Transcript for Media Briefing on
FDA's Draft Guidance for Industry on the Regulation of Genetically Engineered Animals

Moderator: Heidi Rebello

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Coordinator: Good morning and thank you for standing by. I'd like to remind all participants your line will be in a listen-only mode throughout the presentation. This call is being recorded, if you do have any objections you may disconnect at this time.

And I would now like to introduce your host for today's call Miss Heidi Rebello; Miss Rebello, you may begin.

Heidi Rebello: Thank you. Good morning and welcome. My name is Heidi Rebello with the FDA's Office of Public Affairs. This is an FDA teleconference for credentialed media on the FDA's release of a draft guidance for industry and the regulation of genetically engineered animals.

We have three speakers today from the FDA who will make opening remarks: Dr. Randall Lutter, FDA's Deputy Commissioner for Policy, Dr. Bill Flynn, Senior Advisor for Science Policy at the Center for Veterinary Medicine and Dr. Larisa Rudenko, Senior Advisor for Biotechnology at the Center for Veterinary Medicine.

After the speakers make brief remarks we'll move to the question and answer segment. During the question and answer portion of the briefing Dr. Eric

Flamm, Senior Science Policy Advisor at FDA, will be available as a technical expert for your questions.

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 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 as well as posted to FDA's Web site at www.fda.gov.

I'll now turn the call over to Dr. Lutter. Thank you.

Randall Lutter: Thank you, Heidi. Good morning. Today we're announcing how FDA has been and will continue to regulate genetically engineered animals. We're releasing for public comment a draft guidance for industry on the regulation of genetically engineered animals, which clarifies how the FDA has been regulating these animals.

It also provides some recommendations to producers of these animals on how they can meet their responsibilities and obligations under Federal law and regulation.

We also hope that this draft guidance helps the public understand how the agency has been overseeing genetically engineered animals and how this approach protects public health.

As most of you know, genetic engineering is no longer a new technology. It's been widely used in agriculture to make crops resistant to certain pests or herbicides or with improved nutritional qualities.

In medicine genetically engineered microbes produce important drugs such as insulin to help keep diabetics alive and healthy. In food production genetically engineered yeasts aid in baking and brewing while other products from genetically engineered microbes aid in cheese making.

Genetically engineered animals, which were first produced in the 1980s, contain pieces of recombinant DNA. These DNA segments are intended to give the resulting animal the new traits or characteristics. Many kinds of genetically engineered animals are in development although none has yet been approved by the Agency for marketing.

Some are intended to produce pharmaceuticals in their milk or blood. We refer to those as biopharm animals. Some are being altered to be able to provide cells, tissues or organs that are less likely to be rejected by the human immune system thereby helping patients like (Ilid) cells to help diabetics, skin graphs for burn victims and live, kidney or heart replacements for the critically ill.

Other types of GE animals carry traits that help the animals themselves. Scientists are developing animals that are resistant to diseases including BSE, or Mad Cow Disease, and mastitis, a very painful infection of the udder that is extremely difficult to treat.

Other GE animals are being developed to produce high-value industrial or consumer products such as fibers. Yet others are being developed to decrease the footprint that agriculture makes on the environment to decrease the amount of harmful substances in their manure by growing faster and reaching market size more quickly or by making healthier food. For example, some

pigs have been genetically engineered to contain high levels of healthy Omega-3 fatty acids.

This draft guidance should clarify for all of our stakeholders the approach the FDA has been using to regulate GE animals for some time. The approach that we use employs the new animal drug provisions of the Federal Food Drug and Cosmetics Act.

Genetically engineered animals that contain a recombinant DNA segment that is intended to alter the structure or function of the animals are considered to contain a new animal drug. GE animals will therefore require pre-market approval by FDA prior to their introduction into the marketplace. Producers of these animals will also need to comply with the law and regulations established by the National Environmental Policy Act.

We know that this draft also indicates that our business is still unfinished. First, although this draft guidance clarifies our regulatory approach and provides some general recommendations on how to develop and provide data sets we still need to hear from our many stakeholders before we can finalize this guidance.

In addition, the draft guidance doesn't provide much information on how we'll be dealing with biopharm animals designed to produce new pharmaceutical products. Clearly biopharm animals contain our DNA constructs and developers of those animals will need to contact CVM as well as FDA's Human Medical Centers that will approve the final products from these animals.

We're still in the process of determining the best way to do that so we have - so that we have confidence in the animal component of the process yet don't

introduce a process that will be unnecessary duplicative. So we'll be issuing another guidance document on that topic. In the meanwhile, if you are developing a biopharm animal please call us and we'll be happy to talk with you about it.

