applications, the protocols, the 510(k) applications, the PMAs, the meetings, the advisory panels, these are all science-based activities. They are very interesting if we're just talking about procedural issues or those kinds of details.

There are a variety of things that product-class specific, and the guidances that the Center produces, the Centers that we participate or recognize, workshops, special products, cut across products.

Then there's work that is regulatory work that deals with the interaction between the science and the regulatory process itself.

The way we've changed the 510(k) paradigm, to change the evidence rules to incorporate standards, for example, is an example of that. It's very much tied into the science. You couldn't do that just based on saying well, is there some way to streamline, this is an administrative process. We had to say, can the standards actually replace part of the application.

Or, similarly, with MDR reporting when we developed a system for summary reporting for common adverse effects, we did not need every single individual report, is an example of something that requires understanding the epidemiology and the science of the issues.

And there's issues relating to manufacturer's assistance and the other things.

The fourth category in terms of origins of scientific work is one that this group has grappled with, which is how do we develop and maintain the competency of the scientists that we have.

What are the research projects that we do?

How do they relate to the rest of the work that we do?

How well integrated are our scientists in the professional meetings?

And do they do the kind of things in normal sort of scientific citizenship, help plan meetings, help participate in scientific organizations.

This is a much broader grouping of scientific activities than just our research proposals.

If we go back to the total product life cycle and we say well, how does industry see the Center for Devices, in fact, you can even look at the ways we put on meetings and conferences and workshops.

You'll often see them organized around different specific regulatory mechanisms.

Every year, for example, we cosponsor a meeting on how to submit applications in the PMA or the 510(k) process.

(Slide.)

If you look at these, one of the interesting things when you step back and look at them is that they still really aren't the science of product development.

What most of these things are are data holders.

(Slide.)

They are things are either the industry is communicating with us, such as when

they send us protocols or applications or report MDRs which are adverse experiences from devices or when they send us a post-marketing study.

Or there are things we communicate to industry with such as when we provide guidance or we make a determination about product designations or issue, a safety alert, or a warning letter.

(Slide.)

If we come back to sort of say where is the underlying science in the regulatory decisions, we come back to a view that steps back a little more and say, well, if we go back to that life cycle of a product, what are the disciplines and how do they surround that life cycle.

So at the time that you're developing the concept for a product, you're beginning to work with designs and design, think of what the design controls will be.

The engineering that's needed to do prototyping -- and some of these are just

illustrative, they don't apply to every device -- but if you're developing an implant you need to understand biomaterials and biocompatibility.

You need to understand the toxicology of the coatings that you may use or of the materials that may leech out of an implant.

In the preclinical phase, you may be doing and setting up hazard analysis based on the mode of action.

You may be developing bench strength testing or failure mode analysis that allow you to better design the product.

At the clinical phases of developing the science, there are all the issues around study design and statistics and the review of that family that really set up the evidence that is set out in the statute as the basis for allowing the approval of a PMA.

Quality systems. And actually quality systems are more -- are a broader family of concepts than where they are on this chart where they're placed down with manufacturing,

but relates to all of the different kind of things that you need to do to understand how do you manufacture something consistently in a way that it will perform as expected.

When we get to the post-marketing side, we have all of the sciences of epidemiology and the sciences of understanding how to evaluate adverse events or the forensic engineering that occurs when you've got a device that's failed and you've worked backwards and you've found what is the failure mode mechanism which feeds back into the redesign of the program.

And when we do have serious problems, the kind of science in doing quantitative risk analysis and assessment to try and decide what are the appropriate actions to take.

What we would like to do in our science review is to actually be able to present the breadth of the science in the center to you about these products.

We intend to actually tell you quite a bit about our research programs and our

laboratory programs, but I think what our vision of is our science is it's imbedded in everything we do. And if we want your input about how well we do our job, we need to do them well in all of these domains, and we need the issue of the quality of the recruits, the understanding of the scientists that work here, the ability to keep people at the top of their game, applies to all of these standards, as well as to the things that are traditionally thought of as research.

(Slide.)

So, in short, we need to prepare for the workforce of the future. This is a product we're currently evaluating in the Center.

(Laughter)

We'd like to have it battery operated so it would work a little bit better. There's no predicate, that's right. And we started from the most appropriate end here to begin mechanizing. We need a little better informatics to work from top-down on this kind of a system.

(Slide.)

Well, let me tell you what we have done so far and give you a proposed outline for a report which hasn't been written yet, so it's very easy to change this outline, it's very easy for us to take direction about how to change this and about how to make this process the most useful.

The CDRH leadership, by which I mean by deputies and the office directors of the Center, met and convened a science working group, that's been working for about a year, to actually work on the sort of concept of our being deliberative and thoughtful about what the science needs and the organization of science in the Center.

What we're posed to do now is to put together an internal science review group that will produce an internal review document, and we've asked this group to be able to do this in about 3-1/2 to 4 months.

And one of the requests of this group to the Centers that are doing a review is to

have a critical self-assessment, and that's the purpose of this group.

It will be an FDA group, although we've asked one person from outside the Center to come in and at least give us a little non-CDRH perspective.

(Slide.)

It's not intended to put our best foot forward. It's intended to be self-critical and to say "What are the challenges we're facing?" "What are the areas the we really need to have a strategy for dealing with?" Which is why there's an arrow coming in from the side there about our strategic plan, which is very much intertwined with the science review.

The external science review group which have been the groups that this group has heard reports from the other Centers will have the internal document.

They are welcome to interact with any parts of the other groups, and we're anticipating that we will invite them for a three-and-a-half day process to do an in-depth

evaluation, and as a starting point have the internal review document. But identify, perhaps, some of the bigger picture issues that are at the level where this group can particularly help us.

And then, finally, there will be a presentation to you, the FDA, Science Board, and recommendations to us which we will value and incorporate into the way that we move forward with meeting our challenges.

(Slide.)

This is the proposed Table of Contents, an Introduction and Background. We will provide, even in more depth, a description of the device and radiological health programs and give you an idea of the workload of the size and composition of the staff, the way the Center is organized, the description of the industry and the other stakeholders that we deal with, and provide you our mission, vision, and our own conception of the role of science in the Center.

We would like to in this internal

document expand on the topic which I've just introduced this afternoon, which is how science relates to the total product life cycle. The basic paradigm is that this is science based regulation, that if you look at what we do, almost all of it relates on us receiving a scientific, data-driven, information about an issue that's been raised about the product appropriate to where it is in its lifecycle.

Our guidances are often methods guidances on how to provide that evidence.

And the materials that we receive from companies that help us evaluate whether a new biomaterial is appropriate, are in fact usually study reports analysis, and then we review those and work to make a science based decision in that.

So that's the paradigm that we would like to present.

Part of what we have to think about is what are the scientific roles in this process. There was some discussion this morning about what do we really need. We could pick an area,

for example, like pharmacogenomics as an example of an area where I don't think we have anybody in the Center who actually has a background in pharmacogenomics.

If we step back and say, what are we going to eventually be faced with, eventually we'll be faced with a product that wants to demonstrate that when a diagnostic pharmacogenomic test is used with a drug that drug can better be targeted to patients who will really benefit from that, and that will be an evidenced-based decision.

So we can work backwards and say what is it that we're going to need to know to be able to evaluate that? Our responsibility in that will be to evaluate whether or not there is a test that is reproducible and in the setting of a drug evaluation sorts patients from those who will benefit from the drug from those who won't.

And we can come back to it and say, well, what's our role in that? What is it that we have to understand about that? Which of

those are sort of core competencies that cut across in vitro diagnostics and which of them require specialized knowledge of pharmacogenomics?

And it gets back to the issue of where are we with these things? Where in the Center do we need to be able to design the experiments? Where in the Center do we have to be able to look at the results of fairly common clinical issues even though the tools will vary and the products will vary?

We will present to you as part of this section the scientific domains, the clinical disciplines, the engineering, the physical and the life sciences that we currently have in the Center, and take a look at whether or not these are positioned to be the kinds of domains and kinds of disciplines that we need to have represented as we look forward to what we anticipate in the next five to 10 years.

And then we will go through the kinds of scientific work we do and whether or not we are appropriately configured in using our

resources appropriately to do these tasks.

