



U.S. Food and Drug Administration

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## **Transcripts of FDA Press Conference on Toothpaste from China that Contains DEG**

### **FTS-HHS FDA**

**Moderator: Kimberly Rawlings**

**June 1, 2007**

**2:00 pm CT**

Coordinator: Thank you for standing by. We'll begin in approximately three minutes.  
Thank you for standing by.

Thank you for standing by.

All participants will be on listen-only for the presentation. At the time of the question session, you'll be prompted to press star then 1.

Today's conference is being recorded. If you have any objections, you may disconnect at this time.

I'd like to turn the call over to your host for today.

Sir, you may begin.

Rob Ali: Hi. Thank you, (Robin).

Thank you very much, ladies and gentlemen, and welcome. I'm Rob Ali from the FDA's Media Relations Office, and thanks and welcome to today's media briefing.

As a quick administrative announcement, there is a press release forthcoming and in the meantime there's also an Import Alert that's up on our Website and you can search for that by going to FDA.gov and simply entering in Import Alert Number 66-74 on the search engine on FDA.gov and you'll see an Import Alert and you're welcome to do that as the call moves along.

Our speaker for this afternoon is Deborah Autor, the Director of Compliance for FDA Center for Drug Evaluation and Research. We also have several FDA officials here who are available to answer any questions as the briefing progresses.

We will have a brief question and answer segment after Ms. Autor's opening remarks.

At this time, I'd like to turn it over to Ms. Autor.

Deborah Autor: Thank you, Rob, and good afternoon.

Today, FDA is strongly warning consumers to avoid using any toothpaste labeled as "Made in China" because we have found levels as high as 3% to 4% of a poisonous chemical, diethylene glycol also known as DEG, in Chinese toothpaste.

In addition, we have issued an Import Alert, as Rob mentioned, to prevent Chinese toothpaste containing DEG from entering the United States.

Consumers should examine toothpaste products for labeling that says the product is made in China. Out of an abundance of caution, FDA suggests that consumers throw away toothpaste with that labeling.

FDA is concerned that these products may contain diethylene glycol, also known as diglycol or diglycol stearate.

Please note that no major brands of toothpaste have been involved in this matter.

We are taking these actions to protect the health of the American people.

Last week, reports of contaminated Chinese toothpaste found in several countries, including Panama, led FDA to begin testing Chinese toothpaste and dental products that were imported into the United States. As a result, FDA inspectors identified and detained one shipment of toothpaste at the US border containing about 3% DEG by weight.

In addition, FDA inspectors found and tested Chinese toothpaste products located at a distribution center and a retail store. The highest level found was between 3% to 4% DEG by weight. The product at the retail store was not labeled as containing DEG but was found to contain the substance.

In addition, within the last hour, FDA has received other test results indicating that four more brands of toothpaste sold at retail -- two of which were not labeled as containing DEG do in fact contain DEG.

So there were four brands, two labeled containing DEG, two not -- all four tested positive. And one of those was in fact a junior brand, presumably for children.

The Import Alert we have just put into place stops all brands of toothpaste from the previously identified companies that make the brands found to contain DEG.

Companies will have to prove that their toothpaste is free from harmful levels of DEG before this is allowed into the United States.

The FDA will continue to stop all other brands of Chinese toothpaste from other manufacturers for testing as we have been doing since May 23.

FDA continues to investigate this problem.

If the agency identifies other brands of toothpaste products containing DEG, FDA will take appropriate actions, including adding products and their manufacturers to the Import Alert, to prevent those products from entering the United States.

DEG is used in antifreeze and as a solvent. It does not belong in toothpaste even at small concentrations.

Although FDA is not aware of any US reports of poisoning from toothpaste containing DEG, the agency is concerned about chronic exposure to DEG and exposure to DEG in certain populations such as children and individuals with kidney or liver disease.

Toothpaste is not intended to be swallowed, but FDA is concerned about unintentional swallowing or ingestion of toothpaste containing DEG.

DEG poisoning is an important public safety issue.

The agency is aware of reports of patient deaths and injuries in other countries over the past several years from ingesting DEG-contaminated pharmaceutical preparations such as cough syrups and acetaminophen syrup.

FDA recently issued a [guidance document](#) to urge US pharmaceutical manufacturers to be vigilant in assuring that glycerin, a sweetener commonly used worldwide in liquid over-the-counter and prescription drug products, is not contaminated with DEG.

