FTS-HHS FDA

Hydroxycut Dietary Supplement
FDA Warns Consumers to Stop Using Hydroxycut Products
Risk of Liver Injury

Moderator: Susan Cruzan
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Coordinator: Welcome and thank you for standing by. Currently all participants are on listen only for the presentation. At the time of the question and answer session, you'll be prompted to press star then 1 to ask your question.

Today's conference is being recorded, if anyone has any objections they may disconnect at this time. I'd like to turn the conference over to Susan Cruzan. You may begin.

Susan Cruzan: Thank you very much. Ladies and gentlemen welcome. I am Susan Cruzan from FDA's Media Relations Staff. Welcome to the briefing on Dietary Supplements. Our two speakers this morning are Dr. Linda Katz, the Interim Chief Medical Officer with FDA's Center For Food Safety and Applied Nutrition and Dr. Vasilios Frankos, the Division Director with the Office of Dietary Supplements (unintelligible) with FDA.

We will have a brief question and answer segment after the opening remarks. And now I would like to turn the call over to Dr. Linda Katz. Thank you.

Linda Katz: Welcome and thank you for joining us for this important announcement from the United States Food and Drug Administration. Today, the FDA has taken

action to strongly advise consumers of the potential risk of severe liver injury associated with the use of Hydroxycut Dietary Supplements.

These products are marketed as dietary supplements for weight loss as fat burners, energy enhancers, as low carb diet aids and to promote water loss. Under both the Iovate and MuscleTech brand name.

The company has agreed to voluntarily recall 14 Hydroxycut products. A complete list of those products is now available on our Website. Consumers are advised to discontinue use of Hydroxycut weight loss products and to consult a physician or a healthcare professional if they are experiencing any symptoms of liver injury.

Specific symptoms include jaundice and brown urine, as well as nausea, vomiting, light colored stool, unusual tiredness, weakness, stomach or abdominal pain, unexplained itching and loss of appetite.

FDA today has received 23 reports of adverse liver effects in users of Hydroxycut products including asymptomatic blood liver enzyme changes, jaundice, liver damage, liver transplant and death.

In addition, we are aware of four case reports in the medical literature involving sick patients who had consumed Hydroxycut and were diagnosed with serious liver disease.

Hydroxycut products contain a variety of ingredients and herbal extracts. Based on the information available to FDA, the agency has not yet determined which ingredient dosages or other health related factors may be associated with the risk of developing liver disease or other health related problems related to Hydroxycut.

Finally, although the liver damage appears to be relatively rare, FDA contends the consumer should not be exposed to unnecessary risk. FDA continues to investigate the potential relationship between the use of Hydroxycut Dietary Supplements and liver injury and other potentially serious side effects.

The agency will provide updates to the public and if warranted, take additional actions as more information becomes available. I will now turn over to Dr. Vasilios Frankos, Director Division of Dietary Supplement Program here at (Systan) who will give a brief overview of FDA's role in the regulation of dietary supplements particularly when there are safety concerns with a product such as Hydroxycut.

Vasilios Frankos: Thank you Dr. Katz. I will now provide you a short summary of FDA's regulatory authority for dietary supplements and how FDA evaluates the safety of dietary supplements.

Under the 1994 Dietary Supplement Health and Education Act, known as (DSHEA), dietary supplements ingredients sold in the United States before October 15, 1994 are not required to be reviewed by FDA for their safety before they are marketed.

Under (DSHEA) once the product is marketed FDA has to prove that the dietary supplement is unsafe before it can restrict the products used or remove it from the marketplace.

Although manufacturers do not have to provide FDA with evidence that pre (DSHEA) dietary supplements are effective or safe, they are not permitted to market unsafe or ineffective products.

For this reason safety evaluation of dietary supplements under (DSHEA) is primarily a post market process. For the new dietary ingredients that are marketed after October 15, 1994, FDA requires pre-market notification that assures the dietary supplement that contains the new dietary ingredients will be safe under the conditions described on the product label.

FDA can thus protect the public from unsafe products by either refusing to allow new ingredients into products or remove existing pre 1994 grandfather ingredients from the marketplace for safety reasons.

FDA also assures the quality of dietary supplements by requiring supplement manufacturers to follow recently published good manufacturing practice regulations. These GMP rules help to ensure the quality of dietary supplements so that consumers can be confident that the products they purchase contain what is on the label.

