

TRANSCRIPT OF PROCEEDINGS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CFSAN PRIORITY-SETTING

MEETING

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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CFSAN PRIORITY-SETTING
MEETING

Wednesday, June 24, 1998

10:00 a.m.

Auditorium
Cohen Building
333 Independence Avenue
Washington, D.C.

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P R O C E E D I N G S

Opening Remarks

MR. LEVITT: Good morning and welcome. We put out a Federal Register notice about a month ago and we are delighted with the response we have got. We have a very good cross-section of speakers. I would encourage people to not stay only for your presentation but I think an important part of the day to listen to everybody else's also.

There is an agenda that has been passed out and so people can see where they fit on that. We will have up here, along with me, a rotating set of panel members from the senior staff in our center.

Just before we get going and I introduce Dr. Friedman, I just want to take a moment and thank the staff that worked very hard to put this meeting together; Tracy Summers, Lynn Guzens and her entire group from the Office of Constituent Operations. If you could just stand for a minute.

Without further ado, I think we should get going. It is my pleasure to introduce our Acting Commissioner, Dr. Michael Friedman. I can tell you he is someone who cares deeply about the Food Program, has been very actively engaged and is going to slug me if I go on any more.

DR. FRIEDMAN: Thank you. My interest in the Food Program is an intensely personal one. But I also have a

1 programmatic interest as well. Let me thank everybody for
2 being here today. I would like to take just a few minutes
3 at the beginning of this program to go over some general
4 issues that I would like you to think about.

5 This public exchange of ideas comes at a critical
6 time for CFSAN and for the agency. I appreciate people's
7 willingness to participate. With the launching of the
8 President's Food Safety Initiative last year, the attention
9 paid to the quality and the safety of the nation's food
10 supply has never been higher.

11 There are good reasons to focus on this issue.
12 Insuring the nation's food supply is an increasingly complex
13 task. The agency faces growing numbers of imported
14 products, both raw and finished products, the emergency of
15 new food-borne microorganisms, changes in the demographics
16 of our population as we age and as we eat out more. All of
17 this focuses attention on CFSAN, its activities and its
18 needs.

19 While the Center has received additional resources
20 under the Food Safety Initiative in the current budget and
21 we earnestly hope we will receive more next year--but that
22 is a matter being considered by the Appropriations and other
23 committees at this moment--we need to look beyond mere
24 budgetary considerations in thinking about the ways in which
25 to help CFSAN best fulfill its missions.

1 That is what you will be spending the next bit of
2 time discussing. I, personally, look forward to hearing the
3 results of these discussions.

4 What I would like to address, though, this
5 morning, very briefly, is sort of the technical basis for
6 this meeting, that the agency as a whole and the relevant
7 interest groups, both consumer and industry, need to
8 communicate more frequently and more effectively to deal
9 with issues of joint interest.

10 This kind of consideration certainly has been
11 ongoing and I am not suggesting that it is a novel idea, at
12 all. Already, there are a number of points of contacts and
13 communications and these have improved considerably
14 recently. But, as the voice of our **populus**, Congress wants
15 us to do an even better job and our own staff wish to do an
16 even more effective job.

17 Last year, in the FDA Modernization Act, Congress
18 gave the agency many important tasks. I would like to talk
19 about just two of those tasks specifically, now. First of
20 all, FDA was charged with formally assessing the discharge
21 of its statutory obligations under the Food, Drug and
22 Cosmetic and Public Health Service Acts, and then
23 determining if there are any obligations that the agency
24 fails to completely fulfill.

25 This analysis has been initiated and it is ongoing

1 low . As part of that evaluation, Congress directed FDA to
2 consult with, and here I quote, "appropriate scientific and
3 academic experts, healthcare professionals, representatives
4 of patient and consumer advocacy groups and the regulated
5 industry.

6 In other words, what I am doing is soliciting your
7 input as to what FDA is not doing as well as it should and
8 how we can improve. Once this analysis is complete, FDA is
9 directed to develop and publish a plan for achieving
10 compliance--and here, again, I quote--with each of the
11 obligations under the Act.

12 The first edition of this published plan for
13 addressing these shortfalls is due in November of this
14 coming year, November of 1998. We have a great deal of work
15 to do in the next few months under this obligation. For
16 those of you who are interested, it is referred to as
17 Section 406(b) of the FDA Modernization Act.

18 So I am inviting your participation today. We
19 have a lot to do and relatively little time to do it. I
20 hope that today's meeting is an example of the kinds of
21 consultations that Congress had in mind. The Agency
22 benefits very importantly from the input of those who are
23 knowledgeable and who have a stake in the effective
24 operation of the FDA.

25 You have a perspective about the things that the

1 agency is doing **well** and the things that we are not doing as
2 well as we would like and areas where we can improve.
3 Clearly, we do not currently have sufficient resources to do
4 everything conceivable. So this evaluation must be
5 balanced, risk-based and key to the best public-health
6 value.

7 I ask you to think broadly about FDA's mission to
8 promote and protect the public health, help us find the
9 right combinations of initiatives and improvements that can
10 advance our mission. **Proactively**, the agency, itself, has
11 begun to identify areas where we would like to see
12 improvements made.

13 Some of these are obvious areas. Some are less
14 obvious, but all are fairly complex. Let me, if I may,
15 raise three of them for you that we have identified, not to
16 limit your thinking but to give you a sense of the kind of
17 priorities that we see important and to welcome your input.

18 First of all, application reviews. This is an
19 important invisible process for FDA. There is an enormous
20 effort prior to the filing of an application, and I
21 recognize that. But reviewing an application to market a
22 new product is a major activity.

23 I think you are aware of the fact, and let me
24 recall for you, that the agency's workload, as measured by
25 new applications of all sorts, not just food but of all

1 sorts, is increasing at the rate of 12 percent per year for
2 each of the last five years.

3 That is a remarkable growth. What that means is
4 that every six years, the agency's workload for new
5 applications doubles. We have every expectation that that
6 rate of increase will continue or, perhaps, even accelerate.

7 In programs not covered by user fees, such as
8 blood products, animal drugs, generic drugs, medical
9 devices, and, of interest to this office, of course, food
10 additives, the agency, despite our stable budgets that we
11 have had in the past, faces erosion of its ability to
12 perform this job.

13 We need to find solutions to demonstrable gaps
14 posed by the steadily rising workload in the face of static
15 budget projections and the recognition that, for example,
16 with food additives, we are not meeting our statutory
17 deadline of review times.

18 Now, product quality-assurance is a second area
19 that I think is important to this audience. It is really
20 highly relevant to many of the considerations that you will
21 have. **How** does the agency assure the high quality of the
22 products that we regulate. At the beginning of this decade,
23 the average inspection, and now I am talking about all kinds
24 of problems, for FDA was 17 hours at a facility.

25 Last year, because of rising complexity in the

1 correction processes and other considerations, the average
2 inspection more than doubled, 36 hours. In 1990, FDA
3 processed nearly one-and-a-half million shipments of
4 regulated imports. Today, that number is 4 million and,
5 again, it is going up dramatically.

6 Essentially, we have had the same number of staff
7 working on these considerations. Through management changes
8 and improved efficiencies, we have struggled to keep up. I
9 think we have done satisfactorily. What I am concerned
10 about, however, is that we will not **be able** to continue to
11 make these kinds of performance gains in the future.

12 We need to find better, smarter, faster ways to
13 insure the quality of the products that are under our
14 jurisdiction. This is one of things that I ask you all to
15 help us focus on.

16 Let me mention a third area, if I may, and that is
17 adverse events and injury reporting. I think this is a
18 truly critical issue. Recently, **an article in** the Journal
19 of the American Medical Association pointed out the large
20 number of people estimated to either die or be made ill by
21 the use of drugs. These were drugs that were properly
22 prescribed and properly used.

23 Nonetheless, this was an important consideration.
24 The economic costs associated with medicine errors is very,
25 very substantial. There is mis-use or improper use of

1 medical devices. There are errors and accidents associated
2 with biologic products and we are struggling to deal with
3 the large number of new products and new uses for those
4 products for the American public.

5 I think that this has less direct import for foods
6 but it is not completely divorced from foods. And I ask you
7 to think about these things. These are three large areas
8 that the agency has identified as deserving greater
9 attention.

10 There are some themes that are woven into that.
11 Let me just mention a few of the background themes, if I
12 may. The first and the most important here, something that
13 is integrated into **all** of these efforts and underlies
14 everything we do is our desire, our need, for greater
15 scientific expertise within the agency.

16 Please recognize that the National Institutes of
17 Health continues to pour more than \$13.5 billion a year into
18 basic and applied biomedical research. It is hoped, it is
19 estimated, that that amount of money will double over the
20 next five years. That is a widely held consideration.

21 At the same time, pharmaceutical companies are
22 investing \$21.6 billion a year in research and development.
23 Medical device manufacturers, another \$4 billion a year. I
24 don't have good figures for the numbers invested by the food
25 producers or manufacturers but, clearly, we are talking

1 about an incredibly robust period of scientific research.

2 What this means is that, for each dollar invested
3 in research and development, there will be a downstream
4 effect on agencies that must regulate those products, like
5 the Food and Drug Administration. First of all, there is
6 going to be this vast flow of products but, secondly, and
7 equally importantly, these products are going to be novel
8 products, new mechanisms of action, new ways in which they
9 are produced, and they present new scientific problems to
10 the agency.

11 If the agency is not fully competent in science--I
12 don't mean just conversationally competent but thoroughly
13 competent--if we are not, then we will fall behind in our
14 ability to make timely, accurate, rational, science-based,
15 public-health judgments and decisions. That would be a
16 great disservice to the American public.

17 We don't want to slow the development process, but
18 we want to do a very good job in discharging our
19 responsibilities. We are going to work hard to have the
20 agency scientists, but the clinical scientists and the
21 laboratory investigators, continue to have their own
22 scientific expertise, to have access to be able to do their
23 own clinical studies and laboratory studies and to remain at
24 the top of their field.

25 This is a very important consideration for us. We

1 will work hard to enrich and maintain scientific
2 relationships with our sister agencies, especially CDC and
3 NIH, but all other parts of government as well including
4 USDA . Important linkages need to be made to form regulatory
5 bodies, important linkages to academia and important
6 linkages to industry as well. That kind of collaboration
7 with all those parties will be necessary.

8 There are a couple of other themes that I just
9 want to mention to give you the full range of
10 responsibilities here. One is a continuing need for
11 outreach and information. Increasingly, FDA is becoming a
12 purveyor of information. While we are an agency that has
13 regulatory authority, and the power to enforce the law, our
14 decisions are based upon science and we recognize that a
15 large number of the things that we wish to do require good
16 information to be provided; provided to the producers,
17 industry, provided to consumers so that we have the best
18 scheme that we can.

19 I think that is one of the reasons why the
20 guidance documents, the other sorts of guidance that we
21 provide, are so critical. Additionally, it is very
22 important that the public receive good, reliable,
23 understandable information on how to use the products
24 properly. This is a huge responsibility but one of our most
25 important missions.

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1 How we can do that better, I think, is a **real**
2 **challenge** for us, whether we are talking about nutrition or
3 **how** to properly use a prescribed medication. I think the
4 **need** for public education is very important.

5 You recognize that we have important
6 responsibilities in the food-safety activities. I have
7 already mentioned some of those. This is one, of the
8 **highlights** of the administration and one of the most
9 important things that **CFSAN** and the agency are engaged in.

10 No discussion would be complete without at least a
11 **brief** mention of tobacco. This is an important **public-**
12 **health** issue for us. There are several components of our
13 activities that have been ongoing and will continue to be
14 **ongoing**. The courts have been supportive of us in that
15 regard and our efforts to reduce underage smoking will be an
16 important activity for the future and an important
17 investment in the nation's public health.

18 I don't want to just mindlessly **catalogue** a list
19 of everything that we are doing. That is not my intention.
20 My intention is to give you a framework in which to think
21 about the kinds of things we would like from you and ask for
22 your specific input.

23 In the weeks and months ahead, we will be meeting
24 with stakeholders, constituencies who are affected by the
25 agency's decisions. These will be public meetings. There

1 will be discussions with representatives of various groups.
2 We want to have a lot of input but we don't want a totally
3 open-ended process that could be messy, difficult to
4 interpret or not guiding us in a useful way.

5 There are three considerations here. The first is
6 that FDA does not expect the meetings to find specific
7 solutions for all the challenges raised by FDA
8 modernization. Give us the best advise you can. Recognize
9 that it is interim advice but the best advice at that
10 moment.

11 The second is these discussions will be open. The
12 agency is very receptive to constructive input and
13 proposals. This is not a sham operation. The third is that
14 we will make every effort to include the views of
15 stakeholders in new proposals, but we recognize that, at any
16 moment in time, there is going to be some tension and it
17 will not be possible, of course, to satisfy everybody's
18 desires.

19 At the same time, we recognize the decisions and
20 plans that are made today may be very useful today but may
21 not be useful in the future and we will have to continue to
22 revise those. While we are setting up these mechanisms for
23 taking in and analyzing the comments, we have already
24 established the traditional docket to record input and ideas
25 that people would like to submit to us.

1 May I give you that docket number. That docket
2 number is 98N0339. We don't have a way of electronically
3 assessing, inputting, these comments but you can mail or fax
4 us any comments that you have. Our fax number is 301 827-
5 6870. You can mail your comments to the FDA docket
6 management and I think many of you have done this in the
7 past and are familiar with that.

8 If you miss that, it will be available at other
9 times and I don't mean this to be the only opportunity. But
10 I do want to say that we welcome your input in that regard.
11 These are very important issues, in general. The issues
12 that you will be struggling with and discussing are,
13 obviously, very important and very complex as well.

14 I look forward, very much, to hearing about the
15 input from these discussions and what suggestions you will
16 have from us. And I beg your indulgence after the very good
17 advice that Joe Levitt gave, that people should stay around
18 for more than just their presentation. I am not going to do
19 so and I apologize for that very much because I am supposed
20 to be someplace else. But it is still good advice and you
21 all should follow it and do it.

22 I do appreciate this chance to give you these few
23 remarks. I do appreciate your willingness to work with us
24 and provide the kind of input that this open meeting
25 promises to convey.

1 Thank you all very much for your efforts.

2 MR. LEVITT: Thank you very much for trying to set
3 the tone for the meeting and for kind of giving an FDA-wide
4 perspective. I know it is hard, from somebody who has
5 worked in or with just about every FDA program, I recognize
6 that it is hard to really give a good FDA overview because
7 everybody is focussed on their areas. But we thank Dr.
8 Friedman for doing that.

9 **Overview of Research Allocation/Resource Needs**

10 **Let's, now,** start to focus more in on foods issues
11 directly. I will talk just a second on the importance of
12 establishing priorities. A number of people have heard me
13 in my various talks this spring, what somebody jokingly
14 called my stump speech, where I have talked about values,
15 vision, priorities and challenges.

16 I often give the example of too many of FDA's
17 activities are like we are trying to take a hundred pebbles
18 and push them up a mountain an one mile an hour and, after
19 fifty years, what do we have to show for it. We have got a
20 lot of pebbles halfway up the mountain and nothing over and,
21 really, nothing to show for it.

22 So I really am going to try to take the opposite
23 approach, to identify what I call several boulders, get them
24 up and over the hill, to focus, to finish and to move on;
25 that is, I can say something that all of FDA copes with,

1 certainly the Foods Program is no stranger to that, but it
2 is an important thing we are going to try to do.

3 Really, when you stop and think about this
4 meeting, what I would like you to do is help us identify
5 what those boulders should be.

6 I have a couple of slides I want to run through to
7 kind of further set the stage. You will enjoy the splendor.
8 This meeting room is what they call a BYOS, Bring Your Own
9 Screen, and so we are a little into home movies here.

10 [Slide.]

11 In terms of what we are trying to do today, we are
12 trying to look at priorities across CFSAN. I have asked
13 people to focus outside of Food Safety Initiative because
14 there have been lots and lots of public meetings focused on
15 Food Safety Initiative and I want to kind of make time for
16 everything else.

17 To the extent that people want to talk about food
18 safety, that is fine. I would just ask you to focus on FDA-
19 specific issues and not issues involving other agencies. As
20 Dr. Friedman said, this also is part of our general
21 fulfillment of the mandated under the Modernization Act to
22 reach out and meet with stakeholders.

23 [Slide.]

24 I have got a couple of graphs that I want to run
25 through, and let me take a minute with it. I tease myself

1 about when I was asked to take over the program, I had
2 worked in FDA for twenty years. I know exactly how big
3 CFSAN was. CFSAN had 1,000 people. I knew that. Everybody
4 else knew that. I guess I must have a time warp for when I
5 started because when I started, twenty years ago, in 1978,
6 sure enough, CFSAN had 995 people. I am going to round up
7 and call that 1,000.

8 But what has happened, and this chart just covers
9 full-time equivalents or essentially people in the program,
10 but, in FDA, in general, and Foods is similar to that,
11 virtually all of our money is in payroll. So this very much
12 reflects at least how we see our resource base.

13 The first think you see is that, for ten years,
14 there was a cut every year for ten years. That was part of
15 the general downsizing of government during the 1980s but
16 you can see it hit the Food Center particularly hard, and
17 you can see one year in the middle which was probably the
18 Graham Rudman year, if we look back, for when there was even
19 a steeper cut than in other years, but a ten-year constant
20 decline.

21 The second thing that is not obvious but I point
22 out is in the middle, where you start seeing some increases,
23 they were very targeted increases for very specific reasons.
24 And so there was an increase for imported foods. There was
25 an increase for seafood. There was an increase for NLEA for

1 nutrition Labeling and Education Act, and there was a most
2 -cent increase in this year for Food Safety Initiative.

3 Even with those increases, we **still** have
4 20 percent. We are still started this year at 791. We
5 still are 20 percent smaller than the memory I had which is
6 probably the memory that a lot of you have because the FDA
7 budget is presented more as a whole or as a foods program
8 which includes the field. And it is hard to tease apart for
9 public understanding of what the resources of the center
10 are.

11 So that is one thing to look at. Now , there is
12 another thing to look at which is how much people in the
13 center look at it.

14 [Slide.]

15 If you take out those four areas that I mentioned,
16 if you take out the increase of imports and seafood and
17 nutrition and Food Safety Initiative which are important
18 out , nevertheless, very specific increases, if you look at
19 the general base of the program--so if you are working in
20 food additives, if you are working in color additives or
21 cosmetics, if you are working on Codex or if you are working
22 on food standards, you are working on pesticides, you are
23 working on the Milk Program, you are working on any number
24 of activities, this is how your world looks to you.

25 You don't have a 20 percent decrease, although

1 that would be enough. You really are down to 666. You are
2 really down to a full 33 percent decrease. As I said, if
3 you talk to people in the center, that is just naturally how
4 they feel because that is how their program has gotten cut,
5 on average; some more and some less.

6 [Slide.]

7 Now , at the same time, of course, while budgets
8 were going down, additional responsibilities were being
9 given to us, and this lists the major pieces of legislation
10 involving the Foods Center; infant formula, pesticides,
11 nutrition and labeling, dietary supplements, Food Quality
12 Protection Act on pesticides, and, of course, the
13 Modernization Act from last year.

14 So we have those sets of FDA and food-specific
15 Legislation. We also have, as companion to that but it is
16 kind of hidden, all of these general international trade
17 agreements which carry with them their own additional
18 responsibilities. This is something that I know that has
19 had a lot of interest outside, but I can say it is kind of
20 below the surface because it doesn't say Food and Drug on
21 it .

22 It doesn't say Food Safety on it. It says, WTO.
23 Or it says equivalency. Or it **has** words like that. But
24 what that means is that those also are additional
25 obligations we are having to do.

1 So what FDA is realizing more and more is you put
2 all of this together and you can't help but reach the
3 conclusion that there are significant gaps from what we
4 have, in terms of resources, for what the world's
5 expectations are. There is a gap between the ability to
6 deliver and the expectations to deliver.

7 So what we need to do is we need to try in helping
8 to bridge that gap. One of the areas is, "All right; what
9 are we going to do?" I was at a meeting. I was down at IFT
10 in Atlanta earlier this week and I kind of walked in at the
11 end of the one of the presentations because I was on the
12 next panel.

13 One of the presenters, just from a food company in
14 charge of research, said, "You know, in my research program,
15 I have got to set priorities. That means that some of the
16 things that people want to do aren't going to get done but
17 it means some things are going to get done well." I said to
18 myself, "Wow; I want to tape that. I want to replay it at
19 the beginning of our public meeting on Wednesday, " because
20 that is exactly the theme that we have to do if we are going
21 to succeed.

22 [Slide.]

23 In terms of priorities, people ask me, "What do
24 you mean by priorities?" When we looked at regulations,
25 this is kind of how we have scoped it out. We say, number

1 one, if it is a regulation that is going to enhance consumer
2 safety, that has got to be first.

3 That is, after all, why we are here. That is why
4 the Food and Drug Administration exists. That is why the
5 Act was passed in the first place. That has got to be our
6 top priority and a lot of the Food Safety Initiative issues
7 you will see in there.

8 Number two, what is mandated by statute. Number
9 three, health-related labeling, nutrition issues, health
10 claims and so forth. Four, things that improve efficiency,
11 something, I would say, like our proposed GRAS notification
12 process of a year ago. That is something that is going to
13 improve efficiency. It is going to help the whole system
14 run well. We need to give priority to that.

15 Finally, notwithstanding those four categories,
16 there will be other things that have major positive impact
17 and we want to be able to identify those. Again, that is
18 what we want you to kind of do with us today.

19 [Slide.]

20 We have listed six questions in the Federal
21 Register that I want to call people's attention to and hope
22 that you will try to address as we go through. Number one,
23 are there safety issues not being adequately addressed. If
24 there are, we want to know it. We certainly think that the
25 Food Safety Initiative and other things, we have that

1 covered. But , if we don't, please tell us. We want to
2 know.

3 Number two, what should be the top Priorities
4 beyond the implementation of the President's Food Safety
5 Initiative. In all my other speeches, I have a slide that
6 says, on priorities, when you have a Presidential
7 initiative, you know it is first. It is food safety, food
8 safety and food safety.

9 But, beyond that, we have an entire program of
10 activities. What do you think should be the priorities
11 beyond that. Criteria; do you like the criteria I just put
12 up or do you think other criteria are more appropriate.

13 [Slide.]

14 Four, what are the highest priority areas for
15 research. We believe that it is essential to have a
16 science-based program and that research is a critical part
17 of that. But we can't do everything. Where can we best
18 direct our research efforts so we are getting dividends,
19 things that are unique that need to be done here that are
20 not being done other places and are critical to our mission.

21 Number five, international activities, what is the
22 priority of those. I mentioned WTO, equivalency, Codex. I
23 think we recognize these are important but also they are
24 expensive, they are far away, they take time. Where can we
25 best target our efforts so that we get the most payout out

1 of it.

2 Finally, I asked a question about economic fraud
3 and the food supply or economic issues generally, where do
4 they fit? They are not safety issues. We know they are
5 competitive issues. But I get a fair amount of questions on
6 that so I thought I would put the question out, where does
7 it fit in the scheme.

8 [Slide.]

9 We are establishing, and this meeting is the
10 formal kickoff of it, what I call an open participatory
11 priority-setting process for Fiscal Year 1999 and beyond
12 with a goal of establishing blueprint for our priorities.
13 We will be taking today's and tomorrow's meeting and
14 following through internally through the summer in our
15 priority process, and we will be putting something out this
16 fall for foods in addition to the general plan for Congress
17 that Dr. Friedman mentioned.

18 [Slide.]

19 Finally, I want to just jump back, if you will
20 allow me, very quickly, to leave one slide up there for a
21 couple of minutes, which I misplaced as I ran through the
22 slides, and that is really what does all this come down to?
23 As we are looking across the Foods Program, the central
24 issue I want to keep coming back to, and folks can prepare
25 themselves for, because when you are sitting up here, it was

1 going to keep being my question, where do we do the most
2 good for consumers.

3 That is why the FDA is here. Where do we do the
4 best for consumers across all these areas. That is why I
5 keep focussing on safety. That is why I keep focussing on
6 health-related issues. Please help us focus on that and
7 where we are going to do the most good for consumers. That
8 is, I think, where we will be successful.

9 That completes my slide presentation. Let me just
10 say a couple of other things and then we will get the
11 meeting kicked off. This is how we are going to do this.
12 People have the agenda out there and so what we are going to
13 do is we will have a series of panels--I hate to call it
14 Congressional hearing style because I hope the atmosphere is
15 considerably different.

16 But , nevertheless, we have tried to group people
17 that have similar kinds of issues that will be doing
18 presentations as a group. We will have, up here, sitting
19 along with me, a rotating panel of senior staff from our
20 center.

21 What I would like to do, and this is maybe a
22 slight modification, is when we get up here for each group,
23 I think I would like each presenter to do their presentation
24 and then we will have question and dialogue as a group.
25 There will be a little bell and a little sign that goes off

1 is your time. We would like to try to keep to the schedule
2 is much as possible.

3 We also will have a written record. We both will
4 be doing a written summary of the meeting, both for
5 ourselves and we will put that in the docket. In addition,
6 we hold the docket open for 30 days following this meeting
7 for people to submit written comments. So both for those
8 that are here, if you want to get your official submission
9 in, please send it in for that.

10 If you want to supplement, based on other things
11 you hear, we encourage that. If you want to go back and
12 talk to your friends who weren't here, we encourage you to
13 do that, to. So the written submissions will all be looked
14 at in, really, each area.

15 We will have here, at the meeting, a
16 representative from each office and each part of the program
17 is very interested to what you have to say.

18 With that, I think we will take a quick pause. I
19 will invite up the FDA staff on the first panel and we will
20 introduce them, I think once they are up here. So you know
21 who you are. I will introduce them as they are coming up.
22 Janice Oliver, who is our Deputy Director and heading up our
23 Food Safety Initiative. Bob Lake, who is our Director of
24 Policy. Phil Spiller, our Director of Seafood. And Terry
25 Troxell who is our Acting Director in what we finally refer

1 to as land food--plant, dairy and beverages. So we have
2 land and sea.

3 We also have to ask indulgence for our dear Janice
4 Oliver who has laryngitis. So, as many of us will be asking
5 questions, Janice's assignment today is to take good notes
6 and to pass to Bob or me for questions.

7 With that, let me then invite up our first panel,
8 representatives from the states. We have Joe Corby from
9 AFDA, the Association of Food and Drug Officials, and Ken
10 Moore from the Interstate Shellfish Sanitation Conference.

11 I would welcome Mr. Corby.

12 Panel 1

13 State Affiliations

14 Association of Food and Drug Officials

15 MR. CORBY: Good morning, everyone. My name is
16 Joseph Corby. I am the Assistant Director for the New York
17 State Department of Agriculture and Markets, Division of
18 Food Safety and Inspection. I currently serve as the
19 President of the Association of Food and Drug Officials. I
20 am pleased to be the lead-off hitter this morning.

