

FDA Media Briefing on the Sunscreen Proposed Rule
February 21, 2019
11:00 a.m. ET

Coordinator: Welcome and thank you for standing by. All participants are in a listen-only mode. During the question and answer session, please press Star 1 and record your name as prompted. Today's conference is being recorded. If you have any objections, you may disconnect at this time.

I would now like to turn today's meeting over to Sandy Walsh. Thank you. You may begin.

Sandy Walsh: Thank you, good morning. My name is Sandy Walsh from the FDA's Office of Media Affairs. Thank you for joining us for today's media briefing regarding the issuance of the proposed rule on sunscreens. By now our press has been issued. A notification has been posted in the Federal Register.

Today I'm joined by FDA Commission Dr. Scott Gottlieb who will provide remarks on the announcement. I'm also joined by Dr. Theresa Michele, Director of the Division of Non-Prescription Drug Products in the FDA's Center for Drug Evaluation and Research who will then provide details about the proposed rule. After their remarks, we will then move to the question and answer portion of the call. Reporters will be in a listen-only mode until we open up the call for questions.

With that I will now turn it over to Dr. Gottlieb.

Scott Gottlieb: Thanks a lot. I want to thank everyone for taking the time to join us this morning. I'm very pleased to update you on today's important sunscreen policy advances. The comprehensive proposed rule that we issued today would update regulatory requirements for most sunscreen products in the

United States to better ensure consumers have access to safe and effective preventative sun care options in line with the latest science.

This action is an important step in the FDA's efforts to take into account modern science to ensure the safety and effectiveness of sunscreens. And we see it as a major health policy priority and our regulatory obligation is to make sure that products marketed offer protection from the sun's effects the liver those promises to consumers. Broad-spectrum sunscreens with SPF values of at least 15 are critical tools that we have in preventing skin cancer and protecting the skin from damage caused by the sun's rays. Yet some of the essential requirements for these preventative tools haven't been updated in literally decades.

Since the initial evaluation of these products, we know much more about the effects of the sun and about sunscreens absorption through the skin. Sunscreen usage has changed also. Consumer habits with respect to how they use sunscreen has changed. With more people using these products more frequently and in larger amounts at the same time sunscreen formulations have evolved as companies have innovated.

The proposed rule we put for today has the potential to improve the quality, the safety and the efficacy of sunscreens the Americans use every day. It's the culmination of a lot of thoughtful effort and hard work over many years by number of FDA staff that has carefully considered this important topic and science available to inform our thinking. And as we work to finalize this rule, will continue to work with industry and the public health stakeholders and consumer groups to make sure that were striking the right balance among all the considerations.

Among the provisions the proposal addresses today are sunscreen active ingredient, safety, dosage forms, sun protection factor or SPF, and broad-spectrum requirements. It also proposes updates to how products are labeled to make it easier for consumers to identify key product information as they shop for sunscreen in the stores. It's important for me to note that as this rulemaking effort moves forward and as the FDA gathers additional scientific information, given the recognized public health benefit of sunscreen use, consumers should continue to use broad-spectrum sunscreens with SPF values of at least 15 in conjunction with other some protection measures.

Notably to help make sure this effort is successful, the FDA is looking to industry to gather the data that we believe is needed to help ensure the products target to offer protection from the sun's effects are safe and deliver on his promises to consumers. And through this rulemaking process were seeking the balance needed for product innovation with ensuring that consumers are properly protected from the sun's harmful effects based on the latest scientific evidence on these products.

I want to just close by thinking once again all the stakeholders who provided critical input to this rulemaking process including consumer groups, industry partners, a lot of scientific experts who have helped inform our work. And I want to just close finally by thinking that many women of the Center for Drugs here at FDA. This rulemaking has been underway for quite some time and a lot of effort has gone into this. People have been committed to this over many years. So this is the culmination of a really extensive effort on the part of the agency. And I just want to thank them for their commitment to this.

And so now I'll turn it over to (Terry) to discuss the specific divisions of the proposed rule. And she's one of those experts who has been working on this

for a very long time. We're very grateful for her efforts. (Terry), I'll turn it over to you.

(Teresa Michele): Thank you so much Dr. Gottlieb. So I'd like to start off with just some background. This proposed rule applies only to sunscreen active ingredients currently on the market in the United States without FDA approved application. And that's actually the vast majority of sunscreen available in the United States. They are marketed under a regulatory framework called the OTC or over-the-counter monographs system. OTC monograph established conditions under which the FDA permits certain over-the-counter drugs to be marketed without approved new drug applications because they are generally recognized as safe and effective. Or what we call grace and not misbranded.