We're issuing this draft guidance now because the technology has evolved to a point where commercialization of these animals is no longer over the horizon.

We want the producers of these animals to understand their legal and regulatory responsibilities. We also want to make recommendations on data and information that producers should provide so we can make decisions about their marketing applications based on an adequate scientific understanding of the effects of the inserted segment of DNA.

The draft guidance also helps the public understand how the Agency is protecting public health. Most of all we're soliciting input from all of our stakeholders on the recommendations offered in this draft guidance document.

I'll now turn the microphone over to Dr. William Flynn from the Director's Office at the FDA's Center for Veterinary Medicine.

Bill Flynn: Thank you Dr. Lutter and good morning. FDA's Center for Veterinary Medicine is a consumer protection organization. We foster public and animal health by approving safe and effective products for animals by ensuring the safety of animal food and feed.

We have a dedicated staff of veterinarians, scientists and other experts whose goals are to ensure that the products we regulate are safe for animals, safe for

the people who may eat products derived from those animals and that the products do what their manufacturers say they're going to do.

Humans have interacted with animals for millennia. Through animal breeding practices we have continually attempted to select for desirable traits in animals that have provided us food, fiber and companionship. Genetic engineering, which is a more powerful and direct way of introducing desirable traits, offers some very compelling and real benefits for both humans and animals.

Despite these potential benefits, however, we must ensure that the products of animal biotechnology are shown to be safe before they are introduced into the marketplace and that they do in fact do what they're intended to do. CVM has the expertise and the experience as well as the regulatory framework for addressing animal safety and human food safety questions.

This provides us with the fundamentals that we need to have in place to ensure that products of genetic engineering are regulated appropriately. I'm pleased to say that our talented and dedicated staff of veterinarians, micro - molecular biologists, animal scientists, toxicologists and risk assessors have built on CVM's long-standing experience in assessing animal health and food safety to develop what we believe is a rigorous risk-based approach that ensures the health of genetically engineered animals and the safety of the food that may come from them and that protects the general public health.

We believe that this expertise, used in the context of the new animal drug provision of the Federal Food, Drug and Cosmetics Act will ensure the safety of genetically engineered animals and their FDA-regulated products before being introduced into the marketplace.

I think that this draft guidance will serve as an important tool in helping the industry, and the public, understand FDA's approach for regulating these products.

And now I'd like to turn this over to Dr. Larisa Rudenko, CVM's Senior Advisor for Biotechnology, who will provide a little bit more detail regarding the content of the guidance.

Larisa Rudenko: Thanks Bill. First just a little bit more about what GE animals are. Genetically engineered animals are simply animals such as cattle, pigs, fish and goats that have had a piece of DNA added to them to introduce a desirable trait. As Dr. Lutter mentioned earlier, the traits that are being introduced range from faster growth to production of various proteins in their milk.

Some of these traits provide a benefit to humans and some to the animals themselves. If you go to our Web site at www.fda.gov/cvm you can see a step by step picture of how this is done.

Then I'd like to clarify that we're not calling genetically engineered animals drugs. The piece of DNA that's contained in the animal and that's intended to alter the structure or function of the animal, in other words, to produce the new trait, is the new animal drug. And we'll regulate it under the new Animal Drug Provisions of the Act using the extensive tools and expertise that Dr. Flynn has described.

So how exactly will we do that? First we want to work with the producers of these animals so we extend an invitation to any developer of a GE animal, regardless of its intended use, to contact us at the number provided on the draft guidance.

If your GE animal is not developed from a species that is traditionally consumed as food the first thing that we'll do is make a risk-based determination of whether your animal would need to go down the formal approval path or whether we would consider exercising enforcement discretion.

If you are working on a species that is traditionally consumed as food regardless of its intended use we'll work with you via the new Animal Drug Path that's described in more detail in the draft guidance. As Dr. Lutter noted, however, we've yet to work out all the details with regard to animals engineered to produce pharmaceuticals or other therapeutic products.

A couple of points to mention: Each evaluation will be done on a case by case basis with attention paid to the particular risks posed by each line of animals although the basic steps will be the same for all animals that go through this process. Our goal is to work closely with developers as they begin to produce GE animals so that we can provide them with additional recommendations on how best to prepare a regulatory submission.

With respect to the actual evaluation we'll begin by recommending the producers characterize the DNA to be inserted and that they then describe how that DNA integrates into and behaves in the animal itself. We then evaluate the resulting animal itself on a molecular and overall health level to determine that the inserted DNA is safe to the animal.