21 I may be the only state official to offer public
22 comments today and tomorrow but I hope that numerous state
23 and local jurisdictions will provide written comments in
24 this important effort.

25 Before I begin, I wish to remind everyone of

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1 AFDO's visions for a national food safety regulatory system.
2 This vision is one we refer to as a vertically integrated
3 national effort and it is something which I have assured
4 AFDO's state and local government partners that I would
5 aggressively promote during my tenure as president.

6 It is a vision we are so strongly committed to
7 that my appearance here today was so important for AFDO
8 because we believe the cornerstone of this vision of a
9 national food safety structure begins with leadership
10 provided by federal agencies.

11 This leadership is absolutely necessary for the
12 success of a vertical top-to-bottom system. It is this
13 leadership that we have always associated with the Center
14 for Food Safety and Applied Nutrition. Every comment that I
15 have received from AFDO board members, which I used to
16 prepare my remarks today, listed, first and foremost, the
17 need for CFSAN leadership.

18 AFDO concurs with the FDA work priorities as
19 listed and agrees that food safety must be the highest
20 priority. In addition, AFDO strongly supports those
21 programs linked to the President's Food Safety Initiative.
22 What AFDO suggests today are broader than programs and
23 larger, in scope, than merely a top-ten list of priorities.

24 The suggestions we offer are a result of current-
25 day concerns of state and local regulators. Please remember

1 that while the national debate on food safety continues and
2 while we look for answers and solutions to food-borne
3 illnesses, state and local regulatory officials must act
4 immediately even if it means employing interim policies.

5 Time might be useful in developing strategies
6 during the debate, but it is a curse for those who must act
7 today. Accordingly, AFDO is pleased to offer the following
8 comments concerning CFSAN program priorities.

9 Number one; CFSAN must be the scientific leader in
10 food safety. In a vertically integrated food-safety system,
11 AFDO recognizes the scientific expertise located within
12 CFSAN and the reliance that states have on this expertise.
13 However, there are numerous occasions when requests for
14 assistance, both oral and written, are not met with a timely
15 response and, on occasion, met with no response at all.

16 It is incumbent on FDA, with the states as equal
17 partners in food safety, to respond to such requests in a
18 timely fashion. AFDO further believes that a formal
19 procedure should be established whereby FDA can respond or
20 give information to state programs. Perhaps reduced
21 resources in the center has created this problem, but it
22 seems today that state and local governments do not have a
23 central liaison within FDA to get needed information.

24 -- Contacts are arbitrarily made with FDA districts,
25 FDA region folks, region milk, food or shellfish

1 specialists, the **Division** of Federal State Relations, and
2 the Office of Regulatory Affairs when it would be so helpful
3 if we could establish a singular contact liaison.

4 Number two; CFSAN must be adequately funded and
5 staffed to continue research. Government regulators are
6 often criticized for being reactive instead of proactive.
7 In my home state, I have been involved with botulism
8 outbreaks associated with uneviscerated fish and fresh
9 garlic packed in oil.

10 We were reactive to these circumstances and,
11 together with CFSAN, took appropriate counter measures.
12 Research provides us our greatest opportunity to be
13 proactive. For instance, it was CFSAN that cautioned state
14 and local programs about the botulism concern with
15 overwrapped fresh mushrooms.

16 CFSAN's research, as you recall, was a botulism
17 challenge study which demonstrated botulinum toxin could
18 develop prior to sensory rejection of fresh mushrooms. The
19 research concluded the necessity for oxygen to be available
20 at all times within this package. As you know, the
21 application of small holes in packaging materials allows
22 this to occur. This is an example of where government was
23 proactive through the use of research.

24 Number three; CFSAN must expand the application of
25 HACCP. Approximately six years ago, FDA determined that

1 HACCP and the food process industry was essential. A HACCP
2 core committee was created and included state
3 representatives that had been recommended by AFDO. HACCP
4 pilots with various food-processing companies were started
5 to evaluate the effectiveness of the system.

6 Seafood HACCP regulations have been developed and
7 implemented and mandatory HACCP for the juice industry is
8 being considered. It is AFDO'S understanding that HACCP is
9 performance-based and, therefore, applicable to all food-
10 processing industries. Since states are obliged to keep
11 pace with FDA and the regulation of food safety, it has been
12 incumbent upon the state to adopt federal food safety
13 regulations as either state regulations or law.

14 The current approach to HACCP by FDA appears to be
15 piecemeal in a sense and is an increasing hardship for
16 states which must go through the burdensome rulemaking
17 process to promulgate new regulations. This is, frankly,
18 probably one of the main reasons FDA's food code has not
19 been adopted in a more timely fashion.

20 AFDO recommends that CFSAN consider reassembling
21 the HACCP core committee for the purpose of determining
22 whether a universal HACCP regulation for the food-processing
23 industry is warranted.

24 Number four; CFSAN needs to redirect resources for
25 economic fraud and mislabeling issues. It is clear that the

1 Nutritional Labeling and Education Act corrected the
2 misdoing of the 1980s relative to false and misleading
3 advertising. AFDO is deeply concerned that economic fraud
4 issues has reared its ugly head once again and there appears
5 to be a general lack of guidance and concern from FDA on
6 these matters.

7 To compound the problem, states are preempted from
8 setting standards or related labeling requirements and
9 little is being done. AFDO does not believe that we can
10 allow the industry to make whatever label claims they wish
11 in order to suit their competitive market needs.

12 Eventually, government will be required to reenter
13 the arena to clear up the labeling mess, just like they did
14 with NLEA. AFDO believes that it is necessary to redirect
15 some CFSAN resources, if only on an interim basis, to insure
16 that we do not return to the situation created by FDA
17 inactivity in the 1980s.

18 Fifth; **CFSAN** needs to work with state programs to
19 monitor imported foods. At current resource levels, FDA is
20 unable to properly monitor imported foods. In AFDO'S vision
21 of a vertically integrated regulatory system, FDA must
22 devote more attention to import matters while states deal
23 with domestic concerns.

24 Currently, imported foods affect both federal and
25 state agencies with too much resource expelled at state

1 level to deal with illegal or defective imports that have
2 found their way into domestic channels. FDA should work
3 with states and develop strategies on how best to insure the
4 safety of imports.

5 Partnerships and cooperative agreements are only
6 effective on an interim basis. AFDO believes new
7 legislation and additional funding will be needed to fully
8 implement a vertically integrated national food regulatory
9 system.

10 As I close, I must say how important CFSAN has
11 been to AFDO. Please understand that whenever we look for
12 food safety solutions, for interim guidance or direction,
13 and whenever we need scientific assurance that our cause and
14 objective is appropriate, we look to CFSAN. We want to
15 continue that relationship and I thank you for the
16 opportunity to share these thoughts with you.

17 MR. LEVITT: Thank you.

18 Ken Moore.

19 International Shellfish Sanitation Conference

20 MR. MOORE: Good morning. My name is Ken Moore.

21 I am Executive Director of the Interstate Shellfish
22 Sanitation Conference. The ISSC has a long-standing working
23 relationship with the Office of Seafood and CFSAN and it is
24 certainly a pleasure to be here to provide comments today-

25 I have worked with CFSAN for a number of years,

1 out I must admit that, in my review of the appendix to the
2 Federal Register notice which includes the center's list of
3 major activities, I was awed by the magnitude of this list.
4 I do not envy the task you have before you, but I must
5 compliment you for your decision to hold this meeting.

6 Beyond the value of the information you find
7 helpful in the comments, this meeting will help to educate
8 all of us regarding the extent of CFSAN's activities.
9 Should you be unable to implement a particular
10 recommendation, the participants here will have a better
11 understanding of why.

12 First, I will address the six questions you
13 included in the Federal Register notice and then I will make
14 some general comments regarding priority setting. I polled
15 the 20-plus members of the Executive Board of ISSC and their
16 views have been incorporated into these comments.

17 First; are there issues directly affecting
18 consumer safety that are not being adequately addressed?
19 The answer is yes, but, in saying that, I am not saying that
20 they are not receiving attention. I am going to mention
21 three; first, sporadic outbreaks of Norwalk viruses have
22 been attributed to overboard discharges of human waste from
23 boats. It is receiving attention, but, in terms of a
24 solution, the solution that we have found, we aren't sure of
25 the success it will have.

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1 A second is vibrios in shellfish, not related to
2 human fecal contamination. But I don't think the biggest
3 problem is *Vibrio vulnificus*. The incidence rate for *Vibrio*
4 *vulnificus* is between 20 and 30 annually and it
5 predominantly affects immunocompromised individuals. About
6 60 percent have liver disorders.

7 Another vibrio, *Vibrio parahaemolyticus*, on the
8 West Coast last summer; *parahaemolyticus* affects all
9 consumers and is not restricted to the immunocompromised
10 although the health implications are more serious for those
11 with underlying health conditions.

12 These issues are receiving considerable attention
13 and will be major areas of discussion at our annual meeting
14 next month.

15 Two ; which programs and/or activities do you
16 believe should be taught priorities for CFSAN? The first
17 priority should go to programs which directly impact food
18 safety for the general population. The majority of these
19 programs appear to fall into the product safety assurance
20 and outreach programs. Other priorities should focus on
21 support for the programs such as research and enforcement.

22 Three; should the same criteria be used to set
23 priorities for CFSAN regulations be used for setting
24 priorities in other programs? The priority list that Joe
25 Levitt talked about seems practical, but the emphasis should

1 e on process which affect the health of the general
2 opulation.

3 Four; what should be the highest priority areas
4 or conducting research? I have listed three; alternative
5 indicators, rapid methods for specific pathogens and
6 biotoxin identification and risk-assessment models would
7 certainly be helpful for future priority setting.

8 What level of priority should be given to
9 international activities? This is a difficult issue.
10 Compared to domestic foods, less is known regarding the
11 safety of imported foods. States and local food-safety
12 agencies cannot effectively address hazards in imported
13 foods .

14 One executive-board member had concerns regarding
15 the safety of imported thermally processed shellfish
16 Specifically questioning the effectiveness of processing
17 practices and the adequacy of biotoxin monitoring in foreign
18 countries.

19 Monitoring of imported foods should provide more
20 information for identifying problems and programs for
21 addressing these problems. The amount of imported foods
22 should also be given consideration in establishing
23 priorities for international activities.

24 Question six; what level of priorities should be
25 given to economic fraud issues. Again, the focus should be

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1 on general-population food safety. While this area needs
2 considerable attention, priorities should be directed to
3 fraud issues which have food safety implications.

4 With respect to shellfish issues in the National
5 Shellfish Sanitation Program, specific areas which need
6 attention include HACCP implementation, which will require
7 training, technical assistance and modification to the
8 National Shellfish Sanitation Program standardization
9 effort.

10 Two, program evaluation criteria and training to
11 insure consistency and uniformity in state programs. With
12 respect to cooperative programs, this concept offers FDA an
13 opportunity to utilize the resources of state and local
14 agencies to accomplish food-safety goals. Your behavior in
15 these programs dictates your success. I advise you to not
16 underestimate the public-health contributions of state and
17 local food-safety agencies.

18 The food supply in the United States may be the
19 safest in the world. State and local governments have
20 played a significant role in this achievement. The Food
21 Safety Initiative and federal-state partnerships movement
22 have left some state public-health officials feeling
23 unappreciated and alienated.

24 You share common responsibilities and, in future
25 efforts, I suggest you find ways to nurture your

1 relationships in cooperative programs. They will play key
2 roles in the success of the Food Safety Initiative and
3 HACCP .

4 The remainder of my comments address priority
5 setting in general. I suggest you ask yourself who you
6 should be attempting to satisfy. We continue to hear that
7 the American public is demanding a safer food supply but the
8 message is not coming from the American public. It is
9 coming from those who make their living selling
10 sensationalism.

11 The American public does expect you to do
12 everything possible to protect them. They expect you to do
13 what is reasonable. The American public does not want
14 behavior mandated. They want behavior influenced; less
15 regulation, more advice. The most effective public-health
16 efforts that we have seen in our lifetime have been the
17 result of advice and education.

18 In closing, I will share a story my grandfather
19 told me many years ago. It is similar to the Joe Levitt
20 pebble story. He said there was one a farmer who had a two-
21 horse wagon which he used to harvest corn. The wagon got
22 old and the farmer decided to build a new one.

23 When his neighbors came over to help, they
24 convinced him to build a much bigger wagon, one that would
25 hold more corn. Together, they built an enormous four-horse

1 wagon. When the wagon was finished, the farmer realized he
 2 had to acquire two additional horses and harnesses to use
 3 the wagon. When he used the wagon, he found it was
 4 difficult to maneuver, too heavy to use in the fields, too
 5 big to get into the barn.

6 The four horses didn't work well together and, in
 7 a day, he could only fill one-half of the wagon. He soon
 8 realized his ambition had led him to build a wagon that did
 9 not meet his needs. My grandfather told me he learned a
 10 great lesson from this wagon because he was the farmer that
 11 built it.

12 He built a wagon he wanted, not a wagon he needed.
 13 I share this story with you because I find the Food Safety
 14 Initiative and your list of activities to be very ambitious.
 15 I urge you to acknowledge the activities in which you have
 16 an opportunity to excel and which provide the most
 17 protection to the largest portion of the American public.

18 Don't overextend your resources to a point of
 19 mediocrity and ineffectiveness and be careful not to be
 20 drawn in controversial issues which consume tremendous
 21 resources and may only solve small problems. Finally, trust
 22 yourself. You know your programs better than anyone else.
 23 And don't be afraid to acknowledge your limitations.

24 Thank you.

25 MR. LEVITT: Thank you, Bob.

1 I wonder if I could start with Mr. Corby, if you
2 could elaborate a little more on your vision for a
3 vertically integrated inspection program.

4 MR. CORBY: I think the two key words are
5 vertical, in that it is top-to-bottom. It begins with the
6 federal government providing the leadership, providing us
7 the science, providing us the standards, evaluating state
8 programs, those that are not believed to be up to standard,
9 to provide the input on how to upgrade those state programs,
10 certification of inspectors that are working and provide the
11 training and uniform inspection procedures, recall
12 procedures and so forth.

13 In return, the states can provide hundreds of
14 thousands of inspections, hundreds of thousands of
15 investigations of consumer complaints, hundreds of thousands
16 of samples and a database. It is this boulder that we could
17 both push up the hill. That is vertical part of it.

18 The integrated part of it is simply to combine all
19 the data that is available at the state levels. We have
20 fifty food-safety agencies, at least fifty food-safety
21 agencies, doing their own thing. If we had the leadership
22 of the federal government in this system, we could all be
23 doing the same thing together.

24 MR. LEVITT: Thank you. To what extent do you
25 think that can be done within existing funding or to what

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1 extent do you see that as an area that needs additional
2 funding, either for us or for the states?

3 MR. CORBY: I would foresee that it would need
4 additional funding. That is the part I really didn't
5 mention, I guess, on the vertical part of. Part of the top-
6 to-bottom would be a funding mechanism or some of the funds
7 available through the federal government would be sent down
8 to the states, in like fashion, like they are doing with
9 cooperative agreements, partnerships and contracts, anyway.

10 MR. LEVITT: My last question, I'm not sure if it
11 is for you or if it is for Ken. How do you see that relate
12 to the currently existing three cooperative programs that we
13 have in the states of which Shellfish is one? Are they
14 separate or are they part of a more coherent whole?

15 MR. CORBY: I am not sure I understand your
16 question. Whether that would be abolished, are you saying?

17 MR. LEVITT: Whether the cooperative programs, the
18 Shellfish Program, the Milk Program, the Retail program; are
19 they part of this?

20 MR. CORBY: Yes; they are, because they provide
21 the standards, they provide the guidance and the training.
22 Absolutely.

23 MR. MOORE: And they also provide the mechanism to
24 do it.

25 MR. LAKE: Each of you had something to say about

1 fraud, so I am going to follow up on each of you on that a
2 little bit. Mr. Moore, you made an intriguing comment that
3 you thought we ought to focus on those fraud issues that had
4 public implications. I wonder if you could elaborate on
5 that just a little bit.

6 MR. MOORE: Well, there are situations that when
7 you substitute foods, that there may be people that are
8 sensitive to particular kinds of foods. When substitutions
9 occur, you have people consuming foods that otherwise would
10 not be consuming these particular foods because they have
11 known risks and they are aware of them.

12 Those are the situations that, certainly, have
13 food safety implications. But when you look at simply
14 issues of fraud in general which may not, at all, have food
15 safety implications, I think in a time of dwindling
16 resources, you have to make some hard decisions.

17 I think it is unfair to the American consumer that
18 he has to be in a buyer-beware situation but maybe we have
19 to look at that as a reality that, quite frankly, we can't
20 solve with food safety programs.

21 MR. LAKE: Thank you.

22 Mr. Corby, you, also, raised something about
23 fraud. You thought, I think, too, or at least I got the
24 impression you thought there might be some areas or some
25 types of practices that, perhaps, ought to get more

1 attention than they are getting.

2 Could you elaborate on the particular practices?

3 MR. CORBY: Yes. Our impression is, within NLEA
4 which has preempted the states, although we do some of the
5 inspection work during contract work for FDA, violations
6 that we note on the Nutrifacts Panel and submit into FDA,
7 that little or nothing is being done, or at least we are not
8 being advised that anything is being done.

9 We are left with the impression that nothing is
10 being done because we continue to see these violations.
11 Then there is the issue of health claims which, actually, we
12 can do something about. But I think the state has been
13 reluctant to do anything with labeling issues. They feel
14 they are in the preemptive box with the nutritional issues
15 and I think they are much less progressive with some of the
16 other issues that we really can do something about.

17 I think, perhaps, if FDA was as aggressive with
18 NLEA in writing to state governors and recommending that
19 they promulgate NLEA, I think that would help a lot. I
20 don't think a lot of states have promulgated NLEA into their
21 state regulation and if they did, I think you would
22 definitely see an increase of enforcements.

23 MR. LAKE: Thank you .

24 MR. SPILLER: Mr Corby, where FDA has issued a
25 HACCP regulation, seafood, for example, which is in my area

1 O that is what I am most familiar with, under a vertically
2 ntegrated national effort, would it be your expectation
3 hat the states would be the primary inspectors of all
4 lomeestic seafood processors implementing that regulation?

5 MR. CORBY: Yes. Of course, with the oversight of
6 FDA. You know, my association, AFDO, talks about uniformity
7 out yet there is not an awful lot of uniformity out there.
8 If we had the guidance and the leadership from the federal
9 government, whether it be certification, as you do have with
10 seafood HACCP, then there shouldn't be any difference
11 between a state inspector or a federal inspector.

12 The states can do those inspections. Absolutely.

13 MR. SPILLER: Thank you.

14 Mr. Moore, you talked early on about sporadic
15 Norwalk outbreaks from overboard discharge. Is there more
16 that the Food and Drug Administration ought to be doing with
17 regard to the overboard discharge situation?

18 MR. MOORE: Given the last two or three outbreaks,
19 I think the Food and Drug Administration has directed more
20 attention. They have certainly led an investigation in the
21 nest recent outbreak.

22 I think some of the findings are somewhat
23 intriguing and it offers us an opportunity, maybe, to
24 address these things. I think the question was actually are
25 they receiving attention. Yes; they are receiving

1 attention. I was suggesting that, maybe, that these are
2 some of the areas that need to continue to receive attention
3 and maybe we need to find innovative ways to solve them.

4 DR. TROXELL: Mr. Corby, you talked about CFSAN
5 providing leadership. In a world of imperfect science and
6 policy decisions have to be made, do you have some thoughts
7 on our interaction and how we might execute this together
8 with the states and AFDO in some practical way so we can get
9 to these endpoints? Do you have any particular thoughts?

10 MR. CORBY: There are a number of issues that we
11 all deal on, I suppose, if we could deal on them jointly.
12 We have a concern, for instance, with a variance mechanism
13 in the Food Code where it requires a variance for curing and
14 smoking of meat products at retail.

15 AFDO has a guideline program put together. We
16 can't seem to get anybody, particularly USDA, to even look
17 at this. If we could get that thing approved and have the
18 scientific assurance that what is in that guideline is okay,
19 that could be a suitable mechanism for states to comply with
20 that difficult variance requirement in the Food Code.

21 It has always been a problem, these variances in
22 the Food Code. I would just say there was some mention of,
23 perhaps, a science officer being appointed in CFSAN that
24 could work with the states and could be a central liaison.
25 I think that would be very helpful. I know in AFDO we would

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1 probably interact with such a person frequently.

2 MR. LEVITT: I have one more, and that is you
3 mentioned the Food Code which I think is important, but what
4 priority do you think we collectively should be giving to
5 getting the Food Code adopted by more states and what do you
6 think our target should be?

7 MR. CORBY: Quite frankly, I think that you have
8 done it all. I think the battle of the Food Code is over
9 with. We went through the battles in the early '90's. That
10 has all been ironed out. That Food Code is a superb
11 document. It has been supported by the Conference for Food
12 Protection, by AFDO, by industry groups.

13 You have written to governors and I think,
14 perhaps, it is the associations' turn to start doing
15 something. I know AFDO has written to all governors. I
16 think we have to do a little bit more to--again, our motto
17 is uniformity and we should be, I think, doing more to get
18 that promulgated by states, more states.

19 MR. SPILLER: This is for Ken. You mentioned
20 program evaluation criteria as one of the things that we
21 need to consider doing in the future, at least in the
22 Shellfish Program. I can tell you, as a program manager,
23 that this is one of those things that we keep thinking about
24 that we need to get to and we are always dealing with the
25 crisis of the day, and so it is, "Well, we will get to it,"

1 and never quite.

2 How urgent a priority do you think we should make
3 that?

4 MR. MOORE: If you look at the role of FDA in the
5 National Shellfish Sanitation, one of your primary roles is
6 the evaluation of state programs to determine compliance
7 with the interim requirements of the program.

8 If we are going to insure uniformity and we are
9 going to provide the states with assurances that all
10 shellfish that are shipped in interstate commerce are
11 meeting a minimum standard, I think it is important that we
12 at least evaluate these states in a similar manner.

13 With the downsizing that has occurred, there has
14 been, obviously, a number of different approaches in terms
15 of how your regional offices are prioritizing their
16 workloads. It has resulted in some differences in terms of
17 evaluation.

18 You can imagine the difficulties that may present
19 when FDA is finding noncompliance in particular areas. I
20 think it is an immediate need. I think the Interstate
21 Shellfish Sanitation Conference can certainly work with FDA.
22 You and I have actually begun to do this with the submission
23 of a particular issue for consideration at this year's
24 annual meeting where we are beginning to define the kinds of
25 things that FDA should be commenting on in the state

1 evaluation.

2 Quite frankly, in years past, we have looked at
3 :his as though it was a cooperative program. We found
4 situations, quite frankly, in which cooperation may not be
5 the best way to describe some of the relationship I am not
6 blaming either party, but obviously the criteria, when
7 everyone is attempting to be cooperative, is very different
8 than the criteria when parties may choose not to be
9 Cooperative.

10 I think we have to go to that next level and ask
11 ourselves what are the criteria that we are going to use
12 when we are not seeing the kind of cooperation that we
13 initially thought would happen in this program.

14 We have some of those issues out there that we
15 need to deal with and we need to deal with them immediately.

16 MR. LEVITT: Any other questions? If not, let me
17 thank both of you for coming and kicking off our meeting in
18 the best possible fashion. I know also both of you needed
19 to travel from out of state to get here, so we very much
20 appreciate your taking the time for doing that.

21 Thank you very much.

22 Our second group is a group of food trade
23 associations, the American Frozen Food Institute, the
24 Grocery Manufacturers of America, and the National Fisheries
25 Institute. If we could ask those representatives to please

1 come up. I have listed Bob Garfield, Steve Ziller and
2 Robert Collette.

3 Broad-Based Trade Associations

4 American Frozen Food Institute

5 MR. GARFIELD: Thank you, Mr. Levitt. I am Bob
6 Garfield. I am Vice President of Regulatory and Technical
7 Affairs for the American Frozen Food Institute. The
8 American Frozen Food Institute, known as AFFI, appreciates
9 this opportunity to address the agency concerning CFSAN's
10 program priorities.

11 AFFI is the national trade association
12 representing manufacturers and processors of frozen-food
13 products throughout the United States. AFFI's more than 585
14 member companies account for over 90 percent of the total
15 annual production of frozen foods in the United States
16 valued at approximately \$60 billion.

17 AFFI members are located throughout the country
18 and are engaged in the manufacturer, processing,
19 transportation, distribution and sale of products
20 nationwide . AFFI members include processors of frozen
21 bakery, dairy, meat and poultry products as well as frozen
22 prepared foods, seafoods, juices, fruits and vegetables.

23 AFFI applauds CFSAN for its efforts in launching a
24 comprehensive analysis of the system by which it assigns and
25 prioritizes its responsibility. AFFI agrees in principle

1 with CFSAN's work priorities for its regulations program as
2 outlined in the June 3, 1998 Federal Register notice.

3 As a threshold matter, however, AFFI strongly
4 believes any CFSAN prioritization system, whether for
5 regulations or for other program areas, must be guided by
6 the overall goal of a food safety regulation scheme that is
7 uniform with respect to its objectives, consistent in
8 approach and coordinated in implementation and that most
9 effectively and efficiently utilizes current resources to
10 address risks of public health significance.

11 To accomplish this objective, CFSAN must conduct a
12 comprehensive analysis of FDA's current food regulatory
13 approach using the following five principles as its guide in
14 assessing and assigning priority.

15 First, all efforts to reduce risk must be based on
16 scientifically informed and factually based risk
17 assessments. Second, the agency must adopt flexible and
18 responsive regulations that encourage research and
19 innovation. Third, CFSAN must recognize that industry is
20 responsible for the integrity of its products.

21 Fourth, the agency should seek clear, consistent
22 and performance-based regulations. Finally, it is an
23 imperative that all food handlers in the distribution chain
24 from farm to table be educated on food safety practices.

25 With these general principles in mind, I would

1 like to share **AFFI's** thoughts on the specific questions
2 posed by the center in the Federal Register notice. First,
3 **CFSAN** asks whether there are issues that directly affect
4 consumer safety that are not being adequately addressed.
5 Some commoners may posit areas they believe warrant
6 scrutiny. **AFFI** believes, however, that the more pertinent
7 question, and the question the center should be asking is
8 this; based on a scientific and fact-based risk assessment,
9 which issues that directly affect consumer safety should be
10 a priority for the agency and which should not.

11 An example may help illustrate my point. **FDA** has
12 allocated and will allocate significant resources to a whole
13 host of that which it considers to be important consumer
14 safety initiatives including mandatory **HACCP** programs for
15 seafood, safety plans for raw and minimally processed
16 vegetables and egg-safety programs.