Thank you and we look forward to your questions.

Rob Ali: Thank you, Ms. Autor.

And just so everybody knows, Autor is spelled A-U-T-O-R and Deborah, traditional spelling.

At this time ladies and gentlemen, we will take questions from credentialed media. And as always to be equitable, please limit yourselves to one question and one followup and please state your name and affiliation.

Operator, we'll take the first question.

Coordinator: At this time, if you would like to ask a question, please press star then 1. To withdraw a question, star then 2.

Once again, to ask a question, please press star then 1.

Our first question comes from Todd Zwillich with WebMD and Public Radio Int'l.

Your line is open.

Todd Zwillich: Public Radio International. Hi.

What are the brand names of the - well, I guess within the last hour you see - you've gotten four more brands and presumably the one that was detained at the border was a fifth brand, is that right, and what are the brand names that you've held up?

Deborah Autor: Okay. If you - do you have our press release now?

Todd Zwillich: I'm sure that I do. I'm not looking at it. But if they are in there, I guess we can -- I do have it actually right here. Here they are.

Deborah Autor: Okay.

Todd Zwillich: All right. So fine, I have this. Thank you.

Is there any way to know - you've tested some lots that were in stores. Does FDA have any sense of how many lots, how many tubes, how many Americans out there have potentially contaminated toothpaste in their bathrooms?

Deborah Autor: Yeah. Let me first touch on the question of brands.

Todd Zwillich: Okay.

Deborah Autor: As I mentioned, there were some test results we just got within the last hour and those are not in the press release.

So the brands in the press release are ones that have tested positive as well as other ones we know about that have labeling reflecting that they contain DEG. And then in addition, there are the four brands that we just received the results on within the last hour.

And those brands are DentaPro -- D-E-N-T-A-P-R-O, with a capital P -- DentaKleen -- Denta, capital K-L-E-E-N -- DentaKleen Junior, and then actually Bright Max which is already in the press release because we already had some concern about that brand. So those are the brand names.

And then the question of how much, our concern today is potentially about all toothpaste that comes in from China. Our estimate is that China makes up about 3.3 billion of the US toothpaste market which consists in total of 2 billion -- so 3.3 billion out of a total of 2 billion.

Todd Zwillich: I'm sorry. What in dollars?

Deborah Autor: In dollars.

Thank you.

Todd Zwillich: Okay. And is there any sense of absolute number of people who may have bought this or how much has been sold in the last, you know, six months or in terms of the number of the people who might have it on hand?

Deborah Autor: We're still working on trying to pull together an estimate of that.

Todd Zwillich: Okay. Thank you.



Rob Ali: Thanks Todd.

Operator, next question please.

Coordinator: The next question is from Ricardo Alonso-Zaldivar with LA Times.

Your line is open. You may ask your question.

Ricardo Alonso-Zaldivar: Hi. Thanks for taking my question.

And could you go over again what you're doing at the border with regard to, you know, toothpaste coming in from China, I didn't quite hear what you were saying the first time you went through it, and I may have a followup.

Deborah Autor: Sure.

Ricardo Alonso-Zaldivar: Thank you.

Deborah Autor: We're doing two things. One is that we are stopping all toothpaste that is manufactured in China and referring that for testing.

And the other is that we also have a specific Import Alert in place that this specific brand of toothpaste about which we know contains DEG and also would stop any toothpaste label that contains DEG.

Ricardo Alonso-Zaldivar: Okay.

And my followup is why would this chemical be added to toothpaste? Any idea?

Deborah Autor: Well, I can't speak to the intention of the manufacturers but we've seen DEG be used as a low price substitute for glycerin and occasionally propylene glycol. It is less expensive -- but unfortunately, it's not safe for humans.

Ricardo Alonso-Zaldivar: So it's used as some kind of sweetener that's less expensive than the preferred or conventional sweeteners, is that right?

Deborah Autor: It's used as a sweetener and -- hold on one moment.

Ricardo Alonso-Zaldivar: Uh-huh.

Deborah Autor: It also works as a base in the product.

Ricardo Alonso-Zaldivar: As a base meaning what?

Deborah Autor: Meaning a base product...

Charles Ganley: Primary excipient...

Deborah Autor: A primary excipient to hold the product together and to contain the active ingredient.

