FDA Media Call
FDA Study Findings Leading to the Suspension of 3-Nitro (Roxarsone) Sales
Moderator: Stephanie Yao
June 8, 2011

Coordinator: Good morning or good afternoon and thank you for standing by. All participants will be able to listen-only until the question-and-answer portion of today's conference.

To ask a question, please press Star 1.

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

I would now like to turn the conference over to Ms. Stephanie Yao.

Ma'am you may begin.

Stephanie Yao: Thank you, Julie. Welcome, ladies and gentleman. My name is Stephanie Yao from the FDA's Office of Public Affairs.

This is an FDA teleconference for credentialed media, consumer groups, congressional stakeholders and international stakeholders so they can get information on new FDA data on the animal drug 3-Nitro, also known as Roxarsone, and the drug manufacturer's decision to suspend sales of the product.

This briefing is again for credentialed media, consumer groups, congressional stakeholders and international stakeholders only.

Our speakers today are Dr. Bernadette Dunham. She is the Director of the Center for Veterinary Medicine at the FDA.

We also have Dr. David Goldman. He is the Assistant Administrator of the Office of Public Health Science at the U.S. Department of Agriculture's Food Safety Inspection Service.

We also have Dr. Murray Lumpkin, Deputy Commissioner for International Programs at the FDA. He is standing by to address any questions about international issues related to FDA's announcement.

And Dr. William Flynn, Deputy Director for Science Policy at the Center for Veterinary Medicine, and Dr. David White, Director of the Center for Veterinary Medicine's Office of Research. They will be our technical experts today for your questions.

After Dr. Dunham and Dr. Goldman make brief remarks, we will move into the question-and-answer segment. Congressional, international and consumer groups will be in listen-only mode for the entire call. Reporters will be in a listen-only mode until we open the call up for questions.

When asking a question, please state your name and affiliation. Also, please limit yourself to one question and one follow-up question so we can get to as many questions as possible.

The news release for this announcement has been sent to reporters on our media list and it has been posted to FDA's Web site at www.fda.gov.

I will now turn the call over to Dr. Dunham. Thank you.

Bernadette Dunham: Thank you, Stephanie. Good afternoon everyone. I'm Dr. Bernadette Dunham, Director of FDA's Center for Veterinary Medicine.

At the Center for Veterinary Medicine, we are committed to protecting both human and animal health. Today, FDA is releasing new data on the animal drug 3-Nitro, also known as Roxarsone. 3-Nitro is an arsenic-containing animal drug manufactured by Alpharma, a subsidiary of Pfizer.

In 1944, 3-Nitro became the first arsenic-containing product approved by the FDA. It is used primarily in broiler chickens to help control coccidiosis, a parasitic disease that affects the intestinal tracts of animals and is also used for weight gain, feed efficiency and improved pigmentation.

Over the past seven to eight years, published scientific reports indicated that organic arsenic can transform into inorganic arsenic in the environment. These reports caused FDA to question whether the organic arsenic that was present in animal drugs such as Roxarsone would also transform into inorganic arsenic when used in animals.

Scientists at FDA Center for Veterinary Medicine and the Center for Food Safety and Applied Nutrition followed up on those reports by developing a new analytical method capable of detecting very low levels of inorganic arsenic in edible tissue.

Using this method, FDA conducted a study involving 100 broiler chickens fed Roxarsone according to the approved labeling. FDA

scientists found that the levels of inorganic arsenic in the livers of chickens treated with Roxarsone were increased relative to the levels in the livers of the untreated control chickens.

We would like to stress that the levels of inorganic arsenic found in chicken livers are very low and represent a very low health risk to people who eat chicken. We would also like to stress that consumers can continue to eat chicken as 3-Nitro is suspended from the market. Furthermore, FDA does not believe there is a need to recall chicken already in commerce.