One of the strategies we have picked is that since we're not going to actually spend the time going through one part of the program, like our laboratory program in detail, where we could go through those programs in that amount of time and give you detailed descriptions of that, we decided that one way we could drill down and give some depth to the science review and still talk about every part of the Center is to take a product are that could illustrate the way that science is used.

We're not making claims that this is representative that it will serve all purposes. As you can see, it's only part of the proposal.

What we chose was an area of electrical stimulators which includes families of products, probably the pacemakers are the most well known and some of the most mature products in this area.

What we will do is really show you in great depth this product line and how the issues around the entire Center, around the

total product lifecycle, how this product is evaluated and how we use their science.

So to supplement some of the broad views and overarching issues that we'll present for the rest of the Center, we'd propose, actually, having part of the external review panel, having expertise in this area, who can come in and be self-critical and say, "Do you really have what you need to keep up with this area."

We know that this is an area that historically has had market launches for these products in Europe before they were launched here for a variety of regulatory and other reasons.

Let's take a hard look at that and see what is that all about.

So this is one part of our proposal that we would appreciate some feedback, but the concept is that we'd like to illustrate the breadth of the regulatory activity in some depth.

Then, finally, there are a list of

specific issues that we would like to deal with. And, mind you, that this is the Table of Contents for the internal science review document that we're going to present to you. The external group will develop its own Table of Contents.

But we will share with you our assessment of how we prioritize and peer review our projects.

We have a major challenge in front of us sometime in the next five to seven years.

In fact, this year would have had the planning money but it looks like the planning money might be the year after that. But we're going to have to rebuild every laboratory we have at a new facility because the FDA is moving to the White Oak campus.

So our current laboratories, which are a few hundred yards from here are all going to be closed down and moved, and we're going to have to decide what are the configuration we want? Those laboratories which were built for historical reasons and configured the way they

are for a variety of reasons, we're now in a position to start with the architects.

We, internally, shouldn't miss this opportunity to say what is the best way to configure these laboratories for the needs of the future, not just in terms of the contents of the laboratory but how should they be imbedded in the Center?

Do we want the laboratories to be an integral part that interacts with all the scientists in the Center and interspersed with the different groups, close to the review groups that they work with? Or is there more economy of scale and critical mass if they're located together?

And there are also the other issues, such as we obviously share some overlap of tissue-based products, tissue-based devices.

Where should we collocate, not just the laboratory sciences but the reviews sciences with other Centers such as the Center for Biologics. Or if we're building systems that are essentially drug delivery devices, are

there some operates to actually get the connections we need with the Center for Drugs?

So even though this plan was not put together with the primary purpose of dealing with White Oak, it's an opportunity for us to really ask ourselves where do we want to be? What do we want the Center and its science programs to look like? And we can even answer that question and do that physically with this opportunity.

And the timing is perfect with this review because the timing will occur just before the time we need to start talking to architects about how to do the movement.

I've put down the issue of recruitment. It's actually a much broader issue than that. It's all the human resource issues around recruiting a group of scientists and maintaining them at the top of their game.

We will present to you in the Internal Science Review our assessment of the current situation. We will be self-critical. We will, of course, be proud to tell you where we think

our strengths are and where we've made more contributions.

But we will also try and be not apologetic about the fact that there are areas where we can improve.

There are opportunities that we have now that we need to be aware of and plan to take advantage of. And similarly there are threats. We usually think of the budget as a threat.

(Laughter)

But there are other threats. There are threats to just being overwhelmed by advances in science.

There are threats to having an international C change in the way that products are regulated.

There are many things that we need to consider, and we will share our assessment of that with you.

We will look at ourselves and say, where do we do well and where are we improving. And we will identify where we have gaps and

where we're falling behind.

We will also share with you our strategic vision and our plan for ways we can address this and ask you whether or not you think these are the things we need to do.

Our Vision Statement is actually quite short.

The Mission Statement was one long statement. The Vision Statement is also a single statement.

"Insuring the health of the public throughout the products' life cycle with the coda that it's "everybody's business." It's not something we can do alone. It's something that is a shared responsibility. It probably most fundamentally is the manufacturer's responsibility. We have a role, even the consumer has a role in the use of therapeutic products. There's consumers who have a real taste for the cutting edge.

In fact, the idea that it's not approved in this country is practically proof that it must be good.

And then there are those that are more conservative and say, "I can't believe you're asking me to take this when it hasn't even been tested yet and there's old stuff there."

People need to grapple with this notion that we're dealing, really, with a whole family of technologies.

I could actually go on the rest of the afternoon about our goal areas. We will present this in detail in the strategic plan and how we think it addresses the challenges we have to face.

The goal areas that we've identified which we think give us the tools to tackle some of the challenges are things that relate to living the vision of the total product lifecycle. A lot of that has to do with making the connections within the Center.

Many of the questions were asked this morning about are you connected as you work on bioterrorism across the agency.

You could have asked the same question, are you connected inside a Center

when you work on some products. And it's a real challenge for us. We need to do that.

Magnet for Excellence. We borrowed this phrase from the magnet schools. What would we have to do to make the workplace a place that would attract scientists and other staff to come and work with us the same way that a magnet school attracts the best and the brightest in an area?

What do we need to do about the scientific environment and about the culture of the place and the opportunities to do that?

Dr. Woodcock and others talked about knowledge management. We'd started talking about information technology, and then we realized that actually that was just a tool, and that what the real issue is to make sure that we understand what are the knowledge domains that we're having to deal with, that we understand the expertise we need, the reference systems we need, that we have the ability to trade and maintain and develop this.

The final goal area is something we

call "meaningful metrics," which is a little bit of a backwards slap at whatever we're doing now, applies that we're using non-meaningful metrics at the moment, but it was not intended entirely to mean that.

But we really want the things that we do to be measurable in the way that we accomplish our mission, the way that we promote and protect the public health.

We want to be able to understand how our actions translate, what the impact is and to make our priorities based upon that.

We want to take a look at our statutory responsibilities and say, how do we meet those, how do we play in all of those areas and learn from the approaches taken in other disciplines, in other countries, in other regulatory agencies, to make sure that we can do this.

So our Proposed Table of Contents that we're asking for feedback, we're proposing that this be the internal science review document that be made available sometime in March or

early April, that in the meantime we use the process to select an external panel, which it's a stretch, it's a bit of a push, but I think we've designed this so it would be possible to get this done by the spring meeting so that we would be able to have the external panel come back in the spring meeting.

As I mentioned to you before while we've been thinking about this and we have ideas about this, even the internal review is something which is very malleable and can change, and we present this today really to get feedback on how to do this.

Actually, I wanted to finish with a slide that quotes a book that the Commissioner bought us. The Commissioner keeps buying books for the Center directors --

(Laughter)

-- and fortunately they're all about one plane ride in length.

This was a nice short, you didn't even have to have a stopover for this book.

(Slide.)

This is a book, Kevin Kelly talking about the New Economy, the Rules of the New Economy. It really resonated with me when I thought about how we had been grappling with our vision of the Center.

The New Economy has three distinguishing characteristics:

It's global;

It favors the intangible, by which he meant ideas, information, relationships; and,

It's intensely interlinked.

When I go back to sort of the logo of how we think about products being developed and the global nature of device manufacturing and the way that information is increasingly imbedded in the devices themselves, and the need for us to be imbedded in the whole process, both in the process of consumer protection and imbedded in the business cycle of these products to promote their availability;

I think that this actually describes

very well where we see things.

(Slide.)

In short, we don't want the final picture of the campus at White Oak to look something like this.

(Laughter)

We have a much rosier vision of that, and we look forward to your feedback on our proposal. It's ambitious to get this all done by this spring, but we're enthusiastic about doing it.

DR. LANGER: Thank you.

Comments? Suggestions?

I thought you might, since you have just been through it.

DR. FENNEMA: I'd like to commend you, first of all, for a very thoughtful outline for this and most importantly for the recognition of the importance of self-evaluation in this process, because in any review process, it is the self-evaluation that turns out to be about 90 percent of the value.

The reviewers come in for three days

or four days or whatever it is, and causally look over things that are happening and make snap judgments on what they see.

This is done actually much better by the review panel if there's a thorough self-evaluation in advance so that the review panel can consider these things in self-evaluation and offer their opinions on these.

So I think this is really a very, very good first step for a very sound review process, and so I do congratulate you.