Of particular importance to today's announcement on Hydroxycut, is FDA's recently expanded authority to collect adverse event reports on dietary supplements. The passage of the dietary supplement and non prescription drug Consumer Protection Act provides FDA a new tool for monitoring the safety of dietary supplements.

Starting December 22, 2007 any serious adverse events reported to a manufacturer must be reported to FDA within 15 days of receiving the serious adverse event. Furthermore, FDA can inspect a manufacturer's serious and non serious adverse event reports for a period of six years after a company receives a report.

These reports are helping FDA identify unsafe dietary supplement products such as Hydroxycut. In conclusion, it is important that any adverse events

associated with the use of dietary supplements be reported as soon as possible to the manufacturer of the dietary supplement and or to FDA's Med Watch Program by calling the toll free number 1-800-332-1088 or through the Med Watch Website at www.fda.gov/medwatch, medwatch is a single word.

These reports are vital in helping identify unsafe dietary supplements. I would like to now open the mic to any questions. Thank you.

Susan Cruzan: (Catherine) we can take our first question.

Coordinator: Thank you. At this time just a reminder to ask a question, please press star then 1. To withdraw a question press star then 2. Once again. To ask a question please press star then 1.

Our first question comes from (Peggy Pent) with Med Page Today. Your line is open.

(Peggy Pent): Thank you for taking our questions. I'm wondering approximately, you know how wide spread is the use of this supplement? That's my first question, so we can get a sense of what this small risk might be. And my other question is you mentioned for additional actions, what would those actions be?

Vasilios Frankos: Well to put this in perspective. We have been told by the company that in 2008 they sold approximately 9 million units of Hydroxycut products. So they're widespread. They can be purchased in health food stores. They can be purchased in grocery stores. So, as well as pharmacies, so they're very widely sold and a lot of units have been sold.

Susan Cruzan: Okay we can move onto the next question.

Coordinator: Our next question comes from (Ricardo) from the Associated Press, your line is open.

(Ricardo Alonzo Valdavar): Yes hi, thanks for taking my question. (Ricardo Alonzo Valdavar) with the Associated Press. Could you give us some more detail on the serious adverse events that were reported? And again, how many deaths? I guess we have at least one death and when did it occur?

Linda Katz: See, we received, let's see, 23 reports of liver problems in people. Of these there was one reported death. The death occurred in 2007 and was reported to the agency at the end of March of 2009. There was one individual who had liver failure who went onto transplant in 2002. And another individual who reported with liver failure who was on a transplant list.

We do not whether or not that individual did have a transplant or not. There was several other reports of liver failure that did resolve when Hydroxycut was removed.

(Ricardo Alonzo Valdavar): Okay. And to follow up, can we double check the number of units because I seen a figure of a million units as well. So is it 9 million or is a million units?

Vasilios Frankos: I can confirm that for 2008 that the company informed us that they sold over 9 million units.

(Ricardo Alonzo Valdavar): Thank you.

Susan Cruzan: Can we go to the next question please?

Coordinator: Our next question comes from (Brian Heartman) ABC. Your line is open.

(Brian Heartman): Yes hi. I've seen reports of this from several years ago. You mentioned a ton of these severe injuries happened several years ago. Why has this taken so long first off? And second off, if the FDA had mandatory recall authority would this action have taken place long ago? Thank you.

Linda Katz: Let me address the first part of the question which is why did it take the FDA so long? Part of the problem as you know is that the FDA looks at dietary supplements from a post marketing perspective. So that an isolated incident is often difficult to follow.

As we look at through the timeframe that we had, there have been multiple changes in terms of the formulation of the product. The product originally contained ephedra which was banned. And when the product was reformulated after 2004 we again continued following for adverse events.

So that as we've looked at the totality of the evidence presented to the FDA we've looked at the totality of the evidence that's addressed in the medical literature and through discussions with our herpetologist. Now is the time that we felt we had enough information to go forward and to talk with the company about a potential recall and to request a recall of this product.

Vasilios Frankos: And let me address the mandatory recall part of the question. Really this recall would not have been any different given that the company voluntarily agreed to withdraw their product from the market. And so I don't think it would have changed anything.

