Transcript of Media Briefing on FDA's Release of a Final Guidance for Industry on the Regulation of Genetically-Engineered Animals

Moderator: Michael Herndon
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Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode until the question and answer period.

If you would like to ask a question at that time, please press star then 1 on your touch tone telephone. Please clearly state your first and last name when prompted.

Today's conference is being recorded, if you have any objections you may disconnect at this time. Now I'd like to go ahead and turn the call over to Mr. Michael Herndon.

Michael Herndon: Thank you very much. First of all welcome ladies and gentlemen, I want to apologize for us beginning late, we had some technical difficulty. This is Michael Herndon from FDA's Office of Public Affairs.

This is an FDA teleconference for credentialed media to get information on FDA's release of a final guidance for industry on the regulation of genetically engineered animals.

We have speakers today from the US Food and Drug Administration and the Center of Veterinary Medicine. Our three speakers will make opening remarks.

They are Dr. Randall Lutter, FDA's Deputy Commissioner for Policy; Dr. Bernadette Dunham, Director of FDA's Center for Veterinary Medicine and Dr. Larisa Rudenko, Senior Advisor for Biotechnology at the Center for Veterinary Medicine.

We will also have Dr. Eric Flamm, Senior Science Policy Advisor at the FDA who will be available as a technical expert for your questions.

And in addition the members of the USDA Animal and Plant Health Inspection Service are available to answer any questions that may fall under their jurisdiction.

They are Michael Gregoire, Deputy Administrator of Biotechnology Regulatory Services, Beverly Simmons, Associate Deputy Administrator for Emerging and International Programs, also at Biotechnology and Regulatory Services.

Now after the speakers have made brief remarks we will move to the question and answer segment. Now reporters will be in a listen only mode until we open up the call for questions.

When asking a question please state your name and affiliation. But at this time I'm going to turn it over to Dr. Lutter.

Randall Lutter: Thank you and good morning. I am very pleased to announce that today we're releasing the final version of FDA's guidance for industry on the regulation of genetically engineered animals containing heritable recombinant DNA constructs.

This guidance clarifies how the FDA is regulating genetically engineered animals and provides recommendations to producers of these animals on how they can meet their responsibilities and obligations under federal law and regulation.

It serves to reassure stakeholders that FDA has clear standards for regulatory decisions on these animals, allowing us, when appropriate, to bring safe and effective products to market in a timely manner.

As you may remember from the release of the draft guidance, FDA is regulating genetically engineered animals under the new animal drug provisions of the federal food drug and cosmetic act.

Genetically engineered animals contain a recombinant DNA segment that is intended to alter the structure or function of the animal and are considered to contain a new animal drug.

GE animals will therefore require pre-market approval by FDA prior to their introduction to the marketplace.

Producers of these animals will also need to comply with the law and regulations established by the national environmental policy act.

This guidance benefits from public comments received on a draft version of the guidance release for 60 day public comment period on September 18th of 2008.

We got comments from a range of stakeholders, from advocacy groups to trade and professional associations, consumer and environmental groups to

industry, organic growers, food companies, pharmaceutical companies and from the public at large.

We received over 28,000 comments in total and you can access each one at our Dockets website. Almost all of the 28,000 or so comments were form letters and single-issue comments indicating support for, or opposition to, the use of genetic engineering in general and the genetic engineering of animals in particular.

We recognize that many people have strong views on these subjects. It's important to understand, however, that these issues are largely outside the scope of FDA's authority and that the agency's role is clearly described by the law to determine whether the RDNA constructs in genetically engineered animals are safe and effective.

We are a science-led regulatory agency and we will make those decisions based on a predictable science based framework that will ensure the safety and safe use of genetically engineered animals.

We would like to thank all of the members of the public who submitted comments. We'd especially like to extend our appreciation to those individuals and groups who prepared thoughtful, and often lengthy, carefully-researched substantive comments.

We believe that these comments have helped us improve the guidance and that they will serve as useful points on which we can reflect as we proceed with the regulation of genetically engineered animals.

In large part based on these comments, we've made some changes to the guidance. Perhaps one of the most consistent substantive comments was the desire for more transparency in the agency's decision making process.