Ricardo Alonso-Zaldivar: Okay. Okay, thank you.

Rob Ali: Let's go to the next question please.

Coordinator: Next question is from Jane Zhang, the Wall Street Journal.

Your line is open.

Jane Zhang: Hi. Thanks for taking my call.

I have two questions. The first one is you said you found the toothpaste products at a distribution center and in a retail store, can you tell us where they were?

And the second question is could you tell us the difference between Import Alert and sampling at the border?

Deborah Autor: Sure.

The retail stores were two -- one was that we located some DEG-contaminated toothpaste at a Dollar Plus store in Florida.

Jane Zhang: Dollar Plus...

Deborah Autor: And the other retailer was a retailer called Todo A Peso, spelled as P-E-S-O in Puerto Rico.

And the Import Alert and the sample collection both serve similar purposes in that they stop Chinese toothpaste at the border. The sample collection goes a step further to also refer it for testing. But they're both in there to make sure that this toothpaste does not come in and reach American consumers.

Jane Zhang: Could you spell the store name again for the one in Puerto Rico?

Deborah Autor: Sure. Todo, T-O-D-O...

Jane Zhang: Okay.

Deborah Autor: A as in the letter 'A', Peso, P-E-S-O.

Jane Zhang: Thank you.

Rob Ali: Thanks Jane.

Next question please.

Coordinator: Our next question is from Elizabeth Mechcatie from International Medical News Group.

Elizabeth Mechcatie: Hi, Mechcatie.

I wondered if - are there any health effects or reports of adverse health consequences from these contaminated toothpaste products?

Deborah Autor: We don't...

Elizabeth Mechcatie: Or is there anything that a doctor should be alert for?

Deborah Autor: We don't have the reports of actual adverse events but we are concerned about potential risks from chronic exposure...

Elizabeth Mechcatie: Uh-huh.

Deborah Autor: To DEG. And we will be doing some outreach with the dental community so that they - and with doctors so that they can be aware of what the potential medical signs would be.

Elizabeth Mechcatie: Okay.

And when you said that some of the products actually had DEG on their label, it was listed as an ingredient?

Deborah Autor: Some labels reflected either diethylene glycol, diglycol, or diglycol stearate as an ingredient. Those are all synonymous.

Elizabeth Mechcatie: Okay.

Deborah Autor: Others were not labeled as containing DEG under any name but did contain DEG.

And I'm sorry; I just want to take the opportunity to go back to an earlier question to say that DEG serves as a thickening agent and a sweetener in toothpaste.

Elizabeth Mechcatie: Okay. And would you say these are - these tend to be more available in discount types of stores or not?

Deborah Autor: Yes, we've been looking particularly in the dollar-type stores.

Elizabeth Mechcatie: Okay. Thanks.

Rob Ali: Very good.

Next question please.

Coordinator: Our next question is from Lisa Richwine from Reuters.

Lisa Richwine: Hi. Thanks for taking my question.

Did you tell us which brand was the one detained at the border? I didn't hear it if you did, can you let us know?

Deborah Autor: Sure. The ones that we detained at the border were Cooldent Fluoride, Cooldent Spearmint, and Cooldent Coolmint.

Lisa Richwine: Okay. And is there any acceptable level of DEG in toothpaste? You said that manufacturer would have to prove they don't have any harmful level but another point I think you said that there is no acceptable level.

Deborah Autor: We don't consider DEG to be a safe and suitable ingredient for use in toothpaste.

Lisa Richwine: Okay. And if I could ask one last thing, are there symptoms that people should look for that they might have some chronic exposure to DEG?

Deborah Autor: Charlie Ganley, are you there?

Charles Ganley: Yes.

Deborah Autor: Do you want to answer that question?

Charles Ganley: One of the problems is that there's not a lot of good information out of chronic exposure with diethylene glycol. And the best that you can do is point to the symptoms that you may get with acute exposure, which could be vomiting, abdominal pain, diarrhea, headache, altered mental status, decrease in urine output.

Primary toxicity can be neurological or a kidney failure. And again, that's with an acute ingestion.

And there's just not a lot of good data about, you know, what chronic exposure - if it's going to be toxic to the same organ systems, symptoms should be the one to be concerned about.

Lisa Richwine: Okay. But you don't think the 3% to 4% level is enough for an acute reaction?