Susan Cruzan: Thank you. We will take our next question.

Coordinator: Our next question comes from (Susan Orlers). Your line is open.

(Susan Orlers): Hi thanks so much. Can you tell us when you first got some reported problems after the reformulated version from the market? Obviously you probably got reports before then but that was with ephedra.

Linda Katz: The exact time period is difficult to tell. But we've received a (smattering) of reports beginning back in 2000 before it was reformulated and in 2004 which is the time period that the company said it was reformulated.

But the one caveat that I will mention is that this product has gone through a number of iterations and reformulations. So it's not just the removal of the ephedra that is an issue but the product itself has continually been reformulated over this period of time.

(Susan Orlers): And then can you help clarify one thing? In your press release here you list a number of products, I haven't counted to make sure it is 14 but there's two that were, is not affected by that recall, Hydroxycut Cleanse and hoodia. Can you just help me understand why those two products are not affected and what exactly does that mean? Are they still going to be on the market?

Vasilios Frankos: Those two products wee not included because they have completely different ingredients then the other products that are being withdrawn from the market. The Hydroxycut hoodia is - includes just the herb hoodia, no other ingredients and that is not part of the formulation of the other products.

And the Hydroxycut Cleanse products are colon cleanse products that have completely different ingredients from the weight loss products.

(Susan Orlers): Have you gotten any reported problems with those two products or they're okay and still be allowed o the market?

Vasilios Frankos: We have not.

Susan Cruzan: Thank you (Susan). We'll take our next question.

Coordinator: Our next question comes from (John Rokerson) Inside Health Policy. Your line is open.

(John Rokerson): Hi. Would you have identified this problem had it not been for the mandatory reporting requirements?

Linda Katz: We believe that we would have because most of the first event reports that we've received came in before the mandatory requirements.

Vasilios Frankos: Now let me add this caveat. The part of the Mandatory Reporting Act that is very important and has helped us with this effort is the ability of FDA to inspect records. So we have inspected the adverse event records of the manufacturer which is something that we could not do before the passage of this Act.

(John Rokerson): And how does the number of reports compare to the number of reports that you had when you pulled ephedra off the market?

Linda Katz: There's a lot of information on line about ephedra pills so you can go back and look at that I believe. And (unintelligible) as well.

(John Rokerson): Okay, do you have a sense of whether you were able to act faster on this then you did on ephedra? There was a lot of criticism back during ephedra that

FDA didn't act quickly enough because of not being able to, you know it's up to FDA to prove that it's not safe instead of being up to the manufacturer to show that it is safe.

Vasilios Frankos: One thing I can say is that with ephedra we had to go through a long process of (bill) making and public display of information and we're talking many years to get the product off the market. I think given our new authority we're able to collect information much more quickly and to act more quickly.

So I think we can say that we were able to act more quickly.

Susan Cruzan: And thank you (John), we can get that information to you. We will take the next question please.

Coordinator: Our next question is from (J. Val) with Dow Jones. Your line is open.

(Jarrett Val): Hi, thank you all for taking my question. I noticed in the press release that it says that you all don't know yet what ingredient in the Hydroxycut products are causing the problem. Why is that? Because it seems if you know that the Hydroxycut Cleanse and the hoodia are okay because of their ingredients, seems like you must know that there's got to be something wrong with the ingredients in the Hydroxycut products that you're asking to be recalled.

Linda Katz: Part of the reason for not knowing specifically is that these products contain a variety of ingredients, not all of the products that are being recalled contain the exact same ingredients. But they contain overlapping ingredients.

So with the information that's been provided to the agency at this point in time we do not know for sure. What we do know is the reaction is (idiosyncratic) which is part of the concern that we have, and why we want to

get the information out rather quickly to make sure that we can not expose consumers to undue risk.

(Jarrett Val): And what do you mean by the reaction is idiosyncratic?

Linda Katz: By that I mean is that there is not a predictable, it does not appear to be dose response relationship between taking specific amount or taking access amount or taking it for a long versus a short duration of time or that there are any specific risk factors. Most of the individuals in which we've had an adverse event reports have normal liver functions and were otherwise healthy individuals before we started to get a report.

Susan Cruzan: Okay, thank you (Jarrett). We will take our next question.