17 In addition to these, the agency has a number of
18 other important initiatives which it plans to undertake.
19 Given this ambitious agenda, some issues which the agency
20 currently addresses will have to take a back seat. In this
21 context of limited resources, it is difficult to comprehend
22 why the agency has proposed to mandate **HACCP** for all juice
23 processors including processors who pasteurize their
24 product.

25 The reasons cited by the agency for mandating

1 HACCP simply do not rise to the level of high consumer
2 safety priority. Of the sixteen microbiological outbreaks
3 cited, only three were clearly attributed to pasteurized
4 juice. Of those, one was attributed to water or a virus,
5 another to yeast, and a third to an infected worker. None
6 of these would, necessarily, would have been prevented by a
7 HACCP program.

8 The other justifications offered for a HACCP
9 include tin and metal packaging issues, recalls due to
10 inadvertent addition of ingredients like colors and
11 sulfites, and sanitation and equipment recalls.

12 My purpose in presenting this litany is not to
13 plead for the pasteurized juice industry although I think
14 the agency has not made a substantive case for requiring
15 mandatory HACCP for pasteurized juice operations but to ask
16 why, given its limited resources and aggressive food-safety
17 agenda, the agency is even contemplating expending valuable
18 resources on an industry that has a safe record and on a
19 problem, if one even exists, that can be handled through
20 current CGMPS, voluntary HACCP programs, and federal and
21 state inspection programs.

22 I use this example because AFFI strongly believes
23 FDA's food safety resources must be used prudently and, in
24 those circumstances in which a food contains a sensitive
25 ingredient which does not undergo further processing and for

1 which substantial evidence exists that the food may present
2 a significant risk to public health.

3 Only under these circumstances will FDA be able to
4 address, with its limited resources, those issues which
5 directly affect and are most imperative to insuring consumer
6 safety.

7 Other than food safety, let me highlight three
8 areas from CFSAN'S list of priority activities that AFFI
9 believes warrant high priority for the center; food and
10 color-additive petitions, food standards and Codex
11 activities.

12 Let me briefly explain why each of these should be
13 considered important activities. Each day, researchers
14 around the country are working towards breakthroughs which
15 will enhance the safety and efficacy of our food supply,
16 permit the introduction of foods which will attract a
17 broader cross-section of consumers such as foods that taste
18 great and contain less fat and cholesterol, and create
19 colors and additives that make food more appealing and, in
20 general, add more diversity and choice to the American
21 consumer.

22 In many ways, this is no different from the
23 innovation constantly taking place in all segments of the
24 American economy with one important exception. Innovation
25 within the food industry is slowed by the regulatory

1 process. To address this, CFSAN must work to streamline the
2 approval process.

3 AFFI respectfully suggests that the center must
4 strive to use internal resources more efficiently or look to
5 alternate extra-agency resources to move the food and
6 additive color petition process into high gear.

7 I also mentioned food standards. AFFI believes
8 that it is appropriate, as FDA proceeds through its
9 modernization process, that the food industry have the
10 opportunity to do the same. Food standards were established
11 many years ago as a means of assuring consumers that what
12 they saw on the label was, in fact, what they got in the
13 package.

14 Today, as a result of the Nutrition Labeling and
15 Education Act and other laws and regulations, consumers have
16 the tools they need to understand the contents of the food
17 product. Yet food standards that remain on the books in
18 many instances hinder innovation.

19 FDA should allocate resources with industry to
20 explore this area, not necessarily to expunge all food
21 standards but to determine the instances in which standards
22 are inhibiting progress and can be modified to increase
23 innovation.

24 Lastly, let me address Codex and international
25 activities in general. AFFI, through its international

1 organization, the International Frozen Food Association,
2 represents the frozen-food industry on a number of Codex
3 committees as well as the Codex Alimentarius Commission.

4 IFFA has also been active with other international
5 bodies which deal tangentially with food issues such as the
6 Intergovernmental Forum for Chemical Safety which addresses
7 chemicals including food additives and pesticides.

8 From AFFI'S perspective, the U.S. is quite frankly
9 being routed in international activities by voting blocks
10 such as the European Union and now the Mercusor countries
11 which are able to use their members to project an impression
12 of consensus during committee meetings

13 Because a vote on issues is rarely taken, vocal
14 delegates can usually prevail in these fora. Given the
15 importance of Codex and international standards in general,
16 the U.S. simply cannot afford to take a back seat to anyone.
17 The U.S. must exercise leadership in Codex and FDA must play
18 an important role in that effort.

19 With leadership in mind, I offer a few
20 recommendations to strengthen the U.S. role. First of all,
21 U.S. delegates to Codex must be effective and informed
22 leaders who are well-trained in presentation skills.
23 Second, U.S. delegates should be trained in the art of
24 diplomacy.

25 Third, the U.S. Department of State should be

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1 represented in all U.S. delegations to Codex and the State
2 department representatives should be an active component of
3 all delegations' activities. Finally, the U.S. should
4 expend more resources to host Codex committees for which it
5 has responsibilities.

6 Without a comprehensive and consistent
7 international system of food ingredients, food standards and
8 food safety practices that is shaped by the U.S. input, the
9 U.S. jeopardizes both the safety of its consumers and a
10 tremendous economic opportunity available to U.S. business
11 in this globalized economy.

12 CFSAN must also ask what the highest priorities
13 should be for the center's research resources to insure that
14 all agency initiatives are premised on risk assessments that
15 are scientifically sound and factually based. AFFI urges
16 the center to make the development and application of
17 methods to quantify exposure and risk the primary thrust of
18 its research activities.

19 The importance of this research to the overall
20 goal of building a more uniform consistent regulatory scheme
21 for foods cannot be overstated.

22 Thank you for the opportunity to share AFFI's view
23 of CFSAN's prioritization. AFFI plans to submit written
24 comments on this important initiative in the near future.

25 MR. LEVITT: Thank you very much. It sounds like

1 will be getting some comments on the juice HACCP from you,
2 also.

3 Next, Dr. Ziller from GMA.

4 Grocery Manufacturers of America

5 DR. ZILLER: Thank you, Mr. Levitt. I am Steve
6 Ziller, the Vice President for Scientific and Regulatory
7 Affairs for the Grocery Manufacturers of America. We want
8 to thank FDA for the opportunity to present these oral
9 comments at this public meeting addressing the
10 prioritization of programs within the Center for Food Safety
11 and Applied Nutrition.

12 As you know, GMA is the world's largest
13 association of food, beverage and consumer-brand companies.
14 With U.S. sales of more than \$430 billion, GMA members
15 employ more than 2.5 million workers in all fifty states.

16 Our answers to the questions you have posed in the
17 June 3 Federal Register announcement are based on input from
18 our member companies. We asked our Technical Regulatory
19 Affairs Committee to address the details on FDA priorities.
20 This committee is composed of the top quality-assurance and
21 regulatory managers within our member companies.

22 They collectively have hundreds of man years of
23 experience working both the business interest and the
24 interactions with FDA from a regulatory perspective. Thus,
25 they are uniquely qualified to provide the most relevant

1 input in your prioritization process.

2 We will submit a full written report but let me
3 summarize some of the key points in our assessment here.
4 GMA is acutely aware of the extensive responsibilities
5 Congress and the President have assigned to FDA. Every
6 effort should be made to work cooperatively, efficiently and
7 effectively with other government bodies so that the
8 greatest collective bang for the buck can be achieve.

9 This includes cooperation with the states on
10 compliance issues and with USDA, EPA and CDC on issues of
11 mutual interest and responsibility. It is also very
12 important to increase cooperative efforts with the food
13 industry to address key food-safety and regulatory issues.

14 In the final analysis, the food industry, though,
15 is primarily responsible for the safety of its food
16 products. GMA wishes to draw special attention to six key
17 points which stand out for special consideration in
18 prioritization.

19 One; major decisions on prioritization of food
20 safety issues should be based on sound science and risk
21 assessment. Higher priorities should be given for the most
22 important food safety risk and lower priorities for the
23 lower risk or negligible risk.

24 Two; greater research efforts should be focussed
25 on emerging food-borne pathogens, quantitative risk

1 assessment, practical detection methods--for example,
2 ~~cyclospora~~--faster analysis and identification of sources
3 and the means of prevention of contamination in foods with
4 pathogens.

5 Three; greater and more effective food safety
6 educational efforts for food preparers and food service
7 retail in the home should be undertaken. Those efforts
8 should include alternative approaches to insuring food
9 safety including use of new technologies such as
10 irradiation.

11 Four; health contributions for the diet in
12 maintaining health and preventing disease is as important as
13 classic food safety. Therefore, health consideration should
14 have a parallel prioritization as food safety. The
15 healthful contributions of conventional foods, functional
16 foods and dietary supplements will make it increasingly
17 important for FDA to provide the appropriate regulatory
18 environment to support and yet oversee.

19 Five; the international scope of the food supply
20 is a reality today. Efforts must be made to harmonize the
21 regulation of this global food supply for the benefit of
22 consumer health and safety as well as the facilitation of
23 U.S. food trade. A clear shorter-term focus would be
24 harmonization across the NAFTA countries, Canada and Mexico.

25 Six; FDA should also consider to carry out other

1 important functions that are less directly linked to food
2 safety--for example, the modernization of the food standards
3 in the United States--and also exercise an enforcement
4 presence where there is egregious economic fraud such as in
5 the adulteration of high-value juices.

6 Let me elaborate briefly on each of these points.
7 The first point is somewhat self-evident; expend resources
8 on the highest priorities first. However, history has shown
9 it frequently is forgotten in practice. An ex-general
10 counsel at FDA has confessed that a great deal of FDA
11 resources and time went into chasing very low chemical risk
12 for many years, almost to the exclusion of those
13 microbiological risks that the scientific community knew
14 were the highest priority.

15 FDA must set in place prioritization processes and
16 criteria for resource expenditures which will avoid this as
17 far as possible in this time of high budgetary restraints
18 for the agency in the foods area. History should not be
19 repeated.

20 With respect to research, FDA has made the
21 commitment to be a leader in the important effort to develop
22 better quantitative risk assessments, particularly in the
23 area of pathogens. However, this is an area which has drawn
24 attention and funded studies by many excellent scientific
25 groups in government, industry and academia.

1 It will be most important to work cooperatively in
2 Developing strategic approaches to avoid duplication of
3 efforts and to achieve the maximum new information which
4 will aid FDA and the industry in providing safer foods to
5 consumers. Thus , while this is a high-priority area, there
6 may be need to assess where science gaps can be filled
7 outside of FDA itself with FDA using the results of all this
8 research collectively to develop better science-based
9 regulatory policies.

10 Certainly, better methods of analysis and means to
11 prevent pathogens from entering the food chain deserve the
12 highest attention. Educational efforts on safe food
13 preparation and handling should be a high priority.
14 Spearheaded and supported by FDA, these are particularly
15 good investments based on the magnitude and pattern of the
16 current incidence of food-borne illness.

17 FDA has an opportunity to provide the benefit of
18 their scientific and regulatory expertise and experience.
19 FDA and its parent organization, HHS, are in an excellent
20 position to be a full partner in educational coalitions with
21 other government agencies, the food industry and other
22 consumer scientific and educational organizations.

23 While other efforts should attempt to minimize
24 introduction of contaminants as far up the food chain as
25 possible, a strong educational effort like Fight Back can

1 give major assurance that consumers and other food handlers
2 will know how to best protect the food supply from
3 inadvertent contamination.

4 In the current criteria, health is significantly
5 reduced in priority compared to food safety. We believe
6 that this traditional view is outmoded today. Health and
7 safety should be the same priority. This is justified
8 because of the burden of healthcare costs and the general
9 consensus that prevention and maintenance of good health,
10 perhaps optimum health, should be a high national priority.

11 Because of this, we recommend the first criteria
12 be changed to the highest priority will be those regulations
13 that enhance consumer health and safety. Within this
14 criteria, we would include speeding up application reviews
15 for GRAS ingredients, new food additives and extension of
16 existing approvals, threshold of regulation determinants and
17 nutrition content and health-claims petitions.

18 With the advent worldwide of functional foods, it
19 will be important to make necessary adjustments in the
20 current regulatory system for claims to avoid needless
21 barriers while still maintaining appropriate regulatory
22 oversight. Failure to address these areas in a timely
23 fashion constrains manufacturers' abilities to incorporate
24 new and improved technologies in their processing lines

25 In many cases, it also prevents companies from

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1 delivering the nutritionally improved products consumers are
2 demanding and from communicating effectively with consumers.
3 The international program area is one that deserves a high
4 priority also with special emphasis on Codex Alimentarius
5 standards and guidelines which serve to protect human health
6 and facilitate trade.

7 Given the role imported foods play in the U.S.
8 Food supply and the interest of U.S. food producers in
9 expanding exports, GMA strongly urges CFSAN to devote an
10 increased amount of resources to Codex activities,
11 particularly in the area of establishing standards and
12 guidelines for food hygiene and safety, guidelines for
13 import and export inspection and certification systems,
14 general standards for food additives and contaminants,
15 harmonization of flavor regulations worldwide, labeling of
16 foods developed with biotechnology and harmonization of
17 health and nutrition claims.

18 Of course, there is an underlying need with
19 respect to Codex. Codex has a committee which, in essence,
20 is like the Rules Committee. It is called the Codex
21 Committee on General Principles. This is another area
22 where, if you lose an important factor there, it undermines
23 all the work you do in these other groups. So that would be
24 another area to add.

25 These are areas where FDA has been involved in the

1 past, but more effort is required to maintain U.S.
2 leadership on key issues. There is need to assure that the
3 necessary prework for Codex committee meetings is completed
4 on a timely basis with appropriate participation by the
5 industry so that U.S. positions can be decided and shared
6 with other company delegates who will be participating in
7 the respective Codex committee meetings.

8 Our recommendation is to add another criteria at
9 the level of the previous No. 3 which would state, "CFSAN
10 participation in and commitment to establishing an
11 equivalent, consistent and efficient global regulatory
12 system for food and food ingredients. "

13 A subset to the previous international priority is
14 emphasis, in the short term, to harmonization of food
15 regulations between NAFTA trading partners, Canada and
16 Mexico. Different systems of regulations in place today
17 unnecessarily constrain cross-border operations. Many
18 products cannot be shipped across the border without
19 reformulation and preparation of different labels.
20 FDA should take greater initiative in seeking to harmonize
21 or recognize equivalent food regulatory systems.

22 A final category of priorities is composed of
23 programs which are not directly related to food safety but
24 represent an important priority to the food industry and
25 consumers. An example of this category is continuation of

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1 the process first started in reinventing government to
2 modernize the food standards through simplification.

3 Another example is maintenance of a visible
4 compliance program where egregious violations of economic
5 fraud occur such as intentional adulteration of juice
6 products. Without a visible and effective presence in this
7 area, GMA fears that a few bad actors, wholly
8 unrepresentative of the mainstream food industry will
9 victimize consumers and, in doing so, shake public
10 confidence in the food supply.

11 In addition, the reputable food industry will be
12 disadvantaged in the marketplace for complying with the laws
13 and regulations.

14 In closing, GMA welcomes FDA's process to address
15 prioritization. We hope our comments are helpful at this
16 time and we look forward to working with FDA in the future
17 as you make decisions on prioritization and implement
18 specific work programs.

19 MR. LEVITT: Thank you very much.

20 Next is the National Fisheries Institute, Robert
21 Collette.

22 National Fisheries Institute

23 MR. COLLETTE: Thank you. My name is Robert
24 Collette and I am the Director of Food Regulatory Affairs
25 for the National Fisheries Institute. NFI is the largest

1 trade association for the fish and seafood industry in the
2 Us. Our 1,000 member companies are involved in
3 aquiculture, fishing, processing, distributing, importing
4 and/or exporting of fishery products.

5 NFI commends CFSAN for its plans to develop a
6 comprehensive program to address food safety issues in the
7 context of emerging food technology and changing food
8 processing and distributions systems. We also thank you for
9 this opportunity to provide you with our comments and
10 suggestions.

11 You have posed six questions. The first question
12 is whether there are issues that directly affect consumer
13 safety that are not adequately addressed in CFSAN's program.
14 The FDA has done a good service to consumers in adopting its
15 mandatory HACCP inspection program for fish and seafood.
16 Your new inspection program under the guidance of the Office
17 of Seafood is proactive and it has focussed the energies of
18 the industry and the FDA on food safety concerns.

19 It has also provided an opportunity for closer
20 cooperation between our industry and the agency. The
21 present program, however, is not fully comprehensive. Most
22 firms handling fish products are covered and almost all fish
23 reaching consumers passes through the HACCP system.

24 While fishing vessels, which do not process their
25 catch, are exempted, the processors who receive their fish

1 are covered. The requirement that all processors operate
2 under HACCP systems insures that most fish pass through
3 hazard controls before being sold to consumers.

4 There are some fishing-vessel operators, however,
5 who sell direct to consumers; retain food stores and/or
6 restaurants. While the amount of fish sold in this way is
7 small, vessel operators who sell direct to food-service or
8 retail operators or to consumers should be covered by the
9 HACCP regulation.

10 We believe FDA should evaluate the food safety
11 risks associated with this potential loophole and expand
12 HACCP coverage as necessary.

13 You also asked about programmatic priorities. NF I
14 believes research and education are essential and need to be
15 undertaken in cooperation with academia and industry. An
16 excellent example of how research and educational needs can
17 be identified is the Fish and Fishery Products Hazards and
18 Controls Guides developed by FDA to help its inspectors and
19 industry implement the new seafood program.

20 The guide represents a tremendous undertaking and
21 has proven useful for identifying potential hazards and
22 options for their control. The informal process used by FDA
23 to develop and revise this guide is a very good way to
24 identify where further research or educational efforts are
25 needed.

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1 In our review of the guide, for **example**, we have
2 identified several instances where research is needed to
3 reach a better understanding of risks and controls and to
4 fill in data gaps. In this regard, FDA needs to continue
5 working with the industry and the academic community to
6 identify and address areas requiring further investigation
7 and/or study.

8 Your notice for this meeting suggested that your
9 highest research priorities relate to methods development.
10 Risk assessment is identified as a secondary category of
11 research. Given the existing data gaps associated with the
12 significance and control of food safety hazards, research on
13 food risk assessment should be given equal weight and
14 conducted in careful coordination with your research of
15 methods development.

16 Training and education projects should also have a
17 high priority. When preparing for the mandatory seafood
18 HACCP inspection program, FDA worked closely with the
19 seafood-HACCP alliance to develop a uniform curriculum to
20 train industry personnel and FDA investigators in the
21 principles of HACCP and their application to fish and
22 seafood processing.

23 Once that curriculum was completed, industry, FDA
24 and state inspection personnel attended training workshops
25 together. I emphasize "together." The effort was very

1 successful because of the participation of FDA in both the
2 curriculum development and workshops. This effort should be
3 a model for future FDA cooperation with academia and
4 industry.

5 It would be a serious mistake to think that
6 further seafood training is not needed, or training in other
7 areas of the food industry. Our experience so far suggests
8 that the present training program should be strengthened, in
9 particular with fish and seafood, in the areas of sanitation
10 control and verification procedures.

11 Educational programs at the consumer level must
12 also be a priority. In recent years, consumers have
13 received confusing and sometimes conflicting information
14 about food safety. FDA's leadership is needed in defining
15 what the true risks are and to help consumers understand
16 what they can do to minimize exposure to them.

17 Special emphasis should be placed on reaching
18 children and young adults and those persons who are most at
19 risk.

20 Your notice also raises a question about FDA's
21 role in Codex Alimentarius. Much of the U.S. food supply is
22 imported. The U.S. is also a major food exporting country.
23 This is particularly true for fish and seafood products.
24 The market for fish and seafood is global. Codex quality
25 and safety standards are being utilized increasingly to

1 resolve food safety disputes between nations in the World
2 Trade Organization.

3 Therefore, FDA must play an active role in Codex
4 to insure international standards and guidelines are
5 consistent with U.S. requirements. For example, Codex is
6 presently combining all its codes of practice for fishery
7 products into a single comprehensive code and, in the
8 process, is revising the code to include HACCP principles.

9 Given the importance placed on HACCP systems to
10 control the safety of our food supply and the need for
11 consistency in defining and applying HACCP principles, the
12 FDA must help shape the new Fishery Code.

13 More importantly, the FDA must move aggressively
14 in the next few months to negotiate effective international
15 agreements for seafood inspection with nations which are
16 producing much of the seafood Americans eat. FDA's seafood
17 HACCP regulation covers both domestic and foreign
18 processors. At the present time, FDA verifies foreign
19 processor compliance by periodically testing entries and by
20 examining U.S. importer documents describing how U.S. buyers
21 have verified that their suppliers are obeying FDA's rules.

22 However, regulatory verification activities are
23 most effective when they are conducted on site by competent
24 inspectors. Therefore, FDA should negotiate agreements with
25 government agencies possessing the proper authority,

1 :raining and resources to conduct on-site HACCP inspection.

2 Several countries want to enter into such
3 agreements with FDA. Unfortunately, not a single mutual
4 recognition agreement has yet been signed. This must
5 change.

6 In short, put the other governments to work for
7 you. The last question posed in the notice for this meeting
8 dealt with economic fraud. FDA shares the responsibility
9 with industry in assuring that consumers get what they have
10 paid for. Therefore, the agency should not diminish its
11 oversight of economic violations.

12 This oversight, in our view, can be best
13 strengthened with better technology. For example, hundreds
14 of different fish and seafood products are in the
15 marketplace. This vast array of products provides consumers
16 with a great variety of choices but it also creates the
17 potential for mislabeling problems due to the complexity of
18 fishery nomenclature.

19 FDA has addressed this problem in part by
20 developing the Seafood List, a guidance document containing
21 scientific, common and market names of fish and seafood.
22 The Seafood List is great. However, FDA must have accurate
23 methods to verify it is being followed. Presently, there is
24 no proven method for identifying fishery products which have
25 been heat-processed such as cooked crab meat.

1 For enforcement of label accuracy, FDA needs
2 methods which identify the products which have been
3 packaged. Again, for CFSAN, research is the answer.

4 This concludes **NFI'S** oral comments. We plan to
5 submit additional written comments by the July 15 deadline.
6 Thank you again for the opportunity to provide comments on
7 CFSAN'S program.

8 MR. LEVITT: Thank you. As we move into the
9 questions, I have got a few and then, again, we will move
10 down the table here. I think my first would be for Steve
11 Ziller, and all the others who are willing to comment, also.
12 I was impressed with the number or priorities you thought we
13 should have. I looked through our several-page list and I
14 think I found maybe one thing that wasn't grouped under your
15 six categories.

16 If you could identify, say, three boulders that, a
17 year from now, would be up and over the hill, concrete
18 things to do and get done, could you come up with a few?

19 DR. ZILLER: Some of the key issues that I
20 identified are what we believe are sort of major trends in
21 the industry and in the international activities. I think
22 that there are subparts of that that have components that
23 can be accomplished in the time frame that you are talking
24 about.

25 But I think what is needed is to really decide how

1 you are going to deal with the sort of overarching major
2 issues and then subdivide that so that you can parcel out,
3 in a given year, what resources you have available to given
4 pieces.

5 Certainly, the international piece is very
6 important and growing, and there are some time frames there
7 on renegotiation of major international trade agreements,
8 and there are time frames of the major decisions of Codex
9 that occur every two years at commission meetings. So there
10 is a certain sort of bundling of important issues that have
11 to get done in a certain time frame or you miss a window by
12 two years which, for some of these trends, is a long time.

13 But, certainly, there are important things. In
14 the area of Codex, for example, the issues of finalization
15 of standards at Step 8 and those that have a chance to get
16 there can be portioned out and focus put against those
17 issues.

18 Certainly, the meeting in September of the Codex
19 General Principles meeting where they are going to decide
20 what are the rules under which we are going to go by, are we
21 going to base all of our technical and scientific decisions
22 across all the important committees primarily on science or
23 are we going to allow other things like cultural differences
24 and so forth to be major aspects in the development of these
25 standards which, up until this point, the industry,

1 worldwide, really, and the U.S. government has been strongly
2 against.

3 We think that is the correct position, but there
4 is a lot of work to be done there, not just to reevaluate
5 what our position is today but to get alignment with some of
6 the other governments who go to these meetings who have to
7 be with you or you will outvoted.

8 The General Principles meeting is being held in
9 Paris. You can see all of the European countries and their
10 close allies in the developing economic Eastern Europe
11 regions are going to be in one position, in all likelihood,
12 on that matter and we have to find other countries.

13 There is a lot of work that has to be done. But
14 that is a boulder and we need to get the jacks out right
15 away.

16 MR. LEVITT: Thank you.

17 Anybody else want to try to take a crack at some
18 concrete things a year from now we would like to see done?

19 MR. GARFIELD: I would agree with what Steve said.
20 I think we need to focus on the international activities and
21 we need to have better training of the people that we are
22 sending into these areas. They need to understand
23 diplomacy. They need to have the help of the State
24 Department .

25 I am sometimes appalled by the fact that there is

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1 to one from the State Department that goes along with
2 delegations to advise them on international diplomacy and
3 issues like that. It is just unheard of. My wife works for
4 the FCC and, when they go on an international delegation,
5 the State Department is there in force and they advise the
6 FCC and others on issues.

7 They are very, very helpful in getting the FCC to
8 understand the international implications of what is going
9 on. I see that as something that is missing in our
10 delegations that go on to the Codex Alimentarius, General
11 Principles and down through to the committees, themselves.

12 MR. LEVITT: Thank you. Clearly, it sounds like
13 Codex is a major thing and you feel that the general
14 principles, at least in terms of timeliness, is the most
15 important short-term thing. Did I hear correctly that,
16 after General Principles, you would probably list General
17 Hygiene as the next most significant, or did I not hear that
18 right?

19 MR. GARFIELD: I didn't say that. Certainly, from
20 the point of view of things directly related like pathogens,
21 food imports, and so forth, I think it is a critical
22 committee but I think it is a critical committee. But I
23 think there are some other issues that I mentioned in my
24 oral comments that relate to food additives and
25 contaminants .

1 The United States has done an excellent job, for
2 **example**, on things like heavy metals and some other kinds of
3 **contaminants** in foods that is not the case in some other
4 countries. And the Codex is a way, not only to try to get
5 some harmonized standards, but it is also a good process
6 that kind of helps educate other countries on what the key
7 issues are that maybe they ought to be focussing on, also,
8 **which** will have a good impact in terms of the quality of
9 worldwide food trade.

10 so, certainly, the food additives and contaminants
11 standards are being worked on. And then the Australian
12 committee that doesn't meet until after the first of the
13 year has to do with the whole import-export certification
14 system and so forth. And that is kind of linked into many
15 other things that Food and Drug is looking into at the
16 present time.