Charles Ganley: Well, that's - I think it would depend on the size of the individual.

Lisa Richwine: Okay.

Charles Ganley: If you go back, there was a study published in June back in 1998 that looked at an acute intoxication with DEG that occurred in Haiti. And they had calculated the toxic - the toxic in this case was primarily resulting in death and that was 220 milligrams per kilogram and that was an acute intoxication.

So, if a young child was to ingest by accident several ounces of a tube of toothpaste that contained 3% that could be a potential problem.

Lisa Richwine: Okay. Thank you.

Rob Ali: Lisa, it's for Charles spelling, it's Charles Ganley, G-A-N-L-E-Y. And Charles is the Director of Office of Nonprescription Products at the Center for Drug Evaluation and Research at the FDA.

Lisa Richwine: Thanks very much.

Rob Ali: Operator, next question please.

Coordinator: The next question is from Ricardo Alonso-Zaldivar with LA Times.

Ricardo Alonso-Zaldivar: Hi. My question was just answered. It had to do with the toxic dose. Thank you.

Rob Ali: Thanks Ricardo.

Next question please.

Coordinator: Once again, to ask a question, please press star then 1.

Rob Ali: Next question please.

Coordinator: Our next question is from Kevin Freking with Associated Press.

Your line is open.

Kevin Freking: I wanted to ask if the level of concern about consumer products from China has led to - is there a point in time where we shut off the supply of these consumer staples?

Rob Ali: Hey Kevin, hang on a minute, we've got to move the microphone.

Walter Batts: This is Walter Batts. I'm the Deputy Director of FDA's Office of International Programs.

My only response to that question is that we are certainly very concerned about the problems that we're seeing with products from the China.



And fortunately, we had the occasion last week in conjunction with the Strategic Economic Dialogue that was being held in Washington for the Secretary of Health and Human Services to meet with the Chinese Health Minister and other Chinese officials. And we talked about working together going forward in a much closer way and in a more enhanced way to prevent problems with products that are being exported to the US.

Rob Ali: Thanks Walter.

Kevin, did you have a followup?

Kevin Freking: Could you be more specific about steps that are going to be taken to ensure the safety of these consumer staples other than just talks with - between authorities?

Deborah Autor: This is Deborah Autor again.

Let me at least respond on the topic of toothpaste another - we see specific products obviously that present a risk to public health and we will deal with them appropriately to protect public health.

We will, of course, continue to follow up and look for potentially contaminated toothpaste and add any names of any products that are contaminated to the Import Alert and do whatever else we can to make sure that consumers are adequately advised of this problem.

Kevin Freking: Thank you.

Rob Ali: Thanks Ms. Autor.

Operator, next question.

Coordinator: The next question is from Todd Zwillich, WebMD and Public Radio.

Todd Zwillich: Hi.

The super - the dollar store, just the one we talked about before, where in Florida?

Rob Ali: Okay. Hang on, Todd.

Deborah Autor: That was in Miami, Florida.

Todd Zwillich: Great, thank you.

Deborah Autor: Dollar Plus.

Todd Zwillich: Dollar Plus, right.

Rob Ali: Operator, next question.

Coordinator: Our next question comes from (John Bonnetfeld) from CNN.

(John Bonnetfeld): Hi.

I'm curious to know if you're testing samples from the border that you're - they're no longer coming in as imports, when will those test samples be available to the public? Will we know them and when?

Deborah Autor: I'm not sure I understand the question.

We will make the names of any toothpaste that tested positive available immediately to the public...

(John Bonnetfeld): Okay.

Deborah Autor: As quickly as we possibly can. Does that answer the question?

(John Bonnetfeld): Yeah. But are those samples tests then going on right now?

Deborah Autor: Yes, we continue to test samples.

And you'll see in the press release, a number of names that are - of the toothpaste that we are so far have reason to be concerned about.

Also, the Import Alert will continue to be a live document and we'll continue to add any name brands that we know are contaminated.

(John Bonnetfeld): Okay. Thank you.

Rob Ali: Okay.

Operator, next question.

Coordinator: At this time, I'm showing no other questions.

If you would like to ask a question please press star then 1.

We do have a question from John Wilkerson, FDA Weekly.

