

National Institutes of Health, Tobacco Regulatory Science Program Webinar Transcript

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Helen Meissner, Director, Tobacco Regulatory Science Program, NIH Office of Disease Prevention

Good afternoon, welcome to the NIH Tobacco Regulatory Science Program Webinar. We organized this webinar today in light of the current proposed deeming rule for tobacco products that FDA has in response to many questions that we're hearing from investigators about submitting to the NIH docket so we're very pleased today that we have Dr. Allison Hoffman, who's associate director of science, coordination and communication at the Center for Tobacco Products at FDA with us to discuss the process for submitting to the docket and to hopefully answer some of the questions that you have.

Everyone is- -will be muted during the time that Allison is presenting and then we ask that you raise your hand in the chat room when you want to pose a question or have a comment and then when we call on you to press star-six to unmute and ask your question. You can then press star six to mute yourself again afterwards. So thank you and we'll be turning it over to Allison Hoffman.

Allison Hoffman, Associate Director of Science, Coordination and Communication, Office of Science, Center for Tobacco Products, FDA

Thanks Helen, as was mentioned, I'm with CTP in the Office of Science. That means I am not a lawyer, I want to make that very, very clear. You know we're happy to partner with NIH today and we're very excited that everybody is joining us. So today I'm going to briefly go over what a docket is, how it's used, and I think the meat of the presentation will be walking people through how to make a submission and I think you'll find it's very easy, very straight forward, everything's been done to try to make it as simple as possible, to make it as easy for people to submit comments as possible and at the end we'll just have time for questions and there will also be some links for sources of additional information. I should say that everything I'm going to say today is publicly available. And so as I mentioned, I'm not a lawyer, when you ask your questions, if I don't know, I will say that, we will get back to you via the TRSP website. Let's get going.

What is a docket and how is it used? Well dockets are really just a collection of documents or information that are related to rule making or other actions. It's really part of the public record for the action and the docket may contain rules or notices that are published in the federal register, contain analysis or materials that are referenced in those documents, public comments, hearing transcripts, petitions. And we at CTP and FDA in general we request public comment when we're establishing or modifying how tobacco products are regulated and we act through participation when we are publishing proposed rules or regulations which have a force in effective law when we issue guidance documents. These are statements of current thinking on topics and when we conduct public meetings and public hearings. You should know that your comments are recorded and placed in the docket. At any time you can view a docket, any

historical docket that's been created and closed or even documents that are ongoing. You can either do that via the web at [regulations.gov](https://www.regulations.gov) or if you happen to be in the Rockville area and would like to do old school reading of documents, you can go to the document reading room and we consider public comments when we draft the final rule. So how do you make a submission to the docket? I'm going to go over the electronic way first. It's going to be a series of screen shots so hopefully if you are watching this webinar and you have your computer on as well you can actually go through and do this as I am helping you along. This is a screen shot for the main site for [regulations.gov](https://www.regulations.gov) and what you can see there are lots of ways to find a docket. If you're referring to a federal register notice and it has a docket number in there, you can put that docket in this the search term right here or you can put a key word or title. For the purposes of this presentation I'm going to use an example of deeming. So you will type deeming in, where it has a search box and you hit search and this is what comes up.

And what you can see is that I make sure, and this is a clickable link.

I make sure this is what I want, this is a docket I would like to respond to and I click the comment now button.

This is the next screen that you see. First of all, you need to make sure that you're commenting on the correct docket, in this case it's the proposed rule for the deeming proposal.

And there are only two required pieces of information when you're filling out this web submission, the first is your comment. You need to have a comment. You can see that in this box up here. The second, is that you need to select a category or comment whether it's the public comment or affiliation. You may also choose to include your name, first and last, that is totally optional, you can make it anonymous if you like. If you are representing a group on behalf of a third party, you can also enter who that third party is, your organization.

So what makes a good comment? Well, these are just some suggestions for effective comments. First, you know you should say who you are. You should give a little bit of your background, why you're an expert and state clearly why you support or oppose whatever's being considered in this federal notice, why you're submitting to the docket. If you are suggesting changes, you need to explain those changes, you can say, I oppose this proposed guidance or this proposed regulation for the following reasons and give your reasons. You can include data and research and analysis that support your position and you can also include copies of articles and references, you can see on the search page that can you upload files. So if you think there's, you know let's say an article that was not cited in the notice that you think is relevant, explain why you think it's relevant and you can attach the document. If you know the docket number and even if you do a key word search you will find the docket number, for example, if you go to this clickable link, you should include the docket number, too. You will have the opportunity to preview before you actually submit so once you hit this continue button down here, you will have the opportunity to preview what you just entered and then you can submit it and then it will become official. So it's basically a check to make sure you didn't make a mistake page. You should write down your comment tracking number, each comment is given an individual tracking number and you can go back and find your comment. Remember your comments will be public as this is a public docket. You may also make a submission to a docket using mail and basically, in the notice and federal register there will be an address and contact person for you to submit that if you choose not to submit online. Basically here are just some references. You know, what I'm hoping to explain to you is that it's a very easy process to make comments to the docket, that the best ones are the ones that are very clear whether you support or oppose what's in the

notice or the guidance or whatever the docket is held for and be very clear about why you oppose or support.

If you have additional information, be clear about that. It's very helpful for us to have an understanding of why you oppose or support- - or why you support. And that's it.