If the animal is intended to be consumed as food or feed we'll need to do a full evaluation of food and feed safety. Our food safety evaluation looks at the same information as that recommended in the relevant food safety guidelines recently adopted by the Codex Alimentarius Commission, a UM-affiliated international food safety standard setting organization.

We will also perform an environmental assessment. Producers will have to provide data to demonstrate that the new trait performs as claimed. We'll also ask producers to provide a plan for how they'll monitor these animals to ensure that the genetically engineered animals entering commerce in the future are equivalent to those we have approved.

Well that was a lot to tell you about but it's all spelled out in the draft guidance. Please read it and then give us a call if you have any questions.

And finally, let me reiterate a few key points: Genetic engineering of animals is here and has been for some time. As scientists we're excited by the potential societal benefits that genetic engineering of animals may provide. But as regulators we intend to provide a rigorous risk-based regulatory path for developers to follow to help ensure public health and the health of animals.

We hope that the release of this draft guidance clarifies the regulatory authorities under which the Agency operates and provides sufficient information for all of our stakeholders including the public to have an understanding of how we intend to evaluate data on these animals.

We encourage all of you to submit your comments on these recommendations in the draft guidance during the open comment period and we very much look forward to hearing from you. Thanks.

Heidi Rebello: Thank you Dr. Rudenko. At this time, ladies and gentlemen, we'll begin the question and answer portion of the briefing. Operator, let's take our first question please.

Coordinator: Okay, if you would like to ask a question at this time please press star 1, to withdraw your question press star 2. Once again, if you would like to ask a question please press star 1; one moment for the first question.

Okay and our first question comes from (Todd Zuilick), you may ask your question.

(Todd Zuilick): Hi, thanks. It's (Todd Zuilick) with Web MD and with Public Radio in Washington. Could you help me understand how or if the guidance your releasing today interacts with - effects with the - a lot of us, the last time we sort of interacted with this story at FDA was when genetically engineered cattle were approved for - as progenitors for steers I guess or for beef, you know, the beef that people eat.

So can you help explain how this affects those particular animals? Are those animals already on the market and if not, you know, how all of this affects sort of the consumable beef industry and bulls and cows that might be producing those beef?

Larisa Rudenko: Hi, this is Larisa Rudenko answering your question. We've never actually had a release in the past about genetically engineered cattle of any sort.

(Todd Zuilick): Oh.

Larisa Rudenko: What we did do last January was to release a final risk assessment on animal clones. Those animals are very different from genetically engineered animals because they're just genetic replicas of already - animals that are already in use. These are very different because they have new pieces of DNA inserted into them and are therefore genetically engineered.

Just to clarify at this point we have not approved any genetically engineered animal for commercialization including no animals, no GE animals for use in the food supply.

(Todd Zuilick): So, okay, so this does not affect the cloning issue?

Larisa Rudenko: No.

(Todd Zuilick): Okay. And as far as you know then the ones from last January, the cloned animals, on the market yet as far as you know or soon to become so?

Larisa Rudenko: That question is really best answered by USDA. The FDA has no further science-based concerns associated with either clones or their progeny and USDA has been working on a smooth and orderly transition of those animals into commerce.

(Todd Zuilick): Thank you.

Heidi Rebello: Thank you. We'll take our next question please.

Coordinator: Okay, our next question comes from (Bill Thompson), you may ask your question.

Heidi Rebello: (Bill), can you identify who you're with please?

(Bill Thompson): Yeah, I'm with Dow Jones Newswires. And I was going to ask you guys the same thing. Just as - first as a technical thing could you spell your names and - I'd appreciate that. And then my question is - and I understand there's no animals have been - no genetically modified animals have been approved for the market yet but with this release could they now?

In other words, if you have developed an animal that resists Mad Cow Disease, it's been genetically modified, could you apply today to get approval for that product? Or is - does there have to be a massive sort of general risk assessment on general genetically modified animals first? And how long would it take?

Larisa Rudenko: Hi, this is Larisa again. I think Ms. Rebello will make available to you our names and their spellings.

You asked a bunch of questions but I think I'm going to try to answer the one that deals primarily with whether or not an application can come in today and how we would handle that. And the answer is all of these GE animals are going to be considered on a case by case basis so that, no, there will be no general risk assessment on all GE animals before we proceed because each animal poses its own set of risks and so we have to take a look at it on a case by case basis.

People have been working with us for several years now on developing data sets that we can evaluate that will eventually lead to approvals. But, as I told the previous questioners, at this point we have not approved any animals for commercialization.

And further we know of no genetically engineered - I'm sorry - and further we don't know of any genetically engineered animals currently being on the market. And if they were they would be illegal.