This request from the public aligns with the agency's continued efforts to be more transparent. Now that we have this guidance finalized, we expect to be able to hold the transparent scientific Advisory Committee meetings that the public requests prior to any decision to approve applications to market FDA approved products.

When we released the draft guidance we reminded you all that genetic engineering is no longer a new technology and that the purpose of this guidance was to clarify the legal basis of our regulation of genetically engineered animals.

We did so at that time because some applications were approaching commercialization. Just last Friday the Center for Veterinary Medicine participated in a public meeting of the blood products Advisory Committee that serves the Center for Biologics Evaluation and Review.

That distinguished group considered the safety and effectiveness of a new orphan drug to treat a hereditary clotting disorder.

The committee overwhelmingly voted positively in favor of the safety and effectiveness of the drug, although the center for veterinary medicine's review of the genetically engineered animal was informational to this panel in affirming their support for the human drug.

One of the experts on the panel noted the tremendous potential of this technology for improving the health of humans and animals.

We agree that this is indeed the case and with the issuance of this final guidance, we have a rigorous and predictable science based framework.

We can operate in a timely and transparent manner to determine the safety and safe use of genetically engineered animals. I'm pleased now to introduce Dr. Bernadette Dunham, Director of the Center for Veterinary Medicine who will tell you more about that center's role in assessing genetically engineered animals.

Bernadette Dunham: Good morning. Let me join Dr. Lutter in expressing my excitement at the release of this final version of the guidance for industry on the regulation of genetically engineered animals today.

This technology, the introduction of recombinant DNA construct in animals, holds great promise for the health of both animals and humans. Genetic engineering provides the scientific community with some of the most powerful tools available to help introduce resistance to the diseases in animals.

One such example is mastitis in cattle. For those of you who may not know much about mastitis, this is a very painful and difficult to treat bacterial infection of the udder.

In addition to the cow's welfare, this condition costs the dairy industry millions of dollars each year. Genetic engineering can be used to make animals resistant to mastitis.

And genetic engineering can also help address some of our environmental concerns. Those of you who follow the press now know that there are groups of researchers who are attempting to solve some of these global issues.

Pigs have been genetically engineered to produce less phosphorous in their waste to address agricultural run off, and there are fish genetically engineered to grow to market size more quickly so that the wild ocean populations will not be subject to such intense harvest pressure.

These animals hold real promise, but we do not want them on the market until we are certain that the technology is safe for the animals and for humans.

Nor do we want to have food products from these animals entering the market until we are sure that it is safe to eat.

And that is exactly what this guidance does. It provides the producers of these animals with recommendations regarding the data and information the agency needs to review in order to determine safety and to make sure that the traits introduced into these animals do exactly what producers had indicated in their claim.

As Dr. Lutter said earlier, it allows all of our stakeholders to see what science based standards the agency will use in making those decisions.

The guidance clarifies the regulatory authorities under which we can make sure that this technology is safe to use and that food from genetically engineered animals will be safe.

What you may not know as much about is the extensive scientific expertise that we have at the Center for Veterinary Medicine to conduct a review of the applications involving these animals.

CVM is comprised of a dedicated staff of professionals trained to examine the impact of new science on the health of humans and other animals. We have assembled a multi-disciplinary group of individuals from across the center who work together to address the complex and often novel issues that this technology can pose.

They include molecular biologists, veterinarians, environmental specialists, animal scientists, professors and board certified toxicologists.

Our reviewers do not hesitate to reach out to their colleagues across the agency or in other federal agencies for additional expertise or for peer review of their decisions.

That’s easy for them as they’ve worked hard and tirelessly with colleagues across the US government on joint committees and working groups sharing knowledge and experience.

Many of our reviewers are also recognized internationally for their expertise and ability to harmonize scientific concerns. I’m proud of them all and pleased to have such an extensive team of talented individuals on board to evaluate this technology.

And now I’ll turn the podium over to Dr. Larisa Rudenko, the Senior Advisor for Biotechnology who can tell you more about how we intend to assess the scientific and regulatory issues posed by this technology.

Larisa Rudenko: Thanks Bernadette. I too am very pleased that we're making available our final guidance on the regulation of genetically engineered animals.

I've been working with the introduction of the products of biotechnology since 1989 and it's been my personal and professional pleasure to have had the opportunity of working with the very talented and experienced team that Dr. Dunham has nurtured at CVM, and at FDA in general, from our molecular biologists and veterinarians to our policy and legal experts.

