



U.S. Food and Drug Administration

Notice: Archived Document

The content in this document is provided on the FDA's website for reference purposes only. It was current when produced, but is no longer maintained and may be outdated.

**FDA Media Call
Tainted Products Marketed as Dietary Supplements
Moderator: Siobhan DeLancey
December 15, 2010**

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode until the question and answer session of today's conference.

At that time, you may press Star-1 if you would like to ask a question. I'd like to inform all parties that this call is being recorded. If you have any objections, you may disconnect at this time.

With that, it's my pleasure to hand the call over to Ms. Siobhan DeLancey. Thank you ma'am, you may begin.

Siobhan DeLancey: Thank you (Andrea). This is Siobhan DeLancey from FDA's Office of Public Affairs and this is an FDA Teleconference for press to get more information about an FDA announcement about a change in products that sold are as dietary supplements.

This briefing is for credentialed media only.

FDA Principal Deputy Commissioner Joshua Sharfstein is joined today by several representatives from the dietary supplement industry. Dr. Sharfstein will make opening remarks and then the following speakers will make brief statements.

Dr. Joshua Sharfstein, John S. Gay, Executive Director and CEO of Natural Product Association, Loren Israelsen, Executive Director, United Natural Products Alliance, Scott M. Melville, President and CEO, Consumer Healthcare Products Association, and Anthony Young, General Counsel, American Herbal Products Association.

We also have technical experts from the FDA standing by to answer your questions. They are Michael Levy, Director of the Division of New Drugs and Labeling Compliance at the Center for Drug Evaluation and Research here at FDA; Brad Pace, Regulatory Council at CDER; and Robert Moore, PhD, Supervisor Regulations and Implementation Team in the Division of Dietary Supplement Programs at FDA.

After the speakers have made their remarks, we'll open the call up for questions from the media. And when asking a question, please state your name and your affiliation.

We're going to limit you today to one question so that we can get to as many questions as possible.

And now Dr. Sharfstein.

Dr. Joshua Sharfstein: Thank you very much Siobhan. I'm Dr. Joshua Sharfstein: the Principal Deputy Commissioner here at FDA.

Today FDA calling attention to an important public health problem, serious injuries caused by products masquerading as dietary supplements. These products contain the same active ingredients as FDA approved drugs or analogs of these

active ingredients or other compounds such as novel, synthetic steroids that do not qualify as dietary ingredients.

The products are generally poorly labeled so the consumer does not know what he or she is really buying. Consumers who turn to supplements when doctors tell them a prescription might be too dangerous for them can wind up with these products masquerading as supplements, getting the prescription drug after all in uncertain dosages and without any warning.

Some of the products contain analogs of prescription drugs that have never been tested in humans. And the results, as we have seen can be tragic. FDA has received numerous reports of serious adverse events and injuries associated with the consumer use of these tainted products including stroke, acute liver injury, kidney failure, pulmonary embolisms and death.

FDA over the last several years has taken a number of steps to combat this problem including issuing warning letters, seizing products, criminally prosecuting some individuals who are responsible, and issuing broad communications to the public.

Since December 2007, FDA has alerted consumers of nearly 300 tainted products marketed as dietary supplements. Most of these products are marketed in three categories -- weight loss, sexual enhancement, and body building.

This is progress. But we cannot claim success. Far too many supplement products continue to be advertised online and elsewhere. And that's why today to protect the public, FDA is stepping up our efforts.

FDA Commissioner, Dr. Margaret Hamburg, today sent a letter to the dietary supplement industry expressing concern about this public health problem. The

letter outlines the legal responsibility of every company to assure the security and safety of that product and the consequences for failing to do so.

It also announces two additional steps the FDA is taking including establishing new mechanisms of alerting consumers of problems starting with a new RSS feed about tainted products. And establishing a new way for industry to refer such suspect products to the agency including referring them anonymously.

