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UNITED STATES DEPARTMENT OF AGRICULTURE

IN RE:

National Organic Standards Board Meeting

Hearing held on the 22nd day of October, 2003

at 1:30 p.m.

The Radisson Barcelo Hotel Washington
Washington, D.C.

TRANSCRIPT OF PROCEEDINGS

BEFORE: DAVE CARTER, CHAIRPERSON

MEMBERS OF THE BOARD:

- ROSALIE KOENING, COMMITTEE MEMBER
- REBECCA J. GOLDBERG, COMMITTEE MEMBER
- MICHAEL P. LACE, COMMITTEE MEMBER
- ANN L. COOPER, COMMITTEE MEMBER
- KIM DIETZ, COMMITTEE MEMBER
- KEVIN O'RELL, COMMITTEE MEMBER
- JAMES RIDDLE, COMMITTEE MEMBER
- MARK KING, COMMITTEE MEMBER
- GEORGE SIEMON, COMMITTEE MEMBER
- GOLDIE COUGHLAN, COMMITTEE MEMBER
- OWUSU A. BANDELE, COMMITTEE MEMBER
- ANDREA CAROE, COMMITTEE MEMBER

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P R O C E E D I N G S

October 22, 2003

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2
3 MR. CARTER: Okay. In total -- you know,
4 probably violation of federal law, but out of respect
5 for the folks that are here today, we will go ahead and
6 convene the meeting of the National Organic Standards
7 Board, because we do have a lot of work to do. But just
8 to let the record reflect that the time certain called
9 for the meeting was at 1:00 p.m. We're waiting for the
10 folks from USDA to get back from lunch. Legally, we're
11 not supposed to have an advisory committee meeting
12 unless there's USDA folks present, but I think that they
13 will be here shortly, so we will just go ahead and
14 begin. So the first thing I'd like to do is to just go
15 around the table here and have the Board members
16 introduce themselves. And let the minutes reflect that
17 Nancy Ostiguy will not be here until tomorrow. She's a
18 professor and she's finishing up some finals today, and
19 will be not here. Other than that, we have everybody on
20 board. And so we'll start off with Rose.

21 MS. KOENING: Just say who we are?

22 MR. CARTER: Who you are and what do you do.

23 MS. KOENING: My name is Rose Koening. I'm a
24 producer in Gainesville, Florida.

25 MS. GOLDBERG: I'm Becky Goldberg. I work for
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1 an environmental organization in environmental defense.
2 And my office is in New York.

3 MR. LACY: I'm Mike Lacy. I'm a faculty
4 member from the University of Georgia.

5 MS. COOPER: Ann Cooper. I run a shop New
6 York.

7 MS. DIETZ: Kim Burton, a handler
8 representative from Chico, California. For the official
9 records, my name was changing. I got married last week
10 and it's not Kim Dietz, so I'll have to start using that
11 name.

12 MR. O'RELL: Kevin O'Rell, a handler
13 representative from Longmont, Colorado.

14 MR. RIDDLE: Jim Riddle, a homesteader
15 representative from Minnesota. A certifier rep and I'm
16 endowed chair at the University of Minnesota.

17 MR. CARTER: Dave Carter, a consumer rep. But
18 I actually spend half of my time working with buffalo
19 ranchers and half of my time doing ag consulting.

20 MR. KING: Mark King. I'm the retail
21 representative on the Board and I reside in
22 Indianapolis, Indiana, and independent consultant.

23 MR. SIEMON: George Siemon, the farmer rep
24 from Wisconsin.

25 MS. CAUGHLAN: Goldie Caughlan, consumer rep.

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1 I work with food cooperatives in Settle, Washington.

2 MR. BANDELE: Owusu Bandele, professor at
3 Southern University in Louisiana.

4 MS. CAROE: Andrea Caroe, environmental rep.

5 MR. CARTER: In terms of the meeting process,
6 this is kind of a unique -- a different type of meeting
7 format that we've got the next few days, in that because
8 of some of the issues surrounding the materials review
9 process, the department has asked us to focus this
10 meeting specifically on two areas. Number one is a
11 standardized process for the materials review and
12 particularly going through some of our decisions that
13 we've made in the past and putting them into a
14 standardized process that they can use then for the
15 implementation. The second area is the trying to
16 surround and get some consistency around the process
17 that we use as a board on the criteria for the
18 compatibility with organic systems and how do we define
19 that. And so that's going to primarily be the focus of
20 the next couple of days. Today we have a presentation
21 from FDA. Because of some of the issues that have
22 surrounded, let the record reflect we are now legal.
23 Katherine is here, so we have a USDA representative.
24 And let's see. I saw Dennis. Where'd he go?

25 MR. SIEMON: Can we do the minutes now?

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1 MR. CARTER: Well, let me -- no. I just...

2 MR. SIEMON: Okay.

3 MR. CARTER: I want to make some announcements
4 here. Anyway, we do have a representative or some
5 representatives from the FDA to speak to us because of
6 some of the issues that have come about with the
7 livestock materials. Tomorrow we're going to really be
8 looking for public comment and input from the public on
9 this issue of compatibility. Obviously, during the
10 public comment, people are free to use that time for
11 whatever they desire, but we'll particularly be looking
12 for input on the compatibility. If you do want to get
13 public comment file, you need to sign out. There's a
14 sheet at the back, as well as just a general attendance
15 sign-out. And then Friday will be day when the Board is
16 simply going to be going through, and particularly the
17 recommendations that we made -- that were made, going
18 through this sort of standardized template and trying to
19 rework them through that process. The public is welcome
20 to sit in on that meeting. We won't be having any
21 public input at that time, but it is an open meeting.
22 So that is sort of the drill for the next couple of
23 days. Now, as far as other announcements, Jim Riddle
24 has got an announcement that he'd like to share with the
25 Board.

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1 MR. RIDDLE: Thanks Dave. I'll pass these
2 around. There's some copies for the Board and there's
3 some extra copies, as well. And what this is -- I'm
4 very excited to announce is the National Association of
5 State Departments of Agriculture -- these are all of the
6 commissioners and secretaries from all 50 states. NASDA
7 has adopted a policy statement in support of organic
8 agriculture at their meeting a few weeks ago. This is a
9 very significant development, and I just want to
10 highlight a few of the items in the policy statement.
11 NASDA's calling for a full and consistent implementation
12 and enforcement of the final rule. Aren't we all. We
13 all support that cooperation between NOP and experienced
14 private and public certifying agents in addressing the
15 practical aspects of organic production and
16 certification issues, increase federal funding to
17 support adequate NOP staffing levels and activities to
18 accomplish legislative intent, cooperative relationships
19 between NOP and the state departments of agriculture.
20 Federal funding to states to allow them to implement
21 their responsibilities under the Act, inclusion of
22 organic as a defined commodity, and USDA market
23 promotion programs. Increased funding for the organic
24 transition program and other grant programs from the
25 federal government, creation of a national program

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1 leader for organic agriculture, collection and
2 dissemination of organic price data for sale of
3 commodity crops, specialty crops and retail organic
4 sales. There are other points here. That's just a
5 summary of this. The incoming president of NASDA is the
6 Minnesota commissioner of agriculture, Jean Huguson
7 [ph].

8 MR. CARTER: Other announcements from the
9 Board? Okay. With that, then, we'll call on Barbara
10 Robinson. She just stepped out? Okay. The -- then, we
11 have the agenda that is in the meeting book. I would
12 note that Friday morning when we get into the
13 discussion, we will have the materials to chair as is
14 accustomed to give the review of the process and a
15 presentation on that. And at that time we will also be
16 bringing forward the formal process for the adoption of
17 the form that we're using now for our materials
18 consideration. This is an ongoing process that we want
19 to incorporate into our board policy book and so we will
20 take that step at that time. Any other changes or
21 additions to the agenda? I see none. Do I have a
22 motion to adopt this agenda as our working agenda?

23 MR. KING: So moved.

24 MR. CARTER: Second?

25 MS. DIETZ: I'll second.

1 MR. CARTER: Any discussion? Seeing none, all
2 in favor, say I. Opposed, same sign. Motion carries.
3 Can someone locate Barbara for us? Okay. Richard,
4 would you like to make the remarks on behalf of the
5 program?

6 MR. MATTHEWS: Seems like we're always talking
7 about the exact same things. I'm Richard Matthews,
8 program manager. The issues that are probably of
9 greatest concern to people right now is where are we on
10 the rule making process. And as you'll recall, those
11 rules were issued in both April and May. Both of those
12 have cleared almost every single hurdle for publication
13 in the federal register. I'm optimistic that if not by
14 the end of the first week in November, very soon
15 thereafter, both of those proposals will be published in
16 the Federal Register. Where we are right now is that
17 they're in the final clearance. By that I mean they
18 have already gone through the attorneys, they've gone
19 through the Office of Management and Budget. Everything
20 is right down to the last stages. The reason why I'm
21 still allowing another two weeks before we get it done
22 is because it takes approximately five days once the
23 document gets to the Federal Register. What will happen
24 is that the documents will be published in the Federal
25 Register, and effective the day after publication.

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1 People will be able to start using those materials that
2 occur in those two documents. Those two documents
3 address, essentially, all of the crop materials, a few
4 issues related to livestock, some issues related to
5 processing and a number of technical corrections that we
6 had made. There is one material that will be coming
7 back to the Board for reconsideration based on public
8 comment and that material cannot be used. Those that
9 are published as final will be added to the list and
10 will be able to be used starting that date. We're still
11 working the issues on livestock materials. The docket
12 is not yet final. That docket will have to go through
13 proposed rule. At this time, there will be a 30 day
14 comment period for all of those who are concerned about
15 how long the comments periods will be. From now on,
16 they will all be 30 days to comment on the proposed
17 rules. And then those materials would then go through
18 the same process of our analyzing the comments. Part of
19 that analysis is that what we do is we report to the
20 Office of Management and Budget, and what is that
21 commenters are saying about the materials and what it is
22 that we could about it. We have to give our
23 justification as to why we're either adding or not
24 adding it to the Federal Register. So it'll still have
25 to go through that process. We're still quite a ways

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1 down the road from the livestock issues. And that's
2 really the big thing that we've got going now that we've
3 got the Board meeting and working on. As the Board
4 knows, we're taking and looking at the materials process
5 as a system. We internally are working on how we, the
6 NOP, can do our job better. But we're also looking at
7 what it is that we're requiring of those who file a
8 petition. So we're looking to see what can be done
9 better in that area to enhance the quality of the
10 petitions that are submitted. So we're looking at
11 petitions, we're looking at what it is we do. We're
12 going to be working closely with the reviewers to
13 address what it is that is expected of them and then
14 what it is that they end up generating for this board.
15 And the Board, as you know, but the public may not, the
16 Board is looking at how do they make their decision
17 process more transparent and that's what we're going to
18 be working on today, tomorrow and the next day. And
19 then once all of that is done, then those different
20 steps all figure into helping us do a more affective job
21 communicating to the public what it is that we do as the
22 Board, the reviewers and the NOP. I kind of look at
23 this as if it's a three-legged stool. Reviewers, the
24 NOP and the NOSB are all equal partners in this. If one
25 leg is shorter than the other, then the stool doesn't

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1 work very well. Or if one of those legs is cracked or
2 broken, you know, the stool doesn't work very well. So
3 what we've got to do is all get onto the same page and
4 be all working to help each other do each of our own
5 respective responsible areas, to do it more affectively.
6 And that's what we're working on right now. The issue
7 of peer review, that program is underway. Nancy is
8 doing the peer review. The expert has been selected,
9 the review process has begun. Nancy has been in looking
10 at our program, initially. It'll take probably another
11 two to three months before everything is all finished,
12 but I can assure you, it's well on its way and it's
13 working. Any questions?

14 MR. CARTER: Yeah.

15 MR. MATTHEWS: Jim.

16 MR. CARTER: Jim.

17 MR. KING: Yeah, if you could just comment on
18 the Federal Register notice that's open right now
19 through December 8, on the Paperwork Reduction Act
20 compliance.

21 MR. MATTHEWS: That's a requirement that every
22 two years we have to go back through the Office of
23 Management and Budget and get approval for the
24 recordkeeping burdens that are placed on the public.
25 The recordkeeping approval that we have in place right

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1 now expires in January of 2004, so what we're doing is
2 we've gone out and published our intent to continue this
3 process of gathering the information. The public is
4 welcome to comment on the recordkeeping burden. But
5 this is really a formality of putting the public on
6 notice, giving them an opportunity to comment, but it's
7 also necessary for us to continue to gather the
8 information that is required under the national
9 standards.

10 MR. CARTER: Okay. Other questions?

11 MR. BANDELE: Yeah.

12 MR. CARTER: Owusu.

13 MR. BANDELE: Any more information on that one
14 material that is coming back to the Board?

15 MR. MATTHEWS: It's the one that's the meat
16 analog, tetrasodium...

17 MR. BANDELE: Tetrasodiumpyrophosphate [ph].

18 MR. MATTHEWS: ...pyrophosphate or something
19 like that.

20 MR. BANDELE: TSPP.

21 MR. MATTHEWS: TSPP.

22 MR. CARTER: Okay. Other questions or
23 comments? Okay. Oh, I'm sorry, Andrea.

24 MS. CAROE: Did you -- have you publicly named
25 the expert that's going to be on the panel, yet?

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1 MR. MATTHEWS: The expert has been selected,
2 yes. Ken Cummings [ph].

3 MR. CARTER: Okay. Other questions? Okay.
4 Thanks, Richard. A couple of other announcements that I
5 failed to make at the beginning is anyone that speaks
6 either from the Board or the audience that's invited to
7 speak, whatever, you do need to go to the microphone,
8 you do need to identify yourself. This is being
9 transcribed and we need to have an accurate record.
10 Also, would admonish folks to turn the cell phones
11 either to off or vibrate and to keep any conversation
12 out in the hallway, so that we can focus on the
13 discussion here. With that, let me, then, direct the
14 Board's attention to the minutes of the May, 2003,
15 meeting, which minutes have been posted. What is your
16 pleasure? Jim?

17 MR. RIDDLE: I move that we approve the
18 minutes of the May meeting as presented to the Board.

19 MR. CARTER: Okay. There's a motion. Is
20 there a second?

21 MR. HOLBROOK: I'll second it.

22 MR. CARTER: Dennis Holbrook seconds.
23 Discussion? Seeing none, all in favor say I. Opposed,
24 same sign. Motion carries. We also have in the book
25 the review of executive committee minutes from the

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1 meetings that have been held since May. And Jim?

2 MR. RIDDLE: Yeah. Just in looking through
3 those, there at tab three of the meeting book, and just
4 wanted to point out for the record that the July minutes
5 are actually not the final version. What's in your
6 meeting book, that's still the draft minutes, and there
7 was an amendment during our last call to reflect that
8 Kim had left to call at a certain time after her
9 materials committee report. And I did get those final
10 minutes path read, so I just want to make sure that the
11 official record reflects the correct version of the July
12 minutes.

13 MR. CARTER: Okay.

14 MR. MATTHEWS: The website does have the
15 correct minutes.

16 MR. CARTER: The correct minutes are on the
17 website. So, okay. The minutes are always adopted by
18 -- accepted by the Board and generated.

19 MR. RIDDLE: Right. So, again, on the
20 executive...

21 MR. CARTER: You don't...

22 MR. RIDDLE: Yeah.

23 MR. CARTER: I was going to say, you were
24 giving me that look like we...

25 MR. RIDDLE: No.

1 MR. CARTER: So we don't have to act. That's
2 just for informational purposes only. All right. Then,
3 this afternoon we have a couple of individuals who are
4 sitting in, a couple of individuals from the Food and
5 Drug Administration to visit with the Board, and the
6 folks that are here are both from the surveillance and
7 compliance division of the FDA. We have with us Dr.
8 Steven Vahn. And I'm going to butcher this one, I know
9 if for sure. Dr. Vengris? Yeah? What's that?

10 MR. VAHN: No butchering.

11 MR. CARTER: No butchering. Okay. This came
12 about because of the discussion that we had on -- we
13 referring to livestock medication and the actions that
14 were taken. The FDA had responded to the program that
15 there were some of these materials that were not in
16 compliance with FDA provisions. We think -- and
17 particularly in August, during the meeting of the
18 American Association of Feed Control Officers in Denver,
19 I had an opportunity to be there. Jim was there, as
20 well, as was Emily Brown-Rozen from OMRI. We had a
21 chance to have a very informal discussion with some of
22 the FDA folks who were there about some ways that we can
23 bring these materials into compliance with the FDA. So
24 we thought it would be helpful to have the folks from
25 FDA come and visit with the Board and see how we can

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1 start to address this issue. So at this point, I just
2 like to turn it over to our guests from FDA.

3 UNKNOWN: You're asking for an awful lot.

4 MR. CARTER: I'll tell you what, we'll trade
5 you one laptop for approval of ten materials. Okay.
6 Let me -- while they're -- while they're setting up,
7 Owusu has brought to the chair's attention an issue
8 about -- go ahead.

9 MR. BANDELE: Yeah. In the -- in the minutes,
10 and also the section dealing with the materials, the
11 tetrahydraperfluidalcohol [ph], this thing is incorrect,
12 because we considered that. It should read
13 tetrahydraperfluidalcohol will be added to 205601M2,
14 with the annotations of until December 31, 2006.

15 MR. CARTER: Okay.

16 MR. MATTHEWS: Which minutes are those?

17 MR. BANDELE: Yeah. It's in the May summary,
18 as well as the summary that was provided...

19 MR. CARTER: Yeah. Owusu, if you go to page
20 eight of section...

21 UNKNOWN: It's in a different section.

22 MR. CARTER: There at the bottom of the page.
23 That reflects that it was brought. That was the Board
24 entry.

25 MR. BANDELE: Oh, okay. I got it.

1 MR. CARTER: Okay? So we're okay. I did go
2 to a meeting once that they handed out squirt guns to
3 people as they came in and then anybody whose cell phone
4 went off during the meeting was fair game.

5 UNKNOWN: Well, since yours has been going
6 off...

7 UNKNOWN: That's why you're all wet.

8 MR. CARTER: That's why I'm all wet. Okay.
9 Welcome.

10 MR. VAHN: We're all set. Thank you for
11 letting me travel light.

12 MR. CARTER: Yeah.

13 MR. VAHN: My name is Steve Vahn, I'm the
14 director of the Office of New Animal Drug Evaluation at
15 the FDA Center for Veterinary Medicine. The reason that
16 Dr. Vengris and I are here today, we were invited to
17 come down because there has been some confusion about
18 how FDA regulates new animal drug products and food
19 additives. And our intent here today is to be
20 informational, not necessarily to influence the Board in
21 anyway. So what we thought we do is I would first talk
22 about my area, which is the pre-approval area, and talk
23 about the drug evaluation we go through to give you a
24 sense of what an approved drug means. And Dr. Vengris
25 is going to talk about medicines from the Division of

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1 Surveillance and the Office of Surveillance Compliance,
2 and Dr. Vengris will be talking about how we regulate
3 products once they are approved or otherwise on the
4 market. And there's a number of areas there and some
5 fine distinctions that I think would be very useful and
6 probably clear up a lot of confusion that has occurred.

7 MR. CARTER: You might pull the mike just a
8 little bit closer so everybody can hear you.

9 MR. VAHN: Sure. Okay. Do you want to go to
10 the next slide? First of all, where our statutory
11 authority comes from, a number of different acts.
12 Primarily, it's the Federal Food, Drug and Cosmetic Act.
13 We're also subject to the National Environmental Policy
14 Act and Water Act and Air Act and National Aquaculture
15 Act and so on. From that law, we further interpret the
16 statutes through the Federal Code of Regulations. Most
17 of our regulations are in 21CFR, part 500, and I'll show
18 you that in a minute. And we further interpret the
19 regulations, then, through our policies in the
20 guidelines. The statute and the regulations have the
21 force of law. The policies and guidance are more
22 advisory in nature and they're not considered
23 enforceable. In the Federal Food, Drug and Cosmetic Act
24 there's a few things that I think are important to point
25 out. First is, what is the definition of a new animal

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1 drug. A lot of folks think a drug is defined by the
2 chemical that it is. Actually, the statute defines an
3 animal drug by its intended use, so literally, anything
4 can become a new animal drug if it's intended for the
5 diagnosis, treatment, cure, mitigation or prevention of
6 disease, or it's affected -- or it's intended to affect
7 the structure of function of the animal, other than as a
8 food. So we have a very broad umbrella type of
9 definition. Dr. Vengris is going to go into some of the
10 distinctions and limitations of where our act stops and
11 other acts pick up and other agencies regulate similar
12 products. Specifically, within the food, drug and
13 cosmetic act, section 512 deals with the new animal drug
14 applications that I'm going to speak to today. We have
15 three types of applications, for the most part, that we
16 deal with, the original applications, the first time a
17 new entity comes to us for approval. The subsequent
18 changes after approval are dealt with through the
19 supplemental new animal drug applications. And then
20 there are generic new animal drug applications. We call
21 them abbreviated new animal drug applications, and they
22 are close to identical copies of pioneers that have
23 already been appraised and approved. We do allow
24 -- under the Federal Food, Drug and Cosmetic Act it's
25 illegal to market a product if it's not the subject of

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1 an approved application. There's one exemption for that
2 and that is for the investigations that are necessary to
3 prove that a product is safe and affective to get to
4 market. And as I said, as mandated by the Act, a new
5 animal drug cannot be sold in interstate commerce,
6 unless it's the subject of a new animal drug
7 application. And Dr. Vengris is going to speak to the
8 levels of enforcement within that division. So what is
9 a new animal drug, an approved new animal drug
10 application? It means the product is subject to -- is
11 safe and effective for it's intended use. The methods,
12 the facilities and controls that are used for
13 manufacturing and processing and packaging the drug are
14 adequate to preserve it's identity, strength, quality
15 and purity. Anyone can sponsor a new animal drug
16 application. It can be a US resident or if it is a
17 foreign firm, they have to have a US agent in the United
18 States that we would deal with, primarily. Usually, it
19 is pharmaceutical firms, because it does cost quite a
20 bit to get a drug approved and on the market. Generally
21 what'll happen is a pharmaceutical sponsor will do a lot
22 of pre-investigation on a new animal drug discovery
23 research. For example, the discovery of new molecules,
24 the purchase of other patented entities. They'll do a
25 new number of pilot studies to identify the

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1 pharmacologic value of the product. They'll do work in
2 both laboratory species and the target species. That is
3 a species that they intend to develop the product for.
4 They will work on dose and toxicity, doing
5 pharmacokinetic studies, and really trying to
6 triangulate the safety -- the level of safety with the
7 level of effectiveness for a particular biological
8 affect, and the concentration in which they can
9 manufacture the product, subsequent to be put into a
10 reasonable dose. Okay. We don't take the initiative in
11 our center to propose products or label indications.
12 The sponsors do that. And the sponsors conduct the
13 necessary research that supports the drug's safety and
14 effectiveness. We do not do that research at the
15 center. We're responsible for evaluating the results of
16 those studies, and we help companies in designing the
17 studies so that we get the data that we need to make a
18 safety and effectiveness decision. The research is
19 conducted under a 980 [ph] investigation. The legal
20 parts of the requirements for that are in the code of
21 federal regulations. The cite is there. Allows for the
22 shipment of an investigational drug to investigators and
23 it also allows for the authorization for the use of
24 edible tissue -- meat, milk and eggs -- from animals
25 that have been treated with an investigational drug. It

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1 allows for the conduct of studies to collect the data
2 and document it's safety and effectiveness. And there
3 are certain requirements that go along with that,
4 including labeling requirements of the investigational
5 drug, the collection of data, the maintenance of
6 records, accountability of the drug for shipment,
7 receipt and use, accountability of the treated animals
8 and their disposition and the qualifications of the
9 investigators that are allowed to do the studies.
10 Generally, we start off the process with a pre-
11 submission conference. That's a formal process that --
12 it was informal until the 1996 Animal Drug Availability
13 Act was passed, and now it results in an agreement
14 between the sponsor -- the pharmaceutical sponsor and
15 CBM, which is contractually binding on both for what
16 will be done to prove safety and effectiveness.
17 Generally, we discuss -- voluntarily agree on a product
18 development plan and protocol for each studier, or use
19 of a standard protocol for those products in which the
20 claims have proven. We have statutory definitions of
21 safety and effectiveness. For effectiveness it's based
22 on substantial evidence consisting of one or more
23 adequate and well controlled investigations. And it can
24 be done in a number of different types of combinations
25 of studies, studies in lab animals or the target