DR. LANGER: Bob.

Everybody should turn their microphones on.

DR. HENNEY: We'll remember. Congratulations. So don't worry.

DR. NEREM: I thought it was a well-laid plan, David, and I agree with Owens' comments about self-assessment. I've been through university's many times, and that's really a critical part.

A couple comments.

One is: I think it's important that

you do pick something to really go in-depth, and electrical stimulation actually is an interesting one. Because on the one hand, some may think of it as being more traditional, the kind of medical devices that you people have experience with, but in fact I know several companies that are thinking about putting electrical stimulation together with tissue-engineered products.

So it actually represents an opportunity for that kind of broader look.

I was intrigued by one part of your outline.

You talked about assessing internal strengths and weaknesses and internal and external threats and opportunities. I would hope you would also assess internal threats and opportunities.

(Laughter)

DR. FEIGAL: Yes, we have those, too.

DR. LANGER: Yes.

DR. ROSENBERG: Do you have a particular section where you're going to

actually propose recommendations, where you would actually present the set of proposals to the reviewers for response?

DR. FEIGAL: Yes. We do that as part of using the goal areas of the strategic plan, to make recommendations.

We would identify in the situation analysis, which is near the end, where we think are things that we need to address, and we would see if we could build it into one of the theme areas.

So, for example, if the issue had to do with recruitment, retention, development of professional skills, that would fit quite logically both in knowledge management and magnet for excellence, workplace excellence kinds of goals.

By the time spring has started, we will actually have some projects underway that we can point to as works in progress.

In fact, that was another reason that we liked the timing, sort of the convergence of forces, is because we're getting ready to

organize an effort to change things in the Center, and this would be our proposal to you of some of the things we've identified in the science area and some proposals of how we might do it.

Then we would very much welcome other suggestions or comments on things that you might not be as productive as other things we can do.

DR. ROSENBERG: Yes. It will help focus that discussion.

DR. FEIGAL: Yes.

DR. LANGER: Bob?

DR. NEREM: Is all of FDA moving to White Oak?

DR. HENNEY: The parts of FDA that will move to White Oak first will be the Center for Drugs, Center for Devices, next up the ORA and Office of the Commissioner and Biologics will follow in sequence. It's really planned out as a six to seven year, although when we had the ground-breaking a few weeks ago I encouraged the Congressional committees that

our 100th year anniversary of the FDA will be in 2006, and so it would be a very nice way to celebrate it if we were practically completed by that time. So we don't know if we'll move up on their urgency list or not.

But those will be the components that will be consolidated in White Oak.

CVM and the Center on Foods are really over near to the University, more in that area, the University of Maryland kind of campus. So we will have two major components that will be --

DR. FEIGAL: Are there any buildings designed yet?

DR. HENNEY: The Center on Drugs is just undergoing design. All the rest of them will just come in sequence.

They have had an initial design, yes. And, quite frankly, some of that design, while attractive, still I think we want to look at the interior again because it's still very much the silo kind of concept with each Center with their own facilities and some shared facilities

in terms of the animal facilities and like that.

But I have really asked the Center directors along with the architects to -- we think some of the places in which we might have either better interconnectedness by the interface or a plan whereby even after a Center moves that once we would all be out there we can retool the flow. So that's kind of where we are going with this.

DR. FEIGAL: I would strongly encourage you on that. I have become a firm believer that the way you organize people in space does not have to have any relationship to the organizational structure of the institution, and that's a way to build bridges between stovepipes.

DR. HENNEY: Well, intra-Center, David has introduced kind of a novel idea as well within the Center on the Device Center, in that he's also having his major office directors collocate with each other at least two days a week within his own office so that he can make

sure that they are talking to one another too.

So I think that we share your advocacy for looking for unique ways in which we can make sure that the interdisciplinary nature of what we do we can greatly facilitate that.

DR. FEIGAL: When I first came to FDA was with a group that had a rule that no two people from the same discipline could have adjacent offices. And it really --

DR. NEREM: That's the way my Institute's organized.

DR. FEIGAL: -- it really created a sense of teamwork that wouldn't have worked as well had people been grouped in their little departments and been fighting each other for space at the borders and all the rest of that.

DR. NEREM: So the extreme of that is that no two people from the same Center can have adjacent offices.

(Laughter)

DR. FEIGAL: It's one of those map puzzles, you know. How many holes do you need to make a unique map?

DR. LANGER: Other comments?

Is there any other feedback that you'd like?

DR. FEIGAL: Well, I guess one of the most critical logistics questions from those that have done one of the reviews is is this too short of a time frame or do you think we can get this done?

DR. NEREM: I didn't understand the time frame because you talked about the internal document being done by March, at worst early April.

DR. FEIGAL: Yes.

DR. NEREM: Our next meeting is April 13.

DR. FEIGAL: Yes, you're right. May I was thinking February, March.

DR. NEREM: I don't think there's any way you could bring in --

DR. FEIGAL: No, we had worked backwards to give about -- we had thought that it would push an external group to have about six weeks to prepare for this meeting, so that

was what we were working back from.

And so one question is whether that's enough time.

DR. NEREM: I think you can do the internal by then and it would be interesting for this group to see the internal document at that time and then do the external thing after the April meeting.

DR. FEIGAL: How much time would the external group need to prepare for a report back to this group?

DR. LANGER: Owen?

DR. FENNEMA: Well, if we look at the guidelines --

DR. LANGER: Do you have your machine on? I mean your microphone.

DR. FENNEMA: If we look at the guidelines, which a proposed for you in your book, there's supposed to be a six-month lag after -- which could start, actually, before your internal review is over.

DR. FEIGAL: Yes.

DR. FENNEMA: That's a possibility.

But there's supposed to be that six-month, and I think that's desirable because just to make sure there's no misunderstandings on the part of either party.

But once that's done, then I think if the Review Committee has simply, you know, six weeks, eight weeks to look at this internal report and to lay out the procedures for the actual meeting itself, review meeting itself, that would be sufficient.

And then, which is not in the guidelines, it's my feeling that there ought to be a requirement in there that a written report from the Review Committee is prepared within four months or less.

And if all this were done properly, you could have that written report finalized and ready for this group in November again next year. That would, I think, be completely doable.

DR. FEIGAL: So one sequence could be that we could begin convening the group -- it sounds like that you would consider an

invitation for us to come back and present our internal review to the entire Board in the spring and then have an external review that would have until the fall to get back to you, even though they might do their work before summer?

DR. LANGER: Okay. Any other suggestions or comments?

DR. SCHWETZ: A couple of other things that need to happen that David hasn't listed. One of them is to select a chair for the Committee, and we have preferred to have a chair be from the Science Board.

Then David will also, with people in his Center, prepare a list of people to consider as review team members, but I haven't had the Center make the phone calls and ask people -- in fact, what I use is their list of people and begin to make phone calls and ask those people who they would recommend to be on this review panel.

And the chair could help with that process because that makes it go a lot quicker,

and with someone of the stature of Dr. Fennema he was able to get people to answer the phone more quickly because they recognized his name, than for me to make cold calls to people I don't know.

So it's good if I can work with the chair to begin to develop a list of people who could serve as the review team and then make the final cut on that.

The point is this is not the decision of the Center director to make the final cut on the panel. We would work with Dr. Henney for that.

So those are a couple of other things that can begin to happen now.

DR. FEIGAL: Yes. We've taken it as our role to find people to nominate for you to consider, but it's not our place to pick a Committee.

DR. SCHWETZ: Sure.

DR. LANGER: Other comments?

Yes, Bob.

DR. NEREM: Did you say that the

external committee would come in for three-and-a-half days?

DR. FEIGAL: That was the proposal.

DR. NEREM: Is that realistic, Owen? You've chaired one of these things.

DR. FENNEMA: Well, I think this depends -- and I can't speak with any authority about this in terms of the answer -- but it depends on the complexity, the size and complexity of the organization, how many subgroups, distinct subgroups you have in it, because you want at least two members on the Review Committee to be able to look at each major subgroup in their organization.

So that kind of dictates the size of the Committee you're going to have.

And then you want all of these subgroups to report and have ample time for discussion during the meeting, and so you put that all together and it kind of determines how long the meeting has to be, so I don't know how many subgroups you've got, but --

DR. FEIGAL: Yes.