FDA is working with the dietary supplement industry's trade organization in this effort. These organizations know that the dangerous products out there are undermining -- excuse me -- are undermining consumer confidence in legitimately marketed supplements.

I want to express my personal appreciation for the interests of these organizations and their leaders in this issue and my thanks to their commitment to distribute Dr. Hamburg's letter far and wide within the industry.

Joining us in this announcement today are Steve Mister from the Council for Responsible Nutrition, Attorney Young, from the American Herbal Product Association, Lauren Israelsen from the United Natural Products Alliance, Scott M. Melville from, Consumer Healthcare Products Association and John Gay from the Natural Products Association.

I'm going to turn to them for brief comments and then we will be happy to take questions. And I'm going to start with Steve Mister, President and CEO of the Council for Responsible Nutrition.

Steve Mister: Thank you Dr. Joshua Sharfstein. On behalf of the Council for Responsible Nutrition, I want to publicly commend you and FDA for taking these actions to

protect consumers from illegal drug products masquerading as dietary supplements.

From CRN's perspective, today's announcement could put the companies who market illegal products on notice that FDA will flex the full force of its regulatory muscle to punish criminals engaged in illegal activity.

And we fully support increased enforcement for those who put the health of consumers at risk by selling illegal spiked products. And to put the health of the legitimate dietary supplement at risk by injuring our reputation. So we applaud the agency's resolve to get tough with criminals.

And we will support these efforts any way we can. Further, we appreciate the agency's willingness to distinguish between responsible manufacturers and common criminals. The mainstream dietary supplement industry is committed to putting only safe, high-quality and beneficial products into the marketplace.

Our partnership with FDA today underscores that there are legitimate supplements in these three categories highlighted today and the consumers also need to be smart about the choices they make.

Although our companies are not part of this problem; we want to be part of the solution. So we'll be urging all manufacturers to increase their vigilance in their supply chains and manufacturing process to use the new FDA tools that you've talked about today to report contaminated ingredient shipments or tainted products that they identify in the marketplace.

And we'll be posting tips for consumers and retailers on our website to urge them to sign up for FDA's tainted product alerts.

We'll be distributing your letter along with a note of urgency to all of CRN's members this afternoon and raising the visibility of this problem with the larger industry in the coming weeks.

So we look forward to working with you, FDA and the journalists who are on this call to protect consumers and law-abiding companies.

Dr. Joshua Sharfstein: Thank you very much. I'm now going to turn to Tony Young, the General Counsel of the American Herbal Products Association.

Anthony Young: Thank you Dr Sharfstein: The American Herbal Products Association is pleased that FDA recognized our associations can help get the word out about drugs and drug-like substance calling themselves supplement and they're dangerous.

AHPA also applauds FDA for aggressively acting to protect consumers and for sending this strong message to those who ignore the law and spike products with undeclared and illegal ingredients.

AHPA has consistently communicated with FDA about the need for active and well publicized enforcement in this area. FDA letter is strong and firm. It is the strongest letter I've seen in 35 years of law practice.

Our manufacturer, distributor and retailer members can play a role here to help FDA address these supplement hijackers. More eyes and ears on a problem like this always help. Thank you.

Dr. Joshua Sharfstein: Thank you. And now we're going to Loren Israelsen, Executive Director of the United Natural Product Alliance.

Loren Israelsen: Thank you Dr. Sharfstein. We too join with FDA and our colleagues in the dietary supplement industry to drive these pirates out of our industry, to protect public health and safety for the millions of consumers of dietary supplements who do rely on these products for daily health needs.

We have been astonished that the unfortunately growth of this particular class of products which are intentionally spiked. These are illegal acts committed by people who work in the shadows. They are very difficult to find.

We are committed to join FDA to find them. And to drive them out of our industry, out of the United States. That we can assure that our consumers have full confidence and trust in our products.