17 So I think there are some critical elements. Many
18 of these things are not necessarily that much added work
19 because they are focal areas that also apply to concerns
20 within the United States. So it is not so much totally an
21 addition to domestic work. It is reapplication of some of
22 the science and the regulatory thinking that has already
23 gone.

24 Our position is that we think that the U.S., in
25 many of these issues, is in a place to play a leadership

1 role because they have access to a tremendous amount of good
2 science. What has been missing is the translation of this
3 and the communication. We think that government-to-
4 government is a good thing to strengthen in those respects,
5 but we also think that the industry can be helpful because
6 we have connections, we have multinational companies who are
7 in a lot of other countries.

8 We can help from sort of the ground up in some of
9 these other foreign countries develop education and
10 knowledge of these issues so that their governments are
11 willing to take a stand in alignment with the U.S. position.

12 MR. LEVITT: Thank you. Believe it or not, my
13 second, even though it sounds like I already had my three,
14 has to do with application review. A number of you have
15 focussed on food additives and other priorities. One thing
16 that surprised me when I came into CFSAN was that
17 application review extends beyond food additives and color
18 additives.

19 If you think that you have to come to the FDA
20 before something happens, and we have listed a number of
21 them in there, but that we have, in addition to food and
22 color additives, GRAS determinations, threshold and
23 regulation determinations, product notifications,
24 consultations with biotechnology firms and what I will call
25 the food additive stuff, in addition, you have got the

1 notification program for infant formula, the notification
2 program for dietary supplements, the new thing on the FDAMA,
3 the notification for nutrient content and health claims.

4 I know, Steve, you wanted to give equal emphasis
5 to those kinds of things as well as the traditional
6 petitions, or more traditional, on health claims. Is there
7 any way to prioritize among that mass?

8 DR. ZILLER: There is but it is very difficult.
9 The industry would likely have the same difficulty that you
10 would have because we have some members who, if they have a
11 given invention or food additive or a health claim that they
12 are interested in making, obviously, they think that is the
13 number one priority for them.

14 So you have the problem of how do you collectively
15 look at those in some rational way and decide which ones you
16 bring forth first and so forth. There is a variety of
17 alternative ways you can look at that in terms of--the old
18 way was kind of first-in, first-out, but there was little
19 coming out.

20 I think Alan Rulis has done an excellent job under
21 the resource restraints that he has had to move that system
22 in a very positive direction and I think, to a great extent,
23 it is resource-limited. But I also think that there are
24 still some attitudinal and management issues that still need
25 to be worked through to make such a system more efficient.

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1 But , certainly, things that impact more directly
2 nd would be recognized in the scientific community as being
3 ore useful in terms of more helpful diets as opposed to
4 ther things for which there is less justification on that
5 asis.

6 There is a variety of ways that could be looked at
7 .o sort out which ones of those things should happen. I
8 .hink, in some cases--for example, I have heard some people
9 who are very knowledgeable about the details of things
10 around the indirect-additive area. I think that they think
11 that there are a lot of those things that probably could be
12 .ooked at responsibly but with less resource and intensive
13 :ime demands than things have in the past simply because
14 :here is so much experience, now, with handling those that I
15 :hink knowledgeable people reviewing those things could do
16 :hem more quickly.

17 There are other countries that do a reasonably
18 responsible job that use less resources per 25 of those that
19 they get than FDA currently does. So that gets back to your
20 riteria that has to do with things related to greater
21 sufficiency of operation.

22 MR. GARFIELD: If I might ask you what your
23 thoughts are on extra-agency resources to help move this
24 along.

25 MR. LEVITT: I would love to try to answer those

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1 questions, but I think our ground rules are that if you
2 start getting me talking, you won't get a lot of listening
3 alone.

4 The last question has to do with food standards.
5 Food standards got mentioned a couple of times. If YOU go
6 back to my kind of question I closed with in opening in
7 terms of what is the benefit to consumer, what is the case
8 for food standards in terms of consumer benefit.

9 MR. GARFIELD: I think there are a number of food
10 standards out there that inhibit what companies can do, what
11 products they can manufacture and have out there in the
12 marketplace. One that comes to mind in the frozen area is
13 frozen pizzas, for example. With frozen pizzas, frozen
14 pizza manufacturers are restricted by what can be called a
15 frozen pizza just by standards of identity.

16 This isn't an FDA standard, it is an FSIS
17 standard. But they are restricted in that respect because
18 they can't match what the Pizza Huts and others are putting
19 on pizza and calling them pizzas. So whatever can be done
20 to sort of alleviate that and create a level playing field
21 and allow those products to be put out there in the frozen
22 aisle just as they are being served in restaurants would be
23 helpful and give consumers more choice.

24 MR. LEVITT: Thank you very much.

25 I apologize to the Fisheries representative. I

1 will defer to Mr. Spiller. Bob Lake, please.

2 MR. LAKE: Let me have a question for Bob Garfield
3 as follow-on on the food standards. I was intrigued. I
4 thought, as you were talking about food standards, you
5 mentioned the possibility that there are some that we could
6 simply do away with. Could you sort of tell us what those
7 might be? Are you willing to put any on the table?

8 MR. GARFIELD: I don't know if I exactly said
9 that. I would have to get my notes out. But I said not
10 necessarily that we would do away with them but that they
11 may be changed in ways that makes them more flexible So I
12 don't know that there is anything that comes to mind that we
13 would do away with right off the top of my head. There may
14 be after consultation with people.

15 I know that, in talking with some people from
16 industry, they would like to test the waters out there and
17 see what happens by giving a test case and see what happens
18 with that, and then, from beyond that, there might be
19 industry interest in either doing away or amending the
20 current food standards.

21 MR. LAKE: Just one other follow up on that.
22 Again, in terms of modifying food standards, what would you
23 see as the relative priority of putting resources into that
24 activity as opposed to some of the other things you were
25 talking about?

1 MR. GARFIELD: Our members think it is a fairly
2 strong priority. But the problem is, there was supposed to
3 be some guidance given on how to do that. And we still
4 haven't seen that guidance. So everyone is sort of sitting
5 back and waiting to get the guidance from the agency so that
6 they can move ahead and decide how much and how big a
7 priority this should be based on the guidance they get from
8 the agency.

9 Now , I do understand recently that there have been
10 some resources that will be put back into that effort so
11 that guidance can come out, finally, and then industry can
12 react to it and see just how big of a priority this actually
13 will be based on the guidance that is given them, how you
14 have got to go about it to amend or do away with a food
15 standard.

16 MR , LAKE : Thank you.

17 MR. SPILLER: Mr. Collette, you have been passed
18 off to me so I will take advantage of the opportunity. You
19 said something that was really intriguing about the need for
20 further training in the seafood area. You mentioned
21 sanitation control and verification procedures.
22 Verification is something that I have been thinking a lot
23 about lately.

24 I think it is going to be one of the next
25 contentious areas of HACCP in terms of trying to figure out

1 what constitutes adequate verification, both of the entire
2 system and on an individual processor-by-processor basis.

3 Do you feel comfortable--does NFI feel comfortable
4 that it understands what verification ought to consist of
5 now so that the next priority should be to develop training
6 on that? Or do you think that the next priority should be
7 to develop more of a consensus and an understanding as to
8 what ought to constitute proper verification?

9 MR. COLLETTE: Verification of the seven
10 principles of HACCP, for many people, is the most difficult
11 to fully grasp and understand. I think that, through the
12 training that the industry went through and FDA regulators
13 went through provided by the seafood-HACCP alliance, there
14 was a baseline developed there in terms of a general
15 understanding of verification procedures.

16 So I think that there is a general recognition of
17 what verification is, but, really, the devil is in the
18 details, I think, with verification. So, to answer your
19 question, I think that probably from the experience that FDA
20 is having currently, right now, in auditing programs and
21 doing its own regulatory verification, it would probably be
22 beneficial for the agency to get together with the industry
23 and, perhaps, again, seeking the help of the academic
24 community, to further define what is adequate verification
25 in various types of operations.

1 It is not going to be the same across the board
2 for every type of food processing operation and that is even
3 true within the seafood industry. So I think the first step
4 is to further define and characterize that. And then, I
5 think, once we can come to some consensus, which I am
6 optimistic we can, then, perhaps, we can look at whether
7 further training and educational efforts are needed.

8 MR. SPILLER: Thank you. One more quick question
9 for you. You talked about vessels that sell to consumers
10 and restaurants and so they are bypassing the current HACCP
11 system because they are not selling to processors which are
12 covered by the program.

13 Is it a foregone conclusion from NFI's standpoint
14 that the vessels should simply be incorporated within the
15 group or should it be a higher priority--and you mentioned
16 evaluation of the risk posed by this situation. Would that
17 be the first priority to evaluate the risk and that is what
18 should be done or is it already a foregone conclusion from
19 your standpoint that they just should be brought in and
20 would that be a priority for you?

21 MR. COLLETTE: First of all, again, we know that
22 the amount of product that we are talking about here is very
23 small, in the broad range of the entire commercial supply.
24 I think the answer is that we need to further look at that
25 particular situation and judge to what extent, exactly, it

1 is occurring and to really do a risk assessment to determine
2 whether or not these types of operations do represent any
3 potential or significant health risks.

4 I would say if I were to try to answer the
5 question of how much of a risk does this represent right now
6 I would say very small because of the small volume, number
7 one, and, secondly, most of these operations are handling
8 fish species that pose little threat of chemical
9 microbiological or physical hazards.

10 But there may be some exceptions. And I think
11 that is where we need to do a further evaluation. As far as
12 the broad scope of fishing vessels being covered, we don't
13 think that that is necessary at this time, although I think
14 we would look to FDA for guidance and leadership on vessel
15 practices perhaps consistent with Codex.

16 MR. SPILLER: Thank you. Just one quick
17 observation for Mr. Garfield. You mentioned a couple of
18 times the importance of training of Codex, the U.S.
19 delegates to the Fish and Fishery Products Committee. We
20 are just back from that committee. I still have that very
21 much on my mind and I can just advise you that training of
22 delegates has become a high priority for the U.S. Codex
23 Office of the Department of Agriculture.

24 I am cheering them on in that regard. No one has
25 ever yet accused me of being adequately trained in diplomacy

1 so I am looking forward to it.

2 DR. TROXELL: I want to make sure we understand
3 what we are talking about here. Both Dr. Ziller and Mr.
4 Garfield advocated sound science and risk assessment to
5 underpin our decisions. I would like to understand what you
6 mean, what kind of risk assessment you mean, and considering
7 that, in many of the problems that we face, the science is
8 incomplete, imperfect and the risk assessment is far from
9 being able to be quantitative.

10 How shall we be reacting in that situation and set
11 our priorities. For example, in the cyclosporine situation,
12 there are tremendous gaps in the science yet we need to take
13 some protective measures.

14 MR. GARFIELD: I tried to talk about sound science
15 and risk assessment and put that into the context of the
16 juice proposal. I know it is rulemaking now and you can't
17 discuss that but, to me, it seemed like the case was not
18 really made. It almost seemed, as a industry person--and if
19 I could take another example that isn't under rulemaking--it
20 is almost like you had a problem with alfalfa sprouts and
21 you decided to require HACCP for canned beans because of the
22 problem with alfalfa sprouts.

23 There just wasn't a connection with the risk
24 assessment that you did on raw juices and the fact that you
25 equated that over to what was going on in the pasteurized

1 juice industry. I think until you make that connection,
2 until you are able to, or you come out with rules that make
3 that connection, I think that industry is going to have
4 doubts about the purpose behind proposing rules.

5 There are a lot of questions out there as to why
6 you are going about this. Is it because of the sound
7 science and you have done an adequate risk assessment or is
8 it just to implement HACCP? There is a lot of uncertainty
9 out there. If it is the latter, then it should be called
10 the latter. If it is the former, then it should be done
11 soundly.

12 It seems like that is not being done currently. I
13 know you brought Bob Buchanan on board. I know he is an
14 expert in risk assessment and models and risk assessment and
15 I hope that he would be able to develop some things the
16 agency can use to quantify the risk posed by different
17 situations.

18 But , right now, I don't think it is being done and
19 I don't think the agency is doing a service to itself when
20 it comes out with a regulation that seems disconnected or a
21 proposal that seems disconnected.

22 MR. SPILLER: My reference to use of quantitative
23 risk assessment was more in terms of helping assess
24 priorities on what things need to be worked on. But I
25 certainly think there are a number of excellent examples of

1 places where the United States has used sound science and
2 good assessment of risk, and one of them is the one that Dr.
3 Troxell, himself, has used in terms of aflatoxin at the
4 Codex Contaminant meeting, and so forth, in terms of what is
5 the appropriate level, not just in the United States, but
6 internationally where you have problems in terms of just the
7 climate is such that it is virtually impossible to get
8 levels that countries who don't grow certain types of crops
9 are able to set because they have no local constituent who
10 would demand a higher level, so to speak.

11 And in those arguments I think that the United
12 States government has made at those meetings, they have been
13 very firmly based on that. I think other areas where
14 questions are raised about safety of certain ingredients or
15 contaminants in the United States, I think while the full
16 quantitative risk assessment may not be able to be made at
17 the time, there is at least some sort of semi-quantitative
18 or some reasonable best guesses on the data that may be
19 incomplete but is available that you can use to sort whether
20 it should pour tremendous FDA resources against a given
21 question that has been raised publicly or not.

22 And I think it will help sort, to a certain
23 extent, those things that demand a significant effort and
24 those things that demand a careful and continuing look.

25 DR. TROXELL: I actually would like to explore the

1 idea of the scope of use of HACCP. Earlier Mr. Corby
2 suggested the universalized HACCP. Also both of you, Dr.
3 Ziller and Mr. Garfield, advocated--all three of you,
4 actually, advocated that we work towards international
5 harmonization.

6 I would like to understand how you view the
7 limitation of use of HACCP to just in those severe cases,
8 how would that square with trying to develop international
9 harmonization. If we don't have something that is more
10 universal in preventive controls, we will end up with a
11 hedge-podge, maybe, of GMPs and other controls, how can we
12 demonstrate to our foreign trading partners that we have a
13 system of protections equal to theirs especially when many
14 of the countries in Europe are looking towards HACCP as the
15 standard?

16 So how, basically, is the go-slow on HACCP going
17 to get you your goal of we should put more priority on
18 international harmonization?

19 MR. GARFIELD: I think just because you don't have
20 HACCP as a mandated regulatory program doesn't mean it
21 exists. We did a survey four or five years ago of our
22 companies and found out that approximately 80 percent of
23 them had either started their HACCP program or had it fully
24 implemented already.

25 I think it is a foregone conclusion that companies

1 have implemented HACCP to a great extent. They don't need
2 to be prodded into that. Some may. There may be a few that
3 nay, but I think, for the majority of them, they know that
4 this is a good system and they are going to put it into
5 effect.

6 As far as international trade, they can utilize--I
7 mean, there can be ways other than a government-mandated
8 program that they can convince another international
9 government, if they are importing product into that country,
10 that they have an adequate HACCP system.

11 We have members who import into Japan and other
12 countries. And they regularly are visited by officials from
13 Japan, from other places, to inspect the plants and look at
14 what they are doing in there. These are just mutually
15 agreed inspections based on the fact that they are doing
16 business with this country.

17 They don't have a problem with it and it works
18 rather well. There is no need for a mandated system under
19 those circumstances. The people they are dealing with come
20 in and look at their facility and see that it is fine.
21 So I don't know that you need mandatory HACCP to convince
22 any government overseas that, in fact, a U.S. company has a
23 good system.

24 DR. ZILLER: I agree with Bob. I think most of
25 the sort of international discussions use terms like "based

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1 n HACCP principles, " and phrases of that nature. I think
2 hat, for the most part, at least most of the responsible
3 raders in agricultural products and foods follow those
4 ACCP principles.

5 I think that there is a difference and that sort
6 of what we would call, in the industry, regulatory HACCP
7 which has that added extra compliance factors some of which,
8 think, are still really being worked out because, from
9 what I hear, and I am not close to the fisheries business,
10 but I heard some numbers at the IFT meeting earlier in the
11 week where people were bandying about what the percentage
12 compliance of plants was based on the inspections in that
13 area so far with respect to the seafood HACCP, and so forth.

14 of course, the impression which was attempted to
15 be given was that somehow that things were unsafe and things
16 are not well in the industry and so forth. My bet is that
17 if one looks at the details, one would find that, in fact,
18 what it is is there are some record-keeping, paperwork,
19 other types of things which are important, but those are the
20 kinds of things that add significant burdens to the industry
21 and to the government inspectors to look at.

22 I think until we see that we are coming to kind of
23 a steady state in terms of implementation of regulatory
24 HACCP and FDA on the seafood side, and on the meat and
25 poultry in the USDA side, which I don't think that either

1 one is at a steady state quite yet--it is still in the
2 start-up phases in terms of how it is really going to be
3 able to work in a streamlined fashion effectively, and cost
4 affectively, over the long haul.

5 so that is really kind of what you are feeling a
6 push-back on. In terms of working on HACCP principles, I
7 think most of the industry and their associated suppliers,
8 because of their own high expectations worldwide, I think
9 are not that far away.

10 MR. COLLETTE: My perspective is not as broad-
11 based as Bob's and Steve's, but with respect to seafood,
12 particularly as you raise the question in the international
13 context, I guess I have something of a bias.

14 I think the United States, FDA, has done a good
15 job in structuring the HACCP seafood program. I think it
16 correctly targets food safety hazards as the fundamental and
17 central issue in doing a hazard analysis and developing
18 HACCP control programs.

19 You can get into long debates with most people who
20 are familiar with HACCP in talking about its application to
21 foods over the issue of should it focus solely on food
22 safety or can it, or should it, be used for other essential
23 quality factors, sanitation issues, et cetera.

24 As I said, I believe FDA has appropriately
25 targeted it to food safety matters. With respect to events

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1 at Codex, we know that there are some countries around the
2 world who would prefer to see HACCP based, meaning when you
3 talk about HACCP-based, generally, you are talking about
4 going a little beyond food safety hazards being your focus
5 and entering into not only food safety hazards but issues of
6 sanitation and essential quality in some cases.

7 So we are six months into the implementation of a
8 mandatory seafood inspection program and we are learning to
9 live with it. We have to grow into the program. It is
10 fairly complicated enough and it represents enough of a
11 paradigm shift for the industry that we feel you have to
12 learn to walk before you run.

13 Our concern is that there are some in the
14 international community who would have us running before we
15 know how to walk.

16 DR. TROXELL: I believe Dr. Ziller talked about
17 filling some of the science gaps from outside of FDA.
18 Obviously, the job we have to cover the food supply is
19 enormous in many different avenues. And, of course, one of
20 those aspects is to develop the science to underpin the
21 decisions, and so on.

22 So I was just wondering what your thoughts are on
23 the partnering and the role of industry either directly to
24 do some of that research or to fund it through academia, and
25 how could this fit in with our overall prioritization and

1 allocation of our resources here.

2 DR. ZILLER : I think there are some excellent
3 models that have worked well. Some of them, perhaps, could
4 work better with some additional attention. I think,
5 certainly, the forum of ILSI, both in the United States and
6 worldwide in the various bodies they have in Europe and in
7 Asia and so forth around the world has proven to be an
8 excellent umbrella under which to gather with industry,
9 government and academic research scientists to work on
10 issues.

11 I know FDA, USDA and a variety of regulatory
12 agencies have funded research there jointly or separately
13 and found that the results have been very useful as
14 underpinning for regulatory decisions.

15 There are some other areas that I think have shown
16 limited success and have promise for the future. Certainly,
17 the Center for Food Science and Technology in Chicago that
18 the FDA is a partner in is one of those, and then the sort
19 of emerging GFSAN operation will be another opportunity for
20 government and industry to work on problems of food safety
21 where they can jointly run research projects that they think
22 are in their mutual interest.

23 So I think there are a number of those from the
24 past some of which may be able to use some revitalization.
25 I think they are in the process of looking for a new

1 Director of GFSAN, now, and when they get that person on
2 board, I think they will be able to move forward with that.

3 And I think some of the objectives that I have
4 heard relate to some of the things that we were talking
5 about this morning in terms of quantitative assessment and
6 so forth. So I think there are fora and I think that the
7 industry will be willing to cooperate as they have in the'
8 past.

9 MR. LEVITT: With that, I have one kind of comment
10 before we close and that is I am struck by the emphasis on
11 the international. I cannot say I am so surprised but I am
12 struck by the theme and the priority that seems to be placed
13 on that.

14 One thing that would be helpful for us in your
15 written comments or otherwise is--the way I think of it is
16 what should our affirmative goals be in the international
17 area. A lot of times, a worry that comes across as, there
18 are these present meetings and these agenda items and these
19 are the things that we have to answer, and I never feel like
20 we are accomplishing as much as we could in that reactive
21 mode.

22 If we want to be proactive and say, these are the
23 things that we want to accomplish internationally--the
24 seafood gave one good example of it in terms of getting more
25 equivalency agreements and putting the foreign governments

1 to work for us kind of notion. There is certainly one good
2 example of that.

3 But in terms of what we want to affirmatively
4 accomplish in the international area, if we had clear goals
5 there, I think it would help us set priorities. If yOU
6 could give some thinking to that, I think that would be
7 helpful.

8 With that, let me thank each of you for your
9 presentations today. This will conclude our morning
10 session. We will reconvene in the splendor of this
11 auditorium at 1:30.

12 [Whereupon, at 1:25 a.m., the proceedings were
13 recessed to be resumed at 1:30 p.m.]

at

A F T E R N O O N P R O C E E D I N G S

[1:30 p.m.]

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3 MR. LEVITT: Let me welcome everybody back to our

4 **priority-setting** meeting for the Center for Food Safety and

5 Applied Nutrition. As I mentioned this morning, we will

6 have a rotating set of CFSAN senior staff joining me up here

7 so that everybody gets an opportunity to participate and to

8 ask questions.

9 To my right is Kathy Carnevale who is the Director

10 of our Constituent Operations, John Bailey who is the

11 Director of our Office of Cosmetics, and Laura Tarantino who

12 is the Deputy Director of our Office of Premarket Approval.

13 For folks that were not here this morning, let me

14 just kind of quickly go over the format. I think probably

15 **everybody** on the way in has a copy of the agenda. We are

16 calling folks up in small groups that have similar areas of

17 interest. We are asking for each person to do their

18 presentation and then we are grouping the question and

19 answer periods amongst them. And then we will just proceed

20 to the next one.

21 There are a couple of specific announcements I am

22 supposed to make so I don't forget. Number one, your

23 visitors badge. For those that are coming back tomorrow,

24 and I hope a lot of you will be able to come back tomorrow,

25 please just keep your visitors badge. It will be good for

1 tomorrow, also. You **will** be able to get in and out and you
2 **will** have an easier time with that.

3 Second, some people have asked if we are going to
4 **have** a mid-afternoon break. **We** are going to play that by
5 ear in terms of how to program goes but we have a little bit
6 between panels that people can get up and move around if
7 they need to. If it feels like we need a break, we will use
8 that option at the time.

9 One final thing is there were some questions if we
10 would have copies of the slides that I showed this morning
11 available. We are having copies made and they will be
12 available when you leave, assuming you don't leave right
13 away. Let that be a further incentive to stay.

14 With that, let us move to our next panel, our
15 consumer panel. I am glad to see Michael Jacobson sitting
16 right there in the front row. So, Mike, please come on up.
17 If you want Bruce to join you, please do so.

18 We are trying to conduct this as a "looking formal
19 but acting informal. "

20 Panel 2

21 Consumer Groups

22 Center for Science in the Public Interest.

23 DR. JACOBSON: We thank you for this opportunity
24 to give you some of our views about CFSAN's priorities. I
25 think it is a very sensible process for you and CFSAN to go

1 through to get the opinions of the various parties that are
2 speaking here.

3 One thing that is off the table, I guess, is the
4 President's Food Safety Initiative. We just wanted to
5 mention that we completely support that initiative as a top
6 priority for CFSAN but do want to emphasize that CFSAN needs
7 to carry out food inspection and food safety activities more
8 affectively.

9 It needs more authority and it needs more money.
10 We hope that CFSAN and FDA and the Administration will be
11 working very hard to obtain that from Congress and will be
12 working along with the Administration on that.

13 In thinking about how CFSAN should set its
14 priorities, I think there are a couple of things that are
15 clear. One is that the FDA is a public-health agency and it
16 needs to look at the health impact, where can it get the
17 biggest bang for its buck in terms of promoting health,
18 saving lives.

19 It is also a consumer-protection agency. In areas
20 that may not directly affect health, the FDA is charged with
21 protecting the consumer's pocketbook. There, again, it is
22 worth thinking about, what are the biggest problems, where
23 is the most deception, where is the most economic harm.

24 Also, I think, there are some softer things that
25 have to be mixed in with those two criteria. One is where

1 an you actually have an impact, what can you achieve.
2 gain, maybe the biggest bang for the buck , if something is
3 easily done but is somewhat lower, you may want to do that.

4 Also, in terms of the public's interest in some
5 issue; that has to be factored in somehow, that if
6 consumers, if legislators, are bombarding the FDA with
7 information about special concerns, that has to be weighed
8 into the factor, into the decision-making process--not that
9 the FDA should ever be weighing the number of letters that
10 it is receiving on one issue or another, but I think that
11 those beliefs and feelings need to be factored in somehow.

12 In terms of specific, I think improving
13 nutritional quality of the American diet should be a top
14 priority for CFSAN even though the FDA is not a nutrition-
15 education agency.

16 According to a study conducted by HHS, the Office
17 of Disease Prevention and Health Promotion, poor nutrition
18 and lack of exercise account for between 310,000 and 580,000
19 deaths every year. That is in the same ballpark as tobacco,
20 an enormous problem.

21 The FDA, CFSAN, should be doing everything it
22 possibly can be doing to promote a healthier diet. That
23 includes improving nutrition labeling. The most important
24 change that should be made right now is to include trans-fat
25 on the label. There is a consensus in the scientific

1 community that trans-fat raises cholesterol in the blood
2 about as much as does saturated fat.

3 Nevertheless, CSPI's petition to get better
4 labeling has been languishing for four years. We and many
5 academic experts have urged that trans-fat either be
6 included as part of saturated fat or as a separate item
7 within the nutrition label. But it should be an easy thing
8 to do. There is a scientific consensus and we don't
9 understand what the delay is. This simple move could save
10 thousands of lives over the years.

11 Health claims is an important area that must be
12 governed very carefully. The FDA should promptly approve
13 well-founded health claims that would promote an overall
14 healthier diet. The claims approved for high-fiber foods
15 and high-calcium foods, low-fat foods and low-sodium foods,
16 do exactly that. I think the public is benefiting from
17 having that information on the label.