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1 species, field investigations, biocolon [ph] studies,
2 invetro studies, quite a bit of latitude there to be
3 able to mix and match the right kind of data that we
4 need to be able to conclude that the product is
5 effective. And it also has to be conducted by experts
6 that are qualified by scientific training and experience
7 to evaluate the effectiveness of the drug, and it has to
8 be -- and based on that, then the data that's generated,
9 other experts similarly qualified would be able to
10 conclude the drug has the effective -- purports to have
11 or is represented to have under the conditions of use at
12 a prescribed, recommended or suggested way. The sponsor
13 conducts the studies to generate the data following that
14 particular protocol that we work with them to develop.
15 The data is then evaluated both by the sponsor and CBM
16 for data integrity, make sure it's truthful, it's
17 accurate, there's not errors and mistakes. Then we
18 scientifically review the data to determine if it does
19 allow us to conclude that the product is safe and
20 effective. The definition of safety is a very broad
21 definition, and it's adequate tests by all methods
22 reasonably applicable to show the drug is safe under the
23 conditions prescribed, recommended or suggested. Safety
24 means really four areas. We deal with human food
25 safety, target animal safety, environmental safety and

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1 user safety. The way we try to -- the process by which
2 we develop the products, we work under a system called
3 phase review. So during the investigational phase,
4 there's a high level of interaction with the sponsor,
5 who break down the areas that they have to complete in
6 the technical sections. And those are listed there,
7 human food safety, the target animal safety,
8 environmental safety factors -- chemistry, FOI,
9 summaries and labeling. And I'm going to go into each
10 one of those in a minute. The idea is that they can get
11 decisions at each step in the process from us as to
12 whether they're moving in the right direction or if they
13 need to complete another part of that application before
14 them move forward. And when they're all completely
15 finished, then they'll file their new animal drug
16 application. For human food safety, obviously, we're
17 concerned with meat, milk, eggs. Honey is another
18 product. We look at drug residues from a couple of
19 standpoints. First of all, we're concerned about the
20 direct toxic response, and essentially an overdose kind
21 of response. We're also concerned about chronic
22 exposure. It's in our food every day, three meals a day
23 for some many years. We're also concerned about
24 indirect exposures, such as antimicrobial resistance.
25 We do a battery of studies, toxicological studies. And

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1 a few examples are listed there. We'll do genesity [ph]
2 studies, the two 90-day feeding studies in two different
3 non-target species, reproductive studies, teratology
4 [ph]. We do some -- we'll do other gene-tox studies and
5 special studies as we -- depending on the nature of the
6 compound. We ask for user safety information. And we
7 would do a -- for antimicrobials, we'll do a microbial
8 safety risk assessment for determination of the risk
9 associated with the development of antimicrobial
10 resistance in the animals that are being treated. And
11 then we also look at the impact of the drug residues
12 themselves on microbes or flora in the human gut from
13 people consuming residues from those drugs that are used
14 in treating animals. Based on all of that, we will
15 develop an OL [ph], do some calculations and some safety
16 factors. We develop a safe concentration, look at the
17 average dietary intake for each of those and then
18 establish -- excuse me -- establish a safe
19 concentration. That then is the concentration of the
20 total residue that would be allowed for a person to
21 consume in a day. We do -- then we do comparative
22 metabolism studies to make sure we have similar
23 metabolic profiles in the target species to the lab
24 animals that the tox studies were done in. We do a
25 total map, metabolism study, terradialable [ph] study in

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1 the target species, whether it's cows, pigs or turkeys
2 or so on. We develop an analytical method to be able to
3 detect the residues. We generally assign a marker
4 residue, which is either the parent or the most
5 prevalent metabolite that persists for the longest
6 duration of time, and we develop the method to that
7 marker. Then based on that marker and using that
8 method, we will determine through tissue residue
9 depletion studies how long it takes for the total
10 residue to deplete to the safe concentration by using a
11 marker that will in parallel deplete down to a level
12 that we assign as a tolerance. And when that -- the
13 residue depletes and reaches the tolerance, that tells
14 -- then when we know that the total residue has depleted
15 from the animal to a safe concentration. We publish
16 that tolerance in the code of federal regulations and in
17 21CFR, part 556. We also run our methods through
18 validation. There has to be an analytical method that
19 is developed that we can also use for residue monitoring
20 by our agency and by the inspection service in the
21 United States. Target animal safety has a little bit
22 different standard. It's a the cumulative affect of the
23 drug on the animal, such that it does not adversely
24 affect the treated animal. This has a little bit more
25 judgment associated with it. For example, if it was a

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1 drug intended to treat a skin rash, you certainly would
2 want no adverse affects whatsoever. On the other hand,
3 if it was a drug that was an anticancer drug, you would
4 be able to live with a few side affects, because the
5 nature of the drug -- the intended effect of the drug.
6 So we have veterinarians on staff, about 50 of them,
7 that make the target animal safety evaluations and to
8 make sure that the animal is not adversely affected by
9 the treatment. We do a number of studies to get at the
10 target animal safety. We do a tolerance study at 10x,
11 the proposed dose for three times the duration, to
12 characterize the toxic syndrome associated with the
13 drug. And then we'll do a chronic toxicity study, which
14 is at 0, 1, 3 and 5x of the proposed dose. The 3x
15 duration to determine the marginal safety associated
16 with the drug. If it's to be used in reproductive
17 actively animals, we do reproductive safety studies, and
18 in some cases we will go down to breeds, specific age
19 groups or other animals that we feel there's a
20 particular sensitivity associated with the drug. The
21 environmental safety, we want to make sure that use and
22 manufacture and disposal does not pose a significant
23 environmental impact. We're required to do that
24 assessment as part of our approving the new animal drug
25 application under the National Environmental Policy Act.

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1 We also have to make sure that they would be in
2 compliance with the clean water and the clean air act,
3 otherwise if we approve the drug, then the producers
4 will not be able to use the drug, because if they did,
5 they'd be in violation of those acts. What we have to
6 do is include either a categorical exclusion, which
7 essentially says that there's no circumstances under
8 which the use of this drug would cause an environmental
9 affect, or if we think there may be some, we have to do
10 an environmental impact -- an environmental assessment.
11 Excuse me. And then based on that assessment, we will
12 publish either a finding of no significant impact or an
13 environmental impact study. The number of studies that
14 we do, if we have to do an environmental assessment or a
15 number of affect studies, a number of both aquatic and
16 terrestrial species that allow us to determine the
17 impact on the environment. User safety, we're concerned
18 with the hazards associated with manufacturing the
19 product, occupational exposure at the site of
20 manufacturing, manufacturing emissions. We're concerned
21 about hazards associated with administration to the
22 animals. We're also concerned with hazards associated
23 with the use of air, water, solid waste, contaminated
24 via the use of disposal of the drug after the fact. And
25 we deal with everything from what would be the impact of

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1 someone accidentally injecting themselves on up to in
2 feed mills where a lot of the drugs are in powder form
3 and there's dust and inhalation and potential response
4 to that. So I've hit the highlights of that. I didn't
5 go into manufacturing to any great extent, but basically
6 there's a slot earlier. We document the manufacturing
7 process. They have to validate it, develop stability
8 data. All of that ensures that there's adequate
9 protection to make sure that the product is maintained
10 to it's purity in the strength and the quality. And we
11 establish an expiration date. And basically what the
12 expiration date is, is the date of which the product has
13 in test fallen outside of it's specifications and has
14 lost either the quality or the strength. So basically,
15 the NADA is a systematic approach to document the
16 evidence that drug products are safe and effective. The
17 approved drug products consist of not only the drug in
18 the container, but all of it's packaging and it's
19 labeling. And then we describe the documented evidence
20 in a freedom of information summary, an environmental
21 assessment and then the drug labeling. Basically, three
22 different audiences. The FOI summary tells the public
23 the basis upon which we made our decisions. The
24 environmental assessment speaks to any environmental
25 impacts that we anticipate. And the drug labeling is

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1 the information to the user of how to safely and
2 effectively use the product and its conditions of use.
3 And we have to file all of our approvals in the code of
4 federal regulations, and all of these documents are
5 freely accessible. That's it. I think what I'd like to
6 do, if you don't mind, is let Dr. Vengris go ahead and
7 give his presentation. But I think we're going to have
8 to shut, because he has a CD. And what we will do,
9 then, is both of will answer questions for you after
10 you've heard his presentation.

11 MR. CARTER: Okay. While you're changing that
12 and seeing as how some of us sitting here drank a couple
13 of glasses of water while were waiting for me to show
14 up, we'll take a five minute break here.

15 [Off the Record]

16 [On the Record]

17 MR. CARTER: Dr. Vengris?

18 MR. VENGRIS: Good afternoon. My presentation
19 will be different than Dr. Vahn's.

20 MR. CARTER: Please introduce yourself for the
21 record.

22 MR. VENGRIS: Yes. My name is Vitolis
23 Vengris. I'm with the Center of Veterinary Medicine in
24 the division of surveillance.

25 MR. CARTER: Thank you.

1 MR. VENGRIS: I'm pleased to attend this
2 meeting. And will attempt to introduce you to major
3 functions of the Office of Surveillance of Compliance,
4 especially those functions which could be related to the
5 areas of your interest. It was not easy for me to
6 prepare for this presentation, because I have limited
7 knowledge about the National Organic Standards Board and
8 your mandate, and also on federal standards on the line
9 of the marketing of claim of organic food. And my
10 intent today will be to describe how the FDA determines
11 the regulatory status of animal drugs. And I will not
12 imply whether those products should or should not be
13 used in animals which -- from which organic products of
14 food are derived. It is our position that food and drug
15 -- the administration of approved drugs is used
16 according to label directions are safe. The FDA has a
17 broad mandate to assure safety and effectiveness of
18 drugs, including animal drugs. Also, devices and safety
19 of the food supply. This is responsibility is derived
20 from the Federal Food, Drug and Cosmetic Act that
21 Dr. Vahn mentioned. The Act was amended in 1968 to
22 include sections, which specifically addresses animal
23 drugs. And the Center for Veterinary Medicine within
24 the FDA helps to ensure the safety of the food supply,
25 and assist in providing for the healthcare needs of

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1 animals through the approval and post-approval
2 monitoring of animal drugs. And also, we have
3 jurisdiction over medical devices -- animal medical
4 devices, and also oversight of animal feed and food
5 additives. The animal counterpart of cosmetic, which is
6 within Drug and Cosmetic Act jurisdiction, is commonly
7 referred as a grooming aid. And I refer to class of
8 products for cleansing and promoting attractiveness of
9 animals. They're not subject of FDA control, grooming
10 aids are not, unless such product has specific drug
11 ingredients or therapeutical structure or function
12 claim, then they become drugs and they are labeled as
13 such. The next slide, please. Our functions at the
14 office -- I apologize for very rich -- yeah, very poor.
15 Right. A lot of information, but I won't go through the
16 slide. I'll try to use, in the text, the major
17 functions. Our functions at the Office of Surveillance
18 and Compliance are multiple, such as monitor marketing
19 animal products. This includes drugs, devices, food
20 additives, animal feed. We evaluate a drug's direct --
21 withdraw approvals when conditions warrant. Office of
22 Surveillance and Compliance is also responsible for
23 development and implementation of policies that affect
24 marketed products. We render opinions under regulatory
25 jurisdiction, evaluate and grant or deny permission to

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1 market an approved product under regulatory discretion.
2 Also, pursuit and enforcement actions, and assure safety
3 of animal derived foods through a couple of programs,
4 the tissue residue program, which is in cooperation with
5 USDA Food Safety and Inspection Service and the National
6 Drug Residue Monitoring program, which is FDA and state
7 program of the Office of Surveillance and Compliance.
8 Also, in the office we have drug listing program. Also,
9 very important, the national antimicrobial resistance
10 monitoring system called NARMS, and this program is a
11 corroborated effort with FDA, USDA/APHIS and CBC. Also,
12 a significant part of our resources is outreach --
13 various educational outreach, mostly to the field people
14 programs. The structure of the CBM and functions of its
15 office are listed on our CBM page. And I won't go
16 through this, but in short summary, Office of
17 Surveillance and Compliance is comprised of four
18 divisions. There's a Division of Surveillance, Division
19 of Animal Feeds, Division of Compliance and Division of
20 Epidemiology. And functions among the Office of
21 Surveillance and Compliance divisions are varied, yet
22 closely related with a mandate to assure safe and
23 efficacious animal health products, protect public
24 health, including animal-derived human food supply.
25 Next slide, please. Let me stress that while the FDA is

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1 responsible of regulating animal drugs, feeds, foods,
2 devices and most other animal health products, there are
3 some classes of animal products that fall under the
4 jurisdiction of other federal agencies, specifically,
5 USDA/APHIS, which controls veterinary biologics under
6 the authority provided by the Virus and Toxin Act [ph],
7 and Environmental Protection Agency, which regulates
8 pesticides under the Federal Environmental Pesticide Act
9 and Federal Insecticide, Fungicide and Rodenticide Act.
10 However, in all those situations where residues of
11 pesticides are detected in animal derived human food
12 products, FDA has the responsibility for regulatory
13 enforcement. FDA is responsible for programs and the
14 regulatory actions aimed at preventing illegal drug
15 residues in human food derived from treated animals.
16 This is a corroborative effort with USDA Food Safety
17 Inspection Service, and which they are responsible for
18 the inspection part. Also, I should point out that
19 jurisdiction of authority of some of the products is not
20 always clear. And the memorandums of understanding or
21 the memorandums of agreement between the agencies,
22 delineate procedures and responsibility, including
23 criteria in the specific classes of products for
24 regulatory control. For example, some products used to
25 control external pests that intended to act

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1 systematically, are regulated as drugs, such as oral
2 control of anti-flea products. Where it's topically
3 applied, flea control products generally fall under EPA
4 jurisdiction. Currently, center for vet medicine and
5 APHIS, which is USDA, have established working groups
6 mandated to update the memorandum on the health
7 understanding between CBM and APHIS. And also at the
8 present time, representatives from the CBM and EPA are
9 discussing the update of their memorandum of agreement
10 on jurisdiction of the issues between CBM and EPA. Next
11 slide, please. And now let me introduce you to basic
12 statute definitions of animal drug, animal biologic
13 product and pest control, which will better illustrate
14 why we sometimes have these jurisdiction of issues. You
15 saw that definition in previous presentation. Next
16 slide, please. And definition of animal biologic
17 product -- some people maybe cannot see well, because of
18 the -- this animal biologic -- anyway, drugs -- articles
19 intended -- I repeat what was said before -- articles
20 intended for use in the diagnosis, cure, mitigation,
21 treatment or prevention of disease in men or other
22 animals and articles other than food intended to affect
23 the structure and the function of the body of men or
24 other animals. That would be the next slide. Animal
25 biological products, all viruses, serums, toxins or

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1 analogous products which act primarily through the
2 direct stimulation, supplementation and enhancement or
3 modulation of the human system or the human response to
4 diagnose, cure, mitigate, treat or prevent disease in
5 animals. The term, "biological products," includes, but
6 is not limited to vaccines -- allergens, antibodies,
7 toxoids, immunostimulants, certain -- like cytograms
8 [ph], like -- humanizing components of -- microorganisms
9 and diagnostic components of natural or synthetic
10 origin. And the next slide, pesticide definition. The
11 term pesticide means any substance or mixture of
12 substance intended for preventing, destroying, the
13 deterring or mitigating any pest, and second part, which
14 is any substance or mixture of substances intended for
15 use as a plant defoliant or -- it does not apply to the
16 CBM. And continuation of the definition, provided that
17 the term "pesticides" shall not include any article that
18 is a new animal drug, and B, that has been determined by
19 the Secretary of Health and Human Services known to be a
20 new animal drug by a situation establishing conditions
21 of use for that article. And the second part, works as
22 an animal -- or containing this article of -- as you may
23 see, there is an adverse overlap, and it is not all this
24 easy to resolve this problem. Because mechanism of
25 action in animal biologics is the key factor, nature and

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1 mechanism of action, and that's the reason memorandums
2 of understanding and agreement between agencies are
3 very, very important. And with changing science and
4 changing our legislature, processes, it has to be
5 modified. There are two other reasons that expanded the
6 veterinarian's authority in the area of drug use.
7 Specifically, the Animal Medicinal Drug Use
8 Qualification Act of 1994, also known as AMDUQA, and the
9 Animal Drug Availability Act of 1996, ADAA. AMDUQA
10 allows the use of approved animal drugs in an extra --
11 manner, including human drugs for use in animals under
12 certain specified conditions. And ADAA helps streamline
13 the animal drug approval process and also authorizes a
14 new category [ph] of veterinary feed directive drugs,
15 which may be used in animal feeds. Next slide, please.
16 This is also repetition. Dr. Vahn gave that definition
17 of new animal drug. But once a product is determined to
18 be a drug, as I mentioned, it's not always easy, because
19 some products could fall under EPA jurisdiction, ours or
20 the USDA determines it to be a drug. The next step is
21 to establish whether or not it is a new animal drug.
22 And the directive defines a new animal drug -- this is
23 in part -- as any drug intended for use for animals
24 other than men, the composition of which is not
25 generally recognized among experts qualified by

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1 scientific training and experience as safe and effective
2 for use under the conditions prescribed, commanded or
3 suggested in its labeling. Labeling -- label claims are
4 the key factor in the product's status. By virtue of
5 "interpretations," there are, for all practical
6 purposes, no animal drugs which are not out of new
7 animal drugs. Of course, there are exceptions. The
8 approval process, grandfathered, but I won't discuss
9 these issues. Most of us are well aware of the fact
10 that today there are many unapproved new animal drugs on
11 the market. According to our CBM drug listing database,
12 there are about 1,260 unapproved versus 3,160 -- 1,260
13 approved and 3,160 unapproved active products. Drug
14 listing meaning new drug list or active products, which
15 are in the market. The listed requirement, if the
16 company doesn't register manufacture site or drug list
17 -- the number of unlisted unapproved active animal drugs
18 is unknown. We recognize the need for some of
19 unapproved products to be available for veterinary
20 profession, animal growers and animal owners. Center
21 for Veterinary Medicine permits some unapproved new
22 animal drugs to be marketed under so called regulatory
23 discretion. Sometimes CBM does not take regulatory
24 action protocol at this time, because of rather low
25 regulatory priority of a valid product. This is mainly

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1 due to our agency's limited resources. And some
2 misbranded and/or adulterated, unapproved products are
3 subject -- and we take enforcement action. Our priority
4 scale for enforcement of actions is based on following
5 conditions that we have. The highest priority with full
6 products which have potential for a drug's effect on
7 humans, either through unsafe residues occurring in food
8 or from direct exposure of the product. Then a hazard
9 to the target animals, and lastly, the products, which
10 are relatively safe, but of questionable effectiveness
11 in non-life threatening disease conditions. Of course,
12 exceptions always exist. And even in very lean
13 budgetary times, the agency's trying to protect public
14 from any fraud. As I have already mentioned, Office of
15 Surveillance and Compliance is responsible for rendering
16 regulatory discretion and allows some unapproved
17 products to be marketed. It is usually done on a case
18 by case basis for classes of products. And the main
19 criteria for this determination is, of course, safety
20 and ethical -- of a product. I should emphasis that
21 there are a number of factors, such as the nature of --
22 ingredients claims. I always like to use little example
23 that drinking water obtained from some nice spring and
24 labeled to treat brain tumor is a drug -- a new animal
25 drug and action. It means claims, again, meet -- active

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1 ingredients claims meet of the product and availability
2 of approved similar products, published scientific
3 information available, conditions of use also allow
4 regulatory discretion if a product has prescription
5 legend versus OBC [ph]. It's case by case on specific
6 warnings. And that definition of process. At this
7 point, it is important to emphasize the difference
8 between FDA approved and allowed or permitted animal
9 products. I think we have miscommunication with some of
10 the people. As Dr. Vahn illustrated in his
11 presentation, the first approved product goes through
12 very thorough, rigid approval process. And in the
13 latter case, products which were allowed under
14 regulatory discretion, agency grants regulatory
15 discretion, which we always may withdraw. And it could
16 be based on new needs or new information or if a similar
17 product is being approved and appears on the market.
18 That's what -- and also, the organizers of this meeting
19 asked me -- us to come on serious position on the use of
20 homeopathic treatments. And that, I guess -- I have a
21 few sentences on this. We consider them to be
22 unapproved new animal drugs and evaluate them also on
23 case by case basis. The compliance policy regs on human
24 homeopathic drugs do not apply to animal homeopathics.
25 They're also not subject to the provisions of any FDA

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1 policy involving the regulation of human homeopathic
2 drugs. It is -- excuse me. It is our opinion that
3 veterinary homeopathic drugs should be regulated and
4 held to the same scientific status of safety and
5 efficacy as any veterinary drugs. One of the risks in
6 the reliance on homeopathic veterinary products is that
7 there may be a delay in obtaining proper veterinary
8 treatment in some life threatening disease conditions.
9 Moreover, in the ADMA guidelines for a product
10 alternative and complimentary veterinary medicine,
11 recommendation is for product research to be conducted
12 in veterinary homeopathy to evaluate efficacy
13 indications and limitations, because research in
14 veterinary homeopathy is limited. The -- also recommend
15 that veterinary homeopathy be practiced only by licensed
16 veterinarian who have been educated in veterinary
17 homeopathy. For example, over-the-counter veterinary
18 homeopathic products labeled as for -- conditions would
19 be the sufficient priority for our regulatory action.
20 Thank you. That's all I have, as far as presentation is
21 concerned.

22 MR. CARTER: Thank you, Dr. Vengris. Let's
23 open it up for questions. Apparently, we're getting
24 some feedback, because all of us have got laptops
25 running at the same time here and it's causing some

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1 feedback with the microphones, so we'll try to move them
2 away from the microphones or shut them down here. So
3 anyway, let's open it up to questions. Yeah. Rebecca?

4 MS. GOLDBERG: I was wondering if the FDA has
5 a list of unapproved products that the agency is
6 allowing on a basis of regulatory discretion?

7 MR. VENGRIS: No.

8 MS. GOLDBERG: Was it 1,260 unapproved?

9 MR. VENGRIS: No, no. That's 1,200 -- our --
10 we have drug listing database that companies have to
11 list products. 1,260 -- we have about 1,260 approved
12 products in our drug listing, and we have more than
13 3,000 unapproved. But the number of unlisted and
14 unapproved, I don't know. No one...

15 MR. VAHN: What I might add, when we say that
16 a product is marketed without being approved, it's under
17 a certain set of conditions. The FDA and Dr. Vitolis --
18 Dr. Vengris is -- the division that evaluates the
19 labeling to make sure that the reasonable claims and
20 appropriate cautions are on the labels, products have to
21 be drug listed and the establishments where they're
22 manufactured have to be in our official inventory so
23 they can be -- they are still subject to the
24 manufacturing practice regulations for how the products
25 are manufactured. They have to be done in a way that --

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1 similar to approved drugs, where there -- you maintain
2 the quality, purity and strength of the products. The
3 -- when they market them, then they have to drug list,
4 but they're not required to then state the safety and
5 effectiveness prior to approval. But the things on the
6 label may include that they may be limited only to be
7 marketed for certain claims or they may be limited to
8 prescription status.