We applaud both FDA and the Commissioner's office for taking these steps. We commit ourselves and our members to join in in all efforts to assure a clean and reliable supply of dietary supplements to American consumers. Thank you Dr. Sharfstein.

Dr. Joshua Sharfstein: Thank you and I'll turn to Scott Melville, the President and CEO of the Consumer Healthcare Product Association.

Scott Melville: Thank you Dr. Sharfstein and I will echo the comments of the industry colleagues here today in thanking you and Commissioner Hamburg for your leadership in raising this risk and the risk that these products pose to consumer safety.

We share the concern of the FDA over the proliferation of these adulterated products and commit to working with the regulatory agency and our industry colleagues to protect consumers.

We commit to distributing the FDA letter to our members encouraging them to share the letter with their retail customers. And we will promote the use of FDA's new tools to identify and expose those who are breaking the law.

And we will maintain the industry efforts to improve the quality of our product supply chain including working forward on guidelines on supplier qualification. That's an important part of the response here and we're committed to doing it.

So we want to ensure that we are part of the solution. First and foremost, we want to reduce harm to consumers. But we also want to maintain access for patients and consumers to legitimate, healthful dietary supplements.

Dr. Joshua Sharfstein: Great and now I'll turn to John Gay, the Executive Director and CEO of the Natural Product Association.

John Gay: Thank you Dr. Joshua Sharfstein. Well everything that needs to be said has been said and now has everyone has said it. So let me just hit a couple of points to reiterate what my colleagues have said.

Spiking of supplements with drugs is a crime. It endangers the public. It undermines our members and other legitimate retailers and manufacturers of supplements.

We are pleased to support the FDA as it steps up its enforcement efforts to get these criminals off the streets. We were happy to circulate Commissioner Hamburg's letter to our members. And we'll continue to work with you on other effort to educate the industry and the public. Thank you.

Dr. Joshua Sharfstein: Thank you. And I'm going to now turn it back to Siobhan DeLancey for the question and answer session.

Siobhan DeLancey: Thank you Dr. Sharfstein. And at this time, we'll be able to take questions from credentialed media.

Once again just one question per reporter please. And may we have the first question.

Coordinator: At this time, if you would like to ask a question, please press Star-1 on your touchtone phone.

The first question is from Mr. David Brown with the Washington Post. Your line is open sir.

David Brown: Yes, thanks a lot. Dr. Sharfstein, can you describe in a little bit more detail these 300 adverse events including death that you mentioned. And is there anyway that, you know, on the website we can get a look at the details and the sort of time period over which this occurred?

Dr. Joshua Sharfstein: Sure. I'd say I think what I said is there were 300 products, around 300 products that we warned about in 2007. And the actual RSS feed that we're launching today has links to all of the most recent announcements. And it goes through the kinds of adverse events in those particular cases that we're aware of.

I may turn to Michael Levy from drugs to talk about maybe some of the, in a little bit more detail about how this works. How we hear about an adverse event and what we do to identify those tainted products.

Michael Levy: Well typically we hear about adverse events involving these types of products from either consumers themselves or from healthcare practice who are reporting on behalf of a patient.

When we get adverse event reports like this, we do typically (unintelligible). And there are certain types of adverse events that we now associate with these types of products. And usually we have to purchase and test the product which eventually leads to one of the many consumer alerts that are in our RSS feed.

David Brown: Okay well how many deaths have there been? And, you know, serious disabling injuries, things like that, just a few details would be useful.

Michael Levy: I think we'd have to get back to you with specific numbers.

Dr. Joshua Sharfstein: yes, I mean I think it would be fair to say that we're aware of, you know, well over a hundred products over the last few years. And with a number of them, we had serious injuries and even deaths reported.

Siobhan DeLancey: Thank you. Next question please.

Coordinator: The next question is from Matt Canham from the Salt Lake Tribune. Your line is open sir.

Matt Canham: All right, thank you very much for having the call. I was hoping you could talk a little bit about the second part of this. You talked about the RSS feed which I guess consumers can follow.