One of the things that you learn is that there's always more to learn, and so as Dr. Lutter stated earlier, we're very grateful to all of the public who submitted comments to us.

As you know the guidance was intended to clarify our statutory and regulatory authorities to all of our stakeholders and provide recommendations to producers of genetically engineered animals as they prepare submissions for us to evaluate for safety and effectiveness.

The comment period has been helpful because it shows us how we could be more clear and where our recommendations may not have been as instructive as possible.

I just want to remind all of you about the key points in the guidance which haven't changed since we issued the draft. First, we're regulating GE animals under the new animal drug provisions of the act because the recombinant DNA construct used to make these animals is intended to alter the structure or function of the animal, and thus meets the definition of an animal drug. So again GE animals are not drugs, they *contain* drugs.

Secondly, all GE animals are captured under this regulatory rubric. For some such as insects we want you to know that we are continuing to work with the environmental protection agency and USDA's animal and plant health inspection service on which agency will take the lead with regard to which type of insect.

We will make the results of that effort public once we've completed it. For others such as highly contained laboratory animals, species not traditionally consumed as food, or used for research--such as rats and mice--we will exercise enforcement discretion.

That is we will not require those researchers to open investigational new animal drug files or apply for new animal drug application approval.

Then based on risk, another set of non-food animals may also be eligible for enforcement discretion but you will first need to come to the agency and work with us to demonstrate that there are no risks that we need to worry about.

For all animals traditionally consumed as food or that produce food, you must come in and open an investigational new animal drug file.

We found that it works best for the regulated community and for us if you come in as early as possible so that we can help you meet your obligations and responsibilities under the law.

Once you've decided that you want to apply for an NADA, the guidance spells out the kind of data and information. We recommend as being most useful to meet the statutory standard for safety and for validating any claims that you may wish to make about your animals and their introduced traits.

As you may remember, applying the existing regulatory standards, we've developed a hierarchical risk based review strategy that uses a cumulative weight of evidence evaluation process.

That's rather technical jargon for saying that it's impossible for us to perform a safety assessment until we really understand the rDNA construct and the resulting animal lineage.

Now because the introduction of each recombinant DNA construct into an animal results in a unique set of hazards and risks, we will be evaluating the animal health, food safety when appropriate and environmental assessments for each GE animal lineage separately.

We do not intend to perform construct- or species-based evaluation. But the most important thing to remember is that we really want to work closely with the producers of GE animals to ensure that they meet their responsibilities and obligations under the law.

During the past few years we found that having open lines of communication and a willingness to learn from each other results in our being able to ask the right questions about GE animals under development and for sponsors to be able to conduct the appropriate studies to answer those questions.

We look forward to continuing to work together in that way. And finally I want to be able to keep lines of communications open with all of our stakeholders.

And to that end it is our intent to make ourselves available at scientific meetings, conferences and other venues to answer any questions that may exist about our oversight of GE animals and the critical evaluations of safety

and effectiveness required prior to the commercialization of these animals and the foods they produce.

Thank you all very much for your comments and your attention during these presentations. Mr. Herndon.

Michael Herndon: Thank you Dr. Rudenko, at this time ladies and gentlemen, we will begin the question and answer portion of this briefing. Let me remind you that when asking a question please state your name and affiliation, also please limit yourself to one question and one follow up so that we can get as many questions in as possible.

I also want to note that the press release for this announcement was sent to reporters on our media list as well as posted on our website. With that we will take the first question operator.

Coordinator: Yes, thank you. Once again if you'd like to ask a question please press star then 1 and please clearly state your first and last name and as well as your media outlet. Thanks.

The first question comes from Val Willingham, CNN. You may ask your question.

Val Willingham: I know this is going to be a - I feel a little stupid asking this, but is it - these animals, are these cloned animals as well as that or is that a totally separate thing?

Larisa Rudenko: Hi Val, no it's not at all a stupid question. We're - this is very different from the just clones that we talked about in January of 2008. Just clones are copies of existing animals that are produced via nuclear transfer, these are animals

that are different because they have a new piece of DNA added to them and so they're referred to as genetically engineered animals.