9 MR. SIEMON: So one more thing.

10 MR. VENGRIS: Um-hum.

11 MR. SIEMON: Then numbers that you just
12 quoted, and you said 1,260 approved...

13 MR. VENGRIS: Yes.

14 MR. SIEMON: ...and what was the other?

15 MR. VENGRIS: I think 3,000...

16 MS. GOLDBERG: 160.

17 MR. VENGRIS: No, no, no.

18 MR. VAHN: Somewhere over 3,000.

19 MR. VENGRIS: We have more than 3,000
20 unapproved, but drug listed products in our database.

21 MS. GOLDBERG: Can you state which -- I'm
22 sorry.

23 MR. VAHN: Go ahead.

24 MR. VENGRIS: Approved product goes to Office
25 of New Animal Drug Evaluation and goes through the

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1 approval process as established new animal drug
2 application. All conditions which you -- which Dr. Vahn
3 named, safety and efficacy studies, they -- these
4 approved product go through that rigid process.
5 Unapproved products which are allowed to be marketed
6 under regulatory discretion, you know, just meaning what
7 you said, will base that regulatory discretion on label
8 claims on nature of the product, warnings, conditions
9 for use and also manufacture and other requirements, is
10 to ensure that good manufacturing.

11 MR. CARTER: All right. Are there -- oh,
12 let's see. Rose?

13 MS. KOENING: Well, I have a clarification on
14 that and then I have something -- so you're saying that
15 those unapproved...

16 UNKNOWN: Microphone.

17 MS. KOENING: Oh, sorry. So you're saying --
18 oh, I forget. You're saying the unapproved is lawful?

19 MR. VENGRIS: No. We'll allow -- some of them
20 we'll allow under regulatory discretion we have
21 authority to allow.

22 MS. KOENING: Right. As long...

23 MR. VENGRIS: But we can change our mind.

24 MS. KOENING: Right, right.

25 MR. VENGRIS: It's much easier for us to start

1 marketing of unapproved drug than approved. Approved,
2 you have to go through the process and so on and so
3 forth. It is sort of -- rather a complicated process.

4 MS. KOENING: But it's -- but what...

5 MR. VAHN: Or it's semantics, a little bit.
6 If you say is it lawful, we have to say, no, it's not
7 lawful, because it's in violation of the statute. But
8 he executive branch -- all agency's executive branch can
9 set their own limits on regulatory discretion, below
10 which, we're not concerned, above which, we are. So for
11 example, we'll take a product that was on the list of
12 concerns, calcium fluoroglucamate [ph]. It's used for
13 the treatment of milk fever [ph]. It's prescription,
14 it's manufactured under the good manufacturing
15 practices, it's a sterile product -- injection, that is
16 not approved, but we allow it to be marketed under those
17 conditions by regulatory discretion. We have better
18 things to do than to go out and enforce the manufacturer
19 of the calcium fluoroglucamate to go through the
20 approval process.

21 MS. KOENING: Okay. So -- but...

22 MR. CARTER: Okay.

23 MS. KOENING: Yeah. I think...

24 MR. CARTER: Let Rose...

25 MS. KOENING: Well, that's what I'm trying to

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1 understand, you know, digest what you've presented to us
2 and then the work that we do and how it relates to your
3 agency. So what I'm understanding is that number one,
4 we can't -- we certainly can't approve anything that's
5 not -- that's a new claim, because then it would be
6 considered a new drug and it would have to go through
7 this process.

8 MR. VENGRIS: No, you can approve -- you can
9 get approval going through approval process.

10 MS. KOENING: Yeah. But I'm saying if
11 somebody comes to us with a petition that's not in our
12 jurisdiction to make a new label claim, that is
13 considered a new drug, it's got to go through you, and
14 then we can see if that -- once you've said it's -- but
15 what we -- if something is labeled for a specific use,
16 you determined it to be -- you know, you've approved it
17 and it could be on either of these types of products,
18 then we do have the ability then to determine if it is
19 or is not appropriate under organic systems?

20 MR. VENGRIS: I don't know your mandate, but,
21 yes, the products approved -- allowed under regulatory
22 discretion, and the third group which would take them
23 forward to action.

24 MS. KOENING: Okay. And then the last
25 question I have, on those agencies -- APHIS and...

1 MR. VENGRIS: EPA?

2 MS. KOENING: ...EPA. Many of the things that
3 I think fall within what we're looking at are those that
4 are not systemic. A lot of them are -- and I understand
5 that -- so that sounds like it would EPA.

6 MR. VAHN: Right.

7 MS. KOENING: Now, how is that memorandum of
8 understanding set up in terms of what we do? Then do we
9 go then -- if we're going to allow something that is
10 under the jurisdiction of EPA, then who do we -- where
11 do we get our information or who do we have to check
12 with, the EPA or FDA?

13 MR. VENGRIS: I think that if it is a EPA
14 regulated product, you would -- we're talking about
15 pesticides, right? We're not talking about animal
16 biologics.

17 MS. KOENING: Or biologics.

18 MR. VENGRIS: Well, then permission and --
19 what you have to get from them. But if you have a
20 product which you don't know whether it's EPA or FDA
21 regulated, then I would suggest you contact FDA, because
22 we have working groups, we have standing committees, and
23 we try to determine -- and even we have to spend time
24 and discuss the sheet where the specific product belongs
25 to.

1 MR. CARTER: Becky and Jim and Barbara.

2 MS. GOLDBERG: I'd like to get my arms around
3 it a little better about unapproved products. If I as a
4 member of the livestock committee of the NOSB want to
5 find out an approved product, I can go to CFR, I can go
6 to your website and get a fair amount of information.
7 But if I look at a product and to me it makes sense that
8 it's an animal drug, that it's not approved, how do I
9 find out whether it's an unapproved product that you're
10 allowing to be marketed under regulatory discretion? Is
11 there anyway the public can get that information?

12 MR. VENGRIS: You could -- and Dr. Vahn made
13 -- approved products are qualified in 21CFR and green
14 book on our website. It's not difficult to find out.
15 There is now list of products which are allowed under
16 regulatory discretion. And also, I would just like...

17 MS. GOLDBERG: Do you know this? No, no, no.
18 Wait.

19 MR. VENGRIS: No specific list, because also
20 it depends on a claim, because maybe ingredient is same
21 ingredient, but indications -- we would never allow a
22 product to be marketed under regulatory discretion.

23 MR. CARTER: Jim? Or do you need to follow
24 up...

25 MS. GOLDBERG: Can I just follow up a little

1 bit on that? So what you're telling me is there is no
2 way to find out, basically, about these unapproved...

3 MR. VAHN: You can ask.

4 MS. GOLDBERG: We can ask. Right.

5 MR. VAHN: You can ask us.

6 MS. GOLDBERG: Right.

7 MR. VAHN: We'll be glad to help you out...

8 MS. GOLDBERG: Yeah.

9 MR. VAHN: ...because chances are you'll
10 probably trip across a few we weren't aware of...

11 MS. GOLDBERG: Okay.

12 MR. VAHN: ...and probably shouldn't be out
13 there as well.

14 MS. GOLDBERG: Okay. One of the challenges
15 always as a member of the public who's interested in
16 animal drug issues...

17 MR. VAHN: Um-hum.

18 MS. GOLDBERG: ...is to get information
19 because of the -- part of the Food, Drug and Cosmetic
20 act, which basically makes drug approval confidential,
21 does that same secrecy apply to the unapproved products
22 which you're allowing on the market?

23 MR. VAHN: No. There really isn't any
24 confidential proprietary information. The
25 confidentiality is provided only when they are working

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1 under an investigational new animal drug exemption or
2 they have a new animal drug application.

3 MS. GOLDBERG: And once it's approved I still
4 can't get all the information.

5 MR. VAHN: That information is still in those
6 files and it is protected, but it's summarized in the
7 documents that...

8 MS. GOLDBERG: Right, summarized.

9 MR. VAHN: Now, that data doesn't exist if we
10 don't ask for it in those products that are unapproved
11 and we allow to be marketed.

12 MS. GOLDBERG: Right. If you're in a process
13 of decision making about an unapproved product, can I as
14 a member of the public call you and get that information
15 or is that still...

16 MR. VAHN: Generally, not...

17 MS. GOLDBERG: Right.

18 MR. VAHN: ...because it's under development.

19 MS. GOLDBERG: I'm going to yield to Barbara
20 in the follow up, because she...

21 MR. CARTER: Okay. Barbara? And you have to
22 come up to the microphone.

23 MS. BROWN-ROZEN: I just -- do I have to
24 identify me?

25 MR. CARTER: Yeah.

1 MS. BROWN-ROZEN: Yes.

2 MR. CARTER: We have a short attention span.

3 MS. BROWN-ROZEN: Barbara Robinson, NOP, USDA.
4 So what I think you might be able to do -- and I'm going
5 let Steven tell me if I'm wrong -- is that you would in
6 a case of Pepto-Bismol for example, or something like
7 that -- an unapproved, but allowed substance or drug, if
8 you wrote your annotation as in accordance with FDA's
9 permitted use, that would probably cover whether FDA
10 approves it or doesn't approve it, but allows it? Is
11 that -- or have I gotten too specific for FDA? In
12 accordance with FDA's permitted use.

13 MR. VAHN: Yeah, you would need to do that.
14 We could probably help you with a little bit of language
15 -- we may have a little trouble with drug permitted...

16 MS. ROBINSON: Right.

17 MR. VAHN: ...but we can work on that.

18 MS. ROBINSON: Yeah. See, we're not the only
19 agency that has those semantic things.

20 MR. VENGRIS: And also, I would like that --
21 who would -- you offer claim and who could say -- it is
22 very difficult question. We may allow those claims to a
23 product.

24 MR. VAHN: Yeah. I think you're looking for
25 more of an umbrella...

1 MS. ROBINSON: Yeah.

2 MR. VAHN: ...the caveat of what the...

3 MS. ROBINSON: And you're saying the --
4 through FDA is the label claim. Because the minute you
5 make that label claim, you've set in motion some -- you
6 know, you've said, okay, this Pepto-Bismol is for
7 control of or treatment of, and then you've made a label
8 claim and now you've set in motion FDA as saying, well,
9 we don't know if that label claim holds up or whether
10 it's been approved for that. And that sets in motion
11 your whole process.

12 MR. VAHN: It triggers the definition of the
13 drug and not -- that has to be proven, so...

14 MS. ROBINSON: So that's the thing you don't
15 want to do, is you don't want to trip FDA's process
16 they'll go in, because we're likely to be way out in
17 left field forever.

18 MR. VAHN: But...

19 MR. CARTER: Okay. Okay. Because the next
20 couple of questions I think will...

21 MS. ROBINSON: Yeah. We actually were
22 thinking very well alike. Because what I was hearing
23 was that for the materials that are on -- these
24 unapproved materials that obviously are being used by
25 the industry...

1 MR. VAHN: Um-hum.

2 MS. ROBINSON: ...that it's -- the best thing
3 for us to do is to have an annotation to those materials
4 versus being too specific for their use and let that
5 fall under the FDA and the veterinarians use. You know,
6 withholding -- were specific and that's what I'm
7 hearing. So I just want to clarify that.

8 MR. VAHN: And we can -- we'd be happy to help
9 you with some of those examples.

10 MS. ROBINSON: Okay.

11 MR. VAHN: For example...

12 MS. ROBINSON: It doesn't mean that we can't
13 review the material for what it's being petitioned for.

14 MR. VAHN: Right. Let me give you a couple
15 examples. For example, on the list that you sent to us,
16 you were concerned about acculated charcoal,
17 calciumfloragluamate...

18 MS. ROBINSON: Yeah.

19 MR. VAHN: ...and those are products that --
20 and the business -- and those -- well, let me deal with
21 -- those products are products that under those certain
22 label conditions and whatnot, we've allowed to be
23 marketed by regulatory discretion. There were a couple
24 of other products on there like chloral phenol [ph] and
25 xylazine [ph]. Those products we would require an

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1 animal drug application to be approved before those
2 products could be marketed for use. Now, having said
3 that, unless they're on this prohibited list, which
4 is...

5 MS. ROBINSON: And it's not yours.

6 MR. VAHN: ...our prohibited list, from extra
7 label [ph] use. That's 21CFR-530. We do allow those
8 products to be used in an extra label manner by
9 veterinarians with a whole lot of caveats, that there's
10 a valid veterinarian/client/patient relationship,
11 there's not another drug available that is effective for
12 that particular clinical need and there -- the
13 veterinarian has taken adequate steps to ensure the
14 human food safety -- public health safety from the use
15 of those products and that extra labeling.

16 MS. ROBINSON: So from a materials review
17 standpoint, we need to do a little more work up front,
18 which we all know...

19 MR. VAHN: Right.

20 MS. ROBINSON: ...we need to do that, and
21 before it gets to this process, we have exactly what --
22 whether it's an approved and it's use or unapproved or
23 this other -- it allows...

24 MR. MATTHEWS: We're bringing it to you under
25 regulatory discretion.

1 MS. ROBINSON: Right. But the third one,
2 unlisted, unapproved, you're saying there's some that
3 are -- that's a real bad group.

4 MR. VENGRIS: No, not necessarily. Some of
5 them -- there maybe some manufactures don't know that
6 they have to. It's not an excused ignorance, but that
7 they have to drug list. But there is another group
8 which are really violative [ph] products which we take
9 enforcement action. I'm not implying that any
10 unapproved, unlisted is granted because it's not listed.

11 MS. ROBINSON: It hasn't gone through the
12 process.

13 MR. CARTER: Okay. I've got George.

14 MR. SIEMON: Yeah. Barbara, the thing I'm
15 concerned about is the letter that we have from Sharon
16 Bentz [ph], trigger list. It says purely, we cannot
17 have any FDA approved materials.

18 MS. ROBINSON: It may have been...

19 MR. SIEMON: Maybe the FDA...

20 MS. ROBINSON: The word approved there may
21 have a different meaning.

22 MR. CARTER: This is goes back to what like
23 Rosalie was saying. Well, okay. And then that's what
24 we're trying to clear up. It goes back to a point Rose
25 was making. Are they lawful?

1 MR. MATTHEWS: Well, by a strict reading of
2 the Federal Food, Drug and Cosmetic Act, the unapproved
3 drugs we allow to be marketed by regulatory discretion
4 are not lawful. May they be marketed, yes. But just
5 because that's within our purview to say whether they
6 can be or can't be...

7 MR. SIEMON: I know, but -- okay. First of
8 all, so you're disagreeing with the letter from the FDA,
9 is that what I'm hearing?

10 MR. MATTHEWS: Yes, I am.

11 MR. SIEMON: But our list is also a CFR list.
12 And so I thought the conflict is we're going to have one
13 CFR list that has the material that isn't in your CFR
14 list.

15 MS. ROBINSON: No, you won't. You won't.

16 MR. SIEMON: Okay. All right.

17 MS. ROBINSON: In the first place...

18 MR. SIEMON: So...

19 MS. ROBINSON: ...they come first. They say
20 -- they define the universe and we will live with that
21 universe, because you don't supercede their authority.
22 What you need to know is where they are boundaries and
23 where they are permitted uses and stay within that
24 language. And truthfully, except for the drugs that are
25 out there that haven't -- somebody hasn't petitioned for

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1 their use and they haven't gone through your process,
2 whether good, bad or indifferent, you're probably not
3 going to confront -- you're not going to be asked to
4 approve something that FDA wouldn't have already...

5 MR. MATTHEWS: Yeah.

6 MS. ROBINSON: ...I doubt it.

7 MR. MATTHEWS: Well, we do. There's a lot of
8 things that fall under their feed world or grass -- feed
9 that are being used for preventative measures, and
10 that's where you got into that unlisted, unapproved
11 world. If you understand unlisted and unapproved
12 drugs...

13 MR. VAHN: Well, that's the drugs. When we go
14 into the feed world, there's a couple of other
15 provisions that you need to be aware of. Later in the
16 500 parts of the CFR, we do have all of the generally
17 recognized as safe products listed and they are listed
18 not only as a chemical entity, but as the use under
19 which they are considered grass. So they're all -- they
20 are also unlisted.

21 MR. MATTHEWS: As a feed additive.

22 MS. ROBINSON: Right.

23 MR. SIEMON: But now I'm talking about the
24 feed additives that are used rightfully or wrongfully as
25 a preventative measure in livestock health...

1 MR. MATTHEWS: Okay.

2 MR. SIEMON: ...which is very close to what
3 your statement on what you use the ketosis treatment
4 for. That's your discretion where you call it an aid
5 and prevention treatment of ketosis [ph].

6 MR. MATTHEWS: Right. I wouldn't say
7 discretion.

8 MR. SIEMON: Now, these are the same uses that
9 we have...

10 MR. MATTHEWS: Okay.

11 MR. SIEMON: ...for feed or...

12 MR. MATTHEWS: And that's -- some of those
13 products are at least misbranded foods -- have not --
14 unapproved, adulterated new animal drugs by virtue of
15 the claims they make. If you have, let's say, a mineral
16 mix. A mineral mix is for in the supplemental nutrition
17 of the animal. That's fine. If it's intended to allow
18 the animal to live up to it's genetic potential, that's
19 wonderful. But as soon as they cross the line and they
20 say it's intended to -- for the mitigation of disease or
21 cure or treatment, prevention, all those things we put
22 in the definition, then it becomes a drug, and at that
23 point it becomes either a misbranded food or
24 adulterated, unapproved new animal drug.

25 MR. SIEMON: I see.

1 MR. MATTHEWS: And that's where it crosses the
2 line. So you can change the product merely by changing
3 what's on its label.

4 MR. CARTER: Okay. Are you...

5 MR. SIEMON: This is the...

6 MR. CARTER: Go ahead.

7 MR. SIEMON: ...product that have to do with
8 them...

9 MR. MATTHEWS: Um-hum.

10 MR. SIEMON: ...because that's been our
11 authority. Well, now that we've said that the previous
12 letter didn't -- the approved only, now we can go to
13 this allow according to FDA permission. That now gives
14 us permission AMDUQA drugs.

15 MR. MATTHEWS: Okay. Depending under this...

16 MR. SIEMON: They're still approved drugs, I
17 know that. But...

18 MR. MATTHEWS: Okay.

19 MR. SIEMON: But with the approved drug -- and
20 where you state according to permitted use, but we're
21 never going to say for the non-label use in our docket,
22 no. Because we have -- I don't think we use -- there we
23 are -- not approved for dairy. And we know they're used
24 in dairy. We wrote our standard for dairy, you came
25 back and said, no, you can't do that. So now we're just

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1 going to take the for dairy out and it will then still
2 be okay under the veterinarian -- I understand all the
3 conditions there. What was used under AMDUQA will now
4 be okay as long we take the word dairy out of our
5 recommendations.

6 MR. MATTHEWS: Let me make a final
7 distinction. You guys can set the standards wherever
8 you want. We're not trying to tell you where to set
9 your standards.

10 MR. SIEMON: Well...

11 MR. MATTHEWS: If you have an approved -- we
12 have the two classes of drugs, essentially. The
13 approved drugs and the unapproved drugs. And you're
14 allowed -- and you're likely to encounter both. The
15 unapproved drugs that we allow to marketed by regulatory
16 discretion. In other words, we got better things to do
17 than to go after them. Under AMDUQA, the off-label,
18 only approved drugs can be used in an alterable manner.
19 Unapproved drugs marketed by regulatory discretion may
20 not be used. They are not part of AMDUQA. So we'll
21 make that distinction.

22 MR. SIEMON: I understand. That was my
23 question. If we approve an approved drug...

24 MR. MATTHEWS: Um-hum.

25 MR. SIEMON: ...and but our approvals were

1 AMDUQA used, we just can't list that use in the -- our
2 standard?

3 MR. MATTHEWS: That's not our purview.

4 MR. SIEMON: Okay.

5 MR. MATTHEWS: That's your decision as to what
6 you list as...

7 MR. SIEMON: That's not what I've heard. I'm
8 trying to deal with the letter I have from you all here.
9 I'm...

10 MR. MATTHEWS: We would consider that use
11 illegal because of our statute that says it's
12 unapproved. But if the use by a veterinarian under the
13 conditions of AMDUQA is legal. And I was just confusing
14 you.

15 MR. SIEMON: Okay. One more thing. What
16 about unapproved materials? Can we put an unapproved
17 material under our health section?

18 MR. MATTHEWS: That's not our jurisdiction.

19 MS. ROBINSON: There is -- unapproved or
20 allowed with FD -- under FDA discretion.

21 MR. CARTER: Okay. Now, let's go down the
22 order here, because I have Jim and I have Andrea and I
23 have Rose and Mark.

24 MR. RIDDLE: Yeah. Well, we were getting
25 exactly to where I wanted to ask a question. And that

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1 is, it's not just an issue of annotation, but where we
2 place it on our list. It's under the federal -- the
3 organic regulation. There's just five categories for
4 these livestock materials, and that's as a disinfectant
5 and sanitizer, medical treatment as applicable. That's
6 one category. Then that's where we've been placing
7 these kind of products. But otherwise, our only other
8 choices are as a topical treatment, external
9 parasiticide and local anesthetic, as a feed supplement,
10 a feed additive or a synthetic inert ingredient in a
11 pesticide. Should we -- yeah. So you can see that if
12 we place a product -- an unlisted, unapproved, but
13 regulatory discretion under that first list, then we are
14 saying it -- you know, can make a medical claim. And
15 I'm just wondering if we need to be looking at another
16 category there in our list that matches up better with
17 yours?

18 MR. MATTHEWS: Well, I think your list is --
19 totally overlaps...

20 MR. RIDDLE: Okay.

21 MR. MATTHEWS: ...with a lot of different
22 agencies' jurisdiction. And I would say your topical --
23 you know, let's take a product that was invented to
24 treat lice in cattle. That can be -- depending on how
25 it works, if it's topically applied and it works

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1 locally, that's regulated by EPA.

2 MR. RIDDLE: Yeah.

3 MR. MATTHEWS: If it is like viromecta [ph]...

4 MR. RIDDLE: Right.

5 MR. MATTHEWS: ...or, you know, amoxidectrin
6 [ph], some of the other products that are systemically
7 absorbed, that's a drug, the way we divvy that up. And
8 that's regulated by us. And they would -- we would
9 require approval for those products. On the other hand,
10 there are dusts and powders and stuff that are out there
11 that are probably marketed by regulatory discretion as
12 well. So your categories in no way line up with our
13 categories.

14 MS. ROBINSON: I don't think you need to worry
15 about the words in your -- the categories in your list.
16 It's the -- you could put it in box X. The important
17 thing is that you're not prescribing a use or a set of
18 conditions, you're not superceding FDA's authority and
19 you're not saying, well, we know that, you know, sugar
20 is really a sweetener, but we're going to say sugar is
21 used for -- we're going to allow sugar for the treatment
22 of...

23 UNKNOWN: Lice.

24 MS. ROBINSON: ...lice. I mean, because...

25 MR. MATTHEWS: There's people.

1 MS. ROBINSON: These aren't real examples.

2 MR. MATTHEWS: No.

3 MS. ROBINSON: Well, I can't think of any.

4 UNKNOWN: Aloe vera.

5 MS. ROBINSON: Okay. But if you're going to
6 put aloe vera in the category. But then if you say
7 aloe vera is allowed for the treatment of or the
8 prevention of some disease, you've overstepped your
9 bounds. Why don't you just simply say aloe vera --
10 put in the category you want.

11 MR. RIDDLE: Okay. But if we put in A...

12 MS. ROBINSON: No.

13 MR. CARTER: Let Jim finish and then...

14 MR. RIDDLE: Yeah. That's my question. If we
15 put something like aloe or magnesium, you know, in a
16 digestive -- under A, isn't that making a medical use
17 claim by placement on that -- under that category?

18 MS. ROBINSON: I don't think so. I don't
19 think that...

20 MR. MATTHEWS: So long as we, you know, link
21 it to allowed under regulatory discretion.

22 MS. ROBINSON: Yeah. I think that's the --
23 now, I do think we might have to ask our lawyers that,
24 but I don't think the fact that you put it under that
25 category is making a claim that contradicts FDA. I

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1 think it's you annotations that are causing the
2 problems.