DR. NEREM: They are picking one area of technology for in-depth assessment.

But some of the other groups would be looking at issues Center-wide in some of those processes so it's kind of more of a hybrid.

DR. NEREM: I'm just worried about getting the kind of people you would want for that.

DR. FEIGAL: We realize. In the Center of Biologics, they had a five-day review, and we felt that was unlikely to -- it would be hard to find people that would be able to do five days.

DR. NEREM: If you did it in Hawaii you might be able to.

DR. HENNEY: White Oak is not in Hawaii.

DR. NEREM: There must be a White Oak in Hawaii.

DR. FEIGAL: That's right. Black Oak.

(Laughter)

DR. FEIGAL: I think we can work on some of those details and some of the planning.

We can begin to design the review with some of the logistic reality so that we don't get a Committee that feels it's taken too superficial a look or that it hasn't used its time wisely.

DR. CASCIANO: If Hawaii is not available, Arkansas is available.

DR. LANGER: They're close.

(Laughter)

DR. LANGER: Any other comments, suggestions?

DR. SCOLNICK: Would there be voting machines also?

DR. FEIGAL: There were definitely human factors problems with that butterfly. We can talk to you about human factors.

DR. LANGER: That sounds good.

(Laughter)

DR. HENNEY: It's not been classified as a medical device yet.

DR. LANGER: Thank you very much. We'll look forward to that next time.

I guess the next topic is the hiring

update to support the science base of the CFSAN Food Ingredient Safety Program.

Hiring Update

DR. JACOBSON: Yes. If I could just add a couple of words here.

Last time you met you heard CFSAN's plans for hiring 50 or so new people into their food ingredient safety program, and you were very interested in how that recruitment process was being put together and what was going to result from it, and we thought you'd appreciate an update today on how it has been working. That's what we're going to do.

I think Dennis Keefe is going to be giving the presentation. Is it Dennis or Alan?

MR. RULIS: Yes, I'll start.

Can I be heard? Is the microphone going? It's going red here.

Good afternoon. I'm Alan Rulis, the Director of the Office of Premarket Approval in FDA's Center for Food Safety and Applied Nutrition.

With me this afternoon is Dr. Dennis

Keefe of the same office. Dennis has been charged to create a hiring committee within our office and procure new hires as a result of having received -- the Center having received new appropriated funds as of Fiscal Year 2000.

That gave us an opportunity to bring on board about 50 new employees, and we're currently in the midst of that process.

As you recall, in April of this year we met with you to describe the program that we had in mind, and at that time, of course, we were pretty much at a dead stop. We had not hired in a long time. We had not hired nearly that many people in a long time in our office.

We had to relearn how to do that and do that well. The biggest fear I had at the time was where are we going to find highly-qualified candidates who, in the year 2000, want to come to work for the government, who are highly qualified and who are highly diverse.

Today we are going to give you a little bit of a report on this is sort of a

mid-course report on our progress, and Dennis from my office will hopefully provide you some of the answers to those questions.

DR. KEEFE: I'm not from Devices, so I need some help.

(Laughter)

The first slide. (Slide.)

Just to restate. The mission of the OPA recruiting team -- this is the Office of Premarket Recruiting Team -- is to recruit highly qualified --

DR. JACOBSON: Maybe you could pull your microphone up a little because it's hard to hear you. Thanks.

DR. KEEFE: Our mission is to recruit highly-qualified scientists. That's our ultimate mission here, the focusing on the science of what we're doing.

As Allen mentioned, when we spoke to you last April, we were just beginning this process, and we had a lot to learn not only in the office, but we also had to -- I think our personnel office had to

relearn how to do recruiting and hiring. That's something we haven't done for a while.

We take this very serious. The number of FTEs that we're talking about is going to have a dramatic effect on the functioning of our office, of the Center and of the Agency not only for the next few years but in the future.

Personally, for me, this is important because these are the probably the people I'm going to have to work with for the next few years and I want to make sure they're good.

So if I can have the next slide.

(Slide.)

Just to give you a summary of our recruiting team: Again, it's composed of the regulatory scientists in the office and also with participation from the Center's personnel specialists.

We've defined our hiring goals as we have numbers of chemists we want to get, toxicologists, environmental scientists and consumer safety officers we want to bring on board.

We've also identified specific scientific areas of expertise that we want to recruit for in those broader categories. And these include data mining and especially genetic toxicology.

Part of the funding for this program is part of the premarket notification program for food contact materials, and these are areas of expertise that we will need to meet our legislative mandates.

So if I could have the next slide, please. (Slide.)

So about the time we met last year or last April -- I'm sorry, it hasn't been a year; I'm sorry, it seems like it's been a long time -- we had to go through a lot of mundane, sort of personnel efforts.

That is, updating our position descriptions;

We had to develop procedures, SOPs, if you will, for screening the paper applications, developing guidance for people to interview and candidates, and setting up procedures for the

interviewing.

We also set up a procedure for how the office would make recommendations to the director to make decisions on potential candidates, and what we've done is to -- in bringing in candidates for interviews, we've had them meet not only people in their area of expertise but also people in the other disciplines in the office.

So not only does a candidate get a broad breadth view of what the office does and the science involved in the office, but our toxicologists can have input on the decision on whether to hire a particular chemist and vice verse so this has worked very well for us.

Again, we've included FDA personnel specialists in this to help us make the process as efficient as possible.

So if I could have the next slide.

This is a snapshot of all of the hiring under the appropriations, and this includes -- this is about 50 FTEs. About 10 of those are outside of our particular office, and

if you look at the graph, if you look at it back in April, we were down to about five, and most of these hires were outside of the office.

We hadn't made any hires when we last met, and you see the filled circles are committed FTEs, people who are either on board now, physically, in our offices, or will be coming on board soon.

The open circles is just a linear extrapolation from the curve on what we expect in the next few months as far as bringing new people on board.

So, again, this represents the full 51, 52 FTEs that we have appropriations for.

If I could have the next slide.

(Slide.)

We've broken the numbers down for the specific recruiting in the office, which is what our recruiting team is focusing on.

In the first column you have the different disciplines, if you will -- review chemists, review toxicologists, consumer safety officers, et cetera.

In the next column you see the staffing levels in these areas, in April in the office, you see a total of about 90 FTEs dedicated to the review function of the office.

Our targeted goals, initially, were to bring on 6 review chemists, 17 review toxicologists, consumer safety officers, et cetera, for a total of 42 FTEs.

And in the final column, you see where we are now. If you look, we're halfway there. We're about halfway there.

I think when we talked to you in April of last year our goal was to try to reach the halfway point by the end of this fiscal year or, or the past fiscal year. We almost made it.

I think in your package you have the results of a survey that we provided to he recruits that we have on board that provides information on their undergraduate institutions, the graduate institutions, their dissertation topics, any of their postgraduate experiences.

I think if you look at that information, I think you would agree that we've recruited highly qualified individuals from across the nation, and amongst these 20, I think 7 of them are under-represented minorities, so we've been pretty successful there. This has been quite a happy result.

DR. DAVIS: (Off microphone.) Should we ask questions now?

DR. KEEFE: Sure, please.

DR. DAVIS: (Off microphone.) You have a goal of 17 toxicologists but you've only hired 7?

DR. KEEFE: Yes.

DR. DAVIS: (Off microphone.) Could you comment on that? And the fact that you had a goal of 9 clerical people and you haven't hired any. I assume clerical people would be a group you might easily find locally and be able to find those people without a lot of problems.

DR. KEEFE: Right. Our initial targets with the recruiting was to try to get the review scientists on board as soon as

possible so that we could alleviate some of the back -- I don't want to say -- the workload in the office, so we could then more specifically target our specific needs like the data mining expert, a genetic toxicologist.

So we were focusing on the major scientific disciplines. If you look at the numbers, amongst the top three, we're pretty equal there on the number we've brought forward.

Clearly, we need to focus on bringing in more toxicologists and we need to bring in the administrative clerical support, and that's our next steps.

DR. SCOLNICK: Looking at the table that you've provided us with, I don't know whether you can show that to the panel or not, it says: Number of candidates interviewed, number of pending offers, target, numbers of on board, et cetera.

The number of candidates, is the striking of feature of the table, but there's a potential column that's missing.