Heidi Rebello: Okay, thank you. And, (Bill), I'll send you the spellings of the names.

(Bill Thompson): Appreciate it.

Heidi Rebello: Okay, very good. Let's take our next question please.

Coordinator: Okay our next question comes from (Jennifer Tuzen), you may ask your question.

(Jennifer Tuzen): Hi, this is (Jennifer Tuzen) from Science Magazine. I had a couple questions. One was that Dr. Lutter said earlier that, among other things, this guidance clarifies how the FDA has been regulating these animals.

My understanding was that FDA has been for some time sorting out what to do here. And so I was wondering if you could tell me a bit more about whether FDA has been regulating these animals or if it just hasn't really been an issue since you haven't gotten applications up until now.

And my second question was about the environmental impacts of these animals, which I know Larisa touched on in terms of providing an environmental assessment. When you're asking companies to monitor these animals and their environmental impact could you tell me a little bit more about that; how you're going to enforce that.

Are the industry plans binding? Would the product be removed from the market if they're not following up on those plans? And anything else you can say about that. That's a mouthful.

Randall Lutter: This is Randall Lutter. Let me offer an answer to the first part first. How have we been regulating these animals? As Dr. Rudenko mentioned we've been in discussions with a collection of representatives of industry who are developing - in the process of doing research to bring - to develop such genetically engineered animals.

And those discussions will lead to new animal drug applications and eventually those may lead to approvals. And we're not yet at that stage but this guidance offers a clarity to industry and to the public about that process. And as it's a draft it's - we are soliciting comments on it but it is the process that we have been following.

And I'll turn it over to Dr. Larisa Rudenko for the - your question on environmental policies.

Larisa Rudenko: Yeah. If you take a look at the last part of the guidance where we describe recommendations for the kinds of data to be submitted you'll see that the overall review of an application is a cumulative hierarchical review so that as part of the evaluation you need to know a lot about the animal that will help you determine what it's going to do in the environment.

Now some of these animals are going to be contained and some of these will have less containment. But there will be an environmental assessment on each one on a case by case basis and it's hard to predict what we would do in terms of monitoring unless we know the specifics of the case.

(Jennifer Tuzen): I guess what I'm wondering though is it reminds me a little bit of what happens sometimes when new drugs for people go on the market in that it can be difficult to predict based on clinical trials how a drug will do when it's consumed by a very large number of people so you've often had post-marketing studies or other studies to try and track that and, you know, ask people to send in reports of adverse events and that sort of thing.

And then sometimes you do act based on that. So can you - would you do something similar here?

Larisa Rudenko: Yes, absolutely. And these animals are being regulated as animals that contain new animal drugs the same way that animals that contain conventional new animal drugs do and they'd be subject to the same kinds of adverse drug event reporting requirements that animals that are treated with conventional new animal drugs are.

(Jennifer Tuzen): And that would include something like environmental impacts that you might not have foreseen before an animal is out there or not so much?

Larisa Rudenko: Well I, you know, again, it would depend on - it's a case by case approach. And if that was something that we were particularly interested in we would keep a particular eye on it.

(Jennifer Tuzen): Okay, thank you.

Heidi Rebello: Thanks, (Jennifer). Operator, let's take our next question please.

Coordinator: Okay, if you would like to ask a question please press star 1, to withdraw your question press star 2. And our next question comes from (Ricardo Alonzo Salibar), sir, you may ask your question.

(Ricardo Alonzo Salibar): Thank you.

Heidi Rebello: (Alonzo), can you just state your affiliation?

(Ricardo Alonzo Salibar): Sure. I'm with the AP, Associated Press.

Heidi Rebello: Thanks.

(Ricardo Alonzo Salibar): Okay. Yeah, my question has do with GE animals that are intended for human consumption. As you can imagine this is going to be a very big deal for consumers. And your proceeding to review these applications under a drug approval process.

Now a drug approval process, most of it takes place behind the scenes because you're dealing with proprietary information. How are you going to basically inject some sunshine into this process in order to educate the public? And I'll take a follow-up as well.

Randall Lutter: This is Randall Lutter. Let me try and respond to that. The Agency is committed to transparency in all of it - our key decision making. This guidance itself actually is an example of that because we are issuing it for public comment and we welcome that public comment before finalizing it.

With respect to the case-by-case decisions that Dr. Rudenko alluded to a moment ago, we issued a separate guidance document on when to hold advisory committee meetings. And that one articulates several criteria leading to the plain conclusion that we would expect GE animals' decisions - approval decisions to go to such advisory committee meetings, as a matter of course, while the technology is new.