FDA's findings demonstrate a very low but avoidable public exposure to inorganic arsenic, a carcinogen. FDA advised Pfizer of our study findings and concerns and in response the company has decided to voluntarily initiate a plan to suspend sale of 3-Nitro and to facilitate an orderly process for suspending the use of 3-Nitro in the United States.

This plan provides for maintaining sale of the product for 30 days from today to provide time for animal producers to identify and transition to other treatment strategies.

The FDA has been in consultation with the U.S. Department of Agriculture and is working with a drug manufacturer to minimize the impact on the animal agriculture industry as 3-Nitro is suspended from the market.

FDA is also taking steps to alert our international partners about our research findings so they can make their own decisions about what actions to take, if any, with respect to this product within their own communities and regulatory systems.

I would like to applaud Pfizer for working cooperatively with us to take this action to protect public health and to commend my FDA colleagues who have worked diligently to identify this problem and to reach a resolution.

Thank you, Stephanie.

Stephanie Yao: Thank you, Dr. Dunham. We also have Dr. Goldman who will make some opening remarks.

David Goldman: Thank you, Stephanie. This is Dr. David Goldman with the Office of Public Health Science at the Food Safety Inspection Service.

Many of you may know FSIS is charged with protecting public health by ensuring the highest level of safety possible for meat, poultry and processed egg products.

As you've just heard using newly-developed scientific methods, FDA has found that the use of the animal drug Roxarsone results in trace amounts of inorganic arsenic, a cancer-causing compound in chicken liver.

We are pleased to see that Pfizer, the pharmaceutical company currently producing Roxarsone, is cooperating with the FDA to stop domestic sales of the product for use in food animals including chickens.

Based on the current science and information available to us from our colleagues at FDA, FSIS has concluded that the risk to consumers posed by eating chicken is very low and does not believe that there is a

significant increase risk associated with continuing to eat chicken while Roxarsone is being phased out.

Thank you, Stephanie.

Stephanie Yao: Thank you, Dr Goldman. At this time ladies and gentleman we will begin the question-and-answer portion of the briefing.

Julie, we'll take the first question please.

Coordinator: Thank you. If you'd like to ask a question please press Star 1 and you will be prompted to record your first and last name.

Please un-mute your phone before recording your name and to withdraw your question press Star 2.

One moment please.

Our first question comes from Mary Clare Jalonick with the Associated Press.

Your line is open.

Mary Clare Jalonick: Hi, yes my question was does the study just look at chicken livers? But based on your research, can you all quantify to what extent the rest of chicken meat is vulnerable to higher levels of arsenic, you know, the chicken breasts or any other parts of the chicken?

Bill Flynn: Yes, this is Bill Flynn from FDA's Veterinary Medicine.

As you pointed out, the study that was conducted was done using the Roxarsone product in chickens and as part of doing that study FDA developed an analytical method capable of detecting the inorganic form of arsenic.

That method was specifically developed for detecting inorganic arsenic in liver tissue and was not developed or validated for testing or detecting levels of inorganic arsenic in other tissues like muscle.

So, at this time we only have data relative to inorganic arsenic for the liver tissue itself.

Mary Clare Jalonick: It seems though that you all would be saying that this is only a problem in chicken livers, if you weren't somewhat concerned that this would be part of other - that it would be, show up in other parts of the chicken as well?

Is that correct?

Hello?

Stephanie Yao: Hi, Mary Clare. Sorry about that.

Mary Clare Jalonick: That's okay.

Stephanie Yao: You know what, if it's fine with you I'll be happy to follow up on that...

Mary Clare Jalonick: Okay.

Stephanie Yao: ...off the phone with you and we can certainly get that information to you.

Mary Clare Jalonick: Okay, one more quick follow-up, just I understand from the company that this is in swine as well. That this is used in swine feed.

Is this any sort of risk in terms of pork also?

Bill Flynn: The - for your second question, the product is approved for use in chickens, turkeys and in swine. The vast majority of the product - the use of the product upwards of 90% of the use is in chickens.