For chemists you have six candidates interviewed and five on board who accepted the offer.

DR. KEEFE: Yes.

DR. SCOLNICK: How many applied?

DR. KEEFE: That becomes a difficult number to get to because of the way the vacancy announcements are constructed for the agency, there's one open, continuous vacancy announcement agency wide.

So what we've had to do is go out and screen the paper applications and identify potential candidates and then decide whether to interview them or not.

So there isn't a direct application process. So I really can't answer that.

DR. SCOLNICK: For toxicologists there were 16 interviewed and 5 accepted out of the 16. So what would be helpful to me at least is to know even though it looks like you've been successful is among the toxicologists you offered it to, what was your rank versus the number that -- how did you rank them and who

you preferred would accept versus the people who accepted you?

And say the chemists, where there are six offers and five acceptances, how many qualified applicants did you look at to decide to interview six?

Because one of the things, at most institutions, they have many more applicants for their jobs or their slots in schools than they end up accepting, and it various in what institutional situation.

Some places it's 10 to 1, 20 to 1, 2 to 1, 3 to 1, and I think whatever metrics you can bring to bear on your hiring process, like how many applicants you're really getting, what is your rank list for the ones that you put up the offers for, who accepts, who doesn't on that ranking; some additional metrics would help at least me see the quality of what you're hiring.

DR. DAVIS: (Off microphone.) The one in which we look at is are you an employer of choice? So, for instance, if you interview 16

toxicologists and you only hire 7, out of that 16 were 13 of them candidates you would have liked to have had and only 7 accepted?

Or did the 16 that you brought in, they looked good on paper,but when you got them in you wouldn't have made offers to but eight of them?

DR. KEEFE: Right.

DR. DAVIS: (Off microphone.) So you offered 8 and you got 7, which looks pretty good. But if you offered 16 and got 7 that's a whole different story.

DR. SCOLNICK: And if among the top 16 you wanted the top 8 and you only got the bottom 7, then you know you still have a problem. And it just allows you to constantly improve your hiring process and the quality of what you're getting to measure yourself.

DR. HENNEY: Alan, did you have a comment to add to that?

DR. RULIS: No, I don't have the numbers exactly in my mind, but as I think through the process I would guess that we had

quite a few more than -- you know, the numbers up here represent a subset of obviously a small subset of the people who expressed interest, but I think of the people who we interviewed, there were a number that we decided we would not proceed further with.

And I don't exactly know the factor, but perhaps this represents maybe a third or so -- or maybe a half or a third of the candidates available. But we could get those numbers and I think the next time we talk with you we'll expand the table out and try to give you a better feeling for that.

DR. KEEFE: We certainly can produce those, but we just haven't been thinking in those terms. But that would be helpful.

DR. DAVIS: (Off microphone.) It's important that you think in those terms than show us the numbers.

DR. KEEFE: That would be helpful. No, I mean, we can do that. We have the database of the candidates that we've identified as strong candidates.

DR. DAVIS: (Off microphone.) So it's really key that you know whether or not you're getting the people you want, or are you just filling the slots because you've got open head count.

And the other question I have is with this table, does the government have temporary workers? You know, as I look at this, to me, aside from the fact I know you need toxicologists, but I would think you need administrative support, too.

So my question is here you have hired nobody and you've got nine slots. It would seem to me that you have people wanting the jobs.

So if you couldn't bring people in full time, could you hire temporaries? Get them in, see how they worked out? I mean, you can switch them over. Therefore, you'd be able to get that work done while you're looking for the right candidates or something.

If this has taken eight months, six months, you know, and you haven't filled any of

those slots, I would think administrative workers can be quite critical as well.

DR. HENNEY: Alan?

DR. RULIS: Yes, just to put this into a little bit of context.

I think your point is well taken. I think that, you know, we do need to concentrate on that cadre of folks. Dennis' point here is that we have purposefully focused on the scientists we need to do the job.

We do have currently a cadre of clerical people and program support people throughout the office. This is an expansion of that, considerable expansion of that. But in the course of this hiring, we have gone out and hired temps.

We've hired all sorts of part-time workers to carry on while we bring on full-time folks. We've just focused really on the full-time hires. We've focused on the scientists first.

I fully expect that by the next time we get together we will have our cadre of

support people. They're a whole lot easier to find, you're right. And there's no problem, particularly, with doing that. But in the context of what exists in the office now, we have a base of those kinds of workers who are supplying us what we need.

DR. KEEFE: Any other questions?

DR. LANGER: Marion?

DR. NESTLE: Yes. I was curious about this FDA Outreach list. Is that yours or is that somebody else's? It must not be yours if you don't recognize it.

DR. KEEFE: Is this part of the -- there is also in our package of information a strategic plan that I was going to mention later.

DR. JACOBSON: Yes, that's something different.

DR. KEEFE: That's something different?

DR. JACOBSON: They may very well have outreached some of these groups in this hiring effort, but this is Agency-wide.

DR. NESTLE: Yes. I was very curious about this list, which is the list of places where it looks like recruiting was done, and I was curious to know whether you're doing this and whether other places are involved.

DR. KEEFE: I can tell you I'm not doing it.

DR. NESTLE: Okay. How are you recruiting?

DR. KEEFE: If I could have the next slide.

(Laughter)

DR. NESTLE: I set you up.

DR. KEEFE: Thank you.

(Slide.)

I just want to briefly talk about some of the things we've learned, lessons learned.

With regard to getting the word out, advertising in professional scientific journals is great.

Utilizing the web.

Attending scientific professional meetings in person.

Having our scientists go out and not just sending somebody from the personnel office to talk about the science of it what we're doing, to identify candidates and encourage them to apply.

And, surprisingly, using emails to send to department heads as opposed to letters or phone calls, they're much more responsive.

Letters, we go very little response to.

Phone calls, not much either. But the emails really worked.

DR. NEREM: Emails are the easiest to pass on.

DR. KEEFE: Yes, exactly. Exactly.

DR. ANDERS: Do you code your applicants? Do you know which of these strategies is most efficacious?

DR. KEEFE: No.

DR. ANDERS: Where do you most of your applicants come from?

DR. KEEFE: Well, actually, most of our applications, we -- for example, the

chemists. Most of the chemists were identified at scientific meetings and were encouraged to apply, and we worked with them to prepare their packages, to meet the OPM guidelines so that they didn't get lost in the process. That was our best way.

And also with the toxicologists, that's worked very well. In fact, I would say across the board where we've really found people is face-to-face at professional meetings.

DR. ROSENBERG: Are any of your people you've brought on senior people or do they all tend to be senior start-up people?

DR. KEEFE: Most of the people we've brought on are newly hatched PhDs or PhDs with a couple years of post-doc. We have a few more senior people, especially I think we have a couple of toxicologists that we're bringing on board that they're a little higher, more experienced level.

But, again, our initial emphasis was to focus on getting scientists in, qualified

scientists in, and try to refine it, focus these other targeted areas later.

DR. SCOLNICK: This opens up potential bias can of worms. We always look at the kinds of letters you get and people usually say, well, this people is among the best 10 percent post docs I've ever had. Five percent are graduates, 1 percent, 20 percent.

Do you look for that kind of information in your recruiting?

DR. KEEFE: We do a very rigorous screening of the paper presentation that the candidate presents to us and with the personal interactions at the meetings.

We look closely at the references for any identification for weaknesses and in the application.

We focus again on the science and their writing skills because writing skills are critical to us.

And 95 percent of the candidates we brought in for seminars, so we look at their verbal skills, we look at their ability to

organize presentations in a logical manner.

DR. LANGER: I don't know if your question was answered.

DR. SCOLNICK: No, it wasn't answered. But I'm just trying to raise the awareness level as high as possible.

DR. LANGER: I got it. I got it. Okay. Because I think that's exactly what I look for.

(Laughter)

DR. NEREM: Two things, following up on that, number one: There is an old adage that anybody can get good letters, it's only a question of whom they can get them from.

The second thing is you talked about carefully reading the reference letters, but do you talk to these people on the phone? Because frequently they'll say things that they won't put in writing for obvious reasons.

DR. LANGER: That's all the tricks. That's exactly right.

DR. SCOLNICK: That's why I asked the question. I realized I was getting into a

complicated area.