And in that sense there will be an opportunity in those meetings for expert outside opinion to be brought to FDA about whether or not to approve the new animal drug application. That opinion will reflect a diversity of views consistent with the Federal Advisory Committee Act.

There will be an opportunity for consumer representatives and industry representatives to participate and the public as well will have a chance to join in on those meetings and share their views with us.

Heidi Rebello: (Alonzo), your follow-up?

(Ricardo Alonzo Salibar): Yeah, I'd just like to come back to the previous questioners question about adverse events. Say you're talking about farm animals of some kind or another now what if these animals escape and get into the wild and start, you know, reproducing with wild animals. And, you know, there's some kind of untoward effect on the environment.

Are you saying that, you know, basically the case by case adverse event reporting system that only captures a fraction of problems is going to be adequate, you know, to safeguard against that possibility?

Larisa Rudenko: Hi. I think we hope that part of the pre-approval process, which as I stated earlier, and is risk based...

(Ricardo Alonzo Salibar): And this is Dr. Rudenko?

Larisa Rudenko: Yes it is.

(Ricardo Alonzo Salibar): Yeah, okay.

Larisa Rudenko: Yes it is, I'm sorry. So le me restart. The pre-approval process is really quite rigorous and because it is on a case by case basis one of the things that we will be considering as part of the risk questions we ask and the final safety determination is what is the possibility or the probability of these animals escaping and if they do escape what's the probability of them interbreeding and also what are the potential effects of that interbreeding.

We, again, depending on the degree of concern that we have for these animals on a case by case basis will be working very closely with industry to ensure that the appropriate risk mitigation policies are in place prior to the approval of these animals.

And then we intend to follow up very carefully on the adverse drug event reports, which as you know, for the first two years occur every six months. So that's a fairly tight follow up.

Heidi Rebello: Okay.

(Ricardo Alonzo Salibar): Thank you.

Heidi Rebello: Thank you. Let's take our next question please.

Coordinator: Okay our next question comes from (Meredith Wadman) of Nature, you may ask your question.

(Meredith Wadman): Hi. I'm struggling with the sort of the nub of this, which is you described animals from those that would generate less manure to those producing biopharmaceuticals to a pig with more Omega-3 fatty acids in it. And those are going to very different end points, I mean, the first doesn't get eaten at all, on the second is producing a drug and the third is producing a food.

But am I right that you're regulating them all as, in quotes, animal drugs? And can you explain again what that means and its relationship to the Federal Food, Drug and Cosmetic Act?

Eric Flamm: Hi, this is Eric Flamm. I'll take that one. As I think Larisa pointed out we're not regulating the animals as drugs; we're regulating them as containing

drugs. So under that legal framework we have the ability to ensure that the drugs are safe for the animals if the animals are used for food that food from those animals are safe to eat. And that the drug does what it's supposed to do; that it's effective.

And so those are the standard things that we look at for all new animal drugs. And so we don't see that it creates a problem using that framework in the context of genetically engineered animals.

So obviously if we're talking about an animal engineered to produce a pharmaceutical and that animal will not be going into the food supply we're not going to have food safety concerns about food from that animal but we are going to want to ensure that that animal is contained in a way that it doesn't get into the food supply and that it doesn't mate with animals that are intended to get into the food supply.

On the other hand if we're talking about an animal that is intended to go into the food supply, has say enhanced nutritional properties or able to use different kinds of feeds that therefore limits the amount of environmental damage that they can cause then we're going to look at their impact as their use in the food supply including how they will be sold to those producing meat from those animals. So the framework enables us to address all of those issues.

(Meredith Wadman): So just as a quick follow-up, if it was say a pig with more - that generates more Omega-3 fatty acids, what is the drug in that case?

Eric Flamm: Well the drug in all of these cases is the genetic constructs; the segment of DNA that was introduced into the animal to give the animal its new properties. So the Omega-3 fatty acid is a byproduct of that, sort of a result of

that. And we're looking at whether the meat from that pig is safe and if it has new properties such as higher levels of Omega-3 fatty acid then you would have labeling of the meat to indicate that this meat is different than your ordinary meats from pigs.

(Meredith Wadman): Thank you.

Heidi Rebello: Okay, thank you. Let's take the next question please.

Coordinator: Okay, our next question comes from (Judy Fortune) of CNN, you may ask your question.

(Judy Fortune): Thank you for taking my question. I understand that no genetically engineered animals have been approved for market and included in the food supply. However, when that does happen will the public know what it's buying? In other words, will you label these food products as coming from genetically engineered animals?