So more specifically, when issuing this proposed rule as part of the regulatory process of putting into effect a final monograph regulation for over-the-counter sunscreen drug products as required by the Sunscreen Innovation Act. So to establish a final monograph for sunscreen, the FDA is reviewing the active ingredients in these products to determine whether the ingredients are graced for OTC sunscreen use. And it's also a value waiting serious other conditions for use of these ingredients.

So now I'm going to provide you with a brief overview of the main provision in the proposed rule. So first, we've proposed that of the steam currently marketed active ingredients, to ingredients zinc oxide and titanium dioxide are great for use in sunscreen. To ingredients, paba and trolamine salicylate are not great for use in sunscreen due to safety issues. These two ingredients do not currently appear on the US market in sunscreens.

There are 12 ingredients for which we propose there are insufficient safety to make a positive grace determination at this time. So to address these 12

ingredients, we're asking industry and other interested parties for additional data. We are working closely with industry and we've published several guidances to further explain certain tests and make sure companies understand what data the FDA believed it needs to evaluate safety and effectiveness for sunscreen active ingredients. Including the 12 ingredients for which we're seeking more data in this rulemaking.

I want to emphasize that his request for additional data does not mean that FDA has concluded that these 12 ingredients are unsafe. Rather, we're requesting additional information on these ingredients so we can evaluate their grace states in light of changed conditions including substantially increased sunscreen use.

So while these additional data are being gathered, we recommend that consumers continue to use broad spectrum sunscreen of SPF 15 or higher in conjunction with other sun protective measures to reduce the risk of sunburn, skin cancer and early skin aging caused by the sun.

Next, we proposed the dosage forms that are graced for use of sunscreens include sprays, oils, lotions, creams, gels, butters, paste, ointments and sticks. Powders are proposed to be eligible for inclusion in the monograph, but we believe that additional data are needed before powders can be included. Wipes, towelettes, body washes, shampoos and other dosage forms are proposed to be categorized as new drugs requiring premarket approval because the FDA has not received data showing that they are eligible for inclusion in the monograph.

Moving onto SPF, we propose to raise the maximum SPF value on sunscreen labels from a previous proposal of SPF 50+ to SPF 60+ because evidence shows clinical benefit of broad-spectrum SPF 60+ sunscreen. We've also

proposed to require sunscreens with an SPF value of 15 or higher to provide broad-spectrum protection that for broad-spectrum products as SPF increases, the magnitude of protection against ultra violet A radiation also increases.

To address concerns raised by recent evidence further linking UVA radiation to skin cancer and other harms, these proposals are designed to ensure that sunscreens provide consumers with the protection that they expect.

We've also proposed new sunscreen product label requirements to assist consumers in more easily identifying key information including the addition of active ingredients on the front of the package to bring sunscreen in line with other over-the-counter drugs that have this information, including a notification on the label for consumers to read the skin cancer and skin aging alert for sunscreens that have not been shown to help prevent skin cancer. And we've also proposing revised core mats f for SPF, broad-spectrum and water resistant statements.

We propose to clarify FDA's expectations for testing and record keeping, excuse me, for testing and also make sure that record-keeping by entities that conduct sunscreen testing to ensure that FDA can assess industry compliance with regulation. And finally we propose the products that combine sunscreen with insect repellent are not graded.

We're seeking public comments on this proposed rule and we'll carefully consider the comments that are submitted as we work towards developing final rule. We've issued guidance to industry on how FDA intends to enforce sunscreen regulation in the interim while we work towards the final rule.

So in closing I just want to echo Dr. Gottlieb's comment about sun safety. At this rulemaking process proceeds, consumers should continue to use broad

spectrum sunscreen of SPF 15 or higher along with other sun protective measures to reduce the risk of skin cancer and early skin aging caused by the sun.

So with that alternative back over to Sandy Walsh.

Sandy Walsh: Thank you Dr. Gottlieb and Dr. Michele. Operator we're ready to begin our question answer portion. When asking a question please that your name and affiliation. Also please limit yourself to one question and one follow-up so we can get to as many questions as possible. Operator we'll take the first question.