DR. KEEFE: If we have questions about the candidate and especially if there's questions that are deriving from the references, we will call them, and we have called them, and we have actually identified some candidates that looked very strong on paper, but after following up with the references, we decided not to make offers to them.

DR. NEREM: Probably people use a lot of different language, but if someone at the end of the letters says, "If you have any further questions, please contact me," that's sort of saying maybe you ought to contact me.

(Laughter)

DR. KEEFE: No, we take this very seriously. This is --

DR. NEREM: I'm sure you do.

DR. KEEFE: -- these are people we have to work with. We have a mission to do in our office, and we're not just bringing in warm bodies.

DR. NEREM: No, I just want to make sure you're using all the tricks.

DR. KEEFE: No, I appreciate that. I appreciate that.

DR. SCOLNICK: It's especially important when you're starting a new recruitment process like this for a larger group of people, because if you do it well it will be autocatalytic, whatever. Those people will attract the next wave and you just raise the whole level. It's really critical.

DR. LANGER: Bob, you had a question?

DR. BUCHANAN: More a comment than a question.

I also wanted to point out that we're very sensitive to the issue of there's a tendency among scientists to go to the same group of friends or acquaintances to look for new post-docs or whatever, and this winds up, we deal with a very small pool of candidates this way.

So we make a very concerted effort to blind this process in a way and go out to make

sure we're getting the sampling of diversity that's out there and set up the criteria for looking in that manner.

So if it seems like we go to some great deal of extra steps, we are doing it specifically for that reason.

DR. NESTLE: I was just going to comment that I don't know who Greg Diachenko (ph) is, but he must be a great resource in your office, according to these comments?

DR. KEEFE: If you remember we were talking about the chemists, he's head of our chemistry review group.

DR. NESTLE: And so he just goes out and talks and?

DR. KEEFE: Well, he's attended some of the Job Fairs, ACS meetings, et cetera.

DR. NESTLE: Well, have him do more of that. It seems to be working.

DR. KEEFE: Yes.

If I could have the next slide, then.

(Slide.)

So other lessons learned, interacting

with the candidates: As I mentioned before, have the candidate interact with the across-the-board scientists in the offices is very good for not only giving the candidate an idea of what we're doing but also for evaluating the candidate.

When we're interacting with them, we're talking about the science of what we're doing, what the job is like, what the challenges are.

As far as procedurally, once we've identified a candidate that we want to make an offer to, following up with the candidate, being persistent with the candidate, keeping them informed of where they are in the process is very important.

It's very important for the people in the office to learn the hiring rules within FDA and OPM. The FDA personnel office has been very helpful with that, not only at Parklawn but at the Center.

Again, monitoring all aspects of the process when we're trying to get offers to them

and making sure things don't get lost, it's very important.

If I could have the next slide.

(Slide.)

Again, in selecting the candidates, we're focusing on the science and their scientific ability relative to the mission of the office and how they will fit into what the office has to do in the future.

If I could have the next slide.

(Slide.)

So the next steps we envision:

Obviously, we're going to redouble our efforts with the toxicologists.

We are going to be recruiting for candidates for the bridge positions. These are the non-clerical support people. These would be people that have information technology background, help maybe project officers, helping with contracting work, these sorts of positions.

We also are going to use the CFSAN strategic plan for recruiting which is in your

package.

This was prepared by a new hire that was part of one of our FTEs in the Center, and she's developed a recruitment plan that has identified resources that we can tap into to continue this work.

We are also exploring ways we can interact or develop a relationship with universities.

Just this morning I met with somebody from Duke University about setting up a relationship in the future, perhaps an internship program, or somehow we could work together to improve our process here, not only for recruiting but also for getting the word out about what sciences we do in the Center.

I think that's at.

If there's any questions, I would be happy to answer them.

DR. DAVIS: (Off microphone.) I see in the book that you have a listing of universities for diversity outreach sources, and you mentioned having people go to the

university. I don't know if you have any African-Americans in CFSAN who have positions of importance for sending people like that out with you to help recruit.

The same thing would be sending females to Spellman, to a woman's school. People like to be recruited by people who look like them. And when they say it's a great place to work they seem to be more believable.

DR. KEEFE: Right. Actually, I think the fact that we have been somewhat successful with the minority candidates, we make an effort when we do interview them, to make sure that they do meet some people like them in the interviewing process. So I think that's helped.

DR. DAVIS: Okay.

DR. LANGER: Yes?

DR. FENNEMA: Looking at this page of comments from new hires, which is in the stuff that was mailed to us earlier, and as I read over this, I found several places in here which

seemed to be very good source material in your recruiting documents, if you made quotes from this, as to why they selected a position with FDA, there's some very good comments in here that I think other people considering work at FDA would be interested in hearing about. So you ought to consider, I think, using that

DR. KEEFE: Maybe I'm not clear. You mean as a promotional?

VOICES: Yes.

DR. LANGER: That would be effective. That's a good suggestion.

DR. KEEFE: That's a very good idea. That's a very good idea.

DR. FENNEMA: There's some very positive statements there.

DR. LANGER: Other comments or suggestions?

(No response.)

Why don't we take about a 15-minute break and be back at 3:00. We're a little ahead of ourselves.

Yes?

DR. DAVIS: (Not microphone.) I'm going to have to leave after the break, but can you give me some guidance on the follow-up to the public comment, because I'll be gone, but how that's normally handled?

We had a young lade come forward and make a public comment and went away, and we didn't way anything to her. I don't know if she's gone already but do we go into Closed Session with that or get back to the Board? I'd like to know where we stand with that.

DR. LANGER: Absolutely.

DR. DAVIS: I would have appreciated if you told her something, to be honest.

DR. LANGER: Yes. Do you want to go over it?

DR. SCHWETZ: This was an appeal to the Board to make a recommendation -- to urge the Agency to form an advisory committee and some additional steps.

So I think it's up to you as the Science Board to discuss whether you want to just recognize that you listened and be silent

on recommendation or do you want to make a specific recommendation or do you want to disagree with what was recommended?

I think you need to decide how you want to follow-up on that.

DR. JACOBSON: And before you do that, let me just say that she gave us a quite lengthy written version of her remarks. In fact, she didn't have time to give all of her total statement and she did cut it short. So you might want us to distribute to that to you so you can read it before you make your recommendation.

DR. HENNEY: I wasn't here when she made her presentation so don't know the content, but as it might be appropriate, we might want to provide something to the Board to inform you about what the Agency might be doing with respect to the issue as well so then you can come to a better conclusion as to what you might recommend.

DR. DAVIS: Yeah, I would like -- this was about drugs. We'd have to have somebody

from the Center of Drugs respond to the Board on the issues.

But I'd also like to hope that she would be told that there will be a response coming back from the Board just so she doesn't leave thinking that we totally ignored her.

DR. LANGER: Right. So is the suggestion then that we'll get that information from the FDA and we'll have that on the agenda next time? However you think.

DR. HENNEY: If I could leave it to Liz, since I wasn't here. But it seems to me that if there was only one person making a particular point, we should get you the full document that she wanted to provide to you or make sure that you got.

We could give you more information about what the FDA may or may not be doing in that area, and then you could make a recommendation either by mail or at the next meeting. And we certainly will follow-up with her about what your decision has been and any other further Agency action that she might want

to be aware of.

DR. ANDERS: We'll need to know the composition of the Advisory Committee. Because much of her complaint was that it wasn't representative.

DR. HENNEY: Okay.

DR. LANGER: I think what we'll do, then, if it's all right with everybody, we'll get her document to everybody, we'll get some feedback from the FDA to everybody, and then we can probably do something by email, to get some type of follow-up before the next meeting. I think that probably she would appreciate as well.

I think maybe we can write her to tell her we're doing just that, from me or you or maybe both of us.

DR. HENNEY: Yes, that's good.

DR. LANGER: Good point.

So we'll take the 15-minute break. There's some energy-lifters over there.

(Laughter)

(Recess)

DR. LANGER: I guess we'll get started again.

The next topic is an update on remaining action items from the April meeting, and Liz Jacobson is going to do that.

I think that's probably something, my sense, there were a lot of comments made at the last meeting and we wanted to go over with everyone how these were follow-up on and to see if there are any other suggestions.

Action Items

DR. JACOBSON: Okay, great. And I think this is actually something we will tack onto the end of forthcoming meetings as well just to try to make sure we're addressing everything.