3 MR. CARTER: All right.

4 MS. ROBINSON: I don't think...

5 MR. CARTER: Andrea? Andrea's up next. Okay.
6 Oh, okay.

7 MR. RIDDLE: To respond to this one.

8 MR. CARTER: Okay. Sorry. I didn't realize
9 there was...

10 MR. VAHN: It probably does. It's going to
11 take your general counsel's opinion on this, but -- and
12 I'm not sure of the context in which you're listing
13 these products. If you're listing them merely whether
14 they are allowable for use to meet an organic standard
15 or not an organic standard, I'm not so clear that you
16 would be making an assertion that these are, therefore,
17 by definition a drug or a biologic or a pesticide. And
18 I think merely listing them as whether they're allowable
19 for use as an organic would necessarily be saying that
20 -- you're saying they're a new animal drug, or they're
21 approved for use.

22 MR. RIDDLE: Or even if they're approved.

23 MR. VAHN: Yeah.

24 MR. RIDDLE: But they're under the...

25 MR. VAHN: I think what Barbara was trying to

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1 get is maybe what you want to do is put some broad
2 statements and that they are approved in accordance with
3 FDA's regulations or something like that.

4 MR. RIDDLE: Okay. Can I just follow up your
5 one example that's on that list A, aspirin.

6 MR. VAHN: Okay.

7 MR. RIDDLE: That's not an approved drug,
8 correct? That's a low priority...

9 MR. VAHN: Yes.

10 MR. RIDDLE: ...and allowed under regulatory
11 discretion.

12 MR. VAHN: Yes.

13 MR. RIDDLE: And it's in our list A as a
14 disinfectant, sanitizer and medical treatment, as
15 applicable, with the annotation, approved for healthcare
16 use to reduce inflammation.

17 MR. VAHN: Well, when you say approved...

18 MR. VENGRIS: Approved by whom?

19 MR. VAHN: ...you're saying approved for...

20 MR. RIDDLE: Approved for...

21 MR. VAHN: ...organic use.

22 MR. RIDDLE: For organic use.

23 MR. RIDDLE: Yeah.

24 MR. VAHN: You're not making an assertion that
25 it's an approved drug.

1 MR. RIDDLE: So that example, you don't have a
2 problem with...

3 MR. VAHN: I'm not...

4 MR. RIDDLE: Yeah. I think if we were to do
5 it over again, we might shorten or eliminate that
6 annotation.

7 MS. ROBINSON: Right.

8 MR. VAHN: You're not approving the marketing
9 of the product...

10 MS. ROBINSON: Exactly.

11 MR. VAHN: ...you're only approving...

12 MS. ROBINSON: The use.

13 MR. VAHN: ...the use under and still meet the
14 qualifications of an organic product.

15 MR. RIDDLE: Uh-huh.

16 MR. VAHN: Correct?

17 MR. RIDDLE: Yeah.

18 MR. VAHN: Then I think there's a distinction
19 here that we can make.

20 MR. RIDDLE: Okay. And that's not a problem.

21 MR. VAHN: I don't see one.

22 MR. RIDDLE: Yeah. You don't see one.
23 That's...

24 MR. VAHN: But I think Barbara has a good idea
25 of what -- if we need to get a legal interpretation.

1 MS. ROBINSON: Well, you know, also, Rick is
2 suggesting that perhaps that part of the problem lies
3 with the fact that you do have all these sub-categorical
4 uses. It's either suitable for organic livestock
5 production or it's not. And then it has to be --
6 because you always have to be in accordance with
7 existing regulatory schemes of the EPA, FDA and APHIS
8 and FSIS. You could -- no matter what you wrote, you
9 can't -- you can't supercede those existing regulatory
10 forms.

11 MR. CARTER: Okay. Yeah. I've forgotten.
12 Andrea?

13 MS. CAROE: Okay. So based on the facts that
14 you're material would be listed under the A category
15 that specifically states uses at the top of the
16 category, we're not making a structural function claim
17 on the material that has not been approved by FDA for
18 those functions -- for that function. So it says for
19 medical treatment, on the top of the category -- when we
20 put a material in there, we're not saying that you can
21 use that medical -- for medical treatment, if the FDA
22 has not said that that material can be used for medical
23 treatment. Do you see what I'm saying? The category
24 itself seems to make the distinction on the claim that
25 we can't -- I mean, I understand that the -- but -- are

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1 very specific, but also the categories in themselves.

2 MR. VAHN: This is more of a legal issue and
3 you're not allowed to make decisions beyond your
4 statutory authority. And I think that's what Barbara is
5 trying to say, is you're ruling on whether or not it's
6 accepted for use as an organic or in product -- or in
7 animals that will become an organic product. We're not
8 -- and that's a different statutory authority that we
9 have. We can't tell you what's organic or not organic
10 and you can't tell us what can be legally marketed as a
11 drug or what can't be marketed as a drug. So I think we
12 have a nice bright line that language could be, you
13 know, clarified.

14 MS. ROBINSON: Whenever you try and take a non
15 -- you take a non-drug, something that's -- if you
16 decide that you can use it as a drug, that's where
17 you're going to get into trouble, because you've just
18 stepped over the line, and it's these folks that say
19 what's a drug.

20 MR. MATTHEWS: Okay. We've been here.

21 MS. COLE: Well, I just wanted to clarify,
22 because, you know, we understand that what FDA
23 established, such as we can't do opposite of. We
24 understand that. But what I'm saying is that the way
25 we're kind of formatted here, is that we may have --

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1 yeah, we may be in trouble just based on the way we're
2 -- the format of this document and the category, because
3 it's almost impossible for us not to make a strong type
4 of claim on the use of materials. And as soon as we do
5 that, if it's unapproved...

6 MR. MATTHEWS: Let me take a stab at this.

7 MR. CARTER: Go ahead for the record, Richard
8 Matthews.

9 MR. MATTHEWS: It seems to me that there are
10 several issues that are coming to the forefront. One is
11 the categories within the list, and the other major
12 point is the annotation that is used for the material.
13 What we really need, generally, is early on in the
14 process, taking the petitioned use, consult with FDA.
15 But when the Board acts -- maybe what the list needs to
16 do is just be one list. You got a section for
17 synthetics allowed in livestock. No subcategories, none
18 whatsoever. Substances allowed in livestock,
19 synthetics. And then you just list them without putting
20 on annotations, without having subcategories. If you
21 did that, it helps to ensure that you don't run afoul
22 with FDA. But with our implementing these enhanced
23 procedures, we could also address the petition using any
24 time to make sure that we're also not running afoul with
25 FDA.

1 MR. CARTER: Go ahead. Continue, Andrea.

2 MS. CAROE: My concern with it, Richard, is
3 that the materials that are used now in organic
4 production -- and it's taken us a -- it'll take us a
5 like, I would imagine, a very long time to make that
6 amendment to this rule. What do producers do in the
7 meantime?

8 MR. MATTHEWS: Well, what I would look at is
9 why not change the structure of the section at the same
10 time that we're addressing materials. In other words,
11 we come out with a proposed rule that adds certain
12 materials, but at the same time, propose the elimination
13 of the subcategories. If you'll note in the rules that
14 we've already done, we have started to change the
15 structure a little bit because of feedback from the
16 Federal Register about how we list the materials. If
17 you -- when these final rules come out, you'll notice
18 that we did away with some of the numbering system.
19 It's just a whole list now without numbers in front of
20 them, that way it facilitates the alphabetical listing
21 of the items without saying, okay, we're going to change
22 A-5, A-7 and then add a new A-5 and A-6 and, of course,
23 everything else gets changed. So we are already making
24 some enhancements to the sections as we go along. So in
25 my mind, we could take and put out a proposed rule to

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1 add materials and also to change the way they're laid
2 out at the same time.

3 MS. CAROE: And what would your estimate be on
4 to when that list will be available? If we move
5 quickly, how quickly could it be, six months, a year,
6 two years...

7 MR. MATTHEWS: I...

8 MS. CAROE: ...two weeks?

9 MR. MATTHEWS: Well, let me run through the
10 regulatory process a little bit. In a case of where you
11 want to change a section of the regulations that does
12 not deal with the national list, you're looking at a
13 minimum of 18 months, okay, because of the various
14 regulatory hurdles we have to go over. In the case of
15 materials, we have been told that they won't be
16 considered the materials to be non-major. Therefore, we
17 don't have to go through as long a review with OMB.
18 Okay? We do have to go back to them with what is called
19 a -- plan, where we describe for them what it is we're
20 going to do and then they make a ruling as to whether or
21 not they agree with us as to whether the action is,
22 indeed, major or non-major. But we're in the fortunate
23 position that materials changes are considered non-
24 major. So that actually shortens the process, because
25 you don't have that 90 day OMB review, plus the

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1 additional 60 if they decide they want it, not once, but
2 twice -- so it would really go through the same kind of
3 process that we've been going through since about last
4 April, where the rule -- it's out as a proposed rule, it
5 would have a 30 day comment, we would have to analyze
6 the comments, we would send our report to OMB on that.
7 Then we could start our work to write the docket,
8 because then it would get published as a final rule and
9 it would become usable one day after it's published as a
10 final rule. Now, I can't say that we can get it done in
11 three months or five months or nine months, because it's
12 going to vary with every single rule and it's also going
13 to vary with, you know, what else going on. But it's
14 going to be a much shorter process than if we were doing
15 a change, say, to section 105. It's like we were adding
16 a new thou shalt not sin. Then that process would take
17 a good year and a half.

18 MR. CARTER: Okay. Okay. I have -- here's
19 what I want to do is -- yeah, I want to go, because
20 there's Rose, first, then Mark and Kevin and Owusu, and
21 then I know we've got some veterinarians in the
22 audience, too, and I'd like to get some feedback from
23 the veterinarians as well. So first of all, let's --
24 Rose?

25 MS. KOENING: I just want to make a comment

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1 about this and then I'll change the direction of the
2 questioning. Okay. I just want to say is if we look
3 under the crop section, the crops are set up very
4 differently. And if we use the crops model, like --
5 because it's very general categories. It just says
6 pesticides. It doesn't say how those pesticides are
7 applied, it doesn't make recommendations for use. So I
8 think the crop section was -- you know, again, it's how
9 things were written. But I think -- anyway, livestock
10 is just more defined than crops, and if we use crops as
11 kind of a model for that...

12 UNKNOWN: ...FDA.

13 MS. KOENING: Well, but they're generally
14 pesticides. And we list the types of pesticides, but we
15 don't -- and if we do have an annotation, we usually --
16 it's a specific use that's easily checked by the
17 labelings of those products. Anyway, the question I had
18 -- and it was just more of a -- maybe it doesn't belong
19 here, but it's of interest. Did I understand what you
20 were saying, right, on the homeopathic -- so you're
21 saying that animal laws are more strict than human laws?

22 MR. VENGRIS: I'm not saying that, I'm saying
23 human laws do not apply.

24 MS. KOENING: But you're saying that there's
25 no such thing like -- because I know there's

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1 controversy, like, you know, Ginko or whatever. You
2 know, you can go to a health food store and buy a
3 medicinal...

4 MR. VENGRIS: Oh, you are talking about food
5 supplements?

6 MS. KOENING: ...like a homeopathic thing, but
7 it's not the same in animals that...

8 MR. VAHN: That's correct.

9 MS. KOENING: ...also the homeopathic thing,
10 but it would have to be specific -- those are not
11 allowed, like is that...

12 MR. VENGRIS: No. It's also case by case we
13 might allow under regulatory discretion. We might not
14 take enforcement action. But human homeopathic policies
15 and guides do not apply who consider them drugs and new
16 animal drugs.

17 MR. CARTER: All right. Mark?

18 MR. KING: Yeah. This is a big difference. I
19 have two questions that are general. One is a feed
20 question or a feed additive question. And in general
21 terms, can you describe the difference between something
22 being used to optimize health and/or to prevent
23 something?

24 MR. MATTHEWS: Sir, you're getting into an
25 area where we spend a lot of time. In determining

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1 whether a product is a food versus a drug is the degree
2 to which it affects the structure of the function. For
3 example on the one hand, treating ketosis or one of the
4 terms of art these days that you're hearing about is the
5 subclavilti [ph] ketosis, where we have an altered
6 physiological condition changing that function would put
7 it more on the drug side. Whereas if we're merely
8 helping animals reach they're already established
9 genetic potential by having a complete full diet, you
10 know, it's intended for high performance, that falls
11 into the food side. So there is a gray area, but we do
12 spend a lot of time determining, you know, what are the
13 limits of discussion.

14 MR. KING: And then secondly, the drug
15 category, can you describe the difference between an
16 approved indication and a label claim?

17 MR. MATTHEWS: Okay. A label claim --
18 actually, none of those -- those are all terms of art
19 that we throw around probably recklessly. The statute
20 describes the intended use that's prescribed, suggested
21 or recommended in the labeling, so it's very broad. In
22 fact, when we get into some of the products that we end
23 up regulating, there may not be anything adverse in the
24 indication or the claim for a section of the label. But
25 you may go down farther in the label and there's

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1 something buried in there where they're making an
2 intended use -- establishing an intended use. It is
3 egregious. So anywhere on the label, if there's
4 something that suggests an intended use for the product,
5 that would determine its regulatory status. And I will
6 go beyond that, too. Thank you, Dr. Vengris. There's
7 also -- there's different categories of promotion
8 materials. We have advertising. And where we regulate
9 the advertising, prescription products, over-the-counter
10 products are regulated by the Federal Trade Commission.
11 The -- there is also promotional labeling, and there's a
12 number of criteria that's been set up court decisions as
13 to when, essentially, advertising becomes promotional
14 labeling and is subject is to the same provisions as the
15 label would be. So it's fairly complex and a convoluted
16 way of -- the process that we have to go through to
17 establish the intended use of products.

18 MR. KING: And just if I could add to that one
19 thing. When you were discussing in general terms
20 unapproved or natural or homeopathic and those kinds of
21 various -- where do you see that when you, for example,
22 referenced earlier, we believe that at some point in the
23 future these should be regulated?

24 MR. MATTHEWS: At this point in time and
25 probably for your purposes, we don't even go home saying

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1 that we don't recognize natural or homeopathic or any of
2 the other classifications of products. If they have an
3 intended use that meets a definition on the drug, we
4 regulate them as a drug.

5 MR. CARTER: Okay. I got Kevin and then
6 Owusu.

7 MR. O'RELL: Well, just to be clear on this,
8 because I think I heard this flip flop on Jim's
9 explanation -- example, the terms of aspirin and the
10 category that we have it is for medical treatment. And
11 then we an annotation, which -- I can't read it --
12 approved for healthcare, used to reduce inflammation.
13 And I saw you gentlemen shaking your heads at one point
14 after at least conferring. The way we have that
15 structured with our categories, is that allowed by the
16 FDA or would you think we're implying that that's a
17 medical usage? But not for marketing, I guess. You're
18 saying we're okay, because it's under organic?

19 MR. MATTHEWS: I don't think we're in a
20 situation where we can tell you what you consider to be
21 organic or not organic.

22 MR. O'RELL: Right.

23 MR. MATTHEWS: I think -- you know, I think
24 you kind of do a little -- cut a square where you're
25 going to have things that are acceptable by you as

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1 organic, but would be unacceptable by us to be marketed,
2 and things that are organic that you can market, things
3 that are not organic by your standards and we would
4 allow or not allow. I think there are two different --
5 and they could fall into any one of those four
6 quadrants. And whether or not -- I doubt that we would
7 be concerned about what you would consider organic or
8 not organic, because they are still in those two
9 quadrants that were unacceptable to us, we would still
10 take whatever enforcement action we needed to to correct
11 those products or to remove them from the market.

12 MR. O'RELL: So we don't necessarily need to
13 change our categories?

14 MR. MATTHEWS: That would depend on what you
15 and, I guess, USDA decides.

16 MR. O'RELL: If I can just follow up on that,
17 what would really trigger it is the intended use on the
18 label claim of the product itself...

19 MR. MATTHEWS: Yes.

20 MR. O'RELL: ...is that correct?

21 MR. MATTHEWS: Yes. Yes. Let me just add one
22 piece to this, because I think we're going down a path
23 here that you might fall into a potential trap that
24 we've run into. Products have to be truthfully labeled
25 as well. They can't be false and misleading on any

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1 particular, so if the product's truly being marketed for
2 a particular intended use and the label doesn't declare
3 that, it's then misbranded and it's still in violation
4 of our laws. So there is an assumption that it's
5 truthfully labeled and we do -- we have a number of core
6 precedences, particular with bulk drugs, where we have
7 established that the product will be marketed, there was
8 established intended use. If the product's not properly
9 labeled, they were misbranded. And had they been
10 properly labeled, they would've been unapproved
11 adulterated drugs. So they have to be truthfully
12 labeled and then the intended uses established.

13 MR. CARTER: Okay. Owusu?

14 MR. BANDELE: Yeah. I just have a concern in
15 terms of understanding the problems that the annotations
16 create. But to me they are still a mystery. Where I
17 think we run to problems, if we just had the one list
18 without the annotations, because that would -- for
19 people to use these synthetics in a lot broader way than
20 we intended.

21 MR. CARTER: Okay. All right. Now, wait.
22 Before I call -- you don't have -- we've got a couple --
23 at least two vets in the office -- in the audience. We
24 may have more. But I'd like to get some -- you know,
25 any comments that you have as far as -- you know, we can

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1 put on those, and then Goldie and then I see Kim's got
2 her hand up, so -- you?

3 MR. CARRIMAN: Okay. Thank you. Hubert
4 Carriman, veterinarian from Pennsylvania. I want to...

5 MR. CARTER: Stay close.

6 MR. CARRIMAN: ...thank these two gentlemen
7 for coming in, because I think they've really elucidated
8 the situation perfectly. I can follow them since I'm a
9 dairy vet. And I think Jim's question regarding the
10 categorization under the medicine is -- still I think
11 could cause problems down the road, unless -- and the
12 annotations that you're worried about, that we could
13 just have, perhaps, under veterinary direction and leave
14 it at that, instead of like 90 days withholding or
15 whatever. I know it's really sensitive to you all to
16 have extra withholding time. I think you need to
17 uncouple that from whatever the FDA is saying. If you
18 want to say 60 day withholding, just say that, don't say
19 FDA, because then we got to get them in. And that's
20 fine. I mean, that's their job. So I say possibly if
21 you want to do some of these healthcare drugs -- I'm not
22 saying feed additives or anything, I'm speaking as a
23 veterinarian -- you put under veterinarian directions.
24 And as far as the homeopathic drugs go or human drugs
25 that are not approved drugs for animals, if there is a

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1 valid client/patient relationship of ECPR [ph], can a
2 veterinarian label a homeopathic drug or a colostrum
3 whey [ph] derivative or an aloe product that are not
4 even on your radar screen, because they're human or
5 they're nutritionals, if I label that, is that okay, by
6 the inspectors from the public health service and
7 whoever comes to the farm, which I don't know if they're
8 under FDA, but am I allowed to do that, the extra label
9 drug use? Yes, please.

10 MR. MATTHEWS: Okay. It doesn't matter who
11 would label the product. Once the product is labeled
12 and establishes intended use, then it's subject to our
13 jurisdiction. What I think you're speaking to are the
14 labeling provisions under the Grade A Pasteurized Milk
15 Ordinance.

16 MR. CARRIMAN: Yeah.

17 MR. MATTHEWS: Correct?

18 MR. CARRIMAN: Yes.

19 MR. MATTHEWS: Okay. And those are also
20 regulated by FDA and then through our Center for Food
21 Safety and Applied Nutrition [ph], there is a federal
22 safe operative program to which the model for Grade A
23 Pasteurized Milk Ordinance is developed and it's through
24 the national conference of interstate milk shipments,
25 and then subsequently each state then adopts that

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1 pasteurized milk ordinance. And so it's actually as
2 state code, but it has federal oversight, because
3 ultimately, FDA has oversight over the safety of milk.
4 In those kind of situations -- let's say the cost of the
5 product, if it establishes it's intended use and it
6 meets the definition of a drug, it would be considered a
7 drug. Those products would be subject to our
8 regulation, and particularly if they were commercialized
9 or marketed. And we would set our onus of discretion of
10 where and to what extent we would enforce that. They
11 wouldn't be exempt just because they had a veterinarians
12 label. The pasteurized milk ordinance labeling
13 provisions were intended to address products that were
14 allowed to be marketed by FDA, both the approved and
15 those allowed and regulated by regulatory discretion.
16 There's further labeling directions that needed to be
17 put on those labels.

18 MR. SIEMON: I got a little confused there.

19 MR. MATTHEWS: Okay.

20 MR. SIEMON: I thought we were just referring
21 to the veterinary authority to use AMDUQA, to use human
22 drugs.

23 MR. MATTHEWS: Only approved.

24 MR. SIEMON: I know. Only...

25 MR. MATTHEWS: Only approved.

1 MR. CARRIMAN: But human homeopathics are.

2 MR. SIEMON: Human approved. The human
3 approved as well.

4 MR. MATTHEWS: They would have -- right.

5 MR. SIEMON: It's a human approved drug and he
6 has the -- the veterinarian has the privilege to use
7 those on livestock animals under the conditions of
8 AMDUQA.

9 MR. MATTHEWS: Under the conditions of AMDUQA,
10 correct.

11 MR. SIEMON: Even if it's a human approved,
12 but not FDA livestock?

13 MR. MATTHEWS: Yes.

14 MR. SIEMON: And so for example, I don't know
15 if homeopathic...

16 MR. MATTHEWS: And there is -- and there are
17 label requirements under the DMO that they have to meet.

18 MS. COUGHLAN: Homeopathics are a drug. There
19 is such a category.

20 MR. MATTHEWS: There is such a category.

21 MS. COUGHLAN: And that's the problem.

22 MR. MATTHEWS: Yeah. They're not approved,
23 but there is such a category, though.

24 MR. SIEMON: Okay. Then you...

25 MR. CARRIMAN: Well, actually, I thought I

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1 heard -- I thought I heard you say earlier that
2 homeopathic are allowed under human drugs -- but not a
3 human drug, but they are allowed for human use subject
4 to conditions. But then if I label it, is that okay or
5 not? Because it's not a human drug.

6 MR. MATTHEWS: It would have to be an approved
7 human drug subject to an NDA [ph].

8 MR. CARTER: Stand up close to the mike when
9 you're talking.

10 MR. MATTHEWS: Sorry. It would have to be a
11 human drug subject to an NDA, an approved human drug.

12 MS. CAUGHLAN: Even if it is a -- will allow
13 an animal to reach it's full potential?

14 MR. MATTHEWS: If it's -- the intended use as
15 a drug. For example, let's make it simple. It's for
16 the treatment of ketosis, that way we know -- okay? And
17 that product would be -- there would have to be no other
18 approved drug available -- animal drug, or the
19 veterinarian has determined that those approved animal
20 drugs did not work in this particular situation. And
21 then I could go to an animal drug or a human approved
22 drug. Only approved drugs.

23 MR. SIEMON: But the other option is, of
24 course, to flip over to the micro-nutrient world, which
25 had been used for homeopathic remedies inside FDA, to my

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1 understanding.

2 MR. MATTHEWS: But AMDUQA does not apply.
3 There's no provision for use under those conditions.

4 MR. SIEMON: But then they can use it as a
5 micro-nutrient if they had a new group for that under
6 FDA? I understand that's the term being used, micro-
7 nutrients, too, for...

8 MR. MATTHEWS: We don't recognize micro-
9 nutrients. They're -- the intended use establishes for
10 -- as a drug, they're drug. Otherwise, they would have
11 to be -- you know, as a nutrient, they may fall under
12 the food or feed additive...

13 MR. SIEMON: That's what I'm saying.

14 MR. MATTHEWS: ...provisions. Yes.

15 MR. SIEMON: That's what...

16 MR. MATTHEWS: In which case, they wouldn't be
17 a drug and need to have labeling under PMO.

18 MR. CARTER: All right. You -- okay. And
19 what I'd like to do now, because we're running to the
20 time considerations here, but I want to gets some inputs
21 from veterinarians. I know Goldie had her hand up. And
22 I would like Kim, who is materials chair, and George is
23 the livestock chair, they're kind of trying to bring us
24 to what the action -- how we proceed from here, so...