But you also said your changing the way that people can point out questionable supplements including reporting anonymously. Can you detail that a little bit?

Dr. Joshua Sharfstein: Sure. In the letter we mention that we have established an email address for the industry which is taintedproducts@fda.hhs.gov, where people can send in concerns that they have.

We also have a website at fda.gov/oci and OCI stands for Office of Criminal Investigations. And that's where people can report things anonymously. So we have those specific email addresses as well as mechanisms for people to report anonymously.

Siobhan DeLancey: Thank you, next question please.

Matt Canham: Are those both new?

Dr. Joshua Sharfstein: The email address is new and the website has been there but we haven't really specifically used it for this purpose- I mean in this way.

Siobhan DeLancey: Thank you. Next question please.

Coordinator: The next question is from (Elizabeth Mechcatie) with (Elsevier Global Medical News). Your line is open ma'am.

(Elizabeth Mechcatie): Hello. I'm been for a doctor who suspects an adverse effect in a patient is caused by one of these products, where would he or she report it? To Med Watch or one of these or the email site?

Dr. Joshua Sharfstein: Yes, right. We do have a whole system for reporting events and that would be through Med Watch.

(Elizabeth Mechcatie): So that would apply to these too?

Dr. Joshua Sharfstein: Absolutely and that applies to a whole range of products. But what's new about what we're doing is we're reaching out to people how may know the industry well to tell us that they see products that they think could well be spiked

and give us a head start on those hopefully before we have any reports of serious injuries.

(Elizabeth Mechcatie): Thank you.

Siobhan DeLancey: Thank you. Next question please.

Coordinator: The next question is from Matt Perrone with the Associated Press. Your line is open sir.

Matt Perrone: Hi, thanks guys. I'm just trying to clear up how many products we're talking about here for the 103 the 300. In this letter, it says the FDA has worked with industry to recall numerous products, 70 marketed for sexual enhancement and 40 marketed for weight loss and 80 for body building.

So by my count that puts it at a little under 200. Is that and that's just the ones you've recalled. Is that right?

Dr. Joshua Sharfstein: I'm just looking for where in the letter...

Matt Perrone: It's on Page 2.

Dr. Joshua Sharfstein: Yes, I think that involves those are the three areas where we're seeing it most commonly. But I think what we're saying is basically if you go back to 2007, that there were 300 products that we've either recalled or warned the public about.

Matt Perrone: Okay.

Man: Those numbers only cover products that were recalled.

Dr. Joshua Sharfstein: I see.

Michael Levy: There are other products we've issued consumer alerts on that have not been recalled.

Matt Perrone: I see, okay.

Dr. Joshua Sharfstein: We don't have a mandatory recall authority as you may know. So we may warn about a product that are not recalled. So in the letter it refers to recalls. But we warned about a bigger list of products.

Matt Perrone: I see okay, great.

Siobhan DeLancey: Thank you. Next question please.

Coordinator: The next question is from Sandra Young from CNN. Your line is open ma'am.

Sandra Young: Hi thank you. My question has been answered.

Siobhan DeLancey: Thank you, next question.

Coordinator: The next question is from Jennifer Kwok with the Nutritional Outlook Magazine; your line is open ma'am.

Jennifer Kwok: Hi my question is regarding the timing of the letter's issuance. Adulterated products have been a problem for, you know, a long time. We've known about it.

But is there anything significance to the FDA making this move now and does have anything to do with any new dietary ingredient guidance that might be coming soon?

Dr. Joshua Sharfstein: I think that -- this is Joshua Sharfstein. I think that this letter emerged out of sort of an assessment that we did. You know, we are in fact seeing some recalls and we are warning but we do not think that the problem is solved.

And in discussions with these associations that are here, we explored how we could extend our efforts. And so we thought it would be very helpful in thinking about it for the agency to communicate very clearly not just about the fact that it's illegal and the consequences for companies and not just the companies making them but people all throughout the supply chain and distributing them.