I really had three major things I wanted to update you on today.

The first one is the last time you met you had asked for the Office of Women's Health to further discuss their science research program, especially with regard to their peer review process.

We had originally planned, we had it on the agenda for today's meeting to have an update, but we ran into a scheduling conflict, and so we are postponing that with apologies until the next Board meeting.

But it may actually be serendipitously good because we just appointed a new director of that office, Dr. Susan Wood, who actually had run the Office of Women's Health in the department. And she's on board and she'll be six months or so into the job so I think the timing on that may actually be better than if we had done it now.

The next issue was CFSAN's genetically-modified foods. At the last meeting you had suggested that CFSAN consider a public education campaign for genetically-modified foods similar to the Fight Back campaign that they did.

We haven't instituted a specified campaign, although we are utilizing our web site as a tool to get out information about genetically-modified foods and our regulation

of them and what that means.

The industry itself has initiated a public education campaign actually, and we see our role, really, as assuring safety rather than as promoting that particular technology. So we thought that was an appropriate response. Obviously, you'll react in a few minutes as to whether it was or not.

And then the third issue that I wanted to touch on was human resources and recruiting, and you have a fairly large piece of your folder there, the last tab, talks about some of our human resources initiatives.

You had a number of recommendations. You recommended established relationships and networks with more universities, expanding outside the Beltway area, and utilizing more diverse sources such as historically black colleges and universities.

In the last year, FY 2000, we participated in a number of outreach activities. We went to 46 different universities' job fairs and societies.

Eighteen of those were at places with a high minority representation.

We had not just recruiters and our EEO personnel going to those, but we also had our scientists going to those places to do the recruiting.

The list of those is included in the information package.

We also heard from you that we should expand our search outside the Beltway, and we provided you a list of -- in that year, 2000, we hired about 700 people, and those 700 people came from over 200 colleges and universities.

Obviously, not every one of those 700 people was from a college or university because some of them were support staff, et cetera. But there were 200 places represented, and we gave you that list also.

I think if you look at that you can see that we do have some pretty good geographical diversity.

We probably don't lack for hiring mechanisms in terms of bringing people on. We

do have about 18 different mechanisms, personnel type mechanisms we can use. Some of them are long and extremely laborious. Some of them are relatively easy, and we can talk more about those in the future if you'd like to do that.

We also established a new recruitment counsel for FDA to try to make sure that our agency recruiters are up to speed, know about changes in laws and regulations, and recruiting techniques, and they get an hour of training every month as part of their duties.

And we have, again, EEO specialists, staffing specialists and Center recruitment personnel on that counsel.

It meets every month and it helps to promote sharing of applications across the agency, recruitment efforts and also trying to share sort of lessons learned.

We also have job fairs that figure out how they're going to get staffed and things like that.

We also are beginning to explore the

use of headhunters for key personnel. We haven't really don't that in the past, and this is an avenue that may be very promising for recruiting key individuals.

We have a student hiring effort. Through a conference grant, we hosted 160 Hispanic students and provided workshops to them on career opportunities -- tobacco, food safety, HIV AIDS. These are young students.

We had 16 Hispanic interns hired during the summer, and 9 Hispanic students were hired for the fall internship program, and we also have some part-time students from several high schools. Obviously, they're not beyond the Beltway, or at least if they are not too far beyond.

And the students work part time during the week and then full time during vacations.

As I said, in terms of technical hires, we hired just over 200 employees in a number of technical job series. And you had specifically indicated we should target bioengineering.

In 2,000 we hired 10 engineers in CDRH. Of these 10, 5 were biomedical engineers but most had a biomedical background or some related experience. They ranged from people that had just graduated with a Bachelor's to PhD level with prior work experience.

You also asked us for something that we struggled with a bit. You said you wanted to see c.v.s of everyone we had hired. Well, that would have been 700 c.v.s and we thought, well, let's just go back to them with an alternate proposal, and we can kind of negotiate a little.

Rather than do 700, what we dud was we abstracted from these 200 scientists descriptive information, including the grade level, the degrees they had, the schools attended, prior experience, and associations and honors that they had received. That's in your package. We did it by specialty.

So you can get a feeling for what kind of chemists, for example, CDER is bringing on board, and what kind of engineers CDRH is

bringing on board.

If you really want the c.vs, we can talk about that. We did remove the names of the candidates to protect their privacy on this list that we're giving you, but we thought that might be more helpful than just a stack of c.v.s yea big.

And then the other thing you had asked for was information on the publications of staff. We are currently working on a publication database for the Agency. It's available on our Intranet, and we are going to be making it available on our Internet so that you can dial into it.

When we do get that up and running on the Internet, which we hope will be early this next year, you'll be able to see publications of the FDA staff so I think we will have answered your question that way.

DR. FENNEMA: (Off microphone.) When you summarize some of this data, the percentage of offers you make which are accepted, that would be I think useful information.

DR. JACOBSON: Okay.

DR. FENNEMA: Not too difficult to compile.

DR. JACOBSON: I don't know. Mary?

MARY: It's something we can get.

DR. JACOBSON: Yes, it's something we can get. We will.

The last thing I wanted to mention was that if you are interested, I am proposing that next meeting we tell you a little bit our plans for an FDA corporate university. You heard Dennis Baker talk today about the field's Virtual University. We see that would be a component of the FDA corporate university.

In fact, our trainers and the people that run our staff colleges are on a retreat this week to talk about what that might look like and how we would start implementing it.

So we couldn't really fit it in today, but if you're interested --

DR. NEREM: What is the significance of the word "corporate"?

DR. JACOBSON: It's with a small "c."

The idea is a university that spans the entire organization.

DR. NEREM: Okay.

DR. JACOBSON: So if you're interested in that, we would propose to do a brief presentation on that maybe next meeting. We're having a lot of things piled with the next meeting agenda.

Also, we were going to consult with Dr. Rosenberg, because he had promised to talk to us about how SmithKline Beecham approaches the similar corporate university idea in an industry.

That's the end of my report.

DR. LANGER: Comments, suggestions?

Yes.

DR. DOYLE: I noticed the first page here says "FDA Outreach Activities," and job fairs and all. I assume this is part of the recruiting process.

DR. JACOBSON: Yes.

DR. DOYLE: But I see about a quarter of these are law schools. Are you trying to

convert lawyers into scientists?

(Laughter)

DR. JACOBSON: You think we could?

DR. DOYLE: I don't know. I commend you.

DR. NEREM: The more lawyers they hire the fewer that are out there to litigate.

DR. LANGER: That's right. But they have a lot of people to hire. It's a big job.

(Laughter)

Any other comments or suggestions?

DR. NESTLE: Yes. Better find a word other than "corporate."

DR. JACOBSON: Okay.

DR. NESTLE: Because I had exactly the same question. What does that mean?

DR. JACOBSON: I'm not a trainer or educator, per se, but I think it's sort of a term of art that the training community uses which we can certainly get rid of.

I actually empathize with your point because when I worked in CDRH our address is Corporate Boulevard, and that always used to

offend me that I worked on Corporate Boulevard.

DR. NEREM: I do want to thank you for not giving us 700 c.v.s.

(Laughter)

DR. JACOBSON: Well, we were trying to address the spirit of what you asked for.

DR. NESTLE: And the environmental impact.

DR. LANGER: Any other comments that anyone wants to make on this session?

DR. DOYLE: I think the approach that you took with the web site is right on, to inform the public of what FDA's responsibility is and what they're doing in terms of foods genetically-modified. Just right.

DR. LANGER: The last session is Science Board Discussion, Closing Remarks, and Future Direction.

Discussion, Closing Remarks, Future Direction

DR. LANGER: Let me just start this by going over the action items that I at least wrote down.

First of all, there were a lot of

comments that people made, and many of them have been taken down.

I counted three action items, and again people may want to add to this list. One thing that came up was the idea of partnerships between FDA and National Science Foundation, for example, but also NIH, DoD and industry.

And that's one thing that was going to be followed up, I guess, with some discussions, at least certainly with respect to NSF, with respect to Dr. Colwell, and some of the people at the FDA.

I think that that will be expanded into a broader exploration of possible partnerships.

A second action item was the Public Comment that was gone over. The way that's going to be followed up is to send the transcript of those comments, as well as the Agency comments, on that to the Science Board to get their recommendation.