But at this time we only have data specific to the use of the product in chickens. However, in response to the data Pfizer is voluntarily suspending sale of the product and so the product itself will not be available for use in any of the species including chickens, turkey and swine.

Mary Clare Jalonick: Okay, thank you.

Coordinator: Our next question comes from Jennifer Corbett with Wall Street Journal.

Your line is open.

Jennifer Corbett: Yes, I have two questions. The first question, is this the only arsenic-containing drug or are there others on the market? And then the other question I had is does anybody have an idea of how widely this is used in the chicken market?

Bill Flynn: So I think your first question, were there other arsenic-based products?...

Jennifer Corbett: Right.

Bill Flynn: ...and the answer is yes. At this time we're aware of one other approved arsenic-based product that is currently being marketed for use in food-producing animals and that's a product called Nitarsone, also marketed by Pfizer.

That product is limited for use in chickens and turkeys, a much less used product than the Roxarsone product.

At this time we do not have data specific to the Nitarsone product. We only have data relative to Roxarsone.

We are in discussions with Pfizer about any questions related to the Nitarsone product.

Jennifer Corbett: Okay.

Bill Flynn: I'm sorry, can you repeat your second question?

Jennifer Corbett: The second question was just - I was trying to get a sense of how widely this is used, or 3-Nitro is used by chicken producers in the U.S. Is it the majority of chickens sold in the U.S. or?

Bill Flynn: Yes, the product, you know, as you know the product has been on the market for many years. It's fairly broadly used in the broiler industry,

but we do not have specific information regarding actual numbers of chickens or percent of chickens that actually receive the drug.

Jennifer Corbett: Okay.

Stephanie Yao: Thanks, Jennifer. Julie, next question please.

Coordinator: Our next question comes from Helena, is it Bottemiller, with Food Safety News.

Your line is open.

Helena Bottemiller: Hi, thank you so much for taking my question. I have two quick ones. First, can you put these levels into some kind of context? How far away are they from levels that you would consider of health concern?

And also, could you explain how it helps with pigmentation? Is there currently a withdraw period for this drug and is that something you're considering implementing with the other drug you mentioned that you're not - that is not being withdrawn?

Stephanie Yao: Hi, Helena let's dtart off with what this drug is indicated - what its indicated use is.

And we've got...

Bill Flynn: So, yes you had multiple questions there so maybe you could restate maybe one question first and I can try to address that so I don't get them mixed up?

Helena Bottemiller: Okay, sure thank you. Can you first put these levels that you found into some kind of context? How far away are they from levels that you would consider of health concern, that might you know indicate the need for recall?

How far away are we from those levels?

Bill Flynn: Right, what I can say is just for context, understand that arsenic is a compound that's, you know, found in the environment as both a naturally occurring substance as well as a contaminate. And it's been detected in various places including in water, air, in certain food commodities.

The levels that we've detected in the study that FDA conducted are very low and even low with respect to other sources that are out there. So at this point I can't put it more specific, but I think that we want to provide and stress the point that the levels are low.

But the fact that they represent an added source of human exposure and a source that is completely avoidable that the agency feels it's important to take action to help reduce or eliminate an added source of human exposure to a carcinogen.

Stephanie Yao: Thank you. Julie, we'll take the next question.

Coordinator: My next question comes from Kerry Sheridan with Agence France-Presse.

Your line is open.

Kerry Sheridan: Thanks. I was wondering if you could tell me if this applies only to 3-Nitro based in the U.S.? How big is the international market for this and where else in the world is it being fed to chickens, and swine and turkeys?

Bill Flynn: Yes, the action that we're taking here, as you I think mentioned, is that the Pfizer is suspending sale of the product for domestic use in the United States. We understand from Pfizer that a large proportion of the product that they manufacture is used for domestic use in the United States. A much smaller proportion is actually exported to other countries.