Eric Flamm: Hi, this is Eric Flamm again. Well, as I just mentioned with regard to the pig with high Omega-3 fatty acids, we require labeling. Our policies on labeling of food are dictated by what is in the law that we administer and how it applies to labeling.

And essentially if you have changed the food in a significant way that change has to be indicated in labeling. If you've used a new breeding method to produce food that breeding method does not have to be indicated. So it's the same policy here with food from genetically engineered animals as we have with food from genetically engineered plants.

Now of course people can put labeling on their food voluntarily if that labeling is truthful and not misleading. And so there may be marketers who market some foods indicating that they have been derived from genetically engineered animals or if they have not been derived from genetically engineered animals.

But we don't have authority nor do we think as a policy matter that it's appropriate to require on the label of food that's no different from other food on the market the method by which the animal or plant from which it was bred, from which it's derived was bred.

Heidi Rebello: Do you have a quick follow up?

(Judy Fortune): No, thank you very much.

Heidi Rebello: Okay, thanks, (Judy). Let's take the next question then.

Coordinator: Okay, our next question comes from (Jennifer Smith) of FDA Week, you may ask your question.

(Jennifer Smith): Hello you all. I just wanted to - in the sense of - a couple years ago we had written something about FDA considering regulating transgenic animals as food additive. I'm just wondering what happened to that debate? Was that something that could possibly still be mulled over in the sense of when you're developing risk assessments for companies?

And then I'm also wondering as well the - it looks like, at least in the press release that I got so far, that the Agency is working with others to develop I think genetically engineered regulatory framework just USDA and etcetera. Is that new that part or has that also been going on for the past couple of years?

Eric Flamm: Hi, I'll take that one again. This is Eric Flamm. Genetic engineering sort of crosses many different disciplines in different areas. One can look at it as a form of breeding and something that FDA doesn't ordinarily regulate or one can look at it as a method of introducing new substances into the food supply or introducing new therapeutic products into animals.

And the tack that we have taken, which we think is the most reasonable, is that because of the great power of the technology and the fact that you can introduce new things and you can do more things with bioengineering than you can with other breeding methods we have taken the approach that the article introduced into the animal is a new animal drug because it meets exactly one of the definitions of a new animal drug, which is an article intended to effect the structure or function of the body of the animal.

So there was some discussion early on as to whether the approach we use on genetically engineered plants, where we don't have similar authority, something that an article introduced into a plant to effect its structure or function is not something that's subject to FDA oversight.

So there was consideration of whether in fact the article - the genetic construct in the animal met the definition of a new animal drug. We have decided that it does therefore under the Act we regulate it using this new animal drug authority.

The new animal drug authority, as with convention drugs, if the animal - treated animal goes into the food supply one looks at the safety of the food from that.

(Jennifer Smith): Okay.

Eric Flamm: So there's a mechanism that the - evaluation that we do relative to food safety is the same whether we were doing it under the animal drug approach or food additive approach. But...

(Jennifer Smith): Oh, okay.

Eric Flamm: ...we are not using a food additive approach; there is no possibility of deciding well, we're using partly the new animal drug approach and partly the food additive approach.

(Jennifer Smith): Right.

Eric Flamm: I mean, in fact, the law precludes us from doing that.

(Jennifer Smith): Okay, so even going to the food supply it would be solely - it would be the NAD approach?

Eric Flamm: Correct.

(Jennifer Smith): Okay. And then the other question I had again was working with the other agencies like - I didn't quite understand if that was again a new concept now or was this something you've also been working on, just trying to hammer out in the past couple years.

Eric Flamm: The agencies that regulate products of biotechnology have had a process for communicating with each other, for meeting with each other, for working with each other and for coordinating their policies. And in fact that stems from 1986 and what was referred to as the Coordinated Framework for Oversight of Biotechnology Products.

And so that has continued in that we work very closely with the other agencies. Clearly there is some overlap and (complementarity) with the Food Safety Inspection Service of USDA and with the Animal Science Health Inspection Service of USDA. And so we work very closely with them.

(Jennifer Smith): Okay.

Heidi Rebello: Thanks. Next question please.

Coordinator: Okay, our next question comes from (Jamie McGee) of Bloomberg News.

(Jamie McGee): Hi, I was...

Heidi Rebello: (Jamie), could you speak up please?

(Jamie McGee): Yes. I had a question about the - the question asked earlier about if animals do somehow escape the protection against the breeding with other animals. Is there any - if that does happen - any...

Larisa Rudenko: I'm sorry, could you speak up please?

(Jamie McGee): Yes, can you hear me now?