Coordinator: Thank you and again as a reminder, for question or a comment, it is Star 1. Make sure your phone is unneeded and record your name. And our first question or, come from (Ryan Nelson) from (HBW Insight). Your line is open.

(Ryan Nelson): Hey guys, can you hear me?

Sandy Walsh: Yes.

(Ryan Nelson): Okay great. Thanks for taking questions. I'm just curious, you know, about the timeline here. I know you just mentioned that you included some guys to industry about enforcement and the interim while you're working towards the final rule. And I'm sorry, I haven't gotten to that point in actual proposed rule yet. But I'm just curious, I mean, this came out today. You're going to be collecting. Going through what will probably a huge number comments and then under the Sunscreen Innovation Act anyway, the final rule is still in November, I believe. I'm just curious as to sort of what kind of enforcement discretion will be used going forward be on November, beyond the final rule. Or just, you know, how do you expect they're not to be a pretty significant

market disruption as a result of this - of the changes (unintelligible) you're seeking for ingredients?

(Teresa Michele): Right, so I believe that your concern if I might paraphrase, is that it may take industry longer to come up with some of the data that were asking for than the 90 day comment period. Is that correct?

(Ryan Nelson): Yes, I mean I would expect ... I mean seeing how the time and expense application has gone sort of four new, next generation kind of UV filters, I mean it seems like some of the bio availability data and so forth, it be - seems to - FDA seems to be looking for existing ingredients, takes a long time to generate. So we're just thinking, you know, longer term than even this year, you know, yes, what will happen with, sort of, the sunscreen market if suddenly, you know, we have over a dozen ingredients or whatever it is that there are insufficient data currently?

(Teresa Michele): Right, so we're very aware of that. And we're committed to working with industry and other public health stakeholders to help ensure that these sunscreens that are so critical are safe and effective. And are out there on the market for consumers.

So we'll consider requests to defer further rulemaking with respect to a specific sunscreen active ingredient to allow for the submission of new safety or effectiveness data to the record. If such requests are submitted to the docket within the initial 90-day comment period. So we'll review all of the data and information submitted to the record in conjunction with all timely and complete requests to extend.

(Ryan Nelson): Okay, thank you.

(Teresa Michele): Operator, next question please.

Coordinator: Thank you. Our next question/comment comes from (Kathline Downey) from Web MD. Your line is open.

(Kathline Downey): Thank you. Two quick questions; what do you see as the most significant part of this proposed rule and at this point should consumers avoid certain ingredients in sunscreens or not?

(Teresa Michele): So I'm going to take the second question first and then I'll address the first question. So the second question you asked should consumers avoid certain ingredients? And the answer to that is absolutely not. The two ingredients that we are proposing to be not generally recognized as safe and effective are actually not in any marketed sunscreens that we're aware of. The ingredients that we're proposing we need more data on, we're not saying that they're unsafe at this time. And we are, in fact, encouraging consumers to continue to use sunscreens, SPF 15 or higher and broad spectrum.

So the first question that you asked is what do we think the most significant part of this rulemaking is? And there are a lot of exciting parts of this rule that are designed to do one thing, to make sure that consumers have the best possible products available. I think one of the key parts of the rule is actually the additional broad spectrum requirements that are in there that we're proposing. Because right now, as the SPF goes up, it's not absolute that the broad spectrum coverage and the UVA coverage goes up proportionately. But the testing that we are proposing as part of this rulemaking would ensure that that happens.

So that when consumers believe that they are getting a more protective product against skin cancer and early skin aging, they actually are.

(Kathline Downey): And that's due partly to some of the new findings, recent findings about UVA?

(Teresa Michele): That's correct.

(Kathline Downey): Thank you.

(Teresa Michele): Thank you. Operator, we'll take the next question.

Coordinator: Thank you. Our next question/comment comes from (Eileen Francis). And please state your affiliation.

(Eileen Francis): Hi, yes oh, (Eileen Francis) with the (Pink Sheet). I was just wondering how the new rules for labeling SPF would result in less exposure to sunscreen products labeled with potentially misleading some protection information.

(Teresa Michele): Right, so the SPF right now go all the way up as high as sponsors which to include on their label. We had previously proposed that SPF labeling be limited to 50+. We've now extended that to 60+, because as part of the 2011 proposed rule, they - we got additional data showing benefit of the higher SPF sunscreens. So we are proposing that sunscreens would not be labeled with an SPF higher than 60+ because it's not clear that there's a benefit to consumers above that level.