18 But CFSAN should not cave in to every company that
19 markets oatmeal or cranberries or who knows what and allow
20 the label to make that product look like it is a panacea for
21 heart disease or some other ailment.

22 The FDA is saddled with a bad amendment to the law
23 concerning health and nutrition claims but we support the
24 FDA's tentative decision to require that all health claims
25 be supported by significant scientific agreement. That

1 **decision** should be codified in a regulation.

2 In addition, such regulations should specify that
3 **health** and nutrition claims based on authoritative
4 **statements** of other government agencies are limited to
5 statements that were intended to constitute dietary
6 recommendations. Statements made for other reasons or other
7 purposes, such as in the middle of a scientific paper, could
8 result in misleading label claims if they are pursued by
9 industry and accepted by the government.

10 A third labeling issue is that many labels feature
11 claims that can deceive people who are trying to choose more
12 healthful foods. These deceptive labels are traditionally
13 looked at as economic fraud but it is really health fraud,
14 also.

15 For instance, some foods imply that they are made
16 with whole grains, something we should be eating more of to
17 possibly reduce our risks of cancer and heart disease. But ,
18 in fact, they contain mostly refined grains, white flour.
19 Other labels imply that foods are made with lots of fruit or
20 a pure fruit yet they contain small amounts of fruit or are
21 made mostly with denatured fruit juices, apple juice or
22 grape juice.

23 For decades, the FDA has said that it does not
24 have the resources to police label claims that do not
25 introduce a direct health threat. But such claims are still

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1 basically defrauding consumers and oftentimes cheating
2 consumers out of the nutrients they think they are getting.

3 One product that comes to mind is 100 percent
4 spreadable fruit. A naive consumer would think that it is
5 actually 100 percent fruit. It isn't. It is mostly fruit
6 juice, probably grape juice.

7 It is high time that the FDA made it clear to the
8 food industry that deceptive claims are simply illegal.
9 NSPI filed a petition in 1995 that cited numerous deceptive
10 labels, none of which the FDA has stopped although public
11 pressure stopped food companies from continuing some of
12 those claims.

13 If the FDA won't stop deceptive claims, it should
14 tell the public that it is not policing this area and then
15 it should work closely with state officials who collectively
16 might have the resources to protect the public. The FDA,
17 also, obviously, should do what it can to stop outright
18 adulterated products such as juices that contain no juice or
19 honey that is not 100 percent honey.

20 Moving on to the area of dietary supplements, the
21 FDA is burdened with a weak law that limits the agency's
22 authority to protect the public from unsafe and misleadingly
23 labeled supplements. The agency should build a record
24 detailing the need for greater authority.

25 In addition, the agency should adopt a containment

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1 strategy that helps insure that problems with the regulation
2 of dietary supplements do not spread to the regulation of
3 health claims for foods or to the safety and efficacy for
4 drugs. CFSAN should start by monitoring carefully the
5 notifications of proposed structure and function claims and
6 opposing questionable ones.

7 In the area of food additives, we are concerned
8 about the rigor of FDA's approval process. Most additives
9 serve little health purpose and are completely unnecessary
10 to the food supply. Additives should be as close to
11 perfectly safe as possible. However, at times, it seems
12 that the agency has turned the law on its head. Instead of
13 requiring the company to establish safety to a reasonable
14 certainty of no harm, it seems that others are required to
15 prove harmfulness.

16 Olestra and acesulfame K are recent examples, but,
17 over the years, the FDA has bent over backwards to excuse
18 problems with a variety of food additives. Also, with
19 regard to food additives, we hope that CFSAN will defend the
20 Delaney clause. That law is essential to protecting the
21 public's health. Without it, industry toxicologists and
22 statisticians will find all sorts of creative ways to prove
23 that cancer-causing chemicals are actually quite safe.

24 As a subset of food additives, the FDA should
25 carefully watch GRAS chemicals. The FDA has proposed

1 -educing the scrutiny of GRAS substances by asking for just
2 Notifications accompanied by brief documentation. We think
3 that that could be very dangerous.

4 We recently filed comments on one particular food
5 additive that a company is using as a GRAS substance, a fat
6 substance called **salatrim**, that we think poses some safety
7 problems. But the acceptance of **salatrim** as a GRAS
8 substance suggests how easy it is to market a chemical with
9 virtually no FDA scrutiny.

10 If the FDA formally said, "We are not going to
11 affirm GRAS petitions, " I think you are opening the doors
12 wide open to problem chemicals gaining easy access to the
13 food supply.

14 On a somewhat broader issue, the FDA should
15 reconstitute its Food Advisory Committee to increase its
16 credibility. The committee has long been loaded with
17 industry consultants and even industry employees. That
18 committee should include many more bright and independent
19 members whose top priority, as evidenced by their career
20 history, is protecting the public's health. The committee
21 must also include consumer activists to balance the industry
22 activists who have routinely been members of the committee.

23 In the area of international affairs, we are
24 concerned that the FDA is allowing trade concerns to
25 supersede health concerns. CFSAN should be working hard to

1 insure that the Administration's trade policies are
2 consistent with the Food, Drug and Cosmetic Act, not the
3 other way around.

4 Also, it should be seeking to further the
5 objectives of the Act by advocating that safety and labeling
6 standards be harmonized internationally in an upward
7 fashion, not a downward fashion, to reflect the best, not
8 the most mediocre, consumer-protection and public-health
9 requirements from around the world. That clearly is going
10 to be an area of greater and greater interest.

11 One thing that should not be a CFSAN priority is
12 eliminating food standards. Consumers need those food
13 standards. Much of the food industry supports those food
14 standards. The FDA should not be wasting any resources to
15 do any kind of systematic review and elimination of the
16 standards.

17 Finally, we recognize CFSAN's financial
18 constraints. I applaud you for discussing earlier today the
19 financial bind that CFSAN has been in increasingly over the
20 past twenty years. We urge CFSAN to seek additional
21 funding, either through general revenues or by imposing
22 registration fees on food manufacturers. Small fees can go
23 a long way to raising tens of millions of dollars.

24 Over the last twenty years, as I believe you
25 pointed out this morning, the Center has actually

1 experienced a 20 percent decline in staffing. The public
2 cares deeply about food safety and honest labeling and I
3 think would clearly support a greater budget.

4 But CFSAN, the FDA and the Administration must
5 make sure the public knows that CFSAN simply does not have
6 the resources to insure a safe and honestly labeled food
7 supply . I think your statement this morning is a good trial
8 run, floating a trial balloon, about the limitations and
9 resources, but it is the kind of thing that I think the
10 Administration needs to make many more sales pitches on
11 before many more cameras to get the word out to the public
12 that CFSAN simply cannot do its job without further
13 resources. So there; trying to get more money in your
14 pockets.

15 MR. LEVITT: Very good. Thank you.

16 Bruce, do you have anything prepared to add?

17 MR. SILVERGLADE: No. I am just here if there are
18 any questions.

19 MR. LEVITT: First of all, thank you for coming
20 today and for having a nice list for us to work with. Let
21 me start with the whole area of health claims and
22 notifications that you mentioned there. I want to be sure I
23 heard it right. You said, Mike, that the health claims that
24 we had approved so far, by and large, were good ones. Are
25 there additional ones lurking out there that you think

1 **deserve** greater attention than we have got?

2 DR. JACOBSON: We haven't been thinking about
3 that. It is the kind of thing that would be well for us to
4 think about. But when you consider the major dietary
5 problems in this country are too much fat, too much
6 saturated fat, too little fiber, too much sodium and so on,
7 clearly the ones that the FDA has issued are very important
8 ones and ideally would be used much more by the food
9 industry.

10 MR. SILVERGLADE: I think the point we are trying
11 to make on the original health claims is the first eight or
12 nine, depending on how you count them, were general claims
13 about generic dietary patterns that Americans should follow
14 for better health. The last couple of approved health
15 claims dealt with oatmeal, essentially one type of food
16 product.

17 The most recent amendment dealt with **psyllium** and
18 there is only, to our knowledge, one nationally available
19 brand-name food in the United States that contains **psyllium**,
20 a brand of cereal. What we disfavor, and I think most of
21 the public-health community disfavors, is that approval of
22 health claims for specific food products.

23 That is not what we believe the law was intended
24 to facilitate and we believe that that is not the best way
25 to assist consumers in improving their diets because a

1 consumer will benefit by a health claim, for example,
2 discussing fiber and heart disease if it is a general claim
3 that could be used on many food labels rather than a
4 specific claim that can only be used on one brand name of
5 food because it would be more sources of fiber for them to
6 consume.

7 DR. JACOBSON: Advertising Age recently made fun
8 of the oatmeal claim which is being used in Cheerios ads and
9 I think Cheerios labels where the ad says if you eat three
10 bowls of Cheerios a day, you can get a 4 percent reduction
11 in cholesterol levels. It says, "Well, how many people are
12 going to be eating three bowls of Cheerios every day of
13 their life to get that kind of a minimum benefit?"

14 MR. SILVERGLADE: On the other hand, the agency,
15 since 1993, has had an improved health claim for diets rich
16 in foods containing soluble fiber, and that could be cereal
17 and many other foods. That type of generic health claim
18 gives consumers a better education in nutrition and how to
19 improve their diets as opposed to steering them to one type
20 of food.

21 MR. LEVITT: The second question; international.
22 this morning, we heard a lot of interest in the
23 international area for some industry representatives. In
24 addition to your general statement of we ought to use the
25 international area to harmonize up and not down, are there

1 any specific kinds of international goals that we ought to
2 be pursuing affirmatively?

3 MR. SILVERGLADE: I think, within the
4 Administration, FDA needs to be a spokesperson for public
5 health. The whole drive behind international harmonization
6 are trade concerns. In the U.S., that means increasing our
7 agricultural exports and making it easier for companies to
8 do business across borders.

9 That may be fine from an economic standpoint but
10 it has nothing to do with FDA's public-health mission. FDA
11 needs to be there as a break on the process to say, "Wait a
12 second. We have to put public health here, if not first, at
13 least equal to trade concerns. "

14 Frankly, other agencies within the Administration,
15 such as the Environmental Protection Agency, have been a
16 better advocate than FDA. EPA representatives come to
17 Administration meetings, intergovernmental agency meetings,
18 and they speak up on behalf of consumer and public-health
19 concerns more than FDA.

20 On the other hand, of course, you have USDA which
21 is just totally advocating increasing exports as represented
22 by the Foreign Agriculture Service, and so forth. So we
23 hope that FDA is a strong voice within the Administration
24 for public health.

25 The other point I would make is that now that we

1 are in a global economy, and there is no question that we
2 are, and now that we are bound by international agreements
3 to harmonize **regulatory** standards in the area of food
4 **regulation**, this presents not only a threat but an
5 opportunity because if we are going to go about harmonizing
6 **regulatory** requirements, we can go up or down.

7 We can look for the lowest common denominator and
8 say that is the common level and that is what the
9 international standard will become, or we can shop around
10 the world and say, "**Various countries** have interesting
11 regulatory requirements that may protect their consumers
12 better than we are currently protecting American consumers, "
13 and these other requirements for other countries might serve
14 as a model for the United States.

15 While our current requirements may not be that
16 high, we should raise our requirements and advocate the
17 stronger requirements to become the international standard
18 and a model for the U.S. Certainly, in the area of **dietary-**
19 supplement regulation, it is a **clear** example.

20 But , unfortunately, FDA personnel go to
21 international meetings such as those of the Codex Committee
22 on Nutrition and advocate the current dietary-supplement law
23 in the U.S. While we have to follow that law in the U.S.,
24 nothing in that law says that we have to advocate that
25 internationally, that FDA has to advocate that

1 internationally to facilitate trade. So that is a good
2 example.

3 MR. LEVITT: Let me share some time with my
4 colleagues.

5 DR. CARNEVALE: I guess I will stay on the
6 international area for just a moment. I appreciate your
7 sending me the recent CSPI report on food labeling where you
8 actually did a comparison of food labeling approaches in
9 other countries compared with that of the U.S. It is
10 actually a quite interesting analysis so there is some free
11 advertising for your report. That is just a comment.

12 I also would wish that, perhaps, you could
13 elaborate a little bit on a statement that you said right at
14 the beginning where you said that consumer interest should
15 weigh heavily on what we do at FDA. And then you added the
16 caveat that it should not be based on numbers of letters
17 received.

18 DR. JACOBSON: I didn't say weigh heavily. I just
19 said it should be factored into a priority setting.

20 DR. CARNEVALE: If you could elaborate a little
21 bit.

22 DR. JACOBSON: If you have millions of people
23 concerned about something and some number of members of
24 Congress, perhaps, I think it is something that deserves to
25 be looked at even if it didn't show up on an intra-agency

1 list of the ten highest priorities and I don't know of a
2 specific example of that.

3 DR. CARNEVALE: Let me put it a little more in
4 context. This morning, we heard a fair amount about setting
5 our priorities based on risk, risk-based priority setting.
6 I guess I am interested in how you see this compared to that
7 type of priority setting.

8 DR. JACOBSON: I think the health impact of
9 something should be the top priority. And then economic
10 impact should also be considered, economic impact on
11 consumers should be considered as a major priority. Maybe
12 the agency would come up with ten priorities based on that
13 but if the fifteenth priority is something that millions of
14 people care deeply about, are affected by, but it is not--I
15 don't know; reactions to MSG, perhaps. I am not sure if
16 that is a great example but it is something that wouldn't be
17 in the top ten list of health threats or economic problems
18 to consumers.

19 But if you had tens of thousands of people writing
20 to the agency saying, "This is something you have got to
21 deal with; it ruins my quality of life even though it is not
22 sending me to the hospital, " then I think that needs to be
23 factored in. Maybe it needs to be pushed up to No. 13. I
24 am not sure.

25 But it is something that if you have a mob at

1 calls of FOB-8, you should pay some attention to the
2 interest in the consuming public.

3 DR. BAILEY: I would like to ask a quick question
4 about the Delaney clause. There is quite a differing
5 opinion in the scientific community about where we are in
6 understanding mechanisms and how we can make decisions and
7 apply risk assessment. It is beyond my knowledge of it to
8 comment on the science, but I would like to ask, do you see
9 a framework where Delaney could be altered and still
10 preserve the important public-health decisions that need to
11 be made.

12 DR. JACOBSON: It might be. I could envision
13 something, a chemical that causes cancer in rats, through a
14 mechanism because the rat has an enzyme that converts the
15 chemical, an otherwise safe chemical, into a carcinogen that
16 humans don't have and it simply could not cause cancer in
17 humans.

18 If it were demonstrated that that is the only
19 mechanism by which it causes cancer in rats that that would
20 suggest that there could be an amendment saying that if the
21 animal studies, whatever studies, are irrelevant to human
22 concerns with a very high burden of proof, then that could,
23 conceivably, be an appropriate exemption, adding that to
24 other exemptions from Delaney.

25 But converting Delaney into a risk assessment,

1 there are a lot of creative statisticians out there who will
2 **always** find some way to meet the one in a million, or
3 whatever number you want to choose. So the Delaney
4 **Amendment** doesn't always make scientific sense but, as a
5 public-health protection, I think that it has worked
6 reasonably well and it sends a signal to industry and to the
7 administrators that health is the top concern that if a food
8 additive, a generally unnecessary chemical, introduces any
9 risk of cancer, it shouldn't be tolerated.

10 We haven't addressed cosmetics at all, and I don't
11 know if anybody out there today or tomorrow will be
12 addressing it, but I think it is unfortunate that the laws
13 are not stronger. The burden is so heavily on the FDA to
14 find problems and then get rid of them.

15 There was a nitrosamine problem twenty years ago,
16 fifteen years ago, with awesome levels of nitrosamines in
17 cosmetics introducing a cancer threat. Ideally, FDA would
18 seek stronger legislation. This is not the most propitious
19 time for that. We probably have to wait for a crisis but I
20 would like to build up your little division, also.

21 DR. TARANTINO: Your comment about the GRAS
22 notification; I know we have your comments, but I wanted to
23 make sure I knew what you had said today. It sounded as
24 though you were suggesting that we ought to maintain GRAS
25 affirmation as such. I suspect you are aware, and this is

1 bout priorities--I know you are interested in our spending
2 ore time looking at food-additive reviews and that one of
3 he problems with the process that we have now is it
4 robably has discouraged people from coming to us because of
5 ffirmation process, the rulemaking and such, has taken so
6 ong.

7 One of the notions of notification was to get more
8 elks in to us so that we would know more about what is in
9 he market. When you say affirmation, are you proposing the
10 system as it exists now with the rulemaking or are you
11 really talking about scrutiny no matter how it takes place
12 administratively?

13 DR. JACOBSON: I think these chemicals need
14 scrutiny. So far, there really hasn't been a great deal of
15 scrutiny. I think the FDA may be acknowledging resource
16 realities by saying, "Just let us know and we will track you
17 down if we don't like it."

18 But, in a way, that is an invitation to companies
19 to go the GRAS route rather than the food-additive route. I
20 certainly could envision Procter and Gamble having done that
21 with olestra, saying, "It is not absorbed; it is safe." So
22 things kind of work both ways.

23 In terms of companies informing the FDA of what
24 they are using without the FDA's knowledge, maybe there are
25 other ways to do that. But one certainly would like to

1 :now.

2 DR. TARANTINO: Thank you.

3 MR. LEVITT: I have one more question and then
4 just one comment after that. My question, and I asked this
5 a couple of times this morning, a year from now, if we
6 reconvene a year from now, if you could identify maybe two
7 or three maybe medium-sized boulders that it would be nice,
8 a year from now, to see done or merely complete.

9 DR. JACOBSON: Trans-fat labeling is an easy one.
10 As I understand, CFSAN was supposed to be doing something on
11 that, but just nothing happens, it seems. It should be easy
12 for the FDA to find, and if FDA can't, we can help, half a
13 dozen deceptive labels. You should hold a press conference
14 with those products explaining to the public and the food
15 industry why the labeling is deceptive, choosing examples
16 that represent, perhaps, larger issues than one obscure type
17 of deception. In our 1995 petition, we gave a few examples
18 like that .

19 MR. SILVERGLADE: I would just add final rules on
20 the new health claim notification procedures under the
21 Modernization Act that require that new notifications be
22 immediately placed on the public docket. We understand that
23 that is going to be the practice--the FOI office told us
24 that is going to be the practice but we would like to see
25 that codified by regulation.

1 Final rules on obstruction function claims for
2 dietary supplements. And, just, again a word in
3 international issues, that every time the President says
4 that he will protect, or seek to protect, labor and
5 environmental concerns when negotiating trade agreements, it
6 would be nice if he said, "Labor, consumer and environmental
7 concerns," including FDA's work.

8 DR. JACOBSON: One last one would be
9 re-constituting the Food Advisory Committee.

10 MR. LEVITT: This may not be exactly the same
11 point you were mentioning but the Food Advisory Committee
12 has membership renewals and about a third of the people
13 rotate off about every year. I just gave certificates to
14 seven people which means we are in the process of recruiting
15 and identifying. So if you or other people in the audience-
16 -I'm sure you know the process and announcements, but as
17 long as it is raised, I want to be sure that people know
18 there is any opportunity to suggest names.

19 That is the best way, for people that want us to
20 try to think of different places and different kinds of
21 expertise, by all means, give us specific names so we can
22 follow up on it and evaluate.

23 With that, let me thank you very much for your
24 participation. Again, I hope that you are able to stay and
25 hear some of the other speakers as well. We will welcome

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1 ny additional specific written submissions for the record.
2 We are going to hold that open for 30 days.

3 Again, we thank you very much.

4 DR. JACOBSON: Thank you.

5 MR. LEVITT: Our next panel is going to be devoted
6 o food-additive issues. We have a representative from the
7 nzyme Technical Association, a representative from the
8 alorie Control Council. And we have an additional
9 epresentative not on your printed agenda from the Alliance
10 f Food Additive Producers.

11 If my notes are right, I have Nancy Zeman and
12 ichard Cristol and Pamela Graves-Moore. Let's just start
13 ith Nancy and we will move right down. We are giving you
14 bout seven or eight minutes for presentation. If you start
15 oing over, you will see a little sign held up right there
16 n front of you.

17 Food Additives

18 Enzyme Technical Association

19 MS. ZEMAN : Good afternoon. I am speaking on
20 ehalf of the Enzyme Technical Association. I would like to
21 hank you for the opportunity to present the views of the
22 ETA with respect to the program priorities for CFSAN.

23 ETA is a trade association composed of the
24 ajority of enzyme manufacturers and distributors in the
25 nited States. As such, ETA members are directly affected

1 by the priority decisions that are being discussed here
2 today.

3 ETA recognizes that the center faces many
4 difficult decisions in the coming months and years.
5 Obviously, as was pointed out in the Federal Register notice
6 announcing this meeting, funding and resources for the
7 President's Food Safety Initiative is a top priority for the
8 center.

9 However, in addition to this important initiative,
10 ETA would like to point out four additional areas that
11 demand immediate attention and provide the center with an
12 opportunity to complete programs that will benefit both the
13 public and the food industry.

14 First, the center should conclude its review of
15 GRAS Petition 3G0016 which recognizes the safety of a number
16 of enzymes. The GRAS 16 Petition was accepted for filing by
17 the agency in April of 1973, over twenty-five years ago.
18 The petition seeks GRAS affirmation for a significant number
19 of enzymes that are used in food products today.

20 While the enzymes from animal and plant sources
21 have been affirmed as GRAS, there is no final regulation for
22 the remaining enzymes. The GRAS 16 Petition is the lynch
23 pin for much of the food biotechnology industry. The source
24 organisms and the enzymes listed in the petition are the
25 basic building blocks of biotechnology.

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1 Furthermore, any safety concerns related to these
2 **organisms** and enzymes have been resolved long ago. All that
3 remains to be done is the publication of the applicable GRAS
4 Affirmation regulations. At the recent Food Update '98, you
5 said that you wanted to abandon the center's traditional
6 method of trying to push thousands of tiny pebbles up a
7 mountain and, instead, focus the center's efforts on
8 **programs** that can be accomplished in a timely manner.

9 You spoke of getting a few boulders up and over
10 **the** mountain. We feel the GRAS 16 Petition is one of the
11 **those** boulders that should have been cleared a long time
12 ago .

13 Another program that needs to be pushed over the
14 mountain is the GRAS notification regulation. The
15 **regulation** is currently in the proposed stage and needs to
16 be made final. ETA is not alone in its frustration over the
17 current GRAS affirmation petition process. The system has
18 been a dismal failure. Not only does it keep new and safer
19 food products off the market, the current system has an
20 adverse effect on food safety.

21 One of the questions asked in the Federal Register
22 notice announcing this meeting was whether there are any
23 issues that directly affect consumer safety that are not
24 being adequately addressed. We believe that the failure of
25 the GRAS affirmation process falls in this category.

1 The resource-intensive GRAS petition process needs
2 to be replaced with a more streamlined notification system
3 so that vital agency resources can be redirected to address
4 food issues that are a priority with respect to public-
5 health concerns.

6 In addition, a simpler, more effective, GRAS
7 Notification system would provide an incentive for
8 manufacturers to inform FDA of their GRAS determinations.
9 This would improve FDA's ability to insure safer foods by
10 increasing the agency's awareness of the composition of the
11 nation's food supply and the cumulative dietary exposure to
12 GRAS substances.

13 The process would also allow BATF and USDA to
14 improve their review of ingredients by providing the food
15 industry with an FDA statement on the ingredients instead of
16 delaying the review while securing an FDA consideration. A
17 final GRAS notification would go a long way towards
18 fulfilling these vital needs.

19 Finalizing the GRAS notification process also help
20 address many international concerns. International
21 marketing is hit particularly hard by the failure of the
22 current GRAS affirmation process. It is difficult for
23 manufacturers to globally market even unquestionably safe
24 products under a self affirmation. And, as we noted earlier
25 when discussing the GRAS 16 Petition, they can wait a

1 quarter of a century for an FDA affirmation of GRAS status.

2 By finalizing a GRAS notification regulation that
3 provides a public statement of FDA's acceptance of
4 Notifications, the agency could, with one easy step, provide
5 the public with a vastly improved and safer food supply.

6 While commenting on the notification process, we also
7 encourage FDA to add the notifications to its Internet
8 website, similar to what is being done for biotechnology
9 products.

10 Our third recommended top priority is the
11 continuation of the center's final consultation program for
12 biotechnology products. Since 1994, developers of
13 biotechnology-derived food products have been encouraged to
14 submit summaries of their safety and nutritional assessments
15 to the FDA.

16 This provides the FDA with important information
17 concerning what products are being produced and gives the
18 agency a chance to address issues before new products are
19 marketed. The FDA's biotechnology system has been very
20 successful. This is, in part, due to the center's use of
21 new technology. For example, a list of products that has
22 undergone the final consultation process is maintained on
23 the FDA's Internet web page.

24 This is helpful both to the biotechnology
25 community and the general consumer. Up to this point, FDA

1 has recognized the vital role that biotechnology plays in
2 assuring a safe food supply for an ever-increasing world
3 population. ETA would like to encourage the agency to rely
4 on science rather than emotion when addressing the issue of
5 biotechnology-derived foods.

6 For example, several special-interest groups
7 recently filed a law suit against the FDA claiming that the
8 agency should require special labeling on genetically
9 modified foods. The thrust of their argument appears to be
10 emotional. They are attempting to stir up a public outcry
11 by preying on an uninformed public's fear of new technology.

12 The FDA had it right when it published its policy
13 on biotechnology in 1986 and, again, in 1992. With proper
14 safeguards, biotechnology can provide a safe and more
15 abundant food supply. Therefore, we urge the center to
16 continue to monitor the safety and nutritional value of
17 biotechnology-derived foods through the consultation
18 process.

19 Lastly, ETA recommends that the center immediately
20 renew its contract with the Food Chemicals Codex. The five-
21 year contract between the Codex and the FDA expired last
22 year and the agency has yet to renew its agreement to fund
23 this essential service. Although the Codex has been able to
24 survive through contract extensions and frugal use of its
25 resources, the Codex will be totally unfunded as of October,

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1 .998 if nothing is done.

2 Without funding, the Codex may cease to exist
3 Altogether. This would deal a severe blow to both the food
4 industry and the FDA. Despite the FDA's recent decision not
5 to renew the Codex contract, the agency has long recognized
6 the benefit of using the Codex as a reference for
7 specifications and methodologies.

8 The Codex is incorporated by reference in a
9 multitude of food-additive regulations including amino
10 acids, aspartame, and polydextrose, to name a few.
11 Likewise, Section 170.30(h) of the FDA regulations
12 specifically states that any substance listed or affirmed as
13 GRAS must conform to all applicable food-grade
14 specifications of the Codex.