25 MR. CARRIMAN: Just one last thing on the

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1 labeling, because hopefully all organic farmers have
2 veterinarians and hopefully they have valid
3 client/patient relationships for the safety and all for
4 the animals. In Pennsylvania, I don't know if you know,
5 but back in 1997, when the PMO came out regarding aloe
6 vera, homeopathics and tetracycline powder for topical
7 use, and there was one other thing, some veterinarians
8 in Pennsylvania got together with the head sanitary
9 inspector there. And in Pennsylvania, we're allowed to
10 label those specific things. And when the federal
11 public health inspectors have come around, it's been
12 totally fine. Is that -- that concurs with what you're
13 saying? Through the PMO, we're allowed to label it and
14 the public health inspectors have been saying that's
15 okay for six years. They say if you got this label on
16 here, it's going to be okay.

17 MR. MATTHEWS: And what has happened is that
18 they check back with FDA...

19 MR. CARRIMAN: I would hope so.

20 MR. MATTHEWS: They check back with our FDA
21 Center for Food Safety and Applied Nutrition and the
22 states work very closely with our safety group. And we
23 have a working group between CBM and them to go over
24 those kinds of products and those conditions. And we
25 actually publish a memorandum of information, MIs, that

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1 establish those limits under the pasteurized milk
2 ordinance. So those are available on the SYSTAN [ph]
3 website at FDA.

4 MR. CARRIMAN: Okay. Thanks.

5 MR. MATTHEWS: Yeah.

6 MR. CARTER: And Alice Waters [ph] and -- I'm
7 sorry. Okay. Then let me -- Goldie, do you...

8 MS. COUGHLAN: No, I pass.

9 MR. CARTER: Okay.

10 MS. COUGHLAN: I just had one extra and it's
11 been followed up.

12 MS. DIETZ: I had my hand up.

13 MR. CARTER: You did have your hand up? Okay.

14 MS. DIETZ: And it was a question. So if a
15 category was as broad as animal health, okay, so that
16 didn't get into drugs or -- I mean, where drugs could
17 clearly -- but it was broad thing, animal health, that
18 wouldn't -- FDA? If we had a category that was animal
19 health and we didn't -- and then we put just the
20 annotation on some of them that we -- that appears to be
21 FDA jurisdiction and we just put under -- what the
22 veterinarian said, under veterinary discretion or
23 something, would that alleviate any of these problems
24 that we're having in terms of categorization? I don't
25 think it's -- maybe that'll come...

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1 MR. CARTER: Yeah, I think that can have that
2 in our discussion. I'm sorry.

3 MR. MATTHEWS: I thought that was you. I'm
4 sorry.

5 MS. DIETZ: The question was, is it -- instead
6 of -- we definitely have very specific use categories
7 and haven't been able to resolve -- it's definitely
8 going into a legal ground, which again could chew up a
9 lot of time in terms of us trying to get with the
10 process. But do you see anything wrong with just an
11 animal health category? Because we're not being
12 addressed by all of -- both EPA, APHIS and FDA
13 jurisdictions would fall under our general animal health
14 category. And then just put under veterinary discretion
15 on those things, which would then allow the -- you know,
16 it would allow things to be put within a general
17 category and then it would be up to the practitioners who
18 know the law to then go through and make sure they're
19 abiding by all the other agencies that regulate those?

20 MR. MATTHEWS: I wouldn't have a problem with
21 the animal health provision.

22 MS. DIETZ: Category.

23 MR. MATTHEWS: That's up to you as to where
24 you want to set any limits under that. I think that's
25 general enough. It's going to catch the whole umbrella

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1 and probably save you a lot of heartburn from what I'm
2 hearing.

3 MR. CARTER: Okay. We've got one -- another
4 vet, then I want to -- let the minutes reflect that
5 Nancy Ostiguy -- I'm sorry -- Nancy Ostiguy joined the
6 meeting at 3:40. Welcome.

7 MR. LAVER: Thank you for having me. I'm Dan
8 Lave [ph]. I'm not a veterinarian. I'm with Crystal
9 Creek, Incorporated for Scotts [ph] and I'm a
10 nutritionist. I've been a nutritionist for 30 years. I
11 have two vets on staff. One issue that I want to ask --
12 and I want to thank you very much for the enlightenment
13 that I've had here today. I think I've got a grip on
14 some these topics. In the example that he told us, if I
15 understand right and tell me if I'm wrong, I've heard
16 stated that dietary application for the prevention of a
17 disease, condition or ill health of an animal would
18 classify an item as drug. To me, as a nutritionist,
19 that would securely put all nutrients in to the category
20 of a drug. So I need the clarification since my whole
21 realm of activity and purview with our activities for
22 prevention to benign use of nutrition, how do you
23 approach that with not a -- just using plant nutrients?

24 MR. MATTHEWS: That's our definition when we
25 get into structure of -- is it affects the structure or

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1 function of the animal other than as a food. So if it's
2 doing what that nutrient does, you could argue it. If
3 you were providing a vitamin, for example, you are
4 preventing a deficiency of that vitamin. But we would
5 say that's what that nutrient does. And so that would
6 be still considered a food. But if you went on beyond
7 that and were making, for example, production claims
8 that it was for increased rate of gain, it was for
9 improving feed efficiency beyond the genetic potential
10 of the animal much as you'd expect from the birth point,
11 then that would be considered a drug and that's where we
12 draw the line in the structure and function world. When
13 you go over into the disease area, we don't think of --
14 we're assuming the animal's already being fed a proper
15 diet. And then any abnormalities that occur are
16 considered, then, diseases. But otherwise healthy
17 animals receiving nutrients, those nutrients would be
18 considered food.

19 MR. LAVER: Okay.

20 MR. CARTER: Okay.

21 MR. LAVER: I have just one rebuttal or
22 refinement to that. Respectfully, metabolic diseases
23 are not pathogenic diseases. And when you get involved
24 with metabolism or diet such as ketosis, that can be
25 rectified at a preventative level and/or a treatment

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1 level with nutrition. I have a hard time understanding
2 how a nutritional application would be required to be
3 handled as a drug.

4 MR. MATTHEWS: Okay. We don't define diseases
5 as just those things caused by pathogenic agents,
6 diseases -- any abnormal condition in the animal. So
7 things like ketosis and milk fever, even though there
8 are preventative steps that you can take to maintain the
9 animal from getting into an altered disease state,
10 that's not the same as what we would consider for
11 preventing a disease where we're -- when we know the
12 animals are likely to develop a diseased condition and
13 we're putting in place ingredients other than nutrients
14 to keep them from acquiring that diseased condition.

15 MR. CARTER: Okay, Dan, I've got to cut it
16 off, because I wanted -- we need to kind of see where we
17 head from here. So, Kim?

18 MS. DIETZ: I'm first?

19 MR. CARTER: Yeah.

20 MS. DIETZ: Okay. What I've been hearing and
21 just jotting notes down, first of all, we all understand
22 that other regulatory agencies supercede the NOP rule,
23 so that's a given. And similar to food, where FDA
24 regulations take charge, whether it's a food or vitamin
25 or anything, we still have to comply with FDA

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1 regulations. So I think that's kind of an area that we
2 haven't really grasped prior to this point for the
3 livestock. I can see this going two ways, but we have
4 definitely have to restructure the livestock category.
5 We can go the crossway where we generalize specific uses
6 and whether that'd be livestock health, or similar to
7 processing, where we just say synthetics allowed and
8 it's a given that FDA supercedes our materials. And
9 that's probably the area that I would recommend.
10 There's -- if you look at the list -- the national list,
11 it just says synthetics allowed and there's no category
12 to what food group or products that you allow this to go
13 into, so -- or annotations. And I'll just sum that up
14 better. It looks like it's very doable and we can fix
15 it very easily with the materials that make it back and
16 make those recommendations.

17 MR. CARTER: Okay. George?

18 MR. SIEMON: Well, my concern is just the
19 timing about all that. So my question is our we going
20 -- what is NOSB's role in this process? And I think you
21 left out any potential cleanup of annotations.

22 MS. DIETZ: Yeah.

23 MR. SIEMON: And so I think, you know, my
24 question is this is really time critical issue. What is
25 it we can do in the next few days -- what is necessary

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1 for us to do in the next few days? And this issue is
2 getting quite old, so if we can resolve this -- is an
3 action needed by NOSB in the next few days to go through
4 the annotations and to revisit these titles and make
5 recommendations? And so I would really like to look at
6 our agenda and see what we can do to address these.

7 MR. CARTER: Well, again, the question, what
8 can we legally do if it's not on the agenda. So,
9 Richard, let...

10 MR. SIEMON: I mean, this is an issue -- this
11 letter is June 23. And the issue is solvable and it's a
12 top priority.

13 MR. CARTER: We're current. And Richard
14 Matthews.

15 MR. MATTHEWS: We're currently working on a
16 livestock -- if it's the will of this board, we will
17 take out the categories and what we'll do is we'll go
18 back to the draft document, take the categories out and
19 write in what we're doing and why we're doing it and
20 then move on. So, I mean, that docket we're working on.
21 Whatever the Board wants to do, if you want to change
22 the categories, you want to remove the categories, tell
23 us what you want to do and we'll put it into the docket
24 we're currently working on.

25 MR. SIEMON: But the annotations are also part

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1 of this, correct?

2 MR. MATTHEWS: The annotations are a part of
3 it, but it may be something that has to wait. But at
4 least on a category issue, we can fix that right away.

5 MR. SIEMON: But the point is...

6 MR. MATTHEWS: And that's something we could
7 do right now with the docket we're working on.

8 MR. CARTER: The question I have from a
9 procedural point is what are we allowed to do at this
10 meeting when this isn't part of the agenda?

11 MR. MATTHEWS: That's a good question. We may
12 have an answer for you tomorrow.

13 MR. SIEMON: And what about if we need a
14 general disclaimer stating that's what I'm hearing? I
15 don't think you need to put it up for each material, we
16 just need a general disclaimer within FDA permitted
17 rules. I think that -- well, covered the department
18 rules, on it's law, on it's...

19 MR. MATTHEWS: When it comes down to that,
20 we've already -- we've already fought that battle with
21 the attorneys when we were doing the rule making process
22 the first time. There is a concern that if you put in
23 in compliance with FDA or in compliance with the EPA,
24 maybe we missed APHIS or we missed FDA in a spot where
25 we should've included FDA. So in reality, I would say

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1 you got to do it in compliance with all the laws. Now,
2 we'll get -- and go back talk to the attorneys about is
3 whether or not we want to -- not in the national list
4 part, but maybe in the very beginning of the
5 regulations, a new section or a section -- or a
6 subsection within the sections -- talk to the attorneys
7 to see if they would go along with the idea of breaking
8 up the sizing of what's in the Act within the regs.
9 What is already understood -- I mean, the Act -- with
10 the regulations what you do is implement the Act, and
11 the Act already says you have to do it in compliance
12 with everything else. The problem we run into is some
13 people don't quite fully understand that and we'll just
14 have to keep reemphasizing that.

15 MR. SIEMON: But I'm agreeing with you, but
16 I'm going to react to Barbara's saying what we got to do
17 is say as the law applied by FDA. I think it is coming
18 already. and the foundations of the rules and the law --
19 that is already a given. So, Barbara, earlier you were
20 saying this is what we needed is to go over our
21 itinerary -- specific statements.

22 MS. DIETZ: We're getting into old habits and
23 we're taking the cart before the horse again. We have
24 -- you have a docket of approved materials that you're
25 going to publish anyway. We have materials that are not

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1 on that docket and we need to fix this. And we need to,
2 as a board, come up with the recommendation that we all
3 agree on to make those changes on those next written
4 materials, so...

5 MR. MATTHEWS: I don't understand what you're
6 saying. I'm sorry.

7 MS. DIETZ: You have materials on the docket
8 that's going to come out that I would assume are -- do
9 not include some of the materials that we've had
10 problems with the annotations on...

11 MS. ROBINSON: Correct.

12 MS. DIETZ:...correct?

13 MR. MATTHEWS: Okay.

14 MS. DIETZ: So as board and a committee, the
15 materials committee, especially, we can come up with a
16 recommendation of what we recommend to do to the
17 national list and the we have re-review those materials
18 and come up with corrected annotations based on our
19 recommendation. Does that make sense to you? I don't
20 think we can fix the materials that we have problems
21 with today.

22 MR. CARTER: No.

23 MR. MATTHEWS: No.

24 MR. CARTER: We're at this meeting because of
25 the public comment and everything else. I mean, again,

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1 we got to follow...

2 MS. ROBINSON: The USDA can fix the docket in
3 respect to the categories. We do not -- this is a
4 proposed rule, it's going to go out, you know, comment
5 can be received on it. It does not require the Board to
6 tell us please take the categories out of the program --
7 the rules. We can go ahead and do that. We have the
8 authority to do that, and then take comment on it. If
9 it makes you nervous, the Board is free to pass a
10 resolution -- here's the sense of the Board. You can do
11 that even at this meeting -- sometime at this meeting.
12 But you also -- one point I'd like to say is we don't
13 want to really get into public comment and debate. We
14 had an agenda to hear from the TAP reviewers and kind of
15 keep this thing going along.

16 MR. CARTER: We're trying to get there.

17 MS. ROBINSON: So I'll sit down...

18 MR. CARTER: Okay.

19 MS. ROBINSON: ...and shut up.

20 MR. SIEMON: We were supposed to have to give
21 you the summary of our passport visa [ph].

22 MS. ROBINSON: Of your what?

23 MR. SIEMON: Of the passport -- where we --
24 then I'm not clear yet. I'm sorry.

25 MR. CARTER: Well, I think we need to have

1 probably a livestock committee meeting here during the
2 day, then come back with something before adjourn, and
3 then the recommendations on how we move this forward,
4 so...

5 MR. SIEMON: To deal with specifically with
6 the subtitles, but not the annotations?

7 MR. CARTER: Well -- yeah. This is committee
8 work. Okay? We need to take this to the committee and
9 figure out -- given the process that we have to follow
10 and the train wreck that we're in now, how do we get of
11 that. Okay? So -- okay. All right. I am going to
12 declare a seven minute recess and we will get back to
13 our...

14 MR. CARTER: Okay. Rose, Jim, it's coming up.
15 Kevin, Dennis, Mike. Okay. Go ahead.

16 MR. FORSHEE: Thank you. This mike? Yeah.

17 MR. CARTER: Yeah.

18 MR. FORSHEE: First of all, thank you very
19 much for the invitation to speak here today. My name is
20 Richard Forshee. I am the associate director and the
21 director of research for the Center for Food and
22 Nutrition Policy at Virginia Tech. We've been doing TAP
23 reviews for I believe it's about a year and a half now.
24 And we've been asked to come here today and talk a
25 little bit about our experience and our thoughts on what

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1 can be done to improve the process. I'd like to begin
2 by just briefly telling you a little more about the
3 broader mission of the center and what we do, because I
4 think it will help put some context on how we view this
5 particular process and how we come to some of our views
6 on how to the process can be improved. CFNP is an
7 independent, non-partisan academic research center in
8 the College of Agriculture and Life Sciences at Virginia
9 Tech. The mission of the center is to advance rational
10 science based food and nutrition policy. We are
11 recognized as a center of excellence in food and
12 nutrition policy by the Food and Agriculture
13 Organization of the United Nations. And our areas of
14 focus are in food safety and nutrition. We conduct
15 research, outreach, communication and education on a
16 variety of issues within our areas of expertise. This
17 includes doing statistical analyses of national surveys,
18 look at consumption patterns, it includes international
19 education programs for dignitaries from foreign
20 countries, risk analysis programs that we're doing with
21 the FDA, a variety of things in these areas. All of the
22 Activities that we do at the center eventually come back
23 to policy. We believe that better analysis is going to
24 lead to better policy, eventually. It's not always a
25 straight line, but if you get better work out there,

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1 better data, you're going to lead to a better policy
2 outcome. We conduct original research to address
3 questions that are relevant to current food and
4 nutrition policy. We communicate our research through
5 peer review publications, scientific conferences and
6 comments to national and international policy makers.
7 This includes the Food and Drug Administration, the US
8 Department of Agriculture and the World Health
9 Organization, as well as state governments. We also
10 host conferences, roundtables and lectures to bring
11 together scientists, policy makers and stakeholders to
12 foster better communication on this issues. We provide
13 policy analysis through comments, essays and
14 presentations. However, it's important to point out
15 that we are not policy makers. What our role is is to
16 help stakeholders understand what the issues are and
17 what the consequences are for the various policy
18 alternatives that they face. Providing TAP reports for
19 the National Organic Program and the National Organic
20 Standards Board, fits very well with the overall mission
21 of the Center for Food and Nutrition Policy, because we
22 see that this project is that implementing an important
23 food law in a manner that is faithful to the legislation
24 in order to produce useful information to consumers and
25 an objective and transparent process for stakeholders.

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1 In our view, the role of CFNP as a TAP reviewer is to
2 provide factual and scientific answers in an objective
3 manner so that NOSB and NOP can make informed judgments
4 on the petitions they receive for the national list. We
5 do not believe that it is appropriate for CFNP or any
6 TAP reviewer to make value judgments on either specific
7 substances or the philosophy of organic farming. That
8 is a role that congress took on when they established
9 the guidelines for it and that is the role that the
10 National Organic Standards Board has in representing
11 stakeholders to try and see that the law is properly
12 implemented. The role of TAP reviewers, in our opinion,
13 is to facilitate the implementation of OFPA based on the
14 legislation and the regulatory guidance provided by the
15 USDA. I also want to talk briefly about some of our
16 activities in other areas of regulatory policy. In
17 addition to working as TAP reviewers, where it's our job
18 to take petitions and provide the necessary background
19 information for a regulatory decision to be made, we
20 have also worked in situations where our work is used as
21 part of a petition to another agency. In particular,
22 some of you may be aware FDA has recently released
23 interim guidance on qualified health claims for foods.
24 We are currently preparing an evidence a summary of
25 scientific literature that's going to be used for a

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1 qualified health claim that will be submitted by a
2 coalition to the FDA. As part of the qualified health
3 claim project, we developed a rigorous method for
4 conducting an evidence based summary of the scientific
5 literature that conformed to the interim guidance of the
6 FDA, and we also presented this approach to a panel of
7 external experts for validation, and we include
8 extensive internal and external quality control in the
9 process. One of the reasons that this is important to
10 mention today is it shows how the process of regulatory
11 guidance can be used to develop a systematic approach
12 that can then be applied by a wide range of groups. The
13 process that we've developed for implementing a
14 qualified health claims reviews is going to be submitted
15 as a manuscript to be published so that other people can
16 see the systematic approach that we put in place that we
17 believe allows other people to easily replicate this
18 work and come to the same answer based on the available
19 scientific evidence. It's also important that doing
20 this project has helped provide us with firsthand
21 experience in how petitions are put together in other
22 regulatory contexts. It also provided an example of how
23 regulatory guidance, even interim guidance, can put
24 flesh on the bones of legislation in order to improve
25 the consistency, objectivity and transparency of the

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1 regulatory review process. What we have learned in our
2 experience with qualified health claims is that the
3 petitions for qualified health claims are expected to be
4 much more detailed than those that have been used to
5 date in the TAP review process. The petitions for a
6 qualified health claim essentially represent the
7 petitioner's best attempt to address all of the
8 standards that have been set forth in the interim
9 guidance. This includes among other things a summary of
10 the scientific evidence, evidence summary tables to say
11 what the body of evidence suggests about the claim that
12 they wish to make, it also includes copies of all of the
13 scientific articles that are referenced in the petition.
14 So the petition says these are all of the articles that
15 we have found. Here are the copies for FDA to then go
16 and do further review. The petitions also address some
17 of the legal questions that were discussed at the
18 meeting earlier today. The people who are submitting
19 the petitions to FDA do go through a section where they
20 identify, for example, that the food that they want to
21 use the label on meets grass standards. And there are a
22 number of other legal questions that the petitioner
23 addresses when they are submitting the document to the
24 FDA. And finally, the FDA has an initial screening
25 process that they use to ensure that the petitions are

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1 complete, and that they also define explicit criteria
2 that will be used to prioritize the review of the
3 petitions. For example, qualified health claims that
4 would affect a broader segment of the US population
5 receive greater priority in terms of where in the queue
6 they will go for review. Petitions that include
7 consumer research to demonstrate that the claim that is
8 proposed will be understood by consumers and will not be
9 misleading as it's presented also are going to get
10 higher priority when the FDA is considering how to use
11 it's scarce resources in evaluating petitions that come
12 to it. The FDA's interim guidance for qualified health
13 claims is also quite extensive. And this is most of it.
14 This is to implement -- this is the extra guidance that
15 FDA has given to people who want to submit petitions, to
16 give clear guidance as to what all the standards are
17 that need to be met and what objective criteria are
18 going to be used in order to evaluate them. We're not
19 here to suggest that you adopt something like the FDA's
20 qualified health claim criteria. However, based on our
21 experience with the TAP review process with the
22 qualified health claim's regulatory guidelines that
23 we've had experience with as well, and with other
24 regulatory policies used that we as a policy center have
25 been involved with, we will respectfully offer some

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1 suggestions for petitions, the statement of work and
2 regulatory guidance as you asked me to today. Let me
3 begin with some general comments on the regulatory
4 process as we've experienced it. First of all, CFNP
5 would appreciate additional regulatory guidance to make
6 the process more consistent and transparent. I'll go
7 through some of the specific criteria later to talk
8 about some of the issues that we view as particularly
9 troublesome. But in general, we would like more
10 guidance in terms of definitions and objective standards
11 that we can use in order to determine and help you to
12 determine whether the criteria in OFPA have been
13 successfully met. We believe that the TAP reports that
14 we submit should provide concrete objective information
15 and avoid value judgments. We believe that on each of
16 the criteria that we need regulatory guidance that
17 establishes clear objective standards. As TAP
18 reviewers, we would appreciate additional guidance on
19 the expectations for reports and a way to clearly
20 establish what constitutes a complete and satisfactory
21 report. We need a better understanding of what are the
22 minimum requirements that we need to meet. We will
23 always try to exceed that, but we need to know what the
24 minimum standard is in order to reach it and we also
25 need to know when we've reached the finish line, when we

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1 have done enough on the report to provide NOSB and NOP
2 with the information that they need to make an informed
3 regulatory decision on the substance that has been
4 petitioned. Guidance to simply focus on the criteria of
5 OFPA has, in our opinion, not been sufficient to --
6 sufficient guidance for us to successfully address all
7 of these criteria. Because some of the questions in the
8 criteria have not been clearly defined, we need better
9 definitions, and as mentioned, we need more objective
10 standards against which we can measure a substance.
11 CFNP would also find it useful to have lines of
12 communication between NOSB, NOP and the Center for Food
13 and Nutrition Policy more clearly defined and
14 consistently maintained. Communication is always
15 difficult when you have large organizations with diverse
16 memberships, but there has been some confusion in the
17 past over whether communication to CFNP should come from
18 the National Organic Program or the National Organic
19 Standards Board, whether there should be a single point
20 of contact on each, and there have been occasions where
21 the communication has not been as timely as would be
22 helpful for us to complete the project on the timelines
23 that we've dealt with. Furthermore, the communications
24 have sometimes consisted of forwarded e-mail that
25 contains a complicated mix of messages. It can be

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1 difficult for us to sort through the whole set of
2 messages and find out just which point it is. So to the
3 extent that we can get a single point of communication
4 and clear messages as to what needs to be done on the
5 particular substances, that would be very helpful for us
6 at the Center for Food and Nutrition Policy and we
7 believe it would be helpful for other TAP reviewers as
8 well. Another issue that begins to touch on trying to
9 manage the process of doing TAP reports is that it would
10 be useful if we could have more consistency in the
11 timing and quantity of reports in order to maintain
12 proper staffing levels and appropriate quality control
13 at the center. As an organization, we could plan to do
14 about 10 TAP reports a year or we could plan to do about
15 20 TAP reports a year. We could plan to do just about
16 whatever number you choose, but what becomes difficult
17 for us as an organization is if we plan for, let's say,
18 20 TAP reports and we only get five in a given year.
19 Because of the way the payment for the TAP report are
20 structured, we need to have a rough idea how many we're
21 going to be receiving so that we can keep the
22 appropriate specialist on staff to help with doing the
23 reports. Let me be very clear that we recognize that
24 some of the issues regarding the timing and quantity of
25 TAP reports are outside of the control of either NOP or