(Eileen Francis): Okay, thank you.

(Teresa Michele): Operator, we'll take the next question.

Coordinator: Thank you. Our next question/comment comes from (Andrew Siddens) from Congressional Quarterly. Your line is open.

(Andrew Siddons): Hi, thanks for doing this today. So could you just give me a sense of like how many products are on the market now that are not using the ingredients that are - the two ingredients that are generally recognized as safe? And will the products that use those other 12 ingredients, will there be a point when they would have to come off the market at some point?

(Teresa Michele): So to our knowledge there are no sunscreens currently on the market that contain the two active ingredients that we are proposing to be not generally recognized as safe. There are many sunscreens on the market using the 12 ingredients that we're requesting additional data on. We do expect that industry will come in with additional data. And so we'll just have to wait and see to determine where the safety data are for these ingredients going forward.

(Andrew Siddons): But you would have to take it on like a case by case basis to see if something needed to like come off the market while it's pending a review? Or?

(Teresa Michelle): Nothing is coming off the market currently under the proposed rule. That would be only based on the final rule after we have gotten all the data.

(Andrew Siddons): So the, sorry if I'm just confusing things more. But under the - obviously you still have to finalize this rule. But once you finalize it, then that's presumably when the evidence generation would have to begin for the other 12 ingredients. All I'm trying to get a sense of is if, you know, though be subject to some sort of like grace period while they're still on sale while you're undergoing a review. Or, you know, with a, you know, have to hold off on sale while you're reviewing them what the rule is my life.

(Teresa Michele): So let me explain a little bit. So the way the rule making process works, this proposed rule is asking for the additional data. And if industry or other stakeholders need additional time to submit those data, they can request during the comment period to have an extension to deliver that data. And they would have to provide information ensuring that they will be delivering the data that are requested. At that point in time, we may offer a referral for that particular agreement on the final rule. The final rule will include all of the ingredients for which we have not gotten referral requests that we have granted.

(Andrew Siddons): Okay, all right thank you.

Scott Gottlieb: Did that answer your question? I'm -

(Andrew Siddons): Yes, I think so.

Scott Gottlieb: I just want to make sure you're clear on it (unintelligible).

(Andrew Siddons): So - because normally under in a rulemaking you would think that the - it's only the final rule, you know, kind of has the force of things. But it sounds like under this one, the proposed people will actually have to submit things to FDA based on what's in the proposed rule and (unintelligible).

(Teresa Michele): That's usually how it always works. Usually the ...

(Andrew Siddons): Oh, okay.

(Teresa Michele): ... proposed rule asks for information. And the final rule conveys our findings based on the information that was submitted under the proposal.

(Andrew Siddons): Okay, but in this case, like I think when I'm normally covering a rulemaking, the request for - the proposed rule is subject to, you know, public comments. But in this case, the comments will, kind of, come in the form of the data you're asking them to submit for some of these ingredients.

Scott Gottlieb: And request for additional time to generate that data because the rulemaking and the guidance lays out the parameters for how they're going to go about generating that information to be included in the final rule if I'm (unintelligible) correctly. I'm hoping (Terry) can correct me.

(Teresa Michele): Yes.

(Andrew Siddons): Okay, yes that's helpful. Thank you.

Scott Gottlieb: Our goal here just to sort of (unintelligible) point. The goal here is to get the data and, you know, validate the effectiveness and the safety of all of these ingredients and so that's the process we're working towards here.

(Sandy Walsh): Great, thank you Dr. Gottlieb. We'll take the next question, please.

Coordinator: Thank you and again as a reminder. for a question or comment from the phone, please press Star 1. Make sure your phone is unmuted and record your name. And our next question or comment comes from (Matt Perrone) from Associated Press. Your line is open.

(Matt Perrone): Hi, thank you guys. I'm just trying to understand the, kind of, regulatory timeline. Can you talk a little bit about how this differs or complements or supersedes the 2011 rules we got on sunscreen? Is this - does this replace them? Or is this a totally separate process you're going through?

(Teresa Michele): So the 2011 rules covered a variety of aspects of sunscreen. This particular rulemaking covers pretty much everything related to sunscreen. And in the 2011 rules remain in effect, the ones that were finalized. For dosage form, that rulemaking was only a proposal. Actually it was an (ANPR).