Larisa Rudenko: A little bit louder please.

(Jamie McGee): Okay. If the - if there is a specie escape where GE animals do mix with non-GE animals, how do you reconcile that? How is that addressed? How is it fixed? And also I wanted to ask about, you know, the criticism of whether the

FDA has the scientific expertise to be in charge of this. And I wanted to ask your response to that.

Larisa Rudenko: So with respect to the issue of escape, again, we believe that the pre-approval process is really quite rigorous. And because we're doing it on a case by case basis we would, for those animals for which we feel there is concern about inter-breeding with other animals, ask that there be very significant either physical, biological or other constraints - containment so that escape doesn't necessarily result in breeding.

In other words we might ask that there be sterile animals made if we were very concerned about this kind of thing.

(Jamie McGee): Okay.

Larisa Rudenko: With respect to expertise I'm going to pass that to Dr. Flynn so he can talk to you a little bit about who actually works at CVM.

Bill Flynn: Hi, this is Dr. Bill Flynn. As I mentioned in my - in the opening remarks, FDA's Center for Veterinary Medicine has a long history and quite a bit of experience and expertise evaluating products that are intended for use in animals in agricultural settings including settings such as aquaculture. And we have dealt with, you know, and experience dealing with food safety issues, environmental safety issues.

And, you know, have a staff that includes a molecular biologist, animal scientist, chemist, toxicologist, risk assessors, animal scientists. And, you know, so we have the expertise in house to be evaluating the types of issues that would come up relative to applications related to GE animals.

Heidi Rebello: Okay, thank you. We only have time for a few more questions. Let's take the next question, Operator, please.

Coordinator: Okay, our next question comes from (Andy Pollack) of New York Times.

(Andy Pollack): Yes, thanks. I had a couple of questions on the non-food animals. One, I mean, do you intend to regulate or do you intend to exercise this sort of discretion on pets?

Larisa Rudenko: Hi, (Andy), it's Larisa Rudenko.

(Andy Pollack): How are you?

Larisa Rudenko: It would depend on the particular application that was being used; that would be a case by case determination. But our basic assumption is that we would probably not be entertaining an enforcement discretion on what most people would consider to be companion animals.

There is of course the notable exception...

(Andy Pollack): You said you would not do this discretion?

Larisa Rudenko: I don't want to - I don't want to prejudge but it would be a case by case risk-based decision. And, you know, most companion animals are not consumed for food in the United States.

The notable exception, of course, is glow fish where we did exercise enforcement discretion because it was a non-food animal and posed no environmental risk following evaluation of data that was submitted to the agency.

(Andy Pollack): Okay, I just - you used not in a way that confused me a bit. So you're thinking you will exercise discretion on most pets that are not...

Larisa Rudenko: No, I said I don't want to prejudge the situation but we would make a case by case determination based on risk as to whether or not we would exercise enforcement discretion or send those animals down the approval path.

(Andy Pollack): And the main criteria would be whether they're used in food or not?

Larisa Rudenko: Well if you're in a species that's traditionally consumed as food enforcement discretion is not an option.

(Andy Pollack): Right, no but I'm saying a dog and a cat, I mean, is what I'm talking about.

Larisa Rudenko: Well it would depend on the application.

(Andy Pollack): Okay. And then the other question - I know you said that you are going to exercise discretion on laboratory animals that are contained. But it also, from reading the guidelines, sounds like even developers of these animals have to first apply to you to get declaration of sort of discretion.

And it strikes there are, you know, hundreds or thousands of laboratory scientists developing knock-out mice...

Larisa Rudenko: Right.

(Andy Pollack): ...all the time. Are they going all now have to apply...

Larisa Rudenko: No, no, actually the guidance doesn't say that they would have to apply to us for a declaration of enforcement discretion. The guidance says that if you're working in laboratory animals such as rats and mice that you're welcome to contact us if you have a question about that but in general we're not interested in having an application from every post-doc and graduate student who's making a knock-out mouse for this, that or the other thing.

(Andy Pollack): Okay, thanks.

Heidi Rebello: Thanks. Let's take our next question please.

Coordinator: Okay our next question comes from (Jane Zahan) of Wall Street Journal.

(Jane Zahan): Hi, it's (Jane Zahan) of the Wall Street Journal. I have a couple questions. The first one is would you require a human trial involving GE animals as part of the pre-approval process?

Larisa Rudenko: Could you please sort of elaborate on what you mean by a human trial?

(Jane Zahan): Well would you like give humans the GE animals and then see if they got sick from eating them?

Larisa Rudenko: Oh you mean - do you mean to eat?