15 One reason the FDA has found it convenient to
16 reference the Codex is that it is continuously updated.
17 This is an invaluable service to the FDA. If the Codex
18 ceased to exist or is not updated, the agency would not only
19 have to go back and revise all the regulations that
20 reference the Codex but it would also have to continuously
21 monitor the specifications and methodologies contained in
22 those revisions.

23 It is not hard to imagine that, due to budgetary
24 constraints, much like those addressed here today, updating
25 these regulations could be delayed for years, slowing the

1 process of innovative new food processes.

2 We realize that many in the FDA believe that
3 industry does not do its part in funding the Codex. While
4 it is true that industry does not provide direct monetary
5 support, industry has a long history of investing heavily in
6 the Codex by providing invaluable information and analysis.
7 This is in recognition that industry and the FDA need the
8 Codex.

9 Additionally, as the Federal Register notice
10 announcing this meeting pointed out, the **Codex** has grown in
11 significance as more and more of our nation's food supply is
12 either imported or exported. Food regulatory bodies around
13 the world, including the FDA, have begun to recognize that
14 harmonized international standards are not just a good idea.
15 They are essential of the country is going to compete in
16 today's global marketplace.

17 I **will** just close and say thank you for your time
18 and we appreciate the opportunity to speak here today.

19 Thank you.

20 MR. LEVITT: Thank you very much.

21 Next is Richard Cristol, Calorie Control Council.

22 Calorie Control Council

23 MR. CRISTOL: Good afternoon. My name is Richard
24 Cristol. I am the Washington representative for the Calorie
25 Control Council which is an international association which,

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1 or over 30 years, has represented the low-calorie and
2 educed-fat food and beverage industry. We currently have
3 over 60 member companies including manufacturers of products
4 educed in calories and/or fat as well as companies which
5 take ingredients for these products; for example,
6 manufacturers of low and reduced-calorie sweeteners, fat
7 replacers and low-calorie bulking agents.

8 The responsibility for FDA's Center for Food
9 Science and Applied Nutrition are of primary importance to
10 the members of the Calorie Control Council. The Council's
11 brief comments today focus on CFSAN's request to comment on
12 activities which should receive top priority in the center.
13 More extensive written comments will be submitted by the
14 July 15 deadline.

15 For the past several years, one could hardly
16 glance at a magazine or a newspaper without finding some
17 mention of the need to reduce dietary fat intake to
18 30 percent or less of calories. Numerous health and
19 government authorities including the surgeon general, the
20 National Academy of Sciences, the American Heart
21 Association, the American Heart Association, the American
22 Dietetic Association and many other professional health
23 groups advocate this reduction in fat intake.

24 Even the percent daily value of fat now appearing
25 on food labels is based on the 30 percent of calories.

1 oday, an equally important message needs to be underscored.
2 alories still count. With increasing rates of obesity in
3 he United States, Americans need to be concerned about both
4 at and calories and, most significantly, they are.

5 Consumer research conducted by the Council in 1998
6 hews that nine out of ten adult American, 178 million
7 eople in this country, consume light or reduced-calorie
8 roducts. The majority of these consumers want a further
9 ncreased variety of products reduced in fat and calories to
10 become available.

11 A significant number of the food-additive
12 petitions and generally-recognized-as-safe petitions before
13 the U.S. Food and Drug Administration address this need and
14 are of primary importance to both the Council's member
15 companies and the American public. The approval of these
16 petitions would make possible the increased variety of
17 products consumers desire and could assist Americans in
18 increasing significantly their fat and caloric intake

19 The premise was posed this morning by Mr. Levitt
20 that, "Where can we," meaning the agency, "do the most good
21 for consumers?" We certainly believe this is one area. The
22 perception of many outside FDA with an interest in the food-
23 additive approval process is that the FDA process is open-
24 ended, prone to inaction and lengthy delays and without
25 sufficient administrative accountability.

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1 The food-additive approval process thus is **costly**
2 o the petitioner, to the FDA **and**, ultimately, to the
3 onsumer. As a **result**, the current system which fails to
4 ive sufficient priority to these petitions discourages
5 nnovation in the development of new food ingredients and
6 he submission of food-additive petitions to FDA.

7 This has substantial deleterious effects. First,
8 nnovative and potentially important new food ingredients
9 re delayed for years or never make it into the U.S. food
10 upply because manufacturers cannot rationally plan for
11 heir approval and use.

12 Many of these ingredients might assist in
13 achieving healthier diets by substituting for fat or
14 otherwise eliminating calories. Thus, delays in ingredient
15 approval or decisions not to pursue petitions have cost to
16 the public health as well as to the petitioner.

17 The Council urges **CFSAN** to make the approval of
18 new food additives as well as the approval of additional
19 **uses** of approved food additives a priority.

20 The Council also urges **CFSAN** to pay increased
21 attention to the affirmation of long-pending GRAS petitions.
22 The Council supports the concept of a simplified GRAS
23 notification procedure that would allow the Food and Drug
24 Administration to redirect resources from the more resource-
25 intensive GRAS affirmation process to the food-additive

1 approval process.

2 The Council, however, opposes the proposal to
3 eliminate the current GRAS-affirmation process altogether.
4 The GRAS-affirmation process should remain in place for GRAS
5 petitions currently pending before the agency should
6 petitioners wish to receive affirmations. For example, GRAS
7 affirmation by the agency may be essential in certain
8 commercial situations to assure recognition from other
9 federal or international regulatory bodies as well as from
10 commercial customers.

11 Many of the GRAS affirmations pending have been
12 before the agency for many, many years and petitioners have
13 submitted substantial data and dedicated significant
14 resources in support of these petitions. In many cases, FDA
15 also has dedicated significant resources to these petitions
16 and has reviewed the scientific data in support of pending
17 GRAS affirmations very thoroughly.

18 In some cases, FDA has supported additional
19 review, for example, through FACED, of the petition
20 substances. The will to act does not really require
21 additional resources. It simply demands that decisions be
22 made. So we would urge FDA to make affirmation GRAS
23 petitions, particularly where significant data is available
24 and has been thoroughly reviewed, a major priority.

25 The Council requests that CFSAN expedite approval

1 of appropriate nutrient content in health-claim petitions
2 and citizens' petitions related to food labeling. Approval
3 of such petitions would increase recognition of "good for
4 you" products and increase understanding and provide useful
5 information about the contents of products for the consumer.

6 Citizens' petitions are particularly problematic.
7 Apparently, since there is no statutory time frame in which
8 FDA must act on citizens' petitions, FDA appears to rarely
9 address these petitions. The Council has filed a number of
10 citizens' petitions which would assist in providing
11 consumer-friendly information.

12 For example, the Council has requested that FDA
13 allow the term "polyal" in lieu of the term "sugar alcohol"
14 on the food label. This request was supported by a
15 nationally protectable survey demonstrating that the
16 consumer is terribly confused by the term "sugar alcohol."
17 However, as too often, FDA's response, when received,
18 generally has been, "We have not been able to reach a
19 decision on your petition within 180 days for the filing of
20 the petition because of limited resources. "

21 I have a printout here, as of last February, of
22 the citizens' petitions pending before the agency. There
23 are well over 100. Some of these are more than ten years
24 old. Most of these really are not lightning rods. They are
25 not the kind of thing that is going to cause a great deal of

1 criticism to be heaped upon the agency if these things are
2 approved.

3 To be a little glib about it, some of these are
4 really no-brainers, at least in our opinion, and they do
5 provide significant public benefit. The Calorie Control
6 Council has offered an extensive comment through one of
7 these citizens' petitions for how the food-additive approval
8 process could be streamlined. That was offered to the
9 agency in February of 1995 and, frankly, we have had little
10 or no response relative to whether the agency thinks any of
11 these provisions have merit or not.

12 Finally, I would like to come to a close by
13 speaking also to the global food marketplace, as many of
14 your earlier speakers have done. It is critical that FDA
15 promote international harmonization. Specifically, we
16 believe improved leadership in the Codex would be most
17 helpful.

18 My experience in Codex meetings historically has
19 been that U.S. delegates are often reticent to speak out for
20 fear of being viewed as the bully on the block. The
21 political issues do tend to interfere sometimes with the
22 scientific ones. We think that the U.S. has to press Codex
23 for more lead time in responding to documents.

24 Our process in this country appears to be
25 significantly more transparent than that of other countries

1 round the world, particularly those in Europe, and it takes
2 little more time to get things done.

3 When delegates come to various stakeholders with
4 Codex documents a week before they have to prepare and
5 submit a position, it is simply just not enough time to do
6 this. In many cases, we would prefer to see the process
7 extended a bit as opposed to a hasty response that doesn't
8 really reflect the full constituency.

9 We do appreciate the opportunity to address these
10 areas and I guess I would also, even though I didn't have it
11 in my prepared remarks, endorse Nancy's comments about the
12 Food Chemicals Codex. We feel that is an extremely
13 important resource for the FDA, for the industry and,
14 certainly, benefits the public. We would, certainly, again,
15 endorse the continuation of activity.

16 Thank you very much.

17 MR. LEVITT: Thank you.

18 Finally, we have Pamela Graves-Moore.

19 Alliance of Food Additive Producers

20 MS. GRAVES-MOORE: Thank you. Thank you for
21 adding me to this important panel this afternoon. My name
22 is Pamela Graves-Moore. I am the Director of Federal and
23 International Government Affairs at Monsanto and am here
24 today on behalf of the Alliance of Food Additive Producers.

25 This is a coalition of eight companies including

1 Monsanto that are leaders in the research, development and
2 production of the majority of the food additives in the
3 marketplace today.

4 So, on behalf of the Alliance, I would like to
5 respectfully provide comments to CFSAN for its consideration
6 in determining its program priorities in accordance with
7 Section 406 of the FDA Modernization Act of 1997.

8 First, the agency is to be commended for its work
9 to date towards improving the efficiency of the food-
10 additive approval process. However, in our judgment, CFSAN
11 should also seek additional advancements. We believe that
12 there is need for significant improvements to modernize the
13 current FDA food-additive approval process. Today's system
14 lacks the efficiency, predictability and accountability and
15 committed resources necessary to approve new food additives
16 and, ultimately, to enable producers to market high-quality
17 healthy foods.

18 To this end, our Alliance strongly supports
19 legislation which would amend the food-additive rulemaking
20 process, establish specific agency performance goals and
21 authorize user fees for the sole purpose of food-additive
22 review and approval. These steps would augment resources
23 available to FDA.

24 Specifically, the Alliance would propose to
25 improve the food-additive approval process by strengthening

1 the scientific quality of food-additive petitions and the
2 petition-review process, improving the timeliness and
3 predictability of the petition and review process and
4 enhancing the opportunity for timely and meaningful input
5 from the scientific community and interested members of the
6 public.

7 It is important to note that not one of these
8 provisions changes the safety standard or FDA's scientific
9 approach to safety evaluations.

10 In closing, the Alliance would encourage that
11 CFSAN deem as a priority the securing of real improvements
12 to the food-additive approval process. We believe that a
13 more efficient, predictable and accountable system will
14 promote consumer safety, improve efficiency of CFSAN
15 operations and will have positive impacts on the food
16 industry, FDA and, most importantly, the American public.

17 Thank you and we look forward to working with you.

18 MR. LEVITT: Thank you very much.

19 Let me begin. First of all, I appreciate the
20 notion that somebody might give us additional resources,
21 but, for the purpose of my questions, let's assume that we
22 have the level that we have since that is what we have right
23 now.

24 I guess for any of the three, whoever feels moved,
25 when I look at the Office of Premarket Approval and I see a

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1 number of related but, nevertheless, in some ways, different
2 parts--you have got the direct additive, you have got the
3 indirect additives, you have got the GRAS affirmations, you
4 have got several other different specified little areas.

5 And different people spoke to different parts of
6 them. Is there any consensus that we ought, if we have the
7 amount of resources we have now, to put more in one at the
8 expense of another, knowing it is at the expense?

9 MR. CRISTOL: I will be happy to lead off on that
10 one. I think, obviously, that depends on who you ask and
11 which petitioner you consult with.

12 MR. LEVITT: That is why I left it open.

13 MR. CRISTOL: You have got a situation, I think,
14 in the center where a lot of the work has been done. It is
15 just a matter of something has been put on a shelf.
16 Perhaps, there are some that are old and need to be update
17 and, if that is the case, then the petitioners need to be so
18 advised.

19 But I have a feeling that there are many of these
20 that are ready. It is just a question of moving them along.
21 One of the things that the Calorie Control spoke to in its
22 citizens' petition is an opportunity for more informal
23 exchange during the review process.

24 Obviously, that is a difficult situation based on
25 the statutory authority you operate under but, nevertheless,

1 if there is some way that we can make the system a little
2 more flexible so that the petitioner knows when there are
3 questions, instead of having to wait two years to find out,
4 "Well, the reason that was shelved was because there was a
5 significant issue over this particular study."

6 So if there could be more back-and-forth, I think
7 a lot of this could get resolved a lot more quickly. But ,
8 to answer your question, I really don't think you can give
9 focus to one area at the expense of the other because, in
10 many cases, the petitioners will feel that they have
11 invested their time and resources like anybody else.

12 MR. LEVITT: Thank you. I will say, in the spirit
13 of comic relief, that I got an invitation recently to attend
14 an event which was the twelfth anniversary of the filing of
15 the X petition. I think it was a citizens' petition. I
16 don't think it was a food-additive petition. There was a
17 little asterisk, "Of course, if FDA would grant the petition
18 prior to that, the invitation could be discarded. "

19 Kidding aside, I think the issue of old petitions
20 of different kinds is a troublesome one. I guess I would
21 like to ask--let's see if I get a different answer this
22 time--not asking between different areas but, at some point,
23 should something that is old be given a higher priority than
24 something that is new, even if the thing that is new, on its
25 merits, looks more important--or more "something?"

1 In other words, should there be--we are going to
2 spend this month clearing out the closets, or will people
3 say, "No, no; my new product is so important, I don't want
4 anything getting in the way." Any help on the old versus
5 the newer?

6 MS. GRAVES-MOORE : It sounds like you are
7 supporting a senior citizen status for food additives. No;
8 I think that is very legitimate and I think any proposal
9 would have to work out the dilemma of some of the pending
10 petitions. I know our proposal, that is something that we
11 would want to negotiate and collaborate with you on because
12 I am sure many of us have pending petitions as well as hope
13 to introduce more recent new petitions.

14 MR. LEVITT: Anyone else want to touch that one?
15 I will just observe it is very hard when you get down to the
16 setting of priorities to say, "I want something done before
17 something else." But we will continue to probe and you are
18 entitled to continue to give the best answers you can to it.
19 But for our program to be successful, we have to be willing
20 to do something before something else and that means it is
21 at the expense of something else.

22 So I would encourage you to continue in your
23 written submissions to be willing to say, "I am willing to
24 let something else sit." Maybe it is easier for one
25 company to say, "Among my hierarchy that I control, I would

1 like you to do this one before the other."

2 But if there are ways that we can find ways to
3 identify, "Yes; there is agreement. This should be done
4 before something else," instead of just, "Do your best to
5 streamline and do everything, " I think that would be helpful
6 to us.

7 Let me ask if there are other questions up here.

8 MR. CRISTOL: Could I just comment on that for one
9 second?

10 MR. LEVITT: Yes; please.

11 MR. CRISTOL: Obviously, the Council deals with
12 new ingredients that have tremendous impact because of the
13 volume in which they are used; fat replacers and sugar
14 substitutes and items like that. It seems, in the past, if
15 I go back over the last twenty years, that is the very thing
16 that has made the agency so reticent to approves these
17 things is for fear that if they have somehow made a mistake,
18 and I realize I am projecting my own opinion here, but if
19 you fear that the agency somehow has made a huge mistake.

20 That seems to, frankly, have really slowed the
21 process down. So while, certainly, I think our Council,
22 because of the nature of the ingredients it works with,
23 would advocate, "Sure; let's give more attention to those
24 that have the greatest impact, particularly when it is a
25 positive impact or reducing fat and calories in the diet."

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1 DR. TARANTINO: A couple of things. I guess one
2 back, I guess, Dick to your comments on the GRAS
3 Notification 2. I agree. I think we have plenty of
4 evidence at the table today that the GRAS Affirmation
5 petition, the way it is now, is broken partly because I
6 think, in some of those cases where the scientific review
7 has been done, the rulemaking is resource-intensive. It is
8 time-intensive and resource-intensive and there has been, in
9 the notion of priority setting, the notion that food-
10 additive petitions where something can't go to market
11 perhaps get higher priority than GRAS affirmation petitions
12 which is part of the reason for the situation you talked
13 about .

14 Having said that, I am interested to find why you
15 think we should retain GRAS affirmation. In what
16 circumstances do you think people would need a regulation
17 for a GRAS product? I guess I fail to understand that.

18 MR. CRISTOL: With respect to the self-affirmation
19 process, certainly it has been the fastest way to get any
20 ingredients to marketplace. The food-additive process has
21 been so cumbersome and so delayed that it has offered the
22 alternative. Obviously, we are the only country in the
23 world that has this process.

24 I think that if the agency, the industry, the
25 consumer groups, if everybody could come up with some system

1 that worked very efficiently, it certainly would be worth
2 taking a look at. I am certainly not prepared to comment
3 that we should throw out the GRAS process until I see what
4 that would be.

5 DR. TARANTINO: And that is not the GRAS
6 notification, presumably, that you are talking about now.

7 MR. CRISTOL: No.

8 DR. TARANTINO: I guess one other that was kind of
9 related, and I think it goes back to Joe. Right now, today,
10 you think we should be working on spending the resources to
11 do the rulemaking on pending GRAS affirmation petitions or
12 should we be concentrating on finishing up the GRAS
13 notification rulemaking and working on food-additive
14 petitions.

15 There will be three answers to that, I suspect,
16 but I am interested to hear what they are.

17 MS. ZEMAN: Of those, I guess I would choose the
18 GRAS notification process that should be finished. With
19 that, you may get some of your GRAS petitions taken care of.
20 But I will also add that the ETA still wants to see GRAS-16
21 issues. Maybe not all of would need to be, so you might be
22 able to kill two birds with one stone with that.

23 MR. CRISTOL: I guess I would respond something
24 that you probably don't want to hear and that is all of the
25 above. But I think you have got a number of petitions and

1 pending food-additive petitions and GRAS petitions that
2 really are largely done. Now, maybe I am wrong, but it
3 seems to me it would take very little effort to move a lot
4 of these off your plate.

5 I think some of these that have language for so
6 long should be given probably a little bit higher priority
7 and there certainly is an argument to be made for helping
8 the most number of people, obviously, in terms of the
9 consumers.

10 DR. BAILEY: Just one quick question. Do you have
11 in mind alternative approaches for funding through Chemical
12 Codex?

13 MR. CRISTOL: I guess I have to agree with what
14 Nancy said that the industry invests an awful lot of time
15 and effort in terms of providing company staff time to
16 develop data, to travel expenses to provide people to serve
17 on the Food Chemicals Codex. That is a tough issue but we
18 certainly would be willing to help the agency out in terms
19 of calling upon Congress to make more funds available for
20 that.

21 That is going to be a pretty tough sell, I think,
22 just as a small item but we would certainly endorse that.
23 We just feel it has been in place for a long, long time. It
24 is part of the reference library that FDA and the rest of
25 the world, frankly, refers to. Without it, we would be in

1 real trouble.

2 DR. CARNEVALE: I heard you talk about certainly a
3 call for increased resources in premarket approval. Even
4 though I heard you mention that we need to give increased
5 support and leadership within Codex committees, I would say
6 that we have a very strong presence in the Codex Committee
7 For Food Additives and Contaminants and certainly have had a
8 very strong leadership role there.

9 I guess my question is, either for now or later,
10 to ask you if you see any way that our Codex or other
11 international activities, harmonization activities, might
12 assist us in our resource problems within Office of
13 Premarket Approval.

14 MR. CRISTOL: I hate to dominate to conversation
15 here, but--

16 MS. GRAVES-MOORE: I represent a single-focused
17 coalition so my topic is limited, so go ahead.

18 MR. CRISTOL: I am not sure I really know how it
19 is going to help you **resourcewise**. I think that a number of
20 years ago, particularly in the early days where I attended,
21 back in the '70's, of the Codex Committee on Food Additives,
22 that was before they got concerned about contaminants and
23 changed their name.

24 But we used to have a tremendous number of
25 industry observers that attended that meeting. I know there

1 are still a significant number. I think FDA relied on them
2 a great deal for input to generate technical data, to assist
3 in that regard.

4 The consumer groups are now participating and I
5 think that FDA ought to call upon them as well to put some
6 significant resources into this thing. The food industry
7 has long supported this activity and, as we all know, the
8 consumer groups don't seem to have a shortage of resources
9 for other things so, perhaps, they can put some into the
10 Codex process.

11 MR. LEVITT: I just have one final question for
12 the coalition member. You mentioned, and I am paraphrasing--
13 --I didn't write it down exactly--you are supporting
14 legislation that includes user fees, performance goals and
15 what I call process efficiencies.

16 On the last point, on the process efficiencies, do
17 you have a specific lineup of items that you know you are
18 interested in, kind of with or without legislation? I mean,
19 I understand the informal/formal **rulemaking** thing would be
20 legislative, but do you have administrative things that are
21 within there, also?

22 MS. GRAVES-MOORE: Just a few of the specifics.
23 What we want to try to do is engage communication, or more
24 communication between the petitioner and your group. So we
25 would envision having more of an informal rulemaking process

1 hich would allow for a **prefiling** consultation period where
2 he petitioner could come in and discuss what the food
3 additive is, its purpose, functionality, et cetera, and
4 agree to a plan for a petition.

5 Then you would come about 30 days later and have a
6 **prefiling** review before the petition is formally submitted
7 to the record. Then the informal rulemaking process would
8 ensue and it would have more specified time frames in terms
9 of accomplishing the objective.

10 Finally, the agency would have increased access to
11 outside experts per your discretion.

12 MR. LEVITT: So that sounds like a major emphasis
13 is on increased, early-on, collaboration on, "Is this a good
14 petition, what is needed, are we ready?" so when it comes
15 in, it goes more smoothly rather than submitting it and
16 coming back with it.

17 MS. GRAVES-MOORE: Correct.

18 DR. TARANTINO: Can I ask the others on the panel,
19 how they feel about that proposal, what you have heard of
20 it?

21 MR. CRISTOL: I would agree with that particular
22 aspect of it. The earliest that a petitioner can get
23 feedback, it seems to me, the faster the process is going to
24 move along.

25 MS ZEMAN : I would agree with that, too. I seems

1 like, early on, you can have more informal discussions and
2 possibly move along quickly. Once something is filed, as
3 Dick said earlier, the communication gets more difficult and
4 you have to go through more steps. So things can sit on the
5 shelf when they need a piece of work done and that
6 information doesn't get transferred back to the petitioner
7 as quickly.

8 So if you can get through the problem areas
9 initially, I think that would be the way to go.

10 MR. LEVITT: I can tell you, just as an aside from
11 my experience in other FDA product areas, while there is a
12 considerable investment in time and energy devoted to such
13 early consultations, it really seems to pay off. As
14 somebody said, everybody is a lot more open before you spend
15 your money. And that goes to both sides in spending your
16 money.

17 MS. ZEMAN: Right.

18 MR. LEVITT: So we will look forward to working
19 with you on that.

20 Let me thank this panel very much. Again, we will
21 have the record open and we will look forward to any
22 additional written submissions that you may have.

23 In response to an earlier question on whether or
24 not there is going to be a break this afternoon, recognizing
25 that they didn't pass out catheters up here for those on

1 this side of the room, we have taken an informal vote among
2 us and I voted for the group that we take a ten-minute
3 break, that we will reconvene at 3 o'clock. That should
4 give us time to finish by 4:30, which would be our goal.

5 Thank you very much.

6 [Break.]

7 MR. LEVITT: Let's get started for the second half
8 of our afternoon session. We are pleased, for our next
9 group, to have representatives from the cosmetics industry,
10 both the Cosmetic, Toiletry and Fragrance Association, Ed
11 Kavanaugh, and the Independent Cosmetic Manufacturers and
12 Distributors Association, Penni Jones and Winnie Baden.

13 Again, in terms of just general procedures, we
14 would like each of you to talk between seven and ten
15 minutes. If you start going over, you will see little signs
16 that pop up down there. Then, after you are both done, we
17 will open it up for some questions. Afterwards, we will
18 have the record open for an additional period of time for
19 written submissions.

20 For those in the audience that have been patient
21 with us all day, our goal will be to end by 4:30. I think
22 with the number of speakers we have without too much
23 trouble, we will be able to do that.

24 so, with that, Mr. Kavanaugh, why don't we start
25 with you.

1
Cosmetics2
Cosmetic, **Toiletry** and Fragrance Association3
MR. KAVANAUGH: Thank you, Joe. My name is Ed
4
Kavanaugh. I am President of the Cosmetic and Toiletry and
5
Fragrance Association, the **CTFA**, which is the national trade
6
association that has been representing the cosmetic industry
7
now for over a century; in fact, since 1894.8
Because the regulatory program for cosmetic
9
products has been in **CFSAN** since 1969, we have a strong and
10
direct interest in these priorities. Today I will focus on
11
two areas; first, the need for FDA to continue a strong
12
cosmetic regulatory program in order to insure that
13
cosmetics remain safe and properly labeled throughout the
14
United States and, second, the need for FDA to maintain a
15
strong leadership role in efforts to harmonize regulatory
16
requirements around the world.17
We support a vigorous **CFSAN** program for cosmetics.
18
We want to strengthen our long-standing cooperation with FDA
19
through our industry voluntary programs. These industry
20
programs complement **CFSAN** and help save, I think, the
21
agency's resources. We support appropriate efforts to
22
secure the funding necessary for the agency to maintain a
23
credible cosmetic program.24
We recognize that cosmetics are not, and clearly
25
should not be, **CFSAN's** top priority. Joe talked about

1 pebbles and boulders this morning and 100 pebbles rolling up
2 the hill and maybe you only get half way. If you focus on a
3 few boulders, you may get over the top.

4 We are certainly not a boulder, but I don't think
5 we are a pebble either. Maybe we can characterize us as a
6 stone or a rock or something that fits into this. There are
7 certainly millions of consumers every day who use our
8 products, starting in the morning with shampoo and
9 conditioning and shaving cream and toothpaste, deodorant and
10 sunscreens, skin-care products, color makeup cosmetics and
11 fragrances.

12 It would be, I think, a disservice to the public
13 health to let the cosmetic regulatory program wither away
14 for want of resources and attention.

15 In recent months, the CFSAN program has sustained
16 significant cuts. The agency has announced cancellation of
17 its inspection and compliance programs for domestic and
18 imported cosmetics. The staff of the Office of Cosmetics
19 has been cut nearly in half by shifting responsibilities.
20 FDA has announced the suspension of Parts 1 and 2 of the FDA
21 voluntary reporting program, announced the limitations on
22 industry and consumer assistance provided by CFSAN as well
23 as reductions in laboratory studies for cosmetics.