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1 NOSB. And we are happy to work to manage the situation
2 as efficiently as possible and we have already taken
3 steps in order to try and do that. All the faculty
4 staff that work on TAPs reports at the Center for Food
5 and Nutrition Policy have multiple projects that they're
6 engaged in, so we're able to shift people to other
7 projects when there isn't a crunch of TAP reports and
8 bring them back on to focusing on TAP reports during
9 times when we do need more focus. And we do utilize
10 some temporary staffing when we receive high volumes of
11 TAP reports. However, we think it's essential to
12 maintain some expertise and continuity on the faculty
13 and staff so we have people who have had experience on
14 this and that we have people who have the necessary set
15 of professional qualifications in order to do this. So
16 again, we are very happy to work with NOSB and NOP to
17 see if we can find ways to better understand what the
18 volume of work is going to be so that we can keep the
19 right people in place. I also want to mention that TAP
20 reviewers need to be given as much lead time is as
21 possible to prepare the reports. In the statement of
22 work for this particular project, 262 days is specified
23 from the time that a TAP report is given to the TAP
24 reviewer until the report has to be presented. I can
25 say that the CFNP has never had anything close to 262

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1 days in order to complete an assigned TAP report. We
2 also recognize that that's probably not a feasible
3 number for any TAP reviewer to expect. We understand
4 with the nature of your work that you're going to need
5 quicker turnaround than 262 days. And we're very
6 willing to work to meet the needs of you, our partners.
7 But again, we need as much time as possible in order to
8 produce a high-quality report, so if there are ways that
9 we can work together in order to make sure that we're
10 given as much lead time as possible to prepare the kind
11 of report that you need to make a decision, that would
12 help with our project. I have used specific comments on
13 the petitions themselves. We believe that it would be
14 useful if the petitions could be more detailed and
15 consistent. We have had petitions range from a half a
16 page to several pages in length that provided lots of
17 detailed guidance. The more detailed and consistent the
18 reports can be, the better we're going to be able to
19 respond to the questions with regard to that substance.
20 We also think that it would be useful if the petitions
21 began by addressing the criteria themselves and
22 providing some guidance to us as to what the evidence
23 might be supporting whether that criteria is met or not.
24 Instead of having the TAP reviewers begin and do the
25 search trying to get into the mind of the petitioner as

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1 to why they think this is consistent with the OFPA, if
2 we could actually have guidance from the petitioner
3 saying we believe this substance is consistent with
4 OFPA, because it meets each of the criteria in these
5 ways and here is some of the evidence that we believe
6 supports that, that then allow us as an independent
7 third-party reviewer of the information to verify that
8 information, compare it to the objective standards that
9 hopefully we're able to work together to set and
10 determine whether or not this petition is meeting the
11 criteria and objectives of OFPA and the entire organic
12 project. We also think it's important that there be
13 different petition formats for crops, livestock and
14 processing. Some of the issues in each of those areas
15 do differ. We understand that some work is already
16 ongoing on that and we look forward to seeing the
17 result, but we do want to emphasize that from our
18 perspective it would be quite useful to have different
19 petition formats for the different areas. One
20 consistent and serious problem that we've run into at
21 the Center for Food and Nutrition -- pardon me -- one
22 problem that we've consistently run into at the Center
23 for Food and Nutrition Policy is that acquiring
24 confidential information can be quite difficult. In
25 particular, some of the information on how the

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1 substances are manufactured, those can be confidential
2 procedures and oftentimes it is difficult for us to get
3 manufactures to share with us or to develop some sort of
4 blinded process through NOP, NOSB or some other agency
5 that would allow us to get the information that we need
6 to answer some of the criteria. If we could work with
7 NOSB, NOP and petitioners to develop some sort of
8 systematic way of handling confidential manufacturing
9 information, it would make it easier to provide the kind
10 of information on environmental impact and other issues
11 with the criteria. Alternatively, if we're unable to
12 develop a good system for getting that sort of
13 confidential information available to the TAP reviewers,
14 it should be recognized that TAP reviewers should
15 attempt to get this information on manufacturing
16 processes, but there should come a time when the TAP
17 reviewer can document that they have made all valid
18 attempts that they could to achieve the information,
19 where they've contacted, when they made contacts, who
20 they tried to contact in order to get the information.
21 And then it should -- we believe it would be useful for
22 the TAP reviewers to then be able to flag that report as
23 incomplete and say we simply were unable to get the
24 confidential information that we needed to completely
25 address the issues on this substance. And then once

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1 it's flagged as incomplete, to have help from NOSB, NOP
2 or the petitioners to try and address that lack of
3 information. It would also be useful to have more
4 information on the uses of the substance, including
5 information on the specific uses that are envisioned by
6 the petition, other uses of the substance and as well as
7 specific examples of how this substance has been used,
8 specifically in organic agriculture or how it's intended
9 to be used in organic agriculture. I was very
10 interested in the discussion that we saw earlier today
11 with the FDA and the issues of making sure that the
12 substances that are petitioned for use under OFPA are
13 consistent with all existing laws and regulations. As I
14 mentioned, in some of the other activities we've been
15 involved with, qualified health claims, a screening
16 process has been set up, in that case at FDA, in order
17 to evaluate petitions before they go on for further,
18 more detailed review. We do believe that it would be
19 useful to have a screening process established by NOSB
20 and the National Organic Program to determine that
21 petitions are complete and that the proposed substance
22 and use do not violate federal law. We do understand
23 that some of this is already being implemented. And as
24 I said, I found the discussion earlier today to be very
25 interesting and useful. We encourage you to continue to

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1 work to help make sure that a screening process is put
2 in place that will help to guarantee that the petitions
3 that go out are ready for review by the TAP reviewers
4 and that we don't have a waste of resources with doing
5 TAP reviews on substances that would not be allowed to
6 be used because of other federal laws. We also have a
7 few specific comments on the statement of work as you
8 requested us to address. The terms used in the criteria
9 need to be clearly defined and objective standards need
10 to be established on which to judge whether each
11 criteria is met. Again, we believe that these standards
12 need to be established through regulatory guidance, so
13 that value judgments and personal opinions are
14 irrelevant to the evaluation of a substance. In our
15 opinion, the evaluation of a substance should be the
16 same regardless of which TAP reviewer it would be
17 assigned to. In our view, we believe that it's
18 important that when a substance is evaluated any
19 reviewer can point to it and say this meets the
20 standards, because it meets these specific objective
21 criteria and here's the evidence, or it does not. We
22 believe it's also important that the standards be clear
23 to all stakeholders, whether someone is an organic
24 consumer, whether someone is an organic producer,
25 whether is a policy maker in this area. The standards

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1 should be clear enough that people can have a reasonable
2 expectation of what is likely when they submit their
3 petition, and furthermore, they should have some
4 assurance that because there are objective and
5 transparent standards, that the decisions that are
6 reached on these substances would be more defensible in
7 the event of legal challenges. We believe that separate
8 and distinct regulatory guidance needs to be issued for
9 crops, livestock and processing. The issues in the
10 three areas are very different and the TAP reviewers
11 need guidance on each one. So as regulatory -- as you
12 can develop regulatory guidance, if you can think about
13 how the regulatory guidance needs to be different for
14 each one of the areas, that would be very useful to TAP
15 reviewers. We also recommend that a system should be
16 established to provide more consistent and constructive
17 feedback to improve future reports. We understand that
18 NOP and NOSB are developing some forms at this moment
19 that may help with some of the feedback process, but we
20 are very interested in finding out what parts of our
21 reports are successful and useful for the regulatory
22 decisions that need to be made, as well as the parts of
23 the reports where there have been problems, and a
24 consistent means of providing feedback on the reports
25 would be useful for us, both as -- I mean, quality

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1 control, as well as a means of improving our work going
2 forward. As I mentioned at the start of the discussion,
3 the lines of communication need to be clearly
4 established and maintained, in particular, we believe
5 the TAP reviewers need to know whether the assignment or
6 petitions will come through NOP or NOSB and who's
7 direction to follow about whether to proceed, put on
8 hold, additional information that's required, again,
9 some way of making sure that TAP reviewers know whom to
10 turn to with questions and who to listen to as they get
11 additional direction about how to conduct a particular
12 report, it would be useful. As I mentioned, additional
13 regulatory guidance helps to establish more objective
14 criteria are really the heart of what we think could
15 help to improve the consistency and transparency of this
16 process. I'm not going to go through at this point all
17 of the criteria and talk about exactly what we think the
18 regulatory guidance should be. Frankly, I don't think
19 it's the place of the TAP reviewers to say exactly what
20 that guidance should be. I think that's a project that
21 needs to be addressed by all the stakeholders that are
22 involved. However, I will suggest a few examples to
23 show you where we have had difficulty implementing some
24 of the criteria and coming to a recommendation about
25 whether a particular substance does meet particular

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1 criteria. For example, in criteria one, from crop and
2 livestock. The potential substance for detrimental
3 chemical interactions with other materials used in
4 organic farming systems. There are a couple of issues
5 in there where guidance could be useful. To start with,
6 it can be very -- it can be impossible to address every
7 possible interaction between a substance and all of the
8 materials that could possibly be used that have been
9 identified as used in organic farming systems. So some
10 regulatory guidance on how to focus or limit the search
11 for which interactions are important, which are the ones
12 that are of the most concern to either the petitioner or
13 the Board or the National Organic Program, would be
14 useful. Also, the statement as it's written, in our
15 view, doesn't provide an objective standard by which we
16 can determine when the line has been crossed in terms of
17 detrimental chemical interactions. We can define what
18 the chemical interactions are going to be between a
19 proposed substance and substances and materials that are
20 used in organic farming systems. But determining
21 whether something is so detrimental that it fails the
22 criteria is not as clear to us from that statement,
23 whether this means none is allowed, that no detrimental
24 chemical interaction could be allowed, a little and what
25 a little would mean or it depends on other pieces of the

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1 criteria. So regulatory guidance that helps us better
2 understand what the threshold is for a particular
3 criteria would be useful in helping to make sure that we
4 provide objective TAP reports that others could look at
5 and come to the same conclusions. Again, briefly on
6 point two, the toxicity and mode of action of the
7 substance and of it's breakdown products or any
8 contaminants and their persistence in the environment.
9 We can provide objective reports on the chemical and
10 environmental properties of a substance and how it
11 breaks down while it's in the environment. That's
12 something that can be provided objectively that everyone
13 could come to the same conclusion about. But as we read
14 the criteria currently, it does not provide guidance
15 about what level, if any, is allowable. And again, it
16 goes back to the question, is this criteria going to
17 fail to be met if we demonstrate that there is any
18 amount of toxicity as this substance breaks down in the
19 environment, is a that the criteria? Or where should
20 the line to be drawn on in guidance on that, we believe
21 would be useful. On point three, one of the -- point
22 three is the probability of environmental contamination
23 during manufacture, use, misuse or disposal of a
24 substance. One of the issues that we've had with that
25 criteria is the term misuse. It is difficult to

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1 determine all of the possible ways that someone would
2 misuse a product. Guidance on whether we're to look at
3 what would be a likely misuse or how we can limit that,
4 how that term of misuse should be applied in this
5 particular case, we believe that more guidance would be
6 useful. And finally, the most difficult -- the most
7 difficult criteria that we have faced in terms of trying
8 to come up objective standards that we think could be
9 defensible based on the evidence that we could provide,
10 has been the question of compatibility of the substance
11 with a system of sustainable agriculture. There are a
12 number of terms in there that could stand additional
13 definition from our perspective, and guidance on how to
14 determine what that capability is without having to rely
15 on a value judgment of the particular TAP reviewer, we
16 think would be useful and would improve the transparency
17 of the process, as well as the defensibility of
18 regulatory decisions that are made should any legal
19 challenges come along. I also want to give an example
20 of a criteria that we think is quite well laid out in
21 the current system. Under the criteria for processing,
22 point five establishes the criteria that a substance
23 should be graphed, considered generally recognized as
24 safe by the FDA when used in accordance with good
25 manufacturing processes and contains no residues of

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1 heavy metals or other contaminants in excess of FDA
2 tolerances. So this clearly defines what standards are
3 being used to evaluate this question and it gives
4 reference to an objective standard that can be used in
5 order to determine how much is too much. And that
6 objective standard in this case is in excess of FDA
7 tolerances. So now on this question, any TAP reviewer
8 can go through, determine whether the substance is on
9 the FDA grass list, when it's used according to the good
10 manufacturing processes. And good manufacturing
11 processes have been clearly defined in other areas. And
12 then it says what the threshold is that would move a
13 substance in violation of this criteria. So we believe
14 that is an example of a criteria that can be implemented
15 consistently by a TAP reviewer based on evidence about
16 the substance. In conclusion, I want to say that CFNP
17 is committed to making the TAP review process
18 successful. We've gained valuable experience from our
19 previous reports and we have also just brought on an
20 additional project manager to assist with TAP reports.
21 Ms. Gail Heim, who is in the audience today, has several
22 years of experience with environmental chemistry and EPA
23 regulations, as well as an undergraduate degree in human
24 nutrition. Combined with the rest of the experience
25 that we have at CFNP, we believe that our experience and

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1 knowledge base in food safety, nutrition and animal
2 health can provide an excellent breadth of knowledge for
3 continuing to work with you on the TAP reports. Thank
4 you once again for this opportunity to share our
5 thoughts with you. And I would be happy to take any
6 brief questions, or if we need to move on to the next
7 person, Dave, we might as well.

8 MR. CARTER: Okay. Dr. Forshee, how -- what's
9 your timeframe here? Because I understand you may be
10 under kind of a time crunch to...

11 MR. FORSHEE: Yeah. We've actually been able
12 to squeeze out a little additional time, so I have some
13 time that I can stay. How late are you...

14 MR. CARTER: Okay. Well, what I want -- you
15 know, in an ideal world, I think it'd be good to go
16 through the other -- to have OMRI come up and give their
17 presentation, and then we could ask some general
18 questions, so if...

19 MR. FORSHEE: We can stay until after that
20 presentation.

21 MR. CARTER: Okay. We'll be...

22 MR. FORSHEE: Okay. Thank you very much.

23 MR. CARTER: Then I would like to have OMRI.
24 Emily Brown-Rozen or Dave Decou or...

25 MR. DECOU: Hello, this is Dave Decou.

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1 MR. CARTER: Okay.

2 MR. DECOU: I'm introducing the OMRI
3 presentation.

4 UNKNOWN: Hold the mike up, Dave.

5 MR. DECOU: I thought you wanted me to lean
6 over.

7 UNKNOWN: No, we got a PowerPoint and we just
8 go to get...

9 MR. CARTER: Okay.

10 MR. DECOU: Yes, there will be a PowerPoint in
11 a minute. While that's beginning, I'd just like to
12 introduce OMRI, who many of you probably think you know
13 what it is and I'm not sure you all do know what it is.
14 First of all, the three of us who are presenting today,
15 many of you met Emily Brown-Rozen. She's the policy
16 director of OMRI. She's previously worked for -- New
17 Jersey. She's worked for the OTA, involved with the
18 American Organic Standards creation. She's been a
19 materials advisor to the Quality Assurance Counsel of
20 the OTA, and many, many other projects involved in the
21 organic industry. Richard Theuer is a previous member
22 of the NOSB. He's been involved -- heavily involved in
23 your processing industry -- food processing industry and
24 he currently has a consulting firm of his own and he's
25 recently joined the Board of directors of the Organic

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1 Materials Review Institute. He's also a long time
2 member of the advisory council at OMRI, as to give a
3 deeper scientific background on various issues. I
4 happen to be an organic farmer. I have also spent the
5 first six months of this year as the managing director
6 of OMRI in the process of mentoring a new executive
7 director who came -- started working in January and has
8 now taken over as executive director as of July 1. And
9 I'm no longer employed there, but I am on the Board of
10 directors. And point of fact, I'm on the Board of
11 directors of the organic -- the Grohn [ph] Company in
12 Eugene, Oregon. I'm on the Board of directors of the
13 Organic Trade Association and the Board of directors of
14 OMRI. And as you probably figured out, I'm thoroughly
15 bored. What -- as a farmer, I've watched this industry
16 for 20 years and I really do want this industry to
17 continue in the vein that it started with, which --
18 well, not all the veins. There's been too much
19 discussion about too many things and it's all been
20 redundant, but let's find a way to move ahead and be
21 consistent with our history.

22 MR. CARTER: Could you repeat that, please?

23 MR. DECOU: I can't remember what I said.

24 MR. CARTER: That's all right.

25 MR. DECOU: Thank you, Dave. I do want us to

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1 come up with a thorough and a transparent process, and
2 to get truly objective standards that we can all
3 understand and agree with is difficult, if not beyond
4 that. But I do want to be able to have those standards
5 also to apply to when we prohibit a material, as well as
6 add a material. Obviously, the TAP review process is
7 crucial. We need to do it well to maintain the
8 integrity for our customers. How do we get there?
9 That's slide three. I'd like to be at slide two. OMRI
10 as an institution is a non-profit 501C-3 -- okay. Maybe
11 my order's different than theirs, but we'll go on.
12 501C-3, research and education organization. We have a
13 board of directors that is intentionally made up of a
14 diverse portion -- wow, that was pretty -- of the
15 industry. We have a certain number -- we have a minimum
16 number of certifiers, a minimum number of farmers, we
17 have a minimum number of processors, a minimum number of
18 input suppliers and a minimum number of public interest
19 people on the Board. So as we move through we try to
20 make contact with as many aspects of the industry as we
21 can so we don't over-shift ourselves. We also guarantee
22 that we have more certifiers than anybody else, so
23 they're considered to be more objective than the rest of
24 us, and I won't take discussion on that point. The
25 primary focus of OMRI at this point is objective

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1 material review. Our mission, as put up there,
2 professional independent transparent review of materials
3 compatible processes allow to produce, process and
4 handle organic food and fiber. That's really our focus.
5 It shows up in our main activity, which is brand-name
6 review of products appropriate to be used in organic
7 processes, whether it's farming processing or livestock
8 production. We are a former TAP review contractor. We
9 no longer do TAP reviews. We finished our last one in
10 October a year ago and we have no intention of doing TAP
11 reviews in the future. Point of fact, it makes our life
12 much too complicated because of the brand-name review
13 work that we do. We have to be extremely knowledgeable
14 in the materials world, but we cannot be on both sides
15 of the fence in advising ourselves. It becomes much too
16 much of a conflict of interest, which, you know, most of
17 us know how hard that gets to be. So we have
18 consciously as an organization decided to no longer do
19 TAP reviews. OMRI historically is very appropriate --
20 from our history is very appropriate to advise on this
21 because of all the TAP reviews we've done. Many of them
22 we did very well. I think there are probably a few
23 arguments about a few, but in general, we've done a
24 fairly good job. We still are heavily involved in the
25 materials issues of the brand-name -- brand-name review

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1 projects that we do and is the main source of funding
2 for our organization. Our brand-name review work
3 requires us to maintain -- the next slide, please -- a
4 generic materials list, which is considered to be
5 consistent with the National Organic Program's national
6 list, but isn't always identical in the fact that we
7 will probably have some naturals in there, whereas the
8 national list only contains those things that are
9 synthetic and/or prohibited naturals. But we have a
10 larger list that we consider to be more user-friendly,
11 and that's the intent of them. And if you have advise
12 on how to make it more user-friendly, we're always
13 willing to listen. We review inputs and ingredients to
14 see if they're consistent with the rule as the NOP has
15 presented it. That means it's not that we are
16 certifying anything. It's quite hard to not use that
17 word. People still throw it at us, but we've tried --
18 it's consistent with the national rule. When we have a
19 brand-name product and say this is OMRI listed, we're
20 saying that it is consistent with the national rule. We
21 also make no claims to say that we have all the brand-
22 name products listed. We're only doing it for those
23 that passed to do it. We maintain a third-party
24 distance from everything and we are able to work beyond
25 some of those confidential business material issues

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1 because of the standards that we maintain in the
2 organization. Everybody's got a very strict contract
3 that they sign around that issue. We also do a lot of
4 work consulting with certification bodies, government
5 agencies and international organizations. Our people
6 travel all over the world to help set up -- and we work
7 with IFON [ph] and so on. At this point, I want to turn
8 the mike over to Emily, who's going to talk about
9 enhancements to the program -- to the TAP review
10 program, guides, petitioners, and then Richard Theuer
11 will take over and talk about how there's quality
12 improvements that might be done.