The third action item is the CDRH internal review, which is really to go ahead as

planned, first with the internal review and then following that with an external review.

Those are my action items that I would put down for the record. I would be happy to have anybody add to those or modify those and then to add any others just to get people's comments.

Yes, sir.

DR. FENNEMA: I would like to make an addition.

DR. LANGER: Sure.

DR. FENNEMA: This is my perception, and we talked a little bit about this earlier, but it seems to me the single greatest threat to FDA is an inadequate budget, which is inadequate to assure timely science-based, regulatory activities.

I think if nothing else that surpasses that in importance, and I would propose that we make a resolution on this and then follow this up with some activities from the Board to take care of this. So may I read this?

DR. LANGER: Certainly.

DR. FENNEMA: "The Science Board recognizes with concern the absence of appropriate advocacy efforts in behalf of FDA during the Congressional budgetary process."

I look at NIH and I look at the U.S. Department of Agriculture, and they have a whole cadre of advocates in there speaking on their behalf, and FDA does not. I don't think FDA will ever have advocacy with the other groups I've mentioned, but I think this can be done a lot better than it's being done now.

FDA obviously can't do this. They can't be the one to stipulate this. But I think this Board could take some activities in this regard, if that's the sentiment of the Board to do so.

DR. LANGER: First, I want to get the -- I'm not sure how we pursue that. Just structurally?

DR. SCHWETZ: For you to recognize that this is -- the way the situation is that there isn't a large body of support out there from constituents. I don't think there's any

problem with you recognizing that in a written form.

If you have recommendations that you would like to make about how to resolve it, that's fine, unless they are lobbying.

So if you come up with some kind of a written statement that would resemble a lobbyist statement about getting money as opposed to a statement about mechanisms by which the level of attention of the people that we support could be increased, those are two different things.

DR. LANGER: I think there's two points in terms of what Owen is saying.

One is us making a statement like that.

But then the second thing is what we do about it.

DR. SCHWETZ: Yes.

DR. LANGER: Let me just open that up --

DR. NESTLE: Was there more, Owen? Was that the end of your statement or did you

have more?

DR. FENNEMA: That's the end of my statement in terms of the physician. I think it would naturally follow that we would have to talk about what the Board could do in terms of helping in this respect.

I've talked to Bern a little bit during the break about this issue, and one example that I could speak only from the area of the food field is that at the Institute of Food Technologist's annual meeting, they organize a meeting for the chief research officers of our research corporations.

And I think I can get on the program and make a presentation of this kind, talking about the need to do this, particularly if I had some back-up help from FDA there, Bern or a retired official of FDA, to answer questions about this.

So that's one course of action that could be taken. And I think there are many other avenues and other kinds of professional organizations where this could be done.

DR. LANGER: Let me just get the people's comments from the Science Board.

DR. NESTLE: I think if we don't do that we're useless.

DR. LANGER: Okay.

Other comments?

DR. ANDERS: We don't want to be useless.

(Laughter)

DR. LANGER: I don't think anybody could disagree with that.

Bob.

DR. NEREM: Without our going out individually and doing what Owen has proposed he could with his group, our recognizing this problem is useless.

DR. LANGER: Right.

DR. FENNEMA: No, that's right. I agree with you. Just to say it is not --

DR. LANGER: Right. So I guess the point is what do we do? I mean, I think that we can certainly make this statement, put your statement into the record, if that's okay. And

then I think we can try to do the types of things that you're suggesting.

DR. NEREM: Do you want to read that again?

DR. LANGER: Yes, maybe that would be a good idea.

DR. FENNEMA: Okay. "The Science Board recognizes with concern the absence of appropriate advocacy efforts on behalf of FDA during the Congressional budgetary process."

DR. LANGER: I guess what I was trying to ask, is that statement an OK statement? I guess to put in our record? I don't want to put you in a difficult position. I just don't want to have a statement that makes it sounds like we're lobbying, either.

DR. FENNEMA: I know. I wondered about this at the outset, and we don't want to do anything that's going to be embarrassing for FDA in this setting right here.

DR. NEREM: No, I'm not sure that's the kind of statement we ought to make.

DR. LANGER: Yes. I wonder, too. I

mean, I'm almost thinking that the statement that we might want to make is something along the lines that we recognize the FDA is certainly going to need increased funding.

I mean, just to pick an example, that the FDA certainly needs increased funding, and maybe we can work on this; but increased funding if they're going to be able to keep up with, I think a number of people made the point, about all of the information that's coming forward and how without getting more funding to do more science or understand more science, the FDA will be able to do its job in terms of regulating things.

DR. ROSENBERG: I'm even concerned about putting it in terms of science --

DR. LANGER: Yes.

DR. ROSENBERG: -- which always seems to get you nowhere.

DR. LANGER: Yes.

DR. ROSENBERG: It's really in terms of the products that are going to be made available to the public, and that product flow

and the importance to the industries that require that product flow for their continued existence, and that the FDA is the group that has to work efficiently to make sure that product flow and ensure it's value to the people of the United States.

DR. LANGER: Right.

DR. ROSENBERG: And it's to somehow connect the fact that they're not just -- they serve more than just to protect the people. They deliver things to the people that are good for the people.

And if that process doesn't work efficiently, everybody suffers on both ends.

DR. LANGER: Right.

DR. NESTLE: Can I say something? I have to leave and so I'd like to say something before I do.

That is that I think a much stronger statement is needed. I'm not the slightest bit worried about embarrassing FDA. I think if the Board has a position it should take a position.

I wonder if we couldn't develop a much

stronger position or a much more nuanced position in which we talk about this as a public health issue, which is how I see it, a very serious public health issue, and go into some of the details and perhaps write a -- rather than a one-sentence statement write a position on it.

And that would be something that we would develop over time, perhaps not in consultation with FDA officials but separate from FDA officials as something that the Board did on its own.

I don't know how other people feel about it, but that would be my suggestion.

DR. LANGER: What do people feel about that? I guess my only concern is I think this is a -- the spirit of what is being said I think is very good. I think we have to figure out, from what everybody is saying, exactly the right way to say it, whether it's one sentence or 10 pages or what exactly the thrust is.

DR. NESTLE: Yes. This may not be something that we can decide this afternoon.

DR. LANGER: That's actually exactly what I was going to say. You said it for me. But I think it's certainly something that we want to follow-up. I don't know if I'd even put it as an action item, per se, but I think that we should try to find the time to talk about it between now and say the next meeting.

DR. FENNEMA: Well, I'm not married to the statement.

DR. LANGER: No, I understand that.

DR. FENNEMA: But the sentiment I feel strongly about. And what I would really like to know and I think it would be useful to know is whether the group agrees with this sentiment or not. That doesn't need to be in the official --

DR. LANGER: Yes. Not everybody has spoken, but I think everybody that has agrees with, certainly it seems to me in part, but different people feel more strongly about certain aspects of it than others, and that's kind of what I'm hearing.

There are a couple of people that

haven't spoken.

DR. DAVIS: (Off microphone.) To me, we sit here and say we are concerned about FDA's future ability to continue to do what it's done, so we are concerned that as a Board we need to be making our concerns known.

So I'm very much on board with us doing something.

I guess I agree with Marion, to just make that statement and put it in the record will accomplish very little. I think it's time that we probably make our statement as the advisors of this Board to whomever those -- the powers that be.

DR. LANGER: A couple more comments?

DR. ANDERS: It's the issue of efficacy. We could make all the statements in the world. What statement will get to the place where it will do some good, and any statement we construct has to get to that place.

And if there's no statement we can construct that will be efficacious, then we're

wasting our time.

So how do you get a response to something you do?

DR. LANGER: Bob, why don't you make a comment, then Owen. It sounds like a few. That's okay. Bob, you first.

DR. NEREM: I wrote a slightly altered statement. I have a feeling we probably shouldn't pass any resolution today. We may want to put something up and then table it.

DR. LANGER: Sure.

DR. NEREM: But I do think we have to come at it a different way. The statement I wrote, because I think it really expresses where I'm coming from is:

"The Science Board recognizes that as we move into the 21st century the regulatory process will become rate-limiting in the economic development of this country and in providing the best possible health care to our citizens.

"The Science Board, individually, thus commits itself to a leadership role in the