24 We are concerned that this action will have
25 detrimental effects for both the consumer and the regulated

1 industry. It will undermine FDA's credibility and ability
2 to maintain adequate and appropriate national standards for
3 cosmetic safety and labeling. It will undercut the FDA
4 industry cooperative efforts which have fostered efficient
5 and effective industry voluntary programs and will seriously
6 impair the ability of FDA to provide strong and credible
7 enforcement of the law.

8 In short, this action runs the risk of destroying
9 what has been an effective and credible cosmetic regulatory
10 program. And we believe that a credible cosmetic program
11 must include compliance, safety and science. The most
12 important of these is compliance which is as vital to the
13 regulated industry as it is to consumers.

14 Without it, unscrupulous marketers can defraud
15 consumers and undermine legitimate industry. The cosmetic
16 industry needs to know what regulatory requirements apply
17 and that they will be enforced fairly and consistently
18 against all products, imported or domestic, marketed in the
19 Us.

20 To put it in simple terms, if there is no
21 enforcement, there is no law. A crippled cosmetic program
22 will undermine the stature and credibility of the FDA and, I
23 think, encourage states to ignore the agency and establish
24 their own regulatory requirements.

25 Now , the cosmetic industry shares, I believe, an

1 important part of the responsibility for the effective
 2 regulation of cosmetics. To help meet that responsibility,
 3 we support voluntary self-regulation programs. These
 4 industry programs not only complement the FDA but, I think,
 5 also conserve FDA resources by reducing the need for
 6 extensive regulation and by performing functions with
 7 industry dollars that would otherwise be funded by FDA.

8 CFSAN has historically cooperated and participated
 9 in a number of these voluntary programs. The agency's
 10 involvement, no doubt, has strengthened these programs
 11 immeasurably and has provided the industry with valuable
 12 input from FDA personnel. The FDA-industry cooperation has
 13 benefitted all concerned; consumers, the agency and the
 14 industry. And we believe that this cooperative effort
 15 should be expanded and strengthened.

16 The recent cuts in the FDA cosmetic regulatory
 17 program, however, undermine the cooperative approach and
 18 certainly jeopardize a number of important programs.

19 For more than 25 years, parts 1 and 2 of the FDA
 20 Voluntary Cosmetic Reporting Program have provided the
 21 agency and our industry with valuable information about the
 22 ingredients that are used in cosmetic and personal-care
 23 products. These parts 1 and 2 were suspended by FDA a few
 24 months ago.

25 Part 3 of the FDA voluntary program was revoked

1 completely by FDA because the information, as FDA stated,
2 was sufficient to establish a national baseline for product
3 adverse reactions. But the promised FDA publication of that
4 important information I think is now in jeopardy because of
5 FDA program cuts. We need that information. We urge that
6 this document proceed expeditiously.

7 When FDA began to establish inspection checklists
8 to assure adequate practices, we responded by developing the
9 technical guidelines. These guidelines advanced the process
10 substantially and expended the scope and depth of the FDA
11 outlines. FDA has cooperated fully by reviewing the
12 guidelines and providing the perspective of experienced
13 personally who view these matters across the entire cosmetic
14 industry.

15 When FDA required cosmetic ingredient labeling in
16 the early 1970's, we responded by developing a dictionary of
17 our ingredients used in cosmetic products. Our work on this
18 publication has benefitted greatly from the direct and
19 ongoing participation of FDA scientific personnel.

20 The current dictionary is the standard for
21 cosmetic ingredient nomenclature officially adopted by FDA
22 by regulation for use in the United States as the primary
23 source of ingredient labeling and is now being used by
24 numerous other countries around the world and, as this chart
25 shows , there are some 30-odd companies with many more

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1 considering proposals to establish the nomenclature
2 recognized by this dictionary in the U.S. as their
3 nomenclature throughout the world, obviously harmonizing the
4 packaging and listing of ingredients.

5 I want to emphasize that our most deep and serious
6 concern is that the cuts in the FDA cosmetic program will
7 limit the agency's ability to participate in the cosmetic
8 ingredient review, the CIR. CIR is the cornerstone of our
9 efforts to insure the safety of cosmetic ingredients. The
10 CIR program brings together all available published and
11 unpublished scientific data on the safety of cosmetic
12 ingredient for evaluation by an independent-expert panel of
13 seven leading academic scientists and physicians.

14 The expert panel members are subject to the same
15 conflict of interest requirements that apply to FDA Advisory
16 Committee members. We initiated the CIR program in 1976 at
17 the direct suggestion of FDA when Commissioner Max Schmidt
18 stated that FDA did not have the resources to undertake such
19 a program and asked that the industry do it instead.

20 This was some 22 years ago and this program costs
21 now the CTFA more than a million dollars a year and I am
22 sure it saves CFSAN at least that amount. The Director of
23 CFSAN'S Office of Cosmetics serves as a non-voting liaison
24 between the FDA and the CIR panel. He sits with the panel.
25 He attends the meeting and participates in all the CIR

1 proceedings.

2 He is kept up to date on CIR activities including
3 the setting of the program's priority list of ingredients
4 for review. And he conveys to the panel any comments FDA
5 may have. The panel certainly gives, obviously, great
6 weight to comments voiced by FDA and it is very important
7 that a strong FDA liaison function with the CIR continue and
8 actually, I think, be strengthened.

9 The expert panel publishes its findings in a peer-
10 reviewed scientific journal. As of May of this year, CIR
11 had released final reports covering the 720 ingredients most
12 widely used in the industry. I think you can see from this
13 chart that, of those 720, 390 were found safe as used; 228,
14 or almost a third, are safe with qualifications as to
15 product type, area of use or concentration.

16 95, or 13 percent, had insufficient data for the
17 panel to reach a conclusion and 7, or 1 percent, were found
18 to be unsafe.

19 For over two decades, CIR has been a remarkably
20 successful joint effort by academia, industry, government
21 and consumers to advance the public health. The
22 extraordinary achievements of this program should certainly
23 not be undermined by a lack of FDA resources.

24 We unequivocally support the funding of adequate
25 field resources to assure that both domestic and imported

1 cosmetics meet all applicable legal requirements and
2 standards, and consumers and industry need a good cop on the
3 corner. We urge FDA to reverse its announced decision to
4 cancel inspection and compliance programs for cosmetics.

5 In addition to providing for uniform and effective
6 regulations of cosmetics in the U.S., it is essential that
7 CFSAN give priority to international activities. This will
8 insure that FDA maintains the international leadership
9 required to foster harmonization of regulatory requirements
10 for cosmetics throughout the world.

11 In conclusion, let me say that cosmetics are safe
12 and we, in the industry and, I think, FDA alike, want to
13 keep it that way. Despite the difficult resource decisions
14 facing the agency, CFSAN simply must maintain a credible
15 cosmetic regulatory program and the necessary resources to
16 do the job.

17 We are deeply committed to working with you in
18 this effort and we want to continue and strengthen our
19 cooperative programs with the agencies. Let me reiterate
20 what I think is our primary message here. If you have no
21 enforcement, you have no law. Both industry and consumers
22 need that cop on the corner.

23 Thank you.

24 MR. LEVITT: Thank you very much.

25 Ms . Penni Johnson.

1 Independent Cosmetic Manufacturers
2 and Distributors Association

3 MS. JOHNSON: Good afternoon. I am Executive
4 Director of the Independent Cosmetic Manufacturers and
5 Distributors, a trade association that started in 1974 with
6 eight companies and today we represent 660 independent
7 manufacturers, distributors and suppliers.

8 With me today is Winnie Baden, ICMAD's Vice
9 President and Legislative Chair. ICMAD is the voice of
10 small cosmetic businesses. Our small business members
11 represent a portion of those 99.7 percent of the nation's
12 employers who employ 53 percent of the private work force,
13 who contribute 47 percent of all sales, who are responsible
14 for 50 percent of the private gross domestic product and
15 53 percent of exported products.

16 Most of our 660 members do not have legal staffs
17 or research and development departments. That is why they
18 rely on us and the FDA to keep them informed of current
19 regulations. In 1983, we started cosponsoring with the FDA
20 cosmetic education workshops to inform members and
21 nonmembers alike of what they need to know to manufacturer
22 and distribute safe and properly labeled products.

23 At these workshops, attendees have the opportunity
24 to have hands-on experience in labeling, to ask FDA
25 representatives questions, to hear our legal counsel's

1 opinion on regulatory matters and to interact in a
2 constructive way with the FDA on issues of mutual concern.

3 We have worked within FDA budget constraints in
4 the past. For example, several times, we have printed the
5 FDA handbook for cosmetics to give out at these workshops
6 because FDA simply lacked the funds. Today, however, the
7 cutbacks in the Office of Cosmetics and Colors are having a
8 negative impact on the cosmetic industry.

9 These cutbacks particularly affect small business.
10 In these circumstances, we would like to respond to the
11 first five questions that were listed in the June 3rd
12 Register.. Number one was issues affecting consumer safety.
13 Failure to restore adequate funding to the Office of
14 Cosmetics and Colors will directly affect consumer safety.

15 We feel, and Ed backed it up, cosmetics are among
16 the safest products purchased by American consumers.
17 However, issues do arise from time to time. There are too
18 few FDA employees to respond to inquiries from small
19 business owners on safety and labeling matters.

20 There are too few employees to monitor safety
21 questions when they occur. Consumers trust the FDA to
22 protect them from unsafe cosmetic products. Cutbacks in the
23 Office of Cosmetics and Colors directly and irrevocably
24 undermines this trust.

25 One concrete example of how consumer safety is

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1 being threatened by funding cuts is the elimination, in
2 1.996, of the adverse-reaction reporting part of the
3 voluntary reporting program. Ed also mentioned the
4 registration and product ingredient statement portions were
5 suspended in March of this year.

6 The part of the program calling for the reporting
7 of adverse reactions we feel demonstrated again and again
8 that cosmetics have an excellent record of product safety.
9 We know the database line did exist, or does exist, and we
10 are waiting for that report. However, products change
11 because of new formulations and new raw materials.

12 Some of these raw materials may have questionable
13 byproducts. We feel this part of the voluntary program
14 helped FDA monitor safety issues and, without that program,
15 FDA will not be able to respond as quickly to safety
16 problems when they arise.

17 Question No. 2 was program areas we feel should be
18 top priority for CFSAN. That would be the Office of
19 Cosmetics and Colors. They need to be able to answer
20 consumer questions, alert the public to genuine issues, to
21 set the record straight when inaccurate publicity creates
22 unwarranted concerns.

23 The office receives approximately 2500 phone calls
24 annually from scientists, chemists, manufacturers, consumers
25 and the press. The calls require time-consuming technical

1 research. We need a properly funded Office of Cosmetics and
2 Colors to insure that consumer trust in the cosmetic
3 industry does not diminish.

4 Criteria for setting priority; we feel the
5 criteria used for CFSAN regs seem applicable to all program
6 areas. In addition, ICMAD advocates criteria that will
7 minimize consumer deception in the purchase of cosmetics.
8 Cosmetic manufacturers strive to label their products in a
9 truthful and accurate way. We are not advocating technical
10 regulation. However, we are advocating that FDA be
11 available to small businesses that do not have the luxury of
12 full-time lawyers and regulatory staffs.

13 The next two questions I am turning over to Winnie
14 Baden.

15 MS. BADEN: Thank you for this opportunity to be
16 here. Since 1998, I have been a member of the Board of
17 ICMAD. For the last five years, I have served as their
18 legislative chair. Although I have been a small business
19 owner for 18 years, my first projects, upon completion of my
20 formal education, were funded by the National Institutes of
21 Health and the National Cancer Institute.

22 Consequently, I have first-hand experience as a
23 public servant having programs and projects funded or
24 budgets cut and divisions and offices eliminated. I speak
25 today, however, on behalf of ICMAD's other 659 member

1 ompanies who are all small business owners of cosmetic and
2 cosmetic-related businesses, many of whom reside in the
3 grass roots of America.

4 In addressing No. 4, research and scientific
5 information, the first priority is funding. Consistent
6 decrease in funding over the last ten years caused a
7 critical mass of expertise and cosmetic technology to erode.
8 In recent months, our small-business manufacturers have
9 experienced a lag in FDA response time to scientific and
10 technical questions.

11 It has brought to our attention that the situation
12 will get worse over the next three to four years as career
13 scientists retire and resources to hire and train
14 replacement staff are unavailable.

15 Immediate funding is required in order to insure
16 an ongoing credible scientific research program that is
17 adequately staffed with scientific expertise. Ongoing in-
18 house research and testing must continue in order to
19 maintain safe products and trained field workers who must be
20 in place.

21 It is essential that scientists from the Office of
22 Cosmetics and Colors be able to interact with cosmetic
23 ingredient review scientists. Sharing of information from
24 public and private sectors can continue in partnership to
25 maintaining an enviable safety record of the cosmetic

1 industry.

2 However, unless adequate funding is made
3 available, the Office of Cosmetics and Colors will not have
4 the resources available in order to participate in a
5 meaningful way with the CIR program.

6 Of critical priority is to develop and maintain
7 state-of-the-art databases and information systems. At a
8 minimum, sufficient funding must be made available to enable
9 the Office of Cosmetics and Colors to make sure that it is
10 an information system which avoids problems associated with
11 the Year 2000 problem, otherwise known Y2K bug.

12 Looking beyond the Year 2000, it is imperative
13 that funds be allocated to enable all federal and state
14 regulatory agency information systems to be capable of
15 interfacing with each other. It is equally vital that
16 agencies that regulate cosmetics internationally also be
17 able to communicate with one another.

18 To do so, standards will need to be established
19 and a uniform code and nomenclature defined. An allocation
20 of funds will need to be in place for international travel
21 to allow FDA's cosmetic scientists to interact in the
22 decision-making process in order for the U.S. to remain a
23 leader in the new world market.

24 The ability of the Office of Cosmetics and Colors
25 to work efficiently across international boundaries will be

1 a key element in the global marketing of cosmetics when we
2 enter the 21st Century.

3 This brings us to Issue No. 5, international
4 activities. By Year 2002, the European Union will become
5 America's largest competitor. It boasts 370 million
6 potential consumers. Its gross domestic product is 8.5
7 trillion compared to 7.3 trillion for the United States.
8 French workers were described in the June 1998 issue of
9 Newsweek to be the most productive in the world with a
10 rating second only to the Japanese in manufacturing.

11 Nations everywhere grasp Europe's new global
12 economy and the high-tech infrastructure required to make it
13 flow. Its unified monetary system offers potent potential.
14 France, not the United States, is moving at the speed of
15 Light with its extraordinary wealth of science and
16 technological talent.

17 It is a very well-educated population with quality
18 and skilled labor and high quality of lifestyle.

19 Interestingly, the American consumer can expect to see an
20 increasing number of foreign products entering the United
21 States marketplace. The American consumer is entitled to
22 expect that imported cosmetic products will have the same
23 level of quality and truthful labels that has been
24 associated with American cosmetic products.

25 And adequate amount of funding for the Office of

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1 cosmetics and Colors is necessary to allow American small
2 business to compete effectively with foreign cosmetic
3 products. Without sufficient funding, we are faced with
4 economic and safety issues.

5 Conclusion; to maintain the cosmetic industry's
6 outstanding record of marketing safe products in a non-
7 deceptive manner, ICMAD respectfully urges that both CFSAN
8 and Congress take note that it is absolutely necessary to
9 restore adequate funding to the FDA Office of Cosmetics and
10 Colors.

11 Governments all over the world have looked to the
12 FDA for guidance on how to regulate their own cosmetic
13 Industries. Compromising the office in any way by not
14 restoring budget cuts and not increasing funds beyond the
15 projected \$5 million to meet the demands of the European
16 Union will ill-serve American consumers and small business.

17 We should make every effort that this system,
18 which has well-served the American consumer and American
19 business, is not jeopardized.

20 Thank you.

21 MR. LEVITT: Thank you very much.

22 I have a couple of questions and then we will go
23 over to John Bailey after me. You all talked about the need
24 for adequate funding. In your minds, do you have a level
25 that is adequate? I will let whoever answer it who wants

1 0.

2 MR. KAVANAUGH : I think, as you know, we have
3 ried to work with the Appropriations Committees on the Hill
4 o at least restore funding to the levels it was at in the
5 ast year. Obviously, and I think we have heard before,
6 hat these levels have come down over a number of years and
7 think we ought to seek to try and get it back to that
8 evel of a few years ago.

9 But we are trying to take one step at a time with
10 he Congress and get Appropriations at least to restore the
11 oneys, if not, necessarily, the same programs. I think
12 hat is open for discussion as to what are the priorities
13 and why we are here today. But at least the money to try
14 and do the job right.

15 MS. JONES: And there is a bill in the house with
16 a set amount.

17 MR. KAVANAUGH: That's correct.

18 MS. BADEN : \$2.5 million, which really isn't
19 enough.

20 MR. LEVITT : You beautifully led right into my
21 second question which is were the amount of funding
22 restored, would you reallocate it in the same way or would
23 you shift some of the priority for that funding around and,
24 if so, how would you do it?

25 MS. BADEN: I certainly feel that education of

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1 staff is one of the most important things because if we
2 don't have scientists in place to answer the questions, to
3 do the research, we are at a loss to help when problems
4 arise.

5 We must have educational programs in place. They
6 must be funded.

7 MS. JONES: I think we have to be able to keep up
8 with EEU as a competitor, our country. We need to FDA's
9 help to do this.

10 MS. BADEN: And field workers certainly have to be
11 in place.

12 MR. KAVANAUGH: I think, as our remarks indicated,
13 that we feel very strongly that the compliance function is
14 the most important and to cut inspections is our
15 understanding from some 120 to 0 and to cut field resources
16 allocated to cosmetics, you are taking that cop off the
17 corner and we know what happens if you do that in other
18 instances.

19 I think we have had a good relationship with FDA.
20 I think the industry and consumer are working on a number of
21 programs together, but without that enforcement action by
22 FDA or the potential of that, I think we are going to be
23 fortunate to keep the status quo in terms of the high level
24 of safety of these products.

25 MS. JONES: Right . We don't want to encourage

1 fly-by-nighters, so to speak. There is no enforcement so
2 they can put out any product they want.

3 MS. BADEN: And label it any way they want.

4 MR. KAVANAUGH: Joe, there is another issue there,
5 too, that I would emphasize and I stated and I think we can
6 have further discussions on this later, but, in terms of
7 priorities, what is so important to us is the Cosmetic
8 Ingredient Review Program. Perhaps that program, after 22
9 years, as successful as I think it has been and I think FDA
10 believes that it has been as well, it may need some
11 tinkering.

12 If it does, in order to get that to where
13 everybody wants it, then we certainly would consider
14 anything in discussions with you about that.

15 MR. LEVITT: Thank you. My final question, at
16 least for this round, is do you think that FDA needs any new
17 Legislative authority which was commented on earlier by one
18 of the other speakers that FDA has a hard time regulating
19 cosmetics because the legislative authorities are more
20 limited than some other product areas.

21 Are there any areas that you would think we need
22 more authorities in?

23 MR. KAVANAUGH: Are you referring to Dr.
24 Jacobson's remark? I think it is interesting that the
25 example he raised was a 20-year-old issue and, I think, was

1 an example of, really, the cooperation between industry and
2 FDA because I think we resolved the nitrosamine issues, at
3 least for cosmetics, in a pretty satisfactory way to reduce
4 any danger of that.

5 I think that was a very successful example of a
6 cooperative effort between the agency and the industry.
7 There may be some areas. Clearly the legislation that is
8 in place with the FD&C Act certainly gives FDA adequate
9 authority to regulate cosmetics. Our position, at this
10 point in time, would be, without further discussions with
11 you, that there is no need for further need for further
12 legislation but there is that need for the enforcement
13 mechanism, the compliance function, to be a strong one at
14 the agency.

15 MS. BADEN: I can only think that down the road if
16 we have more imports there may, at that time, arise a
17 situation where we may have to relook at legislation.

18 MR. LEVITT: Thank you.

19 DR. BAILEY: I have a couple of questions. The
20 government, in attempting to address some of the resource
21 problems is entering into more public-private partnerships.
22 I think the GFSAN structure is a good example of that. I
23 would ask the question, number one, do you see this as an
24 effective way to address emergent safety issues or to
25 address other non-safety issues in the area of cosmetics.

1 And, secondly, how would you see this divided
2 **between** industry responsibilities and FDA responsibilities?
3 [In other words, what kinds of things can industry do under a
4 partnership and what kinds of things would we keep? Easy
5 question.

6 MR. KAVANAUGH: I think the idea of cooperative
7 testing efforts, as I understand it, would be we would have
8 to look very carefully at that because I don't want it to
9 duplicate what the Cosmetic Ingredient Review is all about.
10 I would like to see that function be supported even more so
11 with FDA. Let's look at it. Let's look at what it may need
12 in terms of strengthening that.

13 Maybe FDA needs to look at what may make that even
14 more credible and more functional for FDA to alleviate some
15 of that burden from CFSAN. We are willing to consider any
16 of those aspects.

17 I think until we were satisfied, or both of us are
18 satisfied, with how that function is working, it would be
19 premature to talk about something that I think may duplicate
20 or go beyond that, but we certainly do want to talk about
21 that.

22 I might say one other point on this. Years ago,
23 there was a--I forget the title of it, John--but an FDA
24 liaison committee with industry which periodically met with
25 industry members, especially on the technical side. I think

1 it may be time try and reinitiate some sort of regular basis
2 between industry, especially in the scientific area, and FDA
3 to identify those kinds of projects, whether it is what you
4 are talking about here or otherwise, that we can work
5 together on.

6 MS. JONES: perhaps an advisory panel.

7 DR. BAILEY: One other question. There have been
8 a number of safety issues that have come up over the past
9 relating to certain ingredients, **nitrosamines** being one,
10 certain fragrance ingredients, and so forth. The way these
11 have typically been addressed is that the industry and FDA
12 work to define the problem and then to solve it.

13 But they are rarely captured in a regulation. My
14 question is do you see a need, a benefit, or what, in terms
15 of capturing these safety issues and guidance documents, for
16 example, or regulations or is the current way of sort of
17 dealing with them on an ad hoc basis, working to protect the
18 public health.

19 MR. KAVANAUGH: I think the current process works
20 pretty well, but there may be some areas where formalization
21 by FDA would be appropriate.

22 MS. JONES: And to post it on the website, I
23 think, would be wonderful, as certain issues have been.
24 That site has improved greatly over the past couple of years
25 and I can get a lot of information off it, which I like.

1 MR. LEVITT: Laura, do YOU have any questions?

2 DR. TARANTINO: I will try one as sort of the
3 naive questioner in this area in that, following up on one
4 of the comments of the previous panel, I know you talked
5 about possible greater industry cooperation and industry
6 support for some of the voluntary programs. At least part
7 of your industry does have direct experience with fees, user
8 fees and certification fees and such.

9 Do you see places where that is something that the
10 industry could support?

11 MR. KAVANAUGH: In terms of user fees to support
12 regulatory functions; no.

13 MS. JONES: It may be something coming, but, in
14 many cases, it would be a worst-case scenario.

15 DR. TARANTINO: As the naive questioner, I could
16 ask.

17 MS. BADEN: I could see how it could work, but it
18 would be very difficult and it would increase price and make
19 us less competitive with the European market. It is
20 important we have safety.

21 DR. CARNEVALE: Just a couple of quick questions.
22 Just briefly, the cosmetic hotline, I was hearing you talk
23 about education and outreach efforts. Do you consider that
24 a major success, something that needs to be continued?

25 MS. BADEN: Yes; we do. We have excellent

1 attendance at our conferences.

2 MS. JONES : She is talking about the hotline.

3 MS. BADEN : Oh; the hotline. I thought you meant
4 the outreach programs that we have had in conjunction with
5 FDA .

6 DR. CARNEVALE: You can talk about that as well,
7 but I was talking about the hotline.

8 MR. LEVITT: Especially since you are so
9 enthusiastic. Please take an extra 30 minutes.

10 MS. BADEN: The program with FDA has been
11 extremely successful. It has good attendance. People have
12 learned from it and I think it has helped, particularly with
13 labeling.

14 MR. KAVANAUGH: We have an 800 number that
15 complements the worldwide web, so I guess the question is
16 does that 800 number serve the intended benefit.

17 MS. JONES: I don't know how many people know
18 about it.

19 MS. BADEN: In fact, I didn't know about it until
20 someone on the Congress, talking about this on the Senate
21 floor, mentioned it.

22 MS. BADEN: That is helpful to know. You
23 mentioned specifically imported cosmetics. I know there was
24 some mention of maintaining the EU market, but I guess my
25 question was not only enforcement for insuring that domestic

1 product is safe and keeping up consumer confidence, but are
2 cosmetic imports a significant issue at this point? I was
3 hearing from you that they are not.

4 MS. BADEN: It is an issue but it is becoming more
5 of an issue. As we look to the Year 2002 with the EU market
6 coming together, we are faced with a tremendous potential
7 increase of products coming in. If we don't have standards
8 in place, we don't have a way to register those companies
9 and products and we have no way of tracking and tracing.

10 It is very time consuming to attempt to if you
11 don't have something in place.

12 MR. LEVITT: I have just one final question which
13 relates to adverse-event reports. I gather there was a more
14 organized program a few years ago than there is now, but are
15 there things we could do now that would enhance, even within
16 the current framework such as it is, that we could enhance
17 adverse-event reporting by companies?

18 MS. JONES: The voluntary program was discontinued
19 in '96. Correct, John?

20 DR. BAILEY: That's correct, the voluntary
21 reporting. But the standing program that we have had in
22 place for taking reports directly from consumers is still in
23 place.

24 MS. JONES: And they can use that 800 number for
25 that; correct?

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1 DR. BAILEY: Correct. There is information about
2 how to report.

3 MR. KAVANAUGH: Joe, the report I referred to
4 earlier which has been discontinued was, I believe, a ten-
5 year summary of baseline by product category which would be
6 very helpful for the industry since FDA won't accept any
7 more adverse-reaction reports. It would be helpful for the
8 industry to know where they stand in a particular product
9 category as compared to the rest of the industry.

10 Clearly, that would become less relevant as time
11 went on but, for the next couple of years, it might be very
12 helpful.

13 DR. BAILEY: We are working on it but resources
14 are limited.

15 MS. BADEN: Not only does it become as relevant
16 but, as time goes on, you may not even be able to get into
17 the system. So it has to be maintained in order to be able
18 to use it.

19 MR. LEVITT: Thank you.

20 DR. BAILEY: One other question; of the hundred or
21 so pebbles that we are trying to push up the hill, which
22 would you put as most important at this time?