But also provide the basic instructions of what people to do to secure their supply chain and make it information to the industry and how they report suspect products.

So it really was an extension of our internal work first on our concern about this public health problem as well as exchanges that we've had with the industry. But I would say it does not ah veto do with the new dietary ingredients guidance.

Jennifer Kwok: Thank you.

Siobhan DeLancey: Okay thank you, next question please.

Coordinator: The next question is from (Sarah Ditta) from FDA Week, your line is open.

(Sarah Ditta): Hi, I have a question about in Commissioner Hamburg's letter it notes that criminal investigations could be initiated. And I was wondering if you expect the number of criminal investigation to increase in the area and if you've been working with DOJ about it?

Dr. Joshua Sharfstein: You know, I think that we can say that -- this is Josh Sharfstein again -- the letter is very clear that we're talking about is illegal and that there are criminal penalties that may be appropriate for people who are engaged at very steps in this.

And that's a very clear message that we want to send. But I'm not going to comment any further than that.

Siobhan DeLancey: Thank you. And I think we have time for two more questions. Next question please. Operator?

Coordinator: One moment please. The next question is from Kathleen Doheny with WebMD. Your line is open ma'am.

Kathleen Doheny: Thank you. You said no figures on death. Is there any figure on incidents or emergency room visits, any statistics we can give our readers to kind of quantify the problem?

Dr. Joshua Sharfstein: Yes, there are two challenges and it gives me a chance to talk a little bit more about this. And one of the challenges is that we don't go into particular case to assess causality. So we have reports of different events. And then we will test the product and we will find something that could be quite dangerous and we think is quite possibly be linked.

But those are just based on the reports that we get in and there may be a whole another group of people who are injured that we don't hear about.

Kathleen Doheny: Can you give a figure on the number of reports per year or maybe since 07?

Dr. Joshua Sharfstein: Actually well if you go to I think we'll probably... We'll try to put something out that fits that and put this on our website that we have on this topic.

We do have on FDA facts, the measures of the reports that we get focused on this. I think we should probably put something special up.

Kathleen Doheny: Okay thank you.

Siobhan DeLancey: Next question and I think this will be our last question.

Coordinator: The next question is from Sandra Young with CNN. Your line is open ma'am.

Saundra Young: Hi thanks for taking my question. What's the take home for consumers? What do you want to tell people who are buying these specific types of products the weight loss, body building, sexual enhancements? What's the take-home for people who are actually using these products?

Dr. Joshua Sharfstein: I think that we -- this is Dr. Sharfstein -- we want consumers to be aware that there are products masquerading as dietary supplements that pose significant dangers. And that warning signs of those kinds of products include number one, products that claim to be alternative to FDA approved drugs to have effects similar to prescription drugs.

Number two, products claiming to be a legal alternative to anabolic steroids. Number three, products marketed primarily in a foreign language. Number four, products that are marketed through mass emails.

Number five, sexual enhancements product promising rapid effects. This is working in minutes to hours or long lasting effects, this is 24 to 72 hours. And number six, products provide warnings about testing positive in performance enhancing drug tests. And we're releasing a consumer advisory today that summarizes some of the advice FDA has.

And I think that we also have some photos of some of the products that have caused a problem. And you can see they don't look like what a lot of legitimate products look like. And between that and the action that we're taking that we're announcing today.

So to really try to get rid of the products pose the danger. We're hoping that consumers can find a safe path.

Siobhan DeLancey: Thank you Dr. Sharfstein. This wraps up conference for today. Thanks for your participation. A replay will be available in about an hour, and will be up for the next seven days.

And of course, if you have follow-up questions, please contact me Siobhan DeLancey at 301-796-4668. Thank you and good bye.

Coordinator: And that concludes today's conference call. Thank you for participating. You may disconnect at this time.

END