Val Willingham: And will these have a - will these be labeled in the stores as such?

Larisa Rudenko: All genetically engineered animals have to be accompanied by labeling so they can be distinguished from non-genetically engineered counterparts.

And with respect to labeling I presume of food from these animals, FDA is required to ask for labeling if there's a material difference in the food that comes from these animals, in other words if the composition of the food changes in any material way. But we are not required by law to ask producers to indicate that animal - that food comes from genetically engineered animals.

Val Willingham: Unless it's a material difference.

Larisa Rudenko: Unless it's a material difference, that's correct.

Michael Herndon: Thank you Val. Thank you. That was Dr. Rudenko for those who don't know. Next question please?

Coordinator: The next question comes from Jennifer Smith, FDA Week. You may ask your question.

Jennifer Smith: Hello, I guess I want to start off here, does FDA intend to convene the Science Board or the Veterinarian Medicine Advisory Committee to review applications or safety issues before FDA approval?

Bernadette Dunham: Yes, good morning, this is Dr. Dunham. We will be using our veterinary advisory board committee as we go through the reviews of these applications.

Jennifer Smith: Okay. But is that going to be for every application or just for system applications?

Bernadette Dunham: It's our intent to convene the veterinary medicine Advisory Committees for all foreseeable applications as we see the need to do so.

Jennifer Smith: And is that food and drugs? Okay, sorry, didn't mean to interrupt you.

Randall Lutter: This is Randall Lutter. Let me elaborate.

Jennifer Smith: Okay.

Randall Lutter: We actually have substantial flexibility in the management and use of the Advisory Committees and in the past we have held meetings which are joint of multiple committees.

We've also borrowed experts from one committee and assigned them temporarily for another committee and we've also used sub-committees. So our commitment here based on this guidance going forward is to ensure that there are Advisory Committees reviewing the questions in hand pertaining to genetically engineered animals.

And the exact details are ones that we're going to have to work out. This is while not a new technology the process of our reviewing these applications in this way is something that is new.

But we can commit to ensuring that there's appropriate scientific expertise in public Advisory Committee meetings that we will review the questions of safety and efficacy of the DNA segments that we're being asked to approve.

Jennifer Smith: Okay, and can I just have one follow up to that please?

Michael Herndon: Go ahead Jen.

Jennifer Smith: Okay thanks. Now I'm wondering is FDA doing in the sense of having an Advisory Committee meeting a public meeting. Is that in response to consumer groups asking for the public to have access to some safety or efficacy information from GE animal producers before FDA approves the product?

Because that was a concern that was raised in the last guidance as to the public having some idea of what the safety or efficacy information that the producers would give FDA.

Larisa Rudenko: Hi Jennifer, this is Larisa Rudenko responding. As Dr. Lutter said in his comments, it turns out that there's a nice confluence of the agency's desire to be more transparent in its decision making that has come along at about the same time the public has been asking for these comments - has been submitting comments in favor of more transparency. So we're very pleased about - that we're going to be moving forward with this as an example of how we can actually use the public process and the Advisory Committee process to be more transparent.

Jennifer Smith: All right, thank you.

Michael Herndon: All right, thanks Jennifer. Next question please?

Coordinator: Once again if you would like to ask a question please press star then 1 and please clearly state your first and last name and as well as your media outlet. One moment for another question please.

The next question comes from Jennifer Smith, FDA Week.

Jennifer Smith: I guess no one else wants to take a chance here. Okay, I guess - what I guess - when it comes to environmental impact that was also a big concern of consumer groups.

They were saying that FDA wasn't taking enough steps to monitor the environmental impact. So has FDA taken additional steps in this final guidance or is it the same as a draft in the sense of what's outlined?

Larisa Rudenko: Hi Jennifer, it's Larisa again. In the first place we have not issued any approval yet, so to say that we haven't taken sufficient steps I think is probably premature.

The substantive nature - the substantive description of how we're going to be handling environmental assessments has not changed from the draft to the final. We will abide by the authorities and regulations of NEPA.

Jennifer Smith: Okay.

Michael Herndon: Thanks Jennifer. Next question please.

Coordinator: The next question comes from Christopher Doering from Reuters. You may ask your question.