13 MS. BROWN-ROZEN: Hi, I'm Emily Brown-Rozen,
14 the policy director for OMRI, which you all know, I'm
15 sure, by now. Thank you for inviting us to speak. This
16 is a great opportunity for us and we really appreciate
17 it. I just want you to realize that I brought my two
18 big-guys with me, so if you have any problems with
19 anything I say, you can talk to them, okay? Okay.
20 Well, let me give a little brief overview of what I'm
21 going to cover here and that is -- there's just these
22 little points here that -- enhancing the petition
23 process overall, including the petition itself. The
24 next big step we see that needs some work is the
25 screening process that Dr. Forshee talked about quite a

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1 bit. I think we actually have a lot in common with some
2 of the points that he made, so I will be reinforcing
3 that. The statement of work and the guidance for the
4 contractors and then a little bit about the decision
5 process itself as -- once it goes out of the TAP
6 contractor's hands into NOSB's hands. Okay. Next,
7 Dave. Okay. First of all, with the petition
8 guidelines, the notice that's in the federal register
9 from July of 2000, is the official notice to the public
10 as to what constitutes a good petition. And this is --
11 you know, I think it was actually a pretty good document
12 at the time. It's now -- the rule has been finalized
13 since that was published. So this came out before the
14 rule was final. So we need some updating in terms of
15 reference to the existing regulation. It doesn't
16 mention, you know, the section numbers or, you know,
17 that they're actually in the rules, so it would be
18 helpful to update it and mention that. It also -- it
19 would also really help to include the Actual
20 prohibitions as are spelled out OFPA, because it's not
21 fair to petitions what's just definitely off the table.
22 You would hope they would take initiative to go look up
23 OFPA, but that doesn't seem to have prevented a lot of
24 petitions from coming in the door. They're just, you
25 know, categorically, you know, not allowed. So that

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1 would be helpful to have that in there. Also, it should
2 reference the permitted categories, because there's a
3 specific pretty narrow list of permitted categories for
4 production, crops and livestock, particularly. And so
5 if it doesn't fit at all into any of those categories,
6 it's a tough call -- you know, it's another, you know,
7 sort of pointless petition. Okay. The other things
8 that need updating there is the processing criteria are
9 not included in that petition notice. There's just a
10 reference that says call the NOP office if you want to
11 find out what they are, so it would be easier if they
12 were right there. The livestock criteria, it just -- it
13 mentions the general of the criteria, but now that the
14 Board has done work on elaborating what -- how to apply
15 the livestock criteria to livestock materials, so it
16 would be good to fill that information into the
17 document, too. Then, again, on your point 12, which is
18 the justification statements in the petition, Dr.
19 Forshee made his point. The petition should address the
20 specific criteria that applies to them. Right now,
21 there's just some general language that says -- talk
22 about, you know, it's affect on the environment, you
23 know, there's sort of a summary of the criteria, but if
24 they really -- the petition statement, the
25 justification, should really be trying to justify

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1 according to the exact criteria, it would make the case
2 stronger in the petitions and it would make it easier
3 for the reviewers to evaluate the data that they
4 submitted. There also needs to be a notice in there
5 that petitioning is not just for adding or prohibiting
6 materials, it's also for amending materials. It's not
7 clear right now when you read that. There needs to be
8 an amendment on the language in I think it's point 12,
9 again, on handling substances. It talks about -- you
10 have to provide a justification statement for synthetics
11 used in handling. But -- so I actually saw a petition
12 come in with no justification statement and it said,
13 well, it's -- you know, it's not synthetic, you know, so
14 we don't have to do that. But the point at issue, that
15 terminology should really be nonagricultural, because
16 synthetic and non-synthetic materials used in handling
17 all have to be on the list and they all should be
18 justified in the petition. So I think that was a case
19 where that was before the final rule on that and, you
20 know, the terminology wasn't quite with it on the rules
21 terminology. Okay. Did I hit everything on that list?
22 I guess so. You moved me on. Okay. So that's the
23 petition notice. Now, I think in addition, guidance for
24 the petitioners would be good and -- so that we get the
25 best quality petition we can up front and they

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1 understand more than maybe what's in the dry language of
2 the notice or -- you know, you need a little more
3 explanation. It always helps. So here are these terms.
4 And these, of course, are tough questions and they're
5 going to take a little policy work. I mean, the Board
6 always is struggling between what is synthetic and what
7 is non-synthetic and -- but, you know, clear examples --
8 you know, summarize the policy making that has come to
9 point, get it on paper, provide that to the petition and
10 also give examples of things that have been determined
11 to be synthetic and non-synthetic, so they would know
12 how to -- you know, or even if they don't even need to
13 petition. We see a lot of unneeded petitions coming in
14 that are for natural materials that -- I mean, it
15 actually -- it doesn't hurt to have them come in and
16 have an official confirmation that it is natural.
17 That's nice to know. I mean, that can be part of this
18 preliminary screening process. But it's a really
19 important step. The other really tough one is
20 agricultural versus nonagricultural. I think everybody
21 in the industry is wrestling over where to draw that
22 line and what does it actually mean. So it's just time
23 to sit down and figure it out and put down some
24 guidelines and draw the line and then, you know, modify
25 it if you have to, but put it on paper. Listing, again,

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1 the categories of permitted substances, you know, go
2 into more detail about prohibited materials and also
3 referencing all the previous NOSB decisions and -- you
4 know, so that people can easily look up what was already
5 petition, was it prohibited. I know there's some great
6 improvements coming on in the website, which is really
7 good. Hopefully eventually we'll have it all tied in
8 there or maybe update the spreadsheet database so that
9 you can see what came in when, when it was prohibited,
10 for what reason and it'll be real transparent to all the
11 petitioners. Okay. Okay. Another thing I think needs
12 clarification is the CBI situation on the petitions.
13 The way the notice is now, it just says, you know, you
14 can do it. You know, if you feel you need to keep this
15 material proprietary, that's your -- you know, and
16 you're entitled to do that. And so petitioners assume
17 that -- fine, I'll do that. But they need to know what
18 happens when they do that. I mean, just clearly spell
19 out who gets access to it. Does it go to the TAP
20 reviewers, does it go to the NOSB, are they supposed to
21 hold it confidential or do they not get to see it at
22 all, just so that everyone knows that, you know, it
23 might cause a delay in their petition, it might cause
24 some difficulties for NOSB to review it, so that they're
25 aware up front when they make that decision, if they

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1 want to hold a CBI or not, so that we don't have to
2 argue about it later and they can just be advised, you
3 know, how they're making their choice to reveal
4 information. Also, that guidance would be helpful to
5 the petitioners on the requirements to document the
6 regulatory status, either on their EPA, FDA -- I should
7 add APHIS to this -- so that they can do the best job of
8 identifying that and save time later when they -- you
9 know, have to consult on that. Okay. The next big
10 topic is what we think is to be a more formalized
11 screening period. Between the time the petition comes
12 in and goes to the contractor, it needs to -- I think
13 just elaborate a little bit more carefully what this
14 screening procedure is. I understand you're all working
15 on it and that's always been a little tricky to monitor,
16 because it's going between committees and NOP and it's
17 just hard to try track all that. But if we have a more
18 formalized process, I think -- and really dedicate a
19 certain amount of time to that, that'll, you know,
20 eliminate a lot of unnecessary work later and just make
21 it real clear and transparent to the public, too, what
22 is the status of this material. So in this period an
23 assessment should be made that whether the petitions
24 meet all the of the criteria -- not all of the criteria,
25 but the basic criteria for the prohibited categories and

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1 that sort of thing. And then it does provide for a
2 better TAP review. Okay, Dave. Okay. Step one of
3 screening. NOP receives the petition, evaluates it for
4 completes. Are all 12 points answered, is it -- you
5 know, seem reasonably complete, and if not, send it back
6 to the petitioner, you know, set a timeframe for that.
7 You know, within 30 days we're going to send it back or
8 we're going to say it passes step one. And then give
9 the petitioner a finite amount to get it back or else
10 it's -- you know, it's got to start over in the queue.
11 So if you put -- and we do this at OMRI all the time.
12 We just give them deadlines, you know, and keep things
13 moving. And if they choose not to do it, then they're
14 going to have to wait. So it just help manage the time
15 there. Step two would be -- I would suggest a joint NOP
16 and NOSB review of the screening of the criteria and the
17 prohibited categories. Maybe NOP does it first and then
18 the materials committee or whoever signs off on it, just
19 to make sure -- or NOP might not be sure and they might
20 ask you for your advice, but you should both sign off on
21 it, I think, because that's kind of a big step. Is it a
22 prohibited substance, is it in a permitted category.
23 And then this goes on the next one, Dave. Is it natural
24 or synthetic, is it, you know, being applied in the
25 right slot, is it agricultural or not. And sometimes

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1 these you can't answer right of the bat, and you might
2 need to say, okay, we're going to go to the TAP
3 contractor, we're going to get an initial assessment of
4 this screening and then we're going to make, you know, a
5 stage-two decision before we go for a full TAP review,
6 so we have an informed decision before we spend a whole
7 lot of money and maybe waste time. So I just think that
8 would be really -- later on. Okay. Next. Okay. I was
9 just going briefly run through the so-called prohibited
10 categories. But this would be the kind of guidance that
11 could also go out to the petitioner. So if they've --
12 you know, if they've got that kind of information, then
13 this would -- you know, this makes this job easier, too,
14 for the screening process. But there's some specific
15 prohibitions in OFPA in the different categories under
16 crops -- you know, synthetic fertilizers are basically
17 all prohibited. Synthetic nitrogen, phosphorus, lime
18 and potash. Under livestock healthcare practices
19 there's a couple of tricky areas in that -- well, no
20 antibiotics, except therapeutic. And then there's this
21 general statement about medication in the absence of
22 illness, which is always hard when we're talking about
23 preventive healthcare practices.

24 MR. CARTER: You have us a little looking
25 dazed and confused...

1 MS. BROWN-ROZEN: Oh.

2 MR. CARTER: ...because that slide is missing
3 from...

4 MS. BROWN-ROZEN: This slide -- you know, it
5 got slipped out of that, too.

6 MR. CARTER: Okay.

7 MS. BROWN-ROZEN: Yeah.

8 MR. CARTER: I thought maybe...

9 MS. BROWN-ROZEN: So we can...

10 MR. CARTER: ...you were just making sure
11 we're awake here.

12 MS. BROWN-ROZEN: Okay. I saw you all were
13 shuffling. Okay. Good, you're reading along.

14 MR. CARTER: That's right.

15 MS. BROWN-ROZEN: That's fine. Okay. Next
16 one, Dave. And so -- and then this is a similar issue
17 with specific prohibition on handling materials, the
18 sulfates and nitrates -- nitrates. Except for sulfates
19 allowance in wine, we know we have that new amendment to
20 the OFPA. The one about packaging materials that might
21 have synthetic preservatives or fumigants or ingredients
22 known to have levels of nitrates, heavy metals or toxic
23 residues. Now, this -- you know, some of these you may
24 not be able to grasp out of the petition, but we should
25 look at those basic ones for the obvious ones that would

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1 fall out at that point. And then the permitted
2 categories that I've been talking about are the -- that
3 long specific list that they wrote in to the OFPA. You
4 know, everything that's going in the crops and livestock
5 list is supposed to fit in one of those categories. So
6 if it doesn't, there's kind of question whether it can
7 be added to the national list. So that's where we have
8 a pretty narrow group of categories there. Although,
9 you might want to spend some time talking about what is
10 a production aid, because I think that's been sort of
11 expanded from time to time to cover things like
12 potassium bicarbonate for disease control. There's no
13 other good category for it that I can think, so -- okay,
14 next. Okay. And then this is really important to do
15 this screening on the regulatory status. We thought --
16 you know, obviously, we run into problems with that. So
17 developing either a process to get, you know, a point-
18 person at the other agencies to respond to questions at
19 this point or, you know, hopefully get good information
20 from the petition on it, and then if you have to verify
21 that before you go on to a full-fledged review. That
22 seems like it would be worthwhile. Oh. And then this
23 is the last most important thing I think about screening
24 is that it needs to go in the public record. You know,
25 you have to point -- make a spot to announce what you've

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1 found. You know, if it didn't go to full TAP review,
2 but you decided it was rejected, then either, you know,
3 NOP notifies them and it gets published somewhere or
4 maybe at your next meeting you say, okay. This is the
5 list of petitions that have been rejected for this
6 reason, so that it's just real clear, you know, and it
7 got -- and people know why and what happened to it and
8 -- you know, because we've had suppliers come to OMRI
9 and say, well, we send in petitions and we never heard
10 about them back and, you know, they could've been
11 terrible petitions. I don't know. But, I mean, it's
12 nice to have that very public so everyone does know.
13 Okay. Moving on to the statement of work and the
14 contractors. Rich is going to talk in more detail about
15 this, but I have a few points I wanted to hit here. The
16 way the contract's written now, it requires bimonthly
17 reporting, which I think is actually a good idea, but it
18 takes some supervision. So you need a back and forth --
19 somebody looking at those monthly reports, and good
20 communication. I think there was a good point made
21 earlier that where are we with the problems, you know,
22 is there a hang-up or does this one need, you know, one
23 question answered and some feedback from the Board
24 before we go further, that kind of thing. So regular
25 reporting and communication I think is good. There's

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1 nothing in the report that require -- in that statement
2 of work that really requires qualifications of your
3 staff people and your -- or your updated -- you know, if
4 you're changing personnel, you know, that should be
5 regularly updated and supplied to the department. The
6 timeline has always been an issue. As was mentioned in
7 the contract, it says 262 days. We feel like you need
8 at least 120 days to prepare a good initial report and
9 then send it on to reviewers, really. So we tried to do
10 work in 120 days totally, but it was really tough to get
11 a really good quality report and have some time for re-
12 view -- you know, have the reviewers really work on it
13 further. And maybe sometimes they need a second -- you
14 know, more questions answered after the reviewers. So I
15 think, you know, a longer time period is definitely
16 warranted. How that's handled, it is difficult. If you
17 don't know how many TAP reviews you're going to be doing
18 in a certain time period, to hire the number of staff
19 and be geared up to do the work is difficult.

20 MS. DIETZ: How long is your normal process
21 for TAP reviewers to have a document, 30 days?

22 MS. BROWN-ROZEN: Oh, we gave them three
23 weeks, actually.

24 MS. DIETZ: Three weeks. Thank you.

25 MS. BROWN-ROZEN: And it was tough. Okay,

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1 next. Scope of the review. I think -- oops -- the --
2 one other thing that needs to be clarified a little bit
3 is, you know, we would always get into to new issues
4 about alternatives. One of the criteria is what are the
5 alternatives for use. I think that and compatibility
6 are the two hardest criteria to answer and they're not
7 totally objective. I mean, you do have to evaluate sort
8 of the scene, but -- and try and do the best you can
9 with the information you have. But alternatives, you
10 know, we feel they should be done based on -- and this
11 is what we tried to do, is base them on the literature
12 -- solid reports, so we could find how they're being --
13 what alternatives were -- not could be used now and what
14 historically have been allowed from, say, older
15 references possibly before this, you know, new product
16 or ingredient was invented. So it's always good to go
17 back into the historical record of how did people used
18 to make the stuff or how did you used to grow this crop
19 without this. And that would give an indication -- so
20 alternatives also need -- I think there needs to be
21 guidance about it's not just alternative substances,
22 it's alternative practices, methods, cultural practice,
23 biological methods, other -- you know, the whole scope
24 there. Availability of the alternatives is difficult to
25 assess. And that -- sometimes you can't tell. You

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1 know, you an search the literature and there's, you
2 know, new stuff out there or it's being used differently
3 and it's very hard to get a very current industry
4 status. So I think that's where, you know, there needs
5 to be additional public comment or maybe other -- if you
6 want to look at economics of an available alternative,
7 you might need to commission a specific means for
8 collecting that information that's different than the
9 TAP review, because that's just really a whole different
10 area. And also that -- I think -- yeah. So economic
11 impact should come from the public, it should be a
12 different source. Economic considerations are really
13 not mentioned in the criteria in the OFPA, so I think
14 that's an additional one. If you're going to consider
15 it, that's a difficult one to tackle. Next. Okay. On
16 to the decision process. Again, I think we've said
17 these things in general before, but, you know, the whole
18 -- you know a good process goes a long way, you know,
19 with having a defensible process and having people
20 accept the decision. So as much as possible, we can
21 move towards complete transparency. I think a great
22 step -- now the petitions are starting to be posted and
23 I think that's very helpful and that's a good step. And
24 then getting all the TAP reviews posted in a timely way
25 before the reading so that people can make comments, is

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1 really important. If possible, the committee
2 recommendations -- and then there's this period after
3 the TAP review is done where the petitioner might be
4 giving more information to the Board, you know, to
5 address some of the issues that were raised in the TAP.
6 It'd be good for that information to be public, too, so
7 it's all aboveboard and, you know, a good balance of all
8 the information that can be made. Standardizing
9 procedures at the meetings. I think we've been working
10 at this on every meeting since I've been attending them
11 and it's come a long way. But I think, you know, it's
12 time to really narrow it down and kind of follow the
13 same way every time. I know -- and you have proposed
14 some forms to record your decisions in terms of the
15 criteria that are required and that's fine. It seems
16 very complete, and then it covers every possible
17 criteria you could think of. I think that you might
18 need a different model for arriving at the answers to
19 those questions. I mean, you might want to -- we've
20 proposed a decision tree in the past and it's attached
21 in the back here. To sort of step by step go through
22 the questions and answer them all, and then I think that
23 would be -- you know, you could fill in the blanks on
24 your checklist, hopefully. And you do have to go
25 through it a little differently. Crops and livestock

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1 and processing are all different, so, you know, you have
2 -- you might want to address that. I think those could
3 be modified for the livestock criteria now. But if you
4 go through them all in an orderly way, then I think
5 whatever forms you need to fill out for NOP will be
6 easier and you're flow will be easier, too. I guess
7 that was what I was talking about, the forms there. If
8 -- yeah. If you get to a point where there's not
9 sufficient information to make a decision, I think there
10 should be no hesitancy in calling for more information
11 and tabling a decision and reconsidering it when you
12 have, you know, good data on hand, and again, adequate
13 time for comment. Okay, Dave. Okay. Always more work
14 needed to be done, so I gave you a little to do list
15 here. But as we mentioned, these guidance's documents
16 could really be helpful, so those -- these are the big
17 ticket issues, agricultural, nonag, synthetic, non-
18 synthetic. What is an antibiotic? We seem to be
19 wrestling with that on some of the drug reviews, because
20 an antibiotic is not like a clearly defined at FDA. You
21 know, they talk about antimicrobials, the talk about
22 antimicrobial properties, and I think it might be
23 helpful to have a little better understanding of when do
24 we say no on those. Commercial availability is a big
25 issue of non-organic ag commodities, because, you know,

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1 then you need to know if you're going to categorize it
2 as agricultural and put it under 60 -- recommend it to
3 go under section 606. How does that -- you know, how
4 does that apply, of if you think it's totally not
5 suitable. So I think that whole policy development is a
6 big area that would be relative to the list of
7 germinations. Next one. We're there. Okay. Well, now
8 I'm going to it over to Rich and then I'll be here to
9 answer questions. Yeah.

10 MR. RIDDLE: You mentioned the decision tree
11 being attached to the back.

12 MS. BROWN-ROZEN: Uh-huh. It should be...

13 MR. DECOU: It'll be...

14 MR. RIDDLE: Okay.

15 MS. BROWN-ROZEN: We have a big hand in that.

16 MR. RIDDLE: Okay.

17 MS. BROWN-ROZEN: He's just giving it to you.
18 He did. Okay.

19 MR. RIDDLE: Keep us attentive.

20 MS. BROWN-ROZEN: All right.

21 MR. THEUER: Well, I'd like to just pass along
22 some remarks that I'm -- how we see a better chance of
23 getting quality TAP reviews. Could I have the first
24 one, please? One thing that we all know is that there's
25 a limit to our competence in the -- in selecting TAP

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1 review contractors. It may be worthwhile considering
2 having them specialize in the different areas, because
3 not everybody is equally good in crops, livestock and
4 processing. Sometimes I'm approached to be TAP reviewer
5 for crops and I, you know, decline very quickly, because
6 I don't know very much about soil. Since that is rare
7 to have organizational competence in all three areas, it
8 might be useful to have specialization. The other
9 element that has, you know, in review and actually
10 creating TAP reviews and doing the boiler chemical
11 review of the -- two years ago, now. Some operational
12 and real life experience with the category is very
13 useful in improving the quality of a review. For
14 example, ammonia. It was thought in a statement that
15 ammonia got into food and ammonia's a boiler chemical.
16 And it turned out it was related to a refrigeration leak
17 in a plant. It was not related to the use as a boiler
18 chemical. But, you know, one has to know about plants
19 and what happens to get that. Could I have the next?
20 TAP reviews are created by investigators. Investigators
21 who are new to the business, in a sense, need to be
22 trained, they need -- and either take time to develop
23 competence -- and time when something's not a good
24 commodity and you need them too quickly. The other
25 option is to have a training program. And so it might

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1 be useful to consider having a requirement for a
2 training program. And the problem is, the current
3 contracts do not fund training. But if you have
4 competent investigators -- and this is a point that's
5 been made before -- they need sufficient time to do
6 quality work. I've tried my hand at doing a TAP review
7 or two and I figure it's 15 to 20 hours of grinding it
8 out, digging into the literature, going and doing it.
9 Well, that means two, maybe three a week if you really
10 push it. And if something comes out of the sky with 5
11 or 10 or 15, it's difficult. You can't keep a timetable
12 when you don't have a steady rate of work. Could I have
13 the next? Providing a complete petition. This has been
14 dwelt on before. The one area you assume is that the
15 processor -- the petitioner knows his system better than
16 anybody else does, so he should know what alternatives
17 might work, he should know what alternatives have been
18 tried. And we all know of TAP reviews where the
19 petition was so complete, it was a joy, and others
20 where, as someone said, it's a two-page document and
21 there's almost nothing in it. Another aspect of
22 completeness is one you might get a chuckle out of.
23 I've seen a document come in as a TAP reviewer where at
24 some point in the system someone tried to save money by
25 printing it on both sides of the page. Well, they faxed

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1 it. And it's very difficult when you only have the odd-
2 number pages to find out what was going on. Could I
3 have the next one? Now, we've talked about TAP reviews,
4 knowing what is expected. The TAP review template is an
5 absolute requirement if you want a good TAP review.
6 They need to be specific, and OMRI will be handing out
7 some of the templates they used historically to give
8 instruction and hopefully solicit good comments to give
9 good TAP reviews. Could I have the next one? Here's
10 where you have to do some work. Many TAP reviews will
11 come back or have comments that doesn't address the
12 question, what about this. It would be lovely to have a
13 blueprint success in the examples of great TAP reviews.
14 It would also be useful to know why you think they're
15 great, so that, you know, beating -- they say teach a
16 man to fish and he can -- you know, you feed him for
17 life. Beating him with the fishing pole doesn't help.
18 And so, you know, it's useful to give a detailed comment
19 on why it's good, instead of always saying this
20 terrible. Because then you'll get more of the good
21 stuff and maybe less of the ones that require massive
22 redoing. Now, the next one. This is another thing that
23 you can do something about. When I was on the Board
24 back in the '92 to '95 area, we actually put out a
25 notice asking people if they would be TAP reviewers, and

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1 quite a few people came back with the answers. As the
2 situation progressed, it's almost like the TAP reviewer
3 people became a proprietary property and you couldn't
4 find out. They were anonymous in the reports. If you
5 were doing a new and you're saying who do I got to,
6 especially if you're trying to find ones who have done
7 it before so you can get -- you know, that's your point
8 of experience. I think it would be useful when we find
9 competent TAP reviewers with operational experience that
10 everybody says are good TAP reviewers, the NOP and NOSB
11 should consider maintaining a roster and maybe
12 petitioning to have people volunteer. What's your
13 specialty, what can you do. Well, if we find them, how
14 do we retain them? The best way of retaining a TAP
15 reviewer is to give him a good TAP review. I've had
16 ones where, you know, the petition was terrible, so the
17 TAP review was incomplete. So you go to the library and
18 you start digging through tons and tons of stuff trying
19 to fit the pieces that aren't there and trying to find
20 out what the alternatives are, are there any other ways
21 of making this material. And so I think the going rate
22 is about \$150. Well, after about six or eight hours,
23 you know, you could go to McDonald's and do hamburgers
24 for a better rate of pay when, you know, that's what
25 your business is. So what also is needed, if you allow

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1 incomplete petitions to go through the process so the
2 work is cascading down on the TAP reviewer -- the TAP
3 creator and then the TAP reviewer, you need to find a
4 way of paying people for the work they do when it
5 expands beyond what they really committed to do.

6 MR. CARTER: Thanks. Let's -- and I'm
7 wondering if Dr. Forshee, if you can come up and the
8 other folks from Virginia Tech, because I think what
9 we'd like to do is just open it up to some general
10 questions and follow-up. Kim?

11 MS. DIETZ: First of all, I want to finally
12 celebrate the fact that I've met Richard Theuer. I had
13 no idea what he looked like, and Richard's obviously
14 been a big contributor to the TAP review process, a past
15 NOSB member, and getting us to the point where we're at
16 today. So thank you for your...

17 MR. THEUER: Thank you.

18 MS. DIETZ: ...commitment to this process,
19 because you have been around since the beginning when
20 there was one-page TAP reviews...

21 MR. THEUER: Right.

22 MS. DIETZ: ...pretty much, where you guys
23 made decisions. We have come a long way, I think, and I
24 gave this spiel this morning, that we approve the
25 process every day, every meeting, every board, every

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1 year, and it's going to continue to get better. So what
2 we're doing here at this meeting, I'm very thankful that
3 we have the commitment by the NOP and by the Board and
4 by the contractors and every to maybe finally get this
5 right. I don't know. We'll see. Again, Richard --
6 excuse me, I'm fighting a cold -- Forshee, you know, you
7 guys have come into this process with, you know, a lot
8 of handicaps and we've acknowledged those and it's been
9 a tough process, but I think that you will see a huge
10 improvement from this point forward, and we'll certainly
11 try to address all of your issues, some of which we
12 won't, because they, quite frankly, have never been
13 within the purview of the NOSB to do. I hear guidance
14 documents, guidance documents, guidance documents. And
15 although I think that's needed, I just don't know who's
16 going to do that. So we need to talk about it as a
17 board and as the NOP.

18 MR. FORSHEE: If I might just say...

19 MS. DIETZ: Sure.

20 MR. CARTER: Go to the mike.

21 MR. FORSHEE: I did just want to emphasize
22 that we stand ready to work with...

23 MS. DIETZ: Yeah.

24 MR. FORSHEE: ...NOSB on these issues. We are
25 committed to making this process work well and to

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1 improve the overall process and our piece in it.

2 MS. DIETZ: And our commitment has to been to
3 improve that process thus far. So I really -- I didn't
4 really have a lot of comments for you other than we've
5 documented and we're certainly going -- we have a
6 commitment, we have a lot of money invested in you to
7 get these -- the best as possible. Emily...