Coordinator: Our next question comes from (Cathleen Dunham) with Web MD. Your line is open.

(Cathleen Dunham): Thank you. Just to follow up with that. Is there any single ingredient that all 14 products have?

Linda Katz: No. There are overlapping ingredients but there’s not really one ingredient that goes throughout all 14.

Vasilios Frankos: Let me commit about that. When we talk about ingredients with these products, it actually not accurate to say ingredients because what we have are proprietary blends of ingredients. And the amount of each component of that blend varies from product to product. So really it makes it very difficult to do that comparison. And I think when you look at the label what you'll see is an amount of a proprietary blend.

And then a whole list of additional ingredients that are included in that blend. So it's very hard to draw a specific individual ingredient determination when you have products like that.

(Cathleen Dunham): So there's no advice you can give consumers about stay away from this, that or the other in other products that might contain the same blends or ingredients?

Linda Katz: At this point not specifically. If consumers have concerns, we can suggest that they might want to contact their physician or healthcare professional if they're concerned about their health before taking any additional dietary supplement.

Susan Cruzan: Okay, thank you (Cathleen). We will have to move on. Thank you, we'll take the next question.

Coordinator: Our next question comes from (Nicole Gray) with Bloomberg News. Your line is open.

(Nicole Gray): Hi. I'd like to go back to that death. I'm curious why there was a two year delay between the death occurring and you're being told about it. And whether it occurred when the Mandatory Reporting Act was in place? And lastly, can you just give us some detail? Male, female, age, where this person lived?

Linda Katz: Some of the questions that you're asking are difficult to know. Remember that our system is a voluntary reporting system. So there's no obligation to report. The time of the death was actually before the required time for the industry to report the incident to us. So that the fact that we got it two years late in a voluntary reporting system is not really that unusual.

As far as the individual, he was a 19 year male and he lived in the Southwest. I don't have the specific location but I'm not sure that that's really all that relevant really.

(Nicole Gray): And you were told about the death in a (unintelligible) report and how did you come to know about it?

Linda Katz: It was reported to us through Med Watch.

(Nicole Gray): Do you know it wasn't reported in 2008?

Linda Katz: Again, the incident happen in 2007 and it may also be a factor of when they received the report.

(Nicole Gray): Do you know when they received the report?

Linda Katz: Excuse me?

(Nicole Gray): Do you know when they received the report?

Linda Katz: That I do not know.

(Nicole Gray): Okay. Thank you.

Susan Cruzan: Do we have another question, please?

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

Our next question comes from (Sandra Young) CNN. Your line is open.

(Sandra Young): Yes hi. Okay, I'm sorry, my question has been answered.

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

Sandra Cruzan: Do we have any further questions?

Coordinator: We have a question from (Chris Cracken) for NBC News. Your line is open.

(Chris Cracken): Yes thanks for taking the question. The agency, the FDA has had several announcements in April alone pertaining to dietary supplements. Is this recall of Hydroxycut part of an overall campaign by FDA targeting dietary supplements?

Vasilios Frankos: This is a response to what we consider a public health concern and we respond when we have concerns. So this was really a response to a health issue and not part of any specific targeted program.

Susan Cruzan: Do you have a follow up question? Or do we have any further questions?

(Chris Cracken): That answers my question, thank you.

Susan Cruzan: Thank you. (Catherine) do we have any further questions?

Coordinator: We have a question from (Amber Heely) Food Chemical News. Your line is open.

(Amber Heely): Hi, good morning. Someone earlier had asked about possible future action as yet taken you need to investigate this. But I don’t believe that was ever answered. So as this continues, what other actions might be taken if needed?

Vasilios Frankos: Well we are looking at the issue of the ingredients, other products that would have those ingredients. So we are investigating and that's really all we can say at this point.

(Amber Heely): You have no idea. They may be looking at fines or any sort of regulatory action?

Vasilios Frankos: No.

(Amber Heely): Okay, thank you.

Vasilios Frankos: We can't address that.

Susan Cruzan: Ladies and gentlemen that concludes our Media Telecom today. Thank you so much for your participation. The replay will be available in about an hour and will be up for about three days. If you have any follow up questions, you're welcome to email me, Susan Cruzan, or call me. Thank you so much and have a great rest of the day.

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

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