Christopher Doering: Thank you for taking my question. I notice you folks mentioned that in terms of the stages which applications are that you've received some that are in the early stage and some that are more mature.

Can you say when perhaps we might see the first application approved, like a time table? I know you can't - you know you don't have a crystal ball, but how mature are they, when could we see the first one actually moving forward?

Larisa Rudenko: Hi, this is Larisa Rudenko again. We will not approve any application until we are convinced of the safety and effectiveness of the RDNA construct.

I think it's fair to say that we have sponsors who have come in at various stages of the development of the animals, but I think the public should rest assured that we are not going to be rushing any decisions.

Christopher Doering: Right, I wasn't saying that you were, but I mean I'm just saying based on how things are, when - and you know understanding you're going to take into account everything to date that you have all the required information.

When do you anticipate the earliest perhaps we could see one of these applications being approved?

Larisa Rudenko: When we've finished evaluating the data.

Christopher Doering: Okay. I mean how close are you to evaluating the data on any of the applications, say the ones that are especially mature or far along?

Larisa Rudenko: Well I think a really good clue for you might be to keep an eye out for a notice of an Advisory Committee meeting. That would be a really good sign that we're approaching completion.

Michael Herndon: Thank you sir. Next question please?

Coordinator: The next question comes from Jennifer Corbett, Dow Jones. You may ask your question.

Jennifer Corbett: Hi, I have two completely unrelated question. The first question is back on the Advisory Committee - advisory panels. You know as you mentioned last week there was the one on the GTC Biotherapeutics drug, but that looked at the product as a drug.

And it didn't look at the specifically at the animal. So are you saying you would be convening Advisory Committee meetings in the future to look at both the animals and the drugs?

Randall Lutter: This is Randall Lutter, Deputy Commissioner for Policy. It's important to note that what the guidance does is articulate our commitment for transparency with respect to Advisory Committees going forward.

We will abide by the standards in the guidance pertaining to Advisory Committees that the guidance describes with respect to the meeting of last week, that - we reviewed there and that meeting was called for the purpose of reviewing the orphan drug product in question.

And we made presentations of - for informational purposes to the Advisory Committee about the process by which we are reviewing the associated new animal drug application.

And henceforth for other actions you can anticipate announcement of further Advisory Committee meetings for other products.

Jennifer Corbett: Okay. Another sort of wonder - fictional question, if you were to have an application pending for I guess a (food) product like a meat, would that then fall under USDA jurisdiction, or...

Randall Lutter: Well if the product were for example any animal used for food so that it is not something that we would exercise enforcement discretion for, then the DNA construct for that animal is one that we would regulate as a new animal drug and therefore it would be covered by the process that we're discussing today.

Jennifer Corbett: Well I guess what I'm talking about is if you, you know for a food that would be consumed, so then that would because it's from a genetically engineered animal then would all fall under FDA?

Bernadette Dunham: In the sense - this is Dr. Dunham. Yes, at CVM we would follow through for any of the genetically engineered animals from which there would be a food product.

It would go through our human food safety review as any other drug would be handled through CVM and that would have to be met to ensure safety of any food product coming from an animal.

Eric Flamm: So just to add on to clarify your question, FSIS is responsible for the slaughter of the food and we communicate with FSIS prior to completing our approval or asking approval so that they're aware, ff there were any actions that they would have to take or monitor at the slaughterhouse. So it's the same as for

any conventional new animal drug. But FDA is responsible for the safety of the drug and the animal.

So FDA is responsible for doing the approval and FSIS has responsible for the meat at the floor.

Michael Herndon: All right, thank you Jennifer. That was Dr. Eric Flamm. Next question please?

Coordinator: The next question comes from Ricardo Alonzo Zaldivar with AP. You may ask your question.

Ricardo Alonzo Zaldivar: Hi, thanks for taking my question. And I was wondering if I could get you to summarize how you've responded to the concerns of the consumer groups. It sounds like on the Advisory Committees that you are pledging to make every one of these animals subject of an Advisory Committee meeting.

But on the labeling and on the environmental safeguard you have not gone as far as the consumer groups wanted you to go.

Randall Lutter: Let me try and answer your question which I think has three parts...

Ricardo Alonzo Zaldivar: Okay, who is speaking please?

Randall Lutter: My name is Randall Lutter, Deputy Administrator for Policy.

