any of the parties' attorneys or counsel connected with the action, nor am I financially interested in the action.

DATED this 1ST day of June 2023

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JULIANNA BUSER