(Matt Perrone): And is this the first time or not the first time, but you're looking at the grass, the new ingredients versus that wasn't part of the 2011 process?

(Teresa Michele): No, the ingredients that we're looking at actually aren't new ingredients. They were on the market at the time of the inception of the monograph in the early '70s. And FDA looked at them initially, but that particular sunscreen monograph has never had a final monograph that was in effect. So we are with this taking an important step in finalizing that sunscreen monograph as required by the Sunscreen Innovation Act.

(Matt Perrone): I see, so this is the monograph process. And what happened in 2011 was?

(Teresa Michele): So what happened in 2011 were important steps that were a portion of the monograph. So they just addressed SPF. They just addressed dosage form.

(Matt Perrone): Okay.

(Teresa Michele): This addresses the entire thing.

(Matt Perrone): Okay, great. Thanks.

(Sandy Walsh): Great, thank you Matt. Operator, we have time for one more question.

Coordinator: Thank you. And our final question or comment comes from (Ryan Nelson) from HBW Insight. Your line is open.

(Ryan Nelson): Sorry, I jumped back in the queue, but I appreciate your taking the question. I'm just wondering if you can offer some more detail, I mean somebody asked about the SPF labeling before. I think we're more interested this new process, I guess, for labeling SPF on products based on the testing that was in the 2011 final, that testing process. So I think it seems like now there's manufacturers will have to be leveling a range of SPF on product or maybe taking the lowest value of the SPF results they get. I'm just wondering if you could talk a little bit more about that, because we definitely did see like, you know, lawsuits against companies for alleged fraud in terms of SPF. And it seems like FDA is trying to address that to some extent with this proposed rule. So I was hoping you could provide some color on that.

(Teresa Michele): Right, so let me talk a little bit about that. One of the difficulties with an SPF value is that isn't a laboratory test. SPF is actually measured via clinical testing by looking at anathema on or redness of the skin after exposure to a light source. And as you might imagine, there's a fair amount of variability in that. And if the SPF goes higher, the variability gets greater. So what we're proposing is a range of SPF that will, Number 1, make it easier for consumers because there's a clear difference between an SPF of 15 and an SPF of 30. In addition, in order to make it clearer, we are asking manufacturers to label the lowest number in the range.

So that should, we think, decrease some of the variability because there's actually pretty much no difference between an SPF of 29 and an SPF of 30. And that's where the ranges come from.

(Ryan Nelson): Okay, and on a related note, could you just say, I know that you're capping or proposing an SPF 60+ cap. And then you note that you could still though have on the market a product that is an SPF of as much of 80 but not higher than 80. That was confusing to me. So that means that if you test your product and it tests higher than SPF 80, that would need a new drug application?

(Teresa Michele): That's correct. So -

(Ryan Nelson) Either way though, you could only label it SPF 60+ but you could have something that's more effective on the market until it gets to SPF 80? And what is the reasoning there?

(Teresa Michele): Well not necessarily more effective. So let me see if I can explain that. So we believe that there are no data to support benefit above an SPF of 60 in terms of measuring of the SPF. However, when you create a sunscreen formulation, you're trying to do two things. You are trying to protect against UVB and you're also trying to protect against UVA. So the sunscreen contain a variety of different ingredients in order to provide coverage across that whole spectrum.

The SPF really only measures the protection against UVB. The UVA protection doesn't show up as a number on the label. It shows up as the term broad spectrum. And we've put in some new requirements to ensure that as SPF goes up, the broad spectrum potential goes up. So we've allowed a little bit of wiggle for manufacturers who are manufacturing a high SPF product to allow that they may need to include additional ingredients to get that broad spectrum or UV A coverage. So that's the cap.

(Ryan Nelson): Okay.

However, we believe that adding a whole lot of additional ingredients to technically push up that number doesn't do anything. And therefore consumers would be getting the negative effects of the - of having more ingredients in their sunscreen without any efficacy benefits to balance it out. That's why there's a formulation cap of 80.

(Ryan Nelson): Interesting, okay thank you very much.

(Teresa Michele): Thank you.

Sandy Walsh: Thank you everyone. Operator, we will conclude the call now. This concludes today's media briefing on the sunscreen proposed rule. A replay will be available in about an hour and will be available for 30 days. Please remember to check the FDA newsroom on our website for the press release which links to all the important materials. Thank you everyone.

Coordinator: That concludes today's conference call. Thank you for your participation. You may disconnect at this time.

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