Ricardo Alonzo Zaldivar: Okay, thank you, thank you. Right.

Randall Lutter: With respect to the Advisory Committee meetings, now that we have this guidance finalized, we expect to be able to hold transparent scientific

Advisory Committee meetings that the public requests prior to any decision to approve applications to market FDA products.

With respect to labeling, we will continue to abide by our existing process and existing standards which is if there's a material difference of - in the food products, then they will be appropriately labeled.

And your third question dealt with the environmental issues, and there we will expect the producers of these animals also need to comply with the law and regulations established by the National Environmental Policy Act.

Ricardo Alonzo Zaldivar: Okay, and could you go a little further and explain to us what is a material difference? What do you mean by a material difference in a food animal that would have to be labeled?

Eric Flamm: Hi, this is Eric Flamm. The law requires us to have labeling to indicate material differences in food and does not allow us to require labeling for such things as the so called consumer right to know.

So if for example there's a substantial difference in the composition of the meat from an animal, that kind of label - that information would be required in the label.

Ricardo Alonzo Zaldivar: You mean for example if it's no fat or something like that, would that be a material difference?

Eric Flamm: Yeah, that would likely be a material difference. We do have to emphasize however that FDA does not have responsibility for labeling of meat per se, that's under the Food Safety Inspection Service.

But generally our requirements are the same, so I can't speak for the Food Safety Inspection Service but your example is the kind of thing that we would anticipate would warrant mandatory labeling.

Ricardo Alonzo Zaldivar: Okay, there in the room could we ask the same question of FSIS? What would be labeled, some examples of what would be labeled?

Eric Flamm: Actually the Food Safety Inspection Service is not in the room, it's the Animal and Plant Health Inspection Service.

Ricardo Alonzo Zaldivar: Oh, I'm sorry.

Michael Herndon: Thanks Ricardo. Thanks. Next question please?

Coordinator: The next question or follow up does come from Jennifer Smith, FDA Week.

Jennifer Smith: Eric, just quick how do you spell your name and then I just have a substantive - two substantive questions for that after that.

Eric Flamm: I'm not allowed to give out that information. No, it's F as in Frank, L-A-M as in Mary, M as in Mary.

Jennifer Smith: Oh, okay. And Eric's with a C or with a K?

Eric Flamm: C.

Jennifer Smith: Okay now what - last time with the previous in the draft guidance, FDA said that it was intending to issue another one for producers on - for using GE animals producing human or animal drugs.

They also said it to additional guidance in applying GMPs to NADA applications. Is that still in the works?

Eric Flamm: This is Eric Flamm with a C and an F as in Frank. Yes, those we are - those are in the works, we can't predict when they will be out. But yes, we do intend to produce them and publish them as drafts for comment.

Jennifer Smith: Okay. And one more just follow up to that, in the sense of the guidance as well, at a meeting, a public - well it was a panel session that was following September issuance, some of the food producers had asked if FDA intended to issue or that FDA should issue GE animal product labeling guidance.

Also that FDA should impose or could impose a national unique identifier program to trace GE animals from birth to death. So I'm wondering if either of the - either that guidance, the animal product labeling, or b, the national unique identifier program would not be something FDA is considering, if it's in the guidance, etcetera.

Eric Flamm: This is Eric Flamm again. We do have a draft guidance that we published quite a few years ago but it's available on our website.

On voluntary labeling of foods from genetically engineered plants, the kinds of issues for animals would be - or meats from animals would be identical so at least at this point we do not anticipate publishing any additional labeling guidance.

And we do not believe we have that - the unique identifier issue would be something that would more likely be a USDA issue than an FDA issue.

Jennifer Smith: Okay.

Michael Herndon: All right, thanks Jennifer. Operator, are there any more questions?

Coordinator: There are no other questions in the queue at this time.

Woman: No.

Michael Herndon: Okay. Ladies and gentlemen, this concludes today's media teleconference. Thank you for your participation. A replay will be available in about an hour and will be available for about 3 days.

If you have any follow up questions please don't hesitate to call FDA Office of Public Affairs at 301-796-4540. And thank you and have a good day.

Coordinator: Thank you for participating in today's conference call. The call has concluded. You may go ahead and disconnect at this time.

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