23 MR. KAVANAUGH: I think we stated that, certainly,
24 the compliance function which includes inspections, which
25 has been drastically reduced or virtually eliminated.

1 econdly is to work out the best possible partnership we can
2 n cooperation on the CIR program which is critical.
3 ithout FDA, the CIR program would be jeopardized and I
4 ertainly don't think anybody wants that, least of all the
5 onsumers.

6 MS. BADEN: I would have to agree; compliance and
7 nforcement.

8 MS. JONES: And training.

9 MS. BADEN: And training, more scientists trained
10 orking in the Office of Cosmetics and Colors.

11 MR. LEVITT: With that, we thank you very much
12 and, again, we encourage you to submit written comments for
13 the record, also.

14 We will now move to our final group of presenters
15 for the afternoon. We have three trade associations, the
16 [international Dairy Foods Association, the In Flight Food
17 Service Association, and the International Sproutgrowers
18 Association. Mr. Tipton, Mr. Simpson, Ms. Snyder.

19 While we are getting ready for the final group of
20 speakers, as the agenda indicates, tomorrow morning we will
21 start again at 10 o'clock in this room.

22 If everybody is settled, why don't we begin with
23 the International Dairy Foods Associations. If you will
24 please introduce yourself.

25 Focused Trade Associations

1 International **Dairy** Foods Association

2 MS. FRYE: Thank you. Mr. Tipton was unable to
3 attend today so I will be presenting the comments. My name
4 is Cary Frye and I am the Vice president of Scientific and
5 Regulatory Affairs and we appreciate the opportunity to
6 provide comments on the program priorities to FDA's Center
7 for Food Safety and Applied Nutrition on behalf of our
8 members that represent the dairy processing industry.

9 The International Dairy Foods Association
10 represents processors, manufacturers, marketers,
11 distributors and suppliers of dairy foods. These include
12 milk, cheese, ice cream and frozen deserts. IBFA serves as
13 an umbrella organization of three constituent groups, the
14 Milk Industry Foundation, the National Cheese Institute and
15 the International Ice Cream Association and we represent
16 85 percent of the U.S. dairy-foods industry.

17 We compliment the Center for Food Safety and
18 Applied Nutrition for requesting input on their program
19 priorities. We have some general observations and also some
20 specific responses to the question that addressed the
21 program priorities of CFSAN.

22 The dairy-foods industry is supportive of
23 effective food-safety regulation. Dairy processors
24 recognize that a strong, effective agency is necessary to
25 provide public confidence in the government that is

1 effectively monitoring and insuring a safe food supply.

2 The dairy industry agrees with the current five
3 priorities set forth by **CFSAN** and we believe that the **CFSAN**
4 priority of dedicating resources to regulations mandated by
5 statute is important. In fact, eliminating expenditures of
6 resources in the areas of enforcement and regulations that
7 are not mandated by statute may prove effective in providing
8 additional resources.

9 The dairy industry fully supports moving towards a
10 science-based assessment in the form of **HACCP-type** programs.
11 The dairy foods industry does not believe that the mandatory
12 **HACCP** program should be enacted for dairy products. The key
13 principle of a sound **HACCP** program is that it specifically
14 developed around the individual manufacturing process, that
15 it is not mandated by set predetermined checkpoints.

16 A **HACCP** plan must be able to be customized,
17 allowing for flexibility when changes occur and new
18 monitoring tools become available. The extent of the
19 proposed juice **HACCP** regulations should be reevaluated with
20 regards to risk before committing as many **CFSAN** resources
21 for implementing and monitoring this program.

22 Juice processing plants that pasteurize their
23 product prior to packaging should not be included in this
24 regulation. Also, dairy-processing plants that are
25 processing both milk and juice should not be included if

1 they are regulated under another food-safety program such as
2 the National Conference of Interstate Milk Shippers or the
3 USDA Dairy Plant Inspection Grading Program.

4 The **CFSAN** outreach program that most closely
5 affects our dairy processors is the Federal State
6 Cooperative Milk Safety Program. The pasteurized Milk
7 Ordinance and the National Conference of Milk Shippers
8 Program have been successful in providing uniform
9 regulations for states and allowing a cooperative process of
10 changing, improving regulations that insure food safety.

11 The program is falling short, though, of utilizing
12 cutting-edge strong science-based concepts to evaluate food
13 safety. The **NCIMA** program still relies mainly on a check-
14 list inspection and prescriptive plant processing
15 regulations. We applaud the recent efforts of the
16 conference in 1996. It formed a resolution to make
17 necessary changes to move towards a **HACCP** science-based
18 system.

19 However, state regulatory agencies who must
20 approve the changes were not willing, at that time, to fully
21 embrace the change. As a result, the milk sanitation
22 regulations remain under study until May of 1999.
23 Hopefully, with a higher priority and a higher level of
24 involvement by CFSAN, this program could move towards a
25 voluntary HACCP-based system.

1 With regards to comments to the specific
2 questions, I would like to talk a little bit about the areas
3 that directly affect consumer safety. We have concerns
4 regarding imported foods. In many cases, the hygienic
5 requirements for production and processing of a food in the
6 United States are more stringent than in countries with
7 competing foods that are exported into the United States.
8 More effort needs to be focused by CFSAN in reducing the
9 risk to the consuming public from the imported foods.

10 The second issue related to the activities of the
11 programs for CFSAN, which should be top priority, we believe
12 that there is a greater need to find outreach education
13 programs such as Fight Back. This would insure safe food-
14 handling practices beyond the control of both dairy and
15 food-processing plants and facilities with the majority of
16 Americans for line on meals away from home, education
17 programs for consumers and food handlers require an increase
18 in resources for retail food safety.

19 The priorities set forth by other CFSAN programs
20 may differ than the applicable regulations. We support an
21 expansion of the health-related product labeling priority to
22 include other product labeling, updating of standards of
23 identity and review of health-claim petitions.

24 Food product labels are important venue for the
25 consumer information. As new ideas develop to streamline

1 labels of dairy products, CFSAN should be willing to commit
2 resources to review these ideas.

3 Also, we feel that the CFSAN priorities need to
4 include resources to review requests to modify the existing
5 standards of identity for dairy products. Many of these
6 standards were developed in the 1970s and early '80s and
7 require updating. A lack of resources to review new
8 proposals for standard of identity will restrict product
9 development and limit wider availability of dairy products
10 to the American public.

11 Requests for health claims have a more direct
12 effect on public health by providing information on the food
13 package that could improve consumers' choices when selecting
14 foods . The availability of scientific-based health
15 information on a product labeling could also have along-term
16 effect of the health of the consumer.

17 We support a higher level of resources to
18 addressing labeling standards and health claims.

19 In keeping with food safety as the highest
20 priority, we believe that research or modeling in the areas
21 of infectious dose for pathogens in food such as Listeria,
22 E. coli 0157H7 and Salmonella should be considered. Current
23 CFSAN policies on the levels of pathogens in food were
24 developed under a crisis mode many years ago and a zero
25 tolerance for policy for pathogens does not reflect always

1 the current scientific information or international public
2 health policy.

3 CFSAN is a primary food-safety agency that is
4 involved in international food-safety activities and we
5 believe it should continue to be a top priority. We support
6 that more resources are allocated in CFSAN's international
7 activities including involvements in bodies outside of
8 Codex. This should increase the U.S. influence in many
9 final Codex food-safety standards and product standards of
10 identify.

11 We place a high priority on the continued
12 maintenance and administration of the Food Standards Program
13 which is important to Codex. The comments received in the
14 recent ANPR in food standards made it clear that a number of
15 existing standards presently serve as a barrier to the
16 utilization of new technologies and the use of required
17 ingredients to improve existing products.

18 It is also apparent that the U.S. delegation in
19 recent Codex committee meetings was restricted to promoting
20 the effective U.S. position in light of the outmoded
21 standards that are now in place.

22 As a result, petitions have been prepared and
23 filed related to new standards. The goal of the ANPR is
24 still important and the standards need to be updated and
25 modernized. Therefore, FDA needs to have resources in this

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1 .rea.

2 In conclusion, the dairy industry strongly
3 supports CFSAN in making food safety as a top priority in
4 its efforts to focus the resources. The U.S. dairy industry
5 would like to be a partner in this effort. We believe that
6 the dairy industry plays an important role in insuring food
7 safety to the consumer.

8 We agree that more emphasis is needed in the area
9 of international Codex activities, increased resources, need
10 to insure uniform application of food-safety requirements
11 for imported foods and we recommend that CFSAN expand their
12 resources in the area of health-related labeling and it is
13 important to include the review of other labeling needs for
14 products such as advances in technology, streamlining
15 existing labeling, and updating the standards of identity
16 that are outdated.

17 International Dairy Foods and our members intend
18 to cooperate with CFSAN and to maintain consumer trust and
19 confidence in the safety, purity and wholesomeness of dairy
20 products.

21 Thank you.

22 MR. LEVITT: Thank you. Next will be a
23 representative from the In Flight Food Service Association,
24 Mr. Simpson.

25 In Flight Food Service Association

1 MR. SIMPSON: Good afternoon. My name is Joel
2 Simpson. I am representing the International In Flight Food
3 Service Association. I want to thank you for the
4 opportunity to be here and to provide our input.

5 IFFSA members include nearly all airlines, airline
6 caterers and the food-product suppliers to the airline
7 industry in the United States, Canada, South America and
8 many overseas locations. Airline caterers in the United
9 States alone provide nearly 300 million meals to the flying
10 public each year, to give you an idea of the magnitude of
11 our industry.

12 We would be inexcusably remiss at this point if we
13 failed to point out that the current atmosphere of
14 communication, cooperation and proactive approach to food
15 safety being practiced by the retail food-protection team
16 and the cooperative food program in CFSAN is extremely
17 encouraging to me and IFFSA as a whole.

18 The past several years, and the past two years in
19 particular, have been the most productive and enjoyable and
20 the more than 35 years that I have spent both in industry
21 and state regulatory agencies working with FDA. This is not
22 to say it has been or will be easy. I think we are
23 regulated by the Interstate Travel Program just as strictly
24 if not more so than we have ever been. The difference is
25 that we strongly feel that the current atmosphere is simply

1 more efficient and more productive.

2 I will now attempt to address the specific
3 questions relating to program priorities. Obviously, we
4 think that the President's Food Safety Initiative should be
5 given first efforts. When the Administration speaks,
6 agencies listen. I am concerned, however, over recent
7 articles concerning the funding issues regarding the FSI
8 and, also, CFSAN because, in my experience, inadequately
9 funded programs have long been a deterrent to food safety
10 success.

11 Beyond the Food Safety Initiative, we feel the
12 highest priority for CFSAN should, obviously, be those
13 regulations, standards and program activities that are
14 intended to enhance consumer safety and those that are
15 mandated by statute, including import regulations because of
16 the increasing trend toward globalization and harmonization
17 and the increased amount of imported foods coming into the
18 country.

19 Next in line should be those program activities
20 that will lead to improved efficiency of operations. This
21 brings up the issues of program location within the
22 government. Speaking again for IFFSA, we feel that the
23 current location of the Interstate Travel Program with in
24 the FDA, within CFSAN and the retail food area, is close to
25 ideal .

1 Again, having worked with a state Program and with
2 the USDA, I am very concerned at recent mentions of program
3 relocation and, particularly, talk of delegation to the
4 states. We realize the limitations of funding, but we also
5 realize that program uniformity and an efficient chain of
6 communication and the uniform applications of standards are
7 absolutely essential to efficient food-safety efforts.

8 I dealing with 30 to 50 different sets of
9 standards or different sets of regulations with 50 different
10 state program heads with hundreds of different inspectors
11 does not bode for an efficient food-safety effort in our
12 minds.

13 In talking about efficiencies, we have to talk now
14 about HACCP. I notice a number of other speakers talked
15 about HACCP. It comes to mind as a potentially very
16 efficient consumer-protection program. I say "potentially"
17 only because of the tendency for HACCP programs to be
18 drowned in micromanagement and in paperwork if we are not
19 careful.

20 IFFSA has been engaged in a HACCP pilot project
21 based out of the Seattle District of FDA for the past three
22 years. This pilot, which has been assembled as a joint
23 IFFSA-FDA project with equal input from both partners is
24 tailored specifically to the application of HACCP at retail
25 where multiple menu items are customarily produced daily.

1 The pilot recognizes that airline catering
2 **kitchens** which commonly produce 100 or more very different
3 menu items daily and that these menus which may change
4 **monthly** cannot be treated the same as a seafood plant or any
5 **other** processing plant where one or several products at a
6 **time** are generally run in production at one time.

7 So the joint pilot project is process-based rather
8 **than** product-based. It depends on the process you are using
9 **rather** than individual menu items. Thus , it is very
10 achievable and efficient for our industry. This efficiency
11 has been official recognized within the past year with the
12 awarding to both FDA and **IFFSA** of Vice President Gore's
13 Hammer Award for cost efficiency which I proudly wear in
14 this lapel over here today as we speak.

15 Based on these results, **IFFSA** encourages **CFSAN** to
16 assign a very high priority to the further development and
17 expansion of this pilot project to other FDA regions and to
18 use it as a potential model for **HACCP** retail.

19 Please bear in mind, we are not advocating **HACCP**
20 regulation at this point. It is far too premature in the
21 pilot process. But **IFFSA** strongly supports **HACCP** as a
22 voluntary program at this juncture.

23 On the subject of those products, are consumer
24 safety issues not being adequately addressed by **CFSAN**, I can
25 only comment for our industry and my feel for what is

1 happening within CFSAN. As I said, I feel we are better
2 regulated now than at any time in my career. But I also
3 feel it can be more improved and made even more efficient
4 through the judicious adoption of HACCP as embodied by the
5 pilot projects that are happening out there now.

6 We do have some concerns, as other people have
7 spoken of, about CFSAN's ability to sustain this current
8 level of productivity over time, given the current staffing
9 and funding levels. I think it is IFFSA's intent, in our
10 written comments and in our other activities, to try to deal
11 with what some of the organizations have said, and that is
12 to press for some funding to return to former levels.

13 It is human nature for good workers to
14 overachieve. Without adequate staffing, funding for
15 adequate staff, staff training and development, even the
16 most dedicated employees will eventually fail because of
17 their human limitations.

18 A second concern we have is a relative lack of
19 visibility of both the retail food and the ITS programs. I
20 think it is common for middle management, in allocating
21 program resources, to read into message from top management
22 and those programs which are visible in downward
23 communications, they are going to get a larger allocation of
24 staff time whereas, if no mention is made of other programs,
25 what happens commonly is the resources are pulled away from

1 .ess visible programs and allocated to more visible programs
2 when push comes to shove.

3 We notice sometimes the interstate travel
4 sanitation people have other responsibilities and they are
5 pulled away to do other things. Although we are certainly
6 not in favor of overregulation, we realize that, without
7 FDA's oversight of the Interstate Travel Program, we would
8 not be nearly as strong as we are in the area of food
9 safety. Although each member has their own program, just
10 about , we must have the FDA oversight.

11 So IFFSA would encourage CFSAN to give more
12 visibility to retail food protection and ITS programs in as
13 many of its downward communications as possible.

14 Finally, and I don't know if anybody in the room
15 knows me, but, if they do, it won't come as a surprise for
16 me to say that we agree, basically, with CFSAN's priorities
17 and the methods for setting priorities as are outlined in
18 the documentation which came for this meeting.

19 One priority we would like to see, though, is a
20 push for adoption of the 1997 Food Code with a few
21 modifications. We were happier with this food code than we
22 have been with any edition of the Food Code that has come
23 out in the last several years

24 I think with the few modifications, what we would
25 like to see is the HACCP pilots be used as the basis of

1 retail food safety programs with critical control points in
2 here and then the Food Code serving as a basis for the
3 standard operating procedure, SOOPs or SOPs.

4 Again, I want to thank you for this opportunity.
5 It represents to me a new direction in food safety, a very
6 exciting positive direction and one I hope to participate in
7 for many years to come. Indeed, IFFSA sees the upcoming
8 July Interstate Travel Sanitation Program meeting in Kansas
9 City with an industry panel on the program as a start to our
10 reinvigorating and ITS program and as an enhancement of
11 program efficiencies for all constituents.

12 But it is only a start. These meetings should be
13 a priority of CFSAN's scheduled at least every other year if
14 not annually.

15 Thank you very much.

16 MR. LEVITT: Thank you. Our final presenter for
17 this afternoon is Nancy Snyder from the International Sprout
18 Growers Association.

19 International Sproutgrowers Association

20 MS. SNYDER: Thank you. I am Mrs. Snyder from
21 International Sproutgrowers. I do appreciate this
22 opportunity to appear before you.

23 To introduce my subject, I would like to give you
24 a few statistics. Worldwide sprout sales are approximately
25 \$1 billion with the U.S. market being about \$250 million.

1 There are approximately 5,000 sproutgrowers worldwide which
2 excludes China as we have no statistics for China, with
3 about 475 billion in the U.S. and Canada.

4 The sprouting industry in the United States and
5 Canada is an exact parallel to the farming industry varying
6 in size from \$5 million to \$50,000. There are many benefits
7 for eating fresh sprouts. Not only are they rich in
8 proteins, vitamins and minerals but government and
9 independent nutrition and health authorities agree that
10 Americans should increase their consumption of fruits and
11 vegetables to at least five servings a day.

12 These same studies show that generous servings of
13 fresh fruits and vegetables in our diet are protective
14 against many cancers and lessen the risk of coronary heart
15 disease. The USDA and government health officials continue
16 to remind the American people they are not eating enough
17 vegetables.

18 It is interesting to note that Americans are still
19 undereating vegetables in spite of the fact that the fresh-
20 cut vegetable industry has grown by leaps and bounds as has
21 vegetable consumption in general. More people are eating
22 sprouts. The recent anti-cancer benefits attributed to
23 broccoli sprouts will help bolster the vegetable and sprout
24 industry.

25 Warning labels on vegetables, fresh-cut vegetables

1 or sprouts will certainly impede the goal of increasing
2 consumption of these items. Considering the minimal risk of
3 food-borne illness, creating anxiety about eating vegetables
4 and sprouts, would be counterproductive to public health.

5 Further, there is no scientific evidence that
6 demonstrates that sprouts are a greater health risk than
7 fresh-cut vegetables. In addition, warning labels on
8 sprouts would seriously jeopardize the ability of the
9 industry to compete with fresh-cut vegetables.

10 Sprout producers are small farmers. They operate
11 with small profit margins. A drop in sprout consumption
12 would be disastrous to this industry. Considering the small
13 risk of contracting illness from sprouts, the similarity of
14 sprouts to the fresh-cut industry and the demonstrated
15 benefits from eating fresh produce, singling out the sprout
16 industry for negative labeling, in my view, cannot be
17 justified.

18 Then what does the sprout industry need from the
19 FDA? If I can give you a little history. Dr. Thayer and
20 Dr. Kathleen Rajkowsky of the Agricultural Research Center,
21 Philadelphia, have demonstrated that the radiation D value
22 for E. coli 157H7 and Salmonella on sprouting seeds appear
23 to be similar to the d values for meat products.

24 They believe that they are able to eradicate both
25 of these pathogens from sprouting seed through irradiation.

1 Further large-scale radiation testing as well as large-scale
2 germination testing of irradiated seed is continuing. When
3 this work is completed, ISGA and ARS will present this data
4 to FDA for approval.

5 We request that the FDA give this approval a high
6 priority and, since sprouts are a secondary product, they
7 not be required to be labeled as irradiated. ISGA, again,
8 is very grateful to ARS for this work.

9 ISGA needs a high priority from FDA to approve
10 more GRAS products as food additives. We have found that
11 hydrogen peroxide as well as ozone to be beneficial in the
12 processing water of sprouts. These products leave no
13 residual chemicals on the final product. However, ISGA
14 needs more research in this area and hopes that ARS
15 Beltsville, who is conducting this research, will continue
16 to support these projects.

17 ARS Beltsville has explored various chemical
18 treatments that will sanitize seed. The most promising is
19 calcium hypochlorite at 2 percent. We need higher
20 priorities assigned to the approval of new products as they
21 become available that can be used to soak seed prior to
22 sprouting.

23 Again, we are grateful to the efforts of ARS
24 Beltsville for the generous help and efforts in our behalf
25 and hope they will continue to support these research

1 projects.

2 MR. LEVITT: Thank you very much.

3 Let me begin with the subject of HACCP. At least
4 two of you mentioned HACCP. What is your view in terms of
5 what I will call passive readiness. Let me start there.
6 What is your view of HACCP readiness to your segments of the
7 industry, if I could ask everybody that.

8 MR. SIMPSON: I will go first. I think, like I
9 said, we have this pilot project in the Seattle District
10 only. We have been trying to expand it to other areas of
11 the country so, at this point, I am not sure that I could
12 say that we are ready to proceed much further.

13 One of the things that we are lacking, not from
14 CFSAN but part of FDA, is that we have had our pilot in
15 front of them for review for quite some time now and we have
16 not gotten the review that we have asked so that we know
17 that we are in the right direction to move forward.

18 As far as our pilot is concerned, we are going in
19 the right direction but we need greater exposure in
20 different districts.

21 MR. LEVITT: Thank you.

22 MS . FRYE : The dairy industry, too, was involved
23 in a pilot program with FDA in the cheese plant and worked
24 very closely with them on that. But , most importantly, is
25 the industry embracing HACCP voluntarily. It goes back a

1 number of years. In 1994, we had a task force made up of
2 industry that looked at developing a voluntary program and
3 also a model program for specific products.

4 We published a dairy-product safety manual that
5 our members embrace and use and that goes also along with a
6 computerized system of record keeping and also can take them
7 through the principles of the process and assessing the
8 critical-control points.

9 So the industry has stepped up to the plate. We
10 have tried to facilitate that with training and consensus in
11 our industry.

12 MS. SNYDER: The sprout industry has a voluntary
13 HACCP plan. We have identified one critical control point
14 which can be verified which is the chlorination of seed. We
15 are working on an ISGA seal of approval. We are down to,
16 really, two possible candidates, I think, at this point to
17 help us complete the development of this, so we are pretty
18 far along.

19 We expect to have this whole program to present to
20 our convention in August. Then, at that point, we would ask
21 for membership approval and for the membership to start
22 participating in this program. It is not a voluntary
23 program. The seal of approval would involve outside
24 inspections by an outside certifying agency that would
25 inspect sprout facilities and certify those facilities as

1 **adhering** to observing the critical-control point of seed
2 sanitizing and whatever other areas are identified as being
3 critical by the companies that we are working with.

4 MR. LEVITT: Thank you. Let me move down the
5 table here.

6 DR. CARNEVALE: I guess I am going to ask a Joe
7 Levitt question because I heard a lot of suggestions for
8 those priorities that we ought to consider important. I
9 guess my question, then, is if you each had to choose two
10 boulders, what would they be?

11 MS. FRYE: I think there are really two areas that
12 are very important to us. **One** is moving more towards
13 science-based in the **NCIMA** program. And we certainly
14 support that. And we welcome the cooperative forum that
15 that occurs in. Secondly, is that there is careful and
16 prompt consideration of labeling and health-claim issues
17 that come forward in our industry to provide a solid base
18 for consumers and also standards for international, as well.

19 MR. SIMPSON: Two boulders? I would say, from
20 listening to just about everyone I have heard here, that one
21 of the boulders, even there is no program for it, would have
22 to be considered the funding issues. I think somebody
23 classified it not as a boulder but as a stone. I think
24 moving toward a more universal application of HACCP
25 programs, whether voluntary or mandatory, I think is a stone

1 because, again, of the tendency that I see for HACCP
2 programs, if we are not careful, to be overwhelmingly paper-
3 heavy.

4 I think that an efficient HACCP program would be a
5 stone, be considered a high priority.

6 I want to make one comment. I have with me Carol
7 Heaver who is Chairman of IFFSA'S Government Affairs
8 Committee. I would certainly defer any questions you may
9 have to Carol if she chooses to answer them in my stead, but
10 those are my boulder and stone.

11 MS. SNYDER: I think I would be very inclined to
12 agree with the Grocery Manufacturers where he mentions
13 research on emerging food pathogens and a more science-based
14 approach in making risk assessment for both food-borne
15 pathogens and chemical contaminants is certainly very close
16 to some of our problems.

17 The other problem, the major problem, that we have
18 in the sprouting industry is finding a method to sanitize
19 our seed to a point where there would be no possibility of
20 any E. coli 157H7 or Salmonella contamination slipping
21 through to our final product.

22 I think we are getting very close to some research
23 answers. Once we have the science, we would like very much
24 to see quick approvals to use whatever methods the science
25 would suggest to clean up our seed.

1 MS. HEAVER: My name is Carol HeaVer. I am with
2 the In Flight Food Service Association. Thank you, Joel.
3 The only other boulder that I might add is to keep ITS in
4 NFSAN . We feel very, very strongly about the progress that
5 we have made in the last few years and the cooperative
6 program that we have going right now is very, very, very
7 helpful to our industry and we feel that it is very
8 efficient way to guarantee public safety, public health.

9 Thank you.

10 DR. BAILEY: I think I will pass to Laura if she
11 has some questions.

12 DR. TARANTINO: Only one. You mentioned, in terms
13 of the dairy standards, that many of the ones we have on the
14 books are outmoded and not very useful and need updating and
15 looking for resources to do that, knowing that that may not
16 be your top priority and it is difficult to do.

17 I gather you do not support notion that we should
18 eliminate the food standards, at least, ourselves?

19 MS. FRYE: Would we support eliminating food
20 standards?

21 DR. TARANTINO: Right .

22 MS. FRYE: We have looked at it from the
23 standpoint of trying to look at the present standards, where
24 some can be consolidated. Some are obsolete, specifically
25 on cheese which is a commodity that is internationally

1 raded. And then that could move forward in going towards
2 'odex and the position.

3 We have truthfully not considered advocating the
4 elimination of standards at this time, so I can't comment on
5 hat .

6 DR. TARANTINO: Just curious. Thank you.

7 MR. LEVITT: If there are no other questions,
8 again, let me thank the three of you for coming and your
9 colleagues, also. Again, the record will remain open if you
10 want to submit written comments.

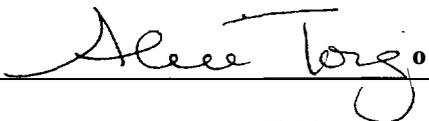
11 I thank those in the audience that have stayed and
12 listened and participated, and we will reconvene tomorrow
13 morning at 10 o'clock a.m.

14 [Whereupon, at 4:15 p.m., the proceedings were
15 recessed, to be reconvened at 10 o'clock a.m., Thursday,
16 June 25, 1998.]

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C E R T I F I C A T E

I, ALICE **TOIGO**, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.



ALICE TOIGO