We're sharing with our international partners so they understand what the information is that we have. You know, again we're stressing that this represents a very low level of arsenic present in the - from this study that we've demonstrated and that it represents a very low risk.

And we're also working very closely with our colleagues at USDA on this issue.

Stephanie Yao: And Dr. Goldman, did you want to make any comments in regard to this question as well?

David Goldman: Yes, thank you. I would say that it's important to keep in mind that chicken can only be imported from foreign countries under our (unintelligible) that FSIS has found to be equivalent or to have an equivalent food safety system to that of the U.S.

And so as a result of the findings here and our continued consultation with the FDA, we will be looking at the potential implications of both

Pfizer's voluntary action and FDA's actions on equivalence determinations for those countries that may be using this product in poultry production.

And then make further determinations about whether those products should be allowed into the country.

Thank you.

Stephanie Yao: Thank you, Dr. Goldman. Kerry, do you have a follow-up question?

Kerry Sheridan: Do you think I should contact Pfizer for some more information? More specifically about which country's this is used in?

Stephanie Yao: You can certainly reach out to Pfizer and, you know, they would be able to provide you with that information.

Kerry Sheridan: Thanks.

Coordinator: Yes, our next question comes from Daniel DeNoon with WebMD.

Your line is open.

Daniel DeNoon: Thank you for taking my question. I'm a little confused about the low levels that are supposedly in the chicken livers. I'm looking at the study and it suggests that while there was a mean - overall mean concentration below the tolerance of 2000 parts per billion, some of these chicken livers seem to have as much as 2900 parts per billion.

And that seems way above the tolerance level. Doesn't that mean these chicken livers are unsafe?

Bill Flynn: This is Bill Flynn from FDA. The one thing - I, just to provide some clarity is the fact that there are tolerances established by FDA in conjunction with the approval related to total arsenic. And so those tolerances relate to arsenic total which is understood to be primarily an organic form of arsenic.

There are no tolerances established for the inorganic arsenic. So you're correct the levels that we are seeing in the livers are 1 point, you know, the mean of 1.4.

Basically what the study did show was that there were increased levels of the inorganic form of arsenic in the treated birds in comparison to the untreated control birds.

Daniel DeNoon: If I might follow-up then the - I see that the Pfizer action is to suspend sales. Is there a chance that sales might be re-begun or is this a final elimination of this product from the U.S. market?

Bill Flynn: Right, this is an initial step where we presented the information and discussed the information that we have with the company. In response to that, Pfizer, as you said, decided to voluntarily suspend sale.

In conjunction with that suspension of sale, Pfizer has continued to work with FDA to evaluate all the relevant information related to the use of the product.

And we have gotten clear assurance from Pfizer that they will not return the product to the market unless they've been first addressed by all of FDA's concerns.

Daniel DeNoon: Thank you.

Stephanie Yao: Julie, next question please.

Coordinator: Our next question comes from Anna Yukananov with Reuters.

Your line is open.

Anna Yukananov: Oh, hi. Actually my question was already answered I think so I'm all good.

Thank you.

Stephanie Yao: Great, thanks Anna. Julie, next question please.

Coordinator: One moment.

Our next question comes from Britt Erickson with Chemical & Engineering News.

Your line is open.

Britt Erickson: Yes, hi. Thanks for taking my question.

I'm wondering if you're able to differentiate between Arsenic 3 and Arsenic 5 or are you measuring total inorganic arsenic?

David White: Hi, this is Dr. David White.

That's a very good question and the method was specifically for As +5 for arsenate.

Britt Erickson: Okay, thank you. And the other question I have is regarding alternatives. Are there currently available alternatives to Roxarsone? Specifically for the parasitic infections?

Bill Flynn: There are other products that are approved for use in treating coccidiosis in poultry.

Britt Erickson: Okay, do you know what they are?