John Wilkerson: Is FDA increasing the percentage of Chinese imports -- food imports in general that it's inspecting -- in other words, are you guys seeing a rise in problems with Chinese imports in general?

I believe that FDA inspects about 2% of Chinese imports compared to, you know, 1% of all imports generally so you guys do, you know, pay a little extra attention to them but are you going to increase that even more now?

Doug Arbesfeld: John, this is Doug Arbesfeld. I'm jumping into this. The people here are from CDER, you know, the Drug Division and others, and I've been involved in the situation around melamine.

We continue to take a risk-based approach. When we see a problem or we know that there's been a problem in the past with certain foods, we take action.

And as you probably know from being on some on of the melamine calls, we currently have an Import Alert for all vegetable protein concentrate from China, so none of that is entering the US until those companies pass a very high burden of proof that their product is safe.

We have other Import Alerts in place that have been in place for quite sometime looking at fish and seafood from China and other things.

So that is the approach and we continue to take. When we see a problem or when we know that there is a historical basis for a problem, we'll take action.

John Wilkerson: So I guess then my question is more to the point, is an import that is coming from China -- the fact that it's coming from China -- is that alone enough to get your attention and make you more likely to test it or it doesn't happen - or

does it have to be, you know, just a product that you happened to have had a problem with in the past?

Doug Arbesfeld: No. I don't think at this point, we can set up a situation where a product from a country where or other products from a country that's, you know, sort of tainted because of their problem products.

So we continue to look at individual products where there are problems and that's what we focus on.

John Wilkerson: Okay, thank you.

Rob Ali: Operator, are there any further questions?

Coordinator: We have one question.

Steve Hurst from The Washington Times.

Steve Hurst: Am I on?

Rob Ali: Yes, Steve.

Steve Hurst: Yeah.

Can you - you said before and have illustrated before that Chinese toothpaste imports in the United States are, I think, \$3.3 million a year, can you tell us these particular brands? How much of these brands are imported into the United States every year?

Deborah Autor: The number that I can tell you is for the toothpaste that's made by a company called Goldcredit and they are listed in our press release and they make several of the brands that have tested positive for DEG.

We estimate since 2005, there has been about \$110,000 of Goldcredit toothpaste imported into the US and again, that's out of a toothpaste market of \$2 billion per year.

Steve Hurst: Okay. Well, so the Goldcredit brands are the ones that are mentioned in the press release?

Deborah Autor: Goldcredit brands are most of the ones mentioned in the press release. There is also another company named in the press release which is the Suzhou City Jinmao Daily Chemicals. They make the ShiR Fresh brand.

Steve Hurst: And what about the brands that you added -- the four more?

Deborah Autor: I don't know about those four because that information is so new.

Steve Hurst: So in essence, you do not - you don't have a figure on the brand covering how much are sold in the United States, is that right?

Deborah Autor: I don't have a total of all the brands that have tested positive for DEG, how much of that is sold in the United States. No, I don't have that.

Steve Hurst: Okay.

Is the DEG that was added in, is this all one Chinese company, for example, the one that's got in trouble before the Panamanian toothpaste?

Deborah Autor: Gold -- hold on.

Man: No.

Deborah Autor: If you're asking about the source of the DEG, we don't know that.

Steve Hurst: Okay.

Doug Arbesfeld: And Steve, it's Doug Arbesfeld.

I just want to reiterate actually for everyone on the phone is that the percentage of the US market accounted for by all Chinese toothpaste is very small. It's \$3.3 million out of a \$2 billion market.

So, you know, we think it's very important that the public be warned about this situation but we also think that the scope of this is it's fairly small when you look at all toothpaste that's consumed in the US.

Rob Ali: Any other followup, Steve?

Steve Hurst: No, thanks. (Unintelligible) are still open.

Rob Ali: Okay.

Operator, are there any other questions in the queue?

Coordinator: Not at this time.

Rob Ali: Okay.

Ladies and gentlemen, seeing no further questions and knowing that you have work to get to and our spokespeople have their duties to return to, we'll go ahead and conclude this media teleconference.

Thank you for your participation.

There will be a replay available in about an hour and will be up for about three days as additionally we'll have written transcripts posted in about a day and half to two days.

If you have follow-up questions, please don't hesitate to call the FDA Media Contact that's listed on the press release.

Thanks and have a great day.

Coordinator: Today's call has concluded. All parties may disconnect.

END