(Jane Zahan): Yes.

Larisa Rudenko: No. You know, we - there's a very well established and historically rigorous and robust process at the Center for evaluating the safety of food animals that receive conventional new animal drugs. Almost all of the food that we eat at some point in its life receives a conventional new animal drug. And we're

actually pretty good at determining food safety. And that generally does not require human food trials.

(Jane Zahan): Okay. The second question is could you clarify the labeling requirements on both GE animals for food use and their offspring or products containing offspring of GE animals?

Larisa Rudenko: Let me take the first part. (Jane), the first thing is I think you're a really good student of our cloning risk assessment where we make a distinction between a clone and the sexually reproduced offspring of a clone. One of the things that's important to remember here is that if an animal contains the genetically engineered construct is a GE animal; we don't count generations there.

After that I'm going to pass it to Dr. Flamm.

Eric Flamm: And as I said before, the requirements for labeling are the same whether the animals are genetically engineered or otherwise, whether the organism is genetically engineered or otherwise so there is no special labeling requirements simply because the animal itself was engineered.

I should point out that for - generally for meat and poultry that - the labeling requirements are set by the Food Safety Inspection Service of the US Department of Agriculture.

(Jane Zahan): Okay, so there's no special labeling requirements for food products containing the GE animals or the offspring, is that correct?

Eric Flamm: There is no special labeling having anything to do with the fact that the animal was genetically engineered or was born from an animal that was genetically engineered, which means it itself is also genetically engineered. The only

labeling requirements pertain to whether the food itself has been changed; the composition of the food is substantively different from other foods of the same kind.

And in that case the change has to be labeled but not the method by which the change was introduced.

(Jane Zahan): Okay, thanks.

Randall Lutter: This is Randall Lutter. We think that's what the public expects of FDA as a science-based regulatory agency, the labeling will be based on changes in the composition of the product in instances where that's relevant.

(Jane Zahan): What kind of change would you include there like is this like disease resistance or more nutritious?

Eric Flamm: If the composition is different so that, for example, high Omega-3 fatty acid pork, that would be labeled to indicate it has high Omega-3 fatty acids.

On the plant side where we have a lot of foods already on the market from genetically engineered plants there have been two oils, one from canola - the canola plant and one from soy plants, where the oil had a change in its fatty acid composition and that oil is labeled to indicate the change, what is different about it but it doesn't say that it's genetically engineered.

(Jane Zahan): So that's mandatory?

Eric Flamm: Yes. If your food is substantively different that's mandatory but if your animal is disease resistant we - that doesn't change the composition of the food and therefore there is no labeling requirements there.

(Jane Zahan): Okay, thank you.

Heidi Rebello: Okay, Operator - thanks, (Jane). Operator, we have time for just one more question.

Coordinator: Okay our next question comes from (Tom Maw) of Los Angeles Times.

(Tom Maw): Can you briefly give us an overview of how you determine the safety of one of these products, if it's being used for food?

Larisa Rudenko: Well it's going to be pretty brief because it gets very, very - it's a very complex and detailed process. I think - in very broad strokes and a very high altitude we need to know the following things: one, is there something about that piece of DNA that's being inserted that could somehow either directly or indirectly affect the health of the animal so that the animal is not as healthy as it should be to produce a safe food.

We need to know - so we need to know an awful lot about the construct itself. We need to know about the health of the animal because we have relied for a millennia on the safety of food from animals that it is safe and a healthy animal is likely to produce safe food.

And finally we need to look very carefully at the composition of the food to make sure that it's not different from food that has been historically consumed.

All these steps are exactly analogous to the steps that the Codex Alimentarius has recently adopted as part of the international standard setting for determining the safety of food from these kinds of animals across the world.

And I would strongly urge you to go to our Web site and read the guidance carefully because we spell out - even though it is at a fairly high altitude, the kinds of steps that you would need to do. And in order to get to a food safety determination you cannot skip any of the steps that come before it.

So just take a look at that. It's the last three or four pages of the guidance and it lays it out pretty carefully.

(Tom Maw): Okay but none of these steps is the equivalent of a, say, a clinical trial for a new drug?

Larisa Rudenko: I think the determination of the health of the animal is equivalent to the clinical trials that would go for a - they are clinical trials for the animals themselves based on the new animal drug provision clinical trials.

(Tom Maw): Okay.

Heidi Rebello: Thank you, (Tom). So ladies and gentlemen this concludes today's media teleconference. Thank you for your participation. Now if you have follow-up questions on this issue please contact FDA's Office of Public Affairs at 301-827-6242. Thank you very much and good day.

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