Bill Flynn: Well, there is quite a number of them. Those we do - that information is available on our FDA Web site. We have a Web site called Animal Drugs @ FDA and there's a listing of all the approved products there.

Britt Erickson: Okay, thanks. And if I may ask one more question, is the study available on your Web site with the data, the arsenic data?

Bill Flynn: Yes, that information should be available up on our Web site.

Britt Erickson: Okay, thank you.

Stephanie Yao: Thank you. Next question please, Julie.

Coordinator: Our next question comes from Sara Ditta with FDA Week.

Your line is open.

Sara Ditta: Hi, I'm wondering is FDA doing any other studies for animal drugs that have been on the market for such a long period of time like this one?

Bill Flynn: Well, what I guess I can say with regard to this particular study, FDA was responding to a very particular concern and had regarding arsenic-based animal drugs based on review of scientific published literature that our scientists became aware of.

So this particular study was in response to that new scientific information that became available that raised questions about this particular class of products.

Stephanie Yao: Thank you. Julie, we'll take one more question please.

Coordinator: Our last question comes from Robert Lowes with Medscape Medical News.

Your line is open.

Robert Lowes: Yes, thanks for taking my call. I have two questions, one - does arsenic accumulate over time in animal or human tissue and is that a factor in its toxicity? And second, what would be the conditions under which the FDA would allow this animal drug to be marketed again domestically after this one month, after the suspension of sales?

We talked about suspension, well under what conditions would Pfizer be allowed to resume sales? What would have to prove to the FDA?

Bill Flynn: Yes, I think to the second question - as I mentioned earlier, we are, you know, in conjunction with suspending sale. Pfizer has committed and is working with us to evaluate all the relevant information related to this issue.

And has made a commitment to us that, you know, the product will not be returned to the market until we've sorted through these issues and all the FDA concerns are addressed.

And obviously we need to wait to see how that plays out.

Robert Lowes: Is arsenic accumulated in human or animal tissue?

Bill Flynn: I think that - and I don't that's why I have a complete answer to that, but I think it somewhat depends as to the form of arsenic. As to the degree to which it is excreted, but a fair amount of arsenic is excreted as opposed to being accumulated.

Stephanie Yao: Great, thank you. Ladies and gentleman this concludes...

Bernadette Dunham: This is Dr. Dunham. I do want to go back to one question that was raised and that was whether or not we actually knew levels in the muscle and as you heard the explanation the testing was done specifically with liver. However, we would expect with all of our understanding of looking at residues and how they're metabolized in tissues from liver as well as muscle that we would almost expect 40 times less to be in the muscle.

Stephanie Yao: Great. Thank you, Dr. Dunham, for clarifying that point.

This concludes the question-and-answer portion of our teleconference.

Before we close the call, Dr. Dunham do you have any closing remarks?

Bernadette Dunham: Thank you, Stephanie. I just want to thank everybody for participating in the call today and we look forward to having you gather further information by going to our links on the Web page.

And we appreciate your interactions today so thank you so much.

Stephanie Yao: Thank you, Dr. Dunham.

Dr. Goldman, do you have any closing remarks?

David Goldman: Thank you. Stephanie. I don't have anything to add to the discussion that's already taken place, but we certainly appreciate the opportunity to join you at FDA in answering these questions.

Thank you.

Stephanie Yao: Thank you, Dr. Goldman.

And thank you, ladies and gentleman, for your participation.

A replay of this conference call will be available in about an hour and we'll be available for the next seven days until June 15.

Domestic callers in the U.S. and Canada can call 1-800-925-4291 to access this replay.

International callers can dial 1-203-369-3966 to access the replay.

The passcode for the replay is 6789. Again the passcode is 6789.

If you have any follow-up questions, please don't hesitate to call the FDA's Office of Public Affairs at (301) 796-4540.

Thank you.

Coordinator: Thank you for your participation. You may disconnect at this time.

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