8 MS. BROWN-ROZEN: Yeah.

9 MS. DIETZ: ...could you sit down?

10 MS. BROWN-ROZEN: Yeah.

11 MS. DIETZ: And I agree with everything you
12 said, too. And the process always gets better. You had
13 one comment in here on the decision process and
14 transparent petitions posted, TAP reviews posted, all of
15 those things we've been trying to work on. You had the
16 committee recommendations posted before meetings. That
17 is something we've never done before and I don't know
18 whether -- legally whether we can post the committee's
19 recommendation before a meeting. So I don't know if we
20 can do a little discussion on that.

21 MS. BROWN-ROZEN: I thought -- haven't you
22 posted this on before? I thought some have been, but I
23 don't know.

24 MS. DIETZ: I don't think they've been
25 publicly posted.

1 MR. CARTER: Okay.

2 MR. MATTHEWS: Richard Matthews. Again, that
3 is part of what the grand scheme of this systems
4 approach to the entire rule making process with regard
5 to material. And what it encompasses is that the idea
6 is that the review would be done 60 days before the
7 meeting. The Board's committees would work on the
8 materials during the first 30 days of that 60 days
9 leading up to the meeting. We would then publish for
10 everyone to see what the committee is going to be
11 recommending to the Board, so that the public would have
12 approximately 30 days to react to what the committee is
13 saying they're going to recommend to the Board. And the
14 full board would have approximately 30 days to react to
15 the committee's recommendation, so that when you get
16 here to the meeting, the Board, itself, has already
17 taken into consideration what the committee is
18 recommending, the public has had a chance to see what
19 the committee is recommending. They then come and make
20 better informed comments to the full board. Then the
21 full board takes what they've already analyzed from the
22 committee, plus what they've just heard from the public
23 and then they try to come up with what is a good, sound
24 recommendation on the material. Now, when we get
25 comments in from the public during the period leading up

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1 to the meeting, we'll also be publishing those so that
2 the Board can even in advance start to see what the
3 public is saying on the materials even before the public
4 comes in and makes a public testimony.

5 MS. DIETZ: Thanks.

6 MR. CARTER: Right. Other -- we're you done,
7 Kim?

8 MS. DIETZ: Yes. Thank you.

9 MR. CARTER: Okay. Other comments or
10 questions? Okay. Rose and then Jim.

11 MS. KOENING: I'd just thank both of you guys
12 for coming in and giving presentations. You know, and I
13 understand -- I mean, a lot of your theme was the value
14 judgment, you know, position. I guess the question is,
15 is that, you know, the criteria -- a lot of the, I
16 guess, documentation from your organization -- now that
17 you say that, now I understand kind of the methodology
18 that you go about it. You do a lot of literature and
19 you even kind of present just that data with not much
20 analysis for us. And I guess the -- I think we have to
21 be somewhere in between not putting in, necessarily,
22 value judgment, but just by getting data, a lot of the
23 people on the Board may not have technical expertise in
24 those areas, even though you're assigning somebody who
25 may have technical expertise to do that literature

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1 search. Somewhere in between there doesn't necessarily
2 have to be a value judgment statement, but there does
3 have to be an analytical kind of pros, cons lane of the
4 decision so that we can at least be presented more than
5 just raw data or files downloaded from the Internet. So
6 where do you draw that line is the question I have for
7 both reviewers. Because there's been a lot of
8 criticism, I guess, with too much value judgment versus
9 presenting something in a format that allows us to
10 critique data, especially those who don't have that
11 expertise to then be able to make a decision based on
12 data and some critique by somebody who has expertise.
13 So if you could comment on that.

14 MR. FORSHEE: I have a comment on that. For
15 the record, Richard Forshee. We have heard that concern
16 and that's one that we're definitely going to work to
17 address so that there is more synthesis of the material,
18 as well as one of the things that we're planning for
19 future reports is essentially an executive summary for
20 the points before going into the Actual data. And so,
21 yes, in terms of summarizing, weighing the quality of
22 the evidence, those are all things that -- things that
23 we are comfortable as an organization doing. And we
24 have heard that concern and in the next round of
25 reports, we're going to work to address that.

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1 MR. CARTER: Okay. Jim?

2 MR. RIDDLE: Yeah.

3 MR. DECOU: Can I...

4 MR. CARTER: Well, I'm sorry. Yeah.

5 MR. RIDDLE: Well, I could...

6 MR. CARTER: I'm sorry.

7 MR. DECOU: I think that's a very good point.

8 And having been a member of the NOSB at an early stage,
9 each NOSB board probably has it's own slightly different
10 sort of Zeitgeist of, you know, why is it -- we each get
11 a philosophical orientation working with each other.
12 And so you do have the dilemma of a great deal of value
13 input as to what's "compatible" and what, you know,
14 interferes with organic integrity and what does not.
15 And I think that's where...

16 UNKNOWN: He's buying drinks tonight.

17 UNKNOWN: Yeah.

18 MR. DECOU: I think that is where if you could
19 take some clarity TAP reviews that provide the
20 information without a ton of bias and without no value
21 judgment and say, you know, I'd like the facts, but I'd
22 like them explained in this particular way, that might
23 be very helpful to tone down the ones who tell you what
24 to do, so to speak, and help those who really don't know
25 what your -- your drug result.

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1 MS. KOENING: So in other words, I mean, we
2 need more of a literature -- like if somebody does a
3 literature review for a dissertation, I mean, you're
4 bringing up all points and you're giving those -- you
5 know, those references and you're really showing
6 different points of view with that documentation. So
7 there is value judgment in the points of view, although
8 you may not state your values until the discussion, but
9 in the literature review, you're bringing out all points
10 and backing them up. But -- you know, and that's where
11 the summarization comes in, it's not necessarily...

12 MR. DECOU: Yes. As an organization, we are
13 comfortable moving more in that direction and that's
14 something that we will be working on. Just to quickly
15 refer to the value judgment issues. I want to be clear
16 that one of the reasons that I made that so important is
17 that as the TAP reviewer, we don't think that it's
18 appropriate for us to be making the decisions about is
19 this particular substance consistent with organic
20 agriculture or not. We are quite happy to try and
21 provide with all of the information that you need,
22 including by doing some of the organization of that
23 information, which we have not done enough of. We're
24 happy to do that piece of it. But again, we feel that
25 as a third-party reviewer, we have to take the

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1 legislation as it has been given to us and the
2 regulatory guidance as it has been given to us and apply
3 to the substances that we're asked to review.

4 MS. KOENING: I have one more question and
5 then...

6 MR. CARTER: Okay. Go ahead, Rose.

7 MS. KOENING: As far as in the current way
8 that things have been done, once you've done that TAP
9 review, then you get your outside reviewers to kind of
10 review that, and then historically, they've actually
11 voted -- you know, there's a value judgment, if there is
12 any value judgment. So then, are you recommending --
13 and this is a question to both OMRI and yourself -- is
14 it better that they just really review the technical
15 merit of what you're saying, rather than giving their
16 opinion? I mean, is that right format?

17 MS. BROWN-ROZEN: All right. I'll go first.
18 No. That was a good point, Rose. And that is
19 historically -- what we would do is say, you know,
20 you've selected these experts to be reviewers. They
21 have good expertise in this area and you've given them
22 guidance. We do give a little guidance about what about
23 capability means. If we can work on -- you guys work on
24 this more, then that could be given to them. In your
25 opinion, given all this other database information here,

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1 do you think it's compatible for system organic
2 agriculture? Now, you don't -- you know, it's three
3 different opinions and you can, you know, judge them for
4 what they're worth. But I think that's useful to have
5 that value, you know, from someone very knowledgeable in
6 the field and knows the area. So I think that these are
7 not totally objective, but that's how they are written
8 in the OFPA, for that reason.

9 MR. DECOU: As a TAP reviewer, the first two
10 questions that you get are in the case of is it
11 synthetic or non-synthetic, and then should it be
12 permitted or not. And the synthetic, non-synthetic is a
13 big factor weighing on the rest. So the critical thing
14 that I would come back to you and say -- let me digress.
15 In 1995, after I got off the Board, they invited me back
16 to facilitate meeting on materials and I gave an
17 exposition on synthetic. And then people went about and
18 said -- 8 out of 13 said citric acid was synthetic. But
19 if you give guidance as to what's synthetic and what's
20 non-synthetic and what's agricultural or nonagricultural
21 so that you give it to the TAP reviewer, it won't come
22 back this crazy way, now, where you got three people and
23 one says it's synthetic and two say it's not. It's the
24 same material. And so it's almost like you need the
25 examples and it has to -- it's almost like the TAP

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1 review for the contractor, it's -- the definitions the
2 clarification and the guidance on this is what synthetic
3 means and this is what agricultural means, and if it's
4 not that, it's not. And so you -- I think that's
5 something that you can create, and that would be
6 permanent and the Zeitgeist of the Board, you know. The
7 1994 board was like this and, you know, it was like
8 boring. It can't be that way.

9 MR. FORSHEE: I would just say that our TAP
10 reviewers ask for that same sort of guidance. That's --
11 the feedback that we get from our TAP reviewers is tell
12 me how to make this decision.

13 MR. CARTER: Okay. Jim?

14 MR. RIDDLE: Yeah. I hadn't wanted to also
15 thank you, both groups, for your presentation. And I
16 think there were incredibly valuable insights here. And
17 that's exactly what we were looking for. I agree -- you
18 know, in the short-term here, I think we're going to
19 have guidance on the capability issue, and I think we
20 need to get down on paper the synthetic, non-synthetic
21 and the ag, nonag guidance. Those are doable. And we
22 have some guidance we've already worked on on the
23 livestock materials, because -- or the livestock
24 criteria, because those really weren't written for
25 livestock materials. And so we need to keep those

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1 alive. Those may have fallen off the table a bit, so
2 I'm glad you brought those back up. I was quite
3 intrigued by Emily's reference to this decision tree.
4 We were -- have a materials review form that the NOP
5 needs at the end of the day, but how we fill that out is
6 a challenge. We heard about Barbara spending over 12
7 hours, I think, doing an example of one that's already
8 been done. And I -- you know, I guess it doesn't matter
9 when I clock in, because my rate doesn't go up or down
10 when I'm working for free, anyway. But, you know,
11 anything that we can use as a tool to help us complete
12 that form I think is valuable. But I turn to that at
13 that back of your handout and see it's date November 13,
14 2000, which is before the final rule was posted. And so
15 it looks like, well, here's another task, you know, that
16 we can do for free to update this. I mean, how far off
17 is this from...

18 MS. BROWN-ROZEN: I don't think it would be
19 that late.

20 MR. RIDDLE: No?

21 MS. BROWN-ROZEN: I just -- you know, I got an
22 example...

23 MR. RIDDLE: Could you speak to the mike?

24 MS. BROWN-ROZEN: ...and, you know, offered it
25 -- I'll get up. Yeah. No. You know, we had thought --

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1 I had thought about this in the past and I dug it out of
2 the archives here. And it seems to me now as if --
3 yeah, we have to revisit it. I think the criteria --
4 but I don't know if it's that far off. You might --
5 based on the new criteria for livestock, I'm not sure
6 what else. There might be a couple of other things.

7 MR. RIDDLE: Well, the handling criteria now
8 is in the rule...

9 MS. BROWN-ROZEN: Okay. Right.

10 MR. RIDDLE: ...and before it was just an NOSB
11 kind of guidance.

12 MS. BROWN-ROZEN: No. Well, it was voted and
13 it was...

14 MS. DIETZ: This has gone to the Board before.

15 MS. BROWN-ROZEN: Yeah

16 MS. DIETZ: : It's come to us.

17 MS. BROWN-ROZEN: Yeah. I was -- yeah.

18 MR. RIDDLE: Yeah.

19 MS. DIETZ: Several times.

20 MR. RIDDLE: But I'm just saying, it's a
21 historical document...

22 MS. BROWN-ROZEN: Right.

23 MR. RIDDLE: ...according to where we are.

24 MS. BROWN-ROZEN: No. It just was a model. I
25 mean, there may not be enough steps in there now.

1 Actually, the screening steps are kind of built in
2 there, so maybe, you know, you could divide it out into
3 phase one screening and then you have this is what the
4 committees do. You know, you could break it out
5 further, because -- you know, the synthetic, non-
6 synthetic, all those things. I was going to tell you I
7 was going to handle it. But, yeah, I'd be happy to work
8 on it some more if you want.

9 MR. CARTER: Okay. Kim?

10 MS. DIETZ: I keep making notes. Richard and
11 Richard, we have talked about a pool of qualified
12 reviewers and this has come up many, many, many times.
13 And then OMRI brought it up in their presentation. And
14 I think that we -- even as a board we've talked about
15 how can we get this done and, you know, have the
16 confidentiality that's needed, yet seek as a board --
17 seek those people to help us. So I just want -- for the
18 record, I think this is something that we do need to
19 enact for the success of TAP reviews and for the success
20 of this program, because we need qualified people to do
21 it and we need to pay them to do it. So I do agree with
22 and I just wanted to bring that out for both of you.

23 MR. CARTER: Richard?

24 MR. FORSHEE: I had not mentioned that in my
25 presentation, but I just want to say I wholeheartedly

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1 agree with your comments and those of Richard.
2 Developing a pool of qualified responsive TAP reviewers
3 is a huge task and anything that can be done to make
4 that more public and more permanent would be...

5 MS. DIETZ: And then I had a comment and a
6 question for you. It was mentioned about specialized
7 contractors and obviously opening up, which we've all
8 agreed for years to do. But do you feel that the Center
9 for Food and Nutrition Policy has the capability to
10 review all three areas for us? Right now you have the
11 sole contract. And do you have the capability to do
12 crops, livestock and processing, the chief fields?

13 MR. DECOU: Or where are you strongest?

14 MS. DIETZ: Or, yeah. Well...

15 MR. FORSHEE: Well, we -- I will say that that
16 is a very wide range of petitions to try to deal with.
17 And frankly, I agree that from a regulatory perspective,
18 it probably is better to have more than one set of TAP
19 reviewers. In terms of our -- one advantage that we do
20 have being part of a major land-grant university is that
21 we do have colleagues within our College of Agriculture
22 and Life Sciences that can provide a tremendous amount
23 of support to us as we are trying to analyze a variety
24 of petitions. And so within the department of food
25 science and technology within the College of Agriculture

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1 and Life Sciences and within the Center for Veterinary
2 Medicine at Virginia Tech, we do have many resources
3 that we can draw on. Within our own organization, we
4 have -- we just recently had a veterinarian who began to
5 work with us, actually within our organization as
6 opposed to on any sort of consulting basis. We have
7 expertise in environmental chemistry and regulations
8 with EPA. We have a human nutrition and we have a lot
9 of background in food safety issues. So we do have a
10 good breadth of knowledge. But again, I would have to
11 agree that from a regulatory perspective, it's almost
12 certainly better to have multiple groups doing TAP
13 reviewers. We're happy to do them, but I think that
14 that probably would be a good move in the long run.

15 MR. CARTER: All right. Rose?

16 MR. k: I guess a final question I had for
17 both TAP reviewers is that on some of this information
18 when we get materials in, it's easy to do a literature
19 review on a compound. The hard thing -- and we talked a
20 little bit about this earlier -- is then taking that
21 information and then applying it to an organic system,
22 because there's not much research on organic systems and
23 the use of those within an organic system and all the
24 alternatives. So any suggestion on how you, I guess,
25 wrestle with those things within an institution such as

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1 your institution, or how has OMRI tried to get those
2 real-world examples without having an extensive bank of
3 literature in organic farming systems? I mean, do you
4 use anecdotal kind of evidence? Ss farmers, have you
5 been able to get that information?

6 MS. BROWN-ROZEN: Are you talking mostly about
7 the alternatives question or...

8 MS. KOENING: Yeah, alternatives and
9 compatibilities, you know, some of those adverse --
10 where you were saying misuse or adverse reactions, that
11 you don't know -- if you do just a literature review on
12 a compound and it's not within an organic context, and
13 then the people at your institution may not have
14 expertise in organic farming systems, they may not know
15 that this thing is used in conjunction with, you know,
16 hydrogen peroxide, because that's not commonly a
17 function of a normal, conventional farming system. So
18 I'm saying how do you come up with that information and
19 how did you come up with that information? How do you
20 guys grasp that kind of information?

21 MS. BROWN-ROZEN: I think -- well, you know,
22 going by what, you know, you can find in the literature
23 and then relying on your reviewers and trying to get
24 people with expertise in an -- actually, an organic
25 application, is familiar with what we -- or if you don't

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1 have the specific reviewers, then making sure you ask
2 some experts that might've, you know, done organic food
3 processing, not just conventional, you know, in a
4 similar kind of product and find out how they're doing
5 it, so that you can sort of fit it into the landscape.
6 There may be nothing. I mean, that's difficult and it's
7 time consuming. But you can try to make an effort to do
8 that.

9 MS. KOENING: So in other words, when you do
10 those TAP reviews, you require them to go through all
11 the criteria and then add in the wholes...

12 MS. BROWN-ROZEN: Well...

13 MS. KOENING: ...of the...

14 MS. BROWN-ROZEN: Well, if you look in that
15 packet we'll be giving this template that, you know,
16 goes through the whole -- all the little categories, and
17 we have a little bit of narrative under each one. This
18 section is supposed to cover, you know, fade and
19 toxicity. And generally, we look at human studies, not
20 -- you know, not just animal studies. You know, we give
21 them a little stealth out of them -- how we look at it.
22 And then -- but then we have a little questionnaire at
23 the end, you know, and do you know of any other way --
24 you know, do you know of any other alternatives? Do you
25 have any other literature? What do you run across,

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1 basically.

2 MS. KOENING: And that...

3 MS. BROWN-ROZEN: So we get feedback from
4 them, from each reviewer.

5 MS. KOENING: So are you saying that that's
6 been more of an OMRI internal document? Do you think
7 that that...

8 MS. BROWN-ROZEN: Oh, yeah, that's -- yes.

9 MS. KOENING: Do you think that that there is
10 a -- do you think we need to be thinking about that as a
11 board, how -- because that's critical a lot of times.
12 That's where a lot of times we, I guess, public comment,
13 or when somebody's looking at a TAP, that's one area
14 that seems like there's always a deficiency or many
15 people say there's a deficiency, so...

16 MS. BROWN-ROZEN: Well, I think that would
17 help if you -- you know, if you have the timeline a
18 little better and more public, you know, availability of
19 the information and maybe a little better outreach on --
20 you know, this is coming up. Everybody's that's
21 interested can write in, because typically -- well,
22 another big problem was there would be one very specific
23 use petition for the substance, but there's -- you know,
24 when you look up in the literature, there's like
25 hundreds and hundreds of uses for this material and how

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1 many of these do we investigate and what are the most
2 likely ones. And that's what to -- usually we had a
3 little period -- or we narrowed down the scope of the
4 investigation to -- you know, look, it's used for, you
5 know, toppings and floor polish and this and that.
6 Which ones do you want us to concentrate on? You know,
7 and so we would, you know, try and make it a little bit
8 more doable. But -- so -- yeah. No. But I think that
9 kind of guidance that we did was -- you know, that was
10 useful for us. We needed to work -- have a standardized
11 way to work and give the information, because we would
12 have, you know, occasionally, new TAP reviewers, so we
13 wanted to give them all the same information. And that
14 kind of a document could be really modified to go to the
15 contractor as whole. You know, this what we would like
16 you to cover under each of these. And you might want to
17 change the template to maybe -- based on, you know, the
18 new outcomes that you're looking for. The template of
19 the TAP review has to be structured a little bit
20 differently to make it easier to answer those questions.
21 You know, we just did it based on, you know, the OFPA
22 criteria, the -- you know, what was in our contract and
23 getting clear information. But it might be time to re-
24 look at that, too.

25 MR. CARTER: Okay. Richard, do you want to
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1 comment?

2 MR. FORSHEE: Yes. I'll just comment briefly
3 on that. That is one of the challenges -- is viewing it
4 in the context of organic production, because as you
5 mentioned, the literature is just beginning to develop
6 on what that means and having the literature on how
7 things get used in that system. So that is a challenge.
8 We did do some of the same things that OMRI has
9 described in terms of directing questions to our TAP
10 reviewers to try and address some of these issues. I'll
11 also mention just very briefly that there is some
12 academic work that's -- I'm sure you all are more aware
13 than I am -- that's beginning to be developed on
14 organics, and some of that is going on at Virginia Tech,
15 as well as, I believe, they'll be getting an office and,
16 of course, working some of the professors who just
17 published a new book on the subject. So within our
18 family at Virginia Tech, some expertise is developing,
19 but it has been scant.

20 MR. CARTER: Okay. If there aren't any other
21 burning questions, what I'd like to do is ask Mark, as
22 the chair of the policy development committee and Kim as
23 the chair of the materials committee, to kind of give us
24 a sense of how we proceed from here, so...

25 MR. KING: Okay. Well, first I'll start by

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1 thanking -- yeah, I know. You're diverting everyone to
2 someone else. Thanks, Dave. But, no. Thank you for
3 participating. I did want to pay particular attention
4 to Emily's slide and it's the policy issues and need of
5 guidance. So we certainly, as a committee, will look at
6 that very strongly and see where we're at and how we can
7 move forward. In a more general sense, I liked the
8 references from everyone concerning the relationship
9 between NOP, the contractors and the NOSB. So I think
10 that that's certainly is more of an elevated view, if
11 you will, that we need to look at and find out
12 specifically what needs to be in the Board policy
13 manual, what role is NOP going to play in this process
14 and how can we help better define those lines of
15 communication, as Richard said earlier. So those are
16 just some things in the general sense off the top of my
17 head that we'll be considering at our next meeting, so
18 from a committee perspective.

19 MS. DIETZ: Well, this morning we spent about
20 four hours just going over the material review process,
21 so you will see a lot of what you have brought up that's
22 already being addressed by the NOP and by the Board.
23 We've got templates that we are going to start using and
24 that -- well, I could say what we could do is take all
25 of the concerns and take these slides and actually go

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1 through in the areas that we have not discussed, kind of
2 go through and address them and say whether -- what we
3 can do and what can't do about it, and kind of a little
4 action plan, so to speak, so that we can at least give
5 you feedback on what some of your concerns are.

6 MR. CARTER: All right.

7 MS. DIETZ: Hopefully that's sufficient.

8 MR. CARTER: Yeah.

9 MS. DIETZ: Sir, Chair.

10 MR. CARTER: Very good. Okay. And I again
11 want to reiterate -- it's been said a couple of times --
12 but thank both Virginia Tech and OMRI for coming in,
13 because I think this is very helpful this afternoon. So
14 is there anything else we need to address this
15 afternoon? Everybody looks pretty road weary here,
16 so...

17 MR. SIEMON: Just whether we're going to have
18 any livestock meeting or not. Maybe we can just get
19 together afterwards...

20 MR. CARTER: Okay.

21 MR. SIEMON: ...over here in this corner...

22 MR. CARTER: Yeah.

23 MR. SIEMON: ...and see if we can decide that?

24 MR. CARTER: Okay. So livestock committee
25 will get corralled in the corner here. Yeah, Kim?

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1 MS. DIETZ: Prior to our last break, we were
2 going through the national for livestock and whether or
3 not we're going to restructure and everybody got all
4 excited. I think we need to step back and not do
5 anything hasty, so to speak, and that the materials
6 committee should really look at -- and it's always been
7 our charge to make recommendations as to how the
8 national list is structured. And so that materials take
9 that and come forth with the recommendation.

10 MR. CARTER: I would concur, because...

11 MS. DIETZ: Okay.

12 MR. CARTER: ...what I heard before the last
13 break was most people weighing in very heavily...

14 MS. DIETZ: Yeah.

15 MR. CARTER: ...that if we could do that by...

16 MS. DIETZ: We had some politicians.

17 MR. CARTER: ...reducing it and/or by
18 extending the list.

19 MS. DIETZ: Yes.

20 MR. CARTER: And so I think that's...

21 MS. DIETZ: Okay.

22 MR. CARTER: ...an indication that we need to
23 take a breath here and then look...

24 MS. DIETZ: Yes.

25 MR. CARTER: ...and see how it's done, so...

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4 IN RE: National Organic Standards Board Meeting

5

6 HELD AT: Washington, D.C.

7

8 DATE: October 22, 2003

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