

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

Thursday, June 25, 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: Why don't we go ahead and get started. I am Joe Levitt. I am the Director of the Center for Food Safety and Applied Nutrition here at the FDA. I want to welcome you to day two of our priority-setting meeting, an opportunity for public input.

Since we have a few new people who were not here yesterday, I am going to take probably five minutes in trying to summarize what we heard yesterday, so we have the right context.

First, Dr. Friedman came and gave a broad FDA overview of the different areas of focus and the different areas we have given priority to, to get feedback on that, as part of our general obligations this year under Section 406 of the FDA Modernization Act to develop a plan by November for Congress on how we are going to meet all of our statutory responsibilities, and as part of that, to meet with all our different constituencies in this meeting as part of that overall process.

Second, I took a few minutes and outlined the purposes of the meeting which is to really especially being a new center director to really take a good look at, you know, where are the priorities recognizing we can't do everything. One of the speakers even said we need to accept

1 what our limitations are and recognize that, too, and I used
2 one of my favorite analogies that FDA too often has 100
3 pebbles moving up a mountain at one mile an hour, and at the
4 end of 50 years, what do we have, 50 pebbles halfway up the
5 mountain, and nothing to show for it, and I prefer the fewer
6 boulder up and over the hill and something to show for
7 yourself theory.

8 I also showed a couple of slides on resource
9 history. I don't have the projector here today, but
10 basically, what it showed for CFSAN, for the Center, and
11 this was a surprise even to me, even though I have been here
12 all this time, is that 20 years ago, in 1978, which was
13 about the peak, the Center had roughly a thousand people, it
14 was 995.

15 Within 10 years, during the eighties, a constant
16 decline every year, and then about '88, '89, there started
17 to be some increases that were dedicated to four specific
18 purposes: imports, food safety, NLEA, and finally, the food
19 safety initiative, and even with those increases,
20 nevertheless, we began this fiscal year at a little under
21 800, or a 20 percent cut.

22 So, the first message is, whether anybody has
23 noticed or not, we have a 20 percent cut from 20 years ago,
24 and what I didn't say yesterday, but I usually do, and those
25 cuts were all taken through attrition, so they were-not

1 planned cuts. Whenever people leave, that is who your
2 reductions are.

3 The second slide I then showed is, of course, if
4 you are somebody working in the Center in one of those
5 programs that is not covered by those four areas--I am
6 sorry, seafood is the second one--so if you are not in
7 imports, you are not in seafood, if you weren't part of
8 NLEA, or you are not part of the food safety initiative, and
9 you take out and subtract those additive resources, then,
10 the rest of the program is really down to about 660 or a
11 full one-third reduction.

12 so, if you are in food and color additives, if you
13 are in pesticides, if you are in dietary supplements, if you
14 are in cosmetics, if you are in the milk programs or the
15 other cooperative programs, this is what your world is at
16 the FDA.

17 Then, the third slide I put up was during that
18 same period of time, the additional laws that Congress has
19 passed--and there are about six or eight of those including
20 most recently the dietary supplement laws and the
21 Modernization Act, and so we have a clear pattern.

22 We have sharply declining resources, sharply
23 increasing responsibilities for the food safety initiative
24 on top of that, and in my mind, it just means it is even
25 more critical that we carefully look at where are our

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1 priorities, are we getting a return on our investment, which
2 for me is the bottom-line question, where do we do the most
3 good for consumers.

4 In the Federal Register notice we outline six
5 questions which I won't repeat because you all have them,
6 and a number of speakers have started speaking to them.

7 Yesterday's discussion was excellent, I look
8 forward to continuing today. The format will continue to be
9 the same as it was, which we will invite people up in a
10 series of panels of people that have something in common in
11 terms of background and interests.

12 We will let each speaker speak for seven or eight
13 minutes. We have a timekeeper sitting right here in front,
14 and she will flash you a sign when you have two minutes
15 left, and a red sign that says you are out, and if you don't
16 notice the red sign, I will remind you of it.

17 Then, at the completion of the speakers, we will
18 have questions, and we have up here a panel in addition to
19 myself, several senior members from the Center, and when the
20 Q's and A's are done, we will proceed to the next. There
21 also will be a written summary of this meeting, and we are
22 holding the record open for 30 days for people to submit
23 written comments, either supplementing what you have done or
24 people who weren't able to speak, some written comments. We
25 certainly encourage everybody to do that.

1 With that, we anticipate that we will be done
2 certainly by 1 o'clock. If we need to take a short break
3 later in the morning, we will. We kind of play that by ear.

4 With that, let me invite up first the FDA panel.
5 We have Beth Yetley, our Director of our Office of Special
6 Nutritional; Ken Falci, our Director of the Office of
7 Scientific Analysis and Support, Arnie Borsetti, who is the
8 Director of Executive Operations Staff, and we have Juanita
9 Wills' name up here, but I don't believe she is here because
10 she usually needs to be in Parklawn on Thursday mornings.

11 I invite you to come up and join me, please, and
12 we will also invite up the first set of speakers from the
13 dietary supplement industry. We have representatives from
14 the Council for Responsible Nutrition, the Nutrition
15 Network, and the National Nutritional Foods Association. I
16 have listed Annette Dickinson, Charlene Rainey, and Michael
17 Ford.

18 I am having additional copies of the slides from
19 yesterday made up, so for people who were not able to get a
20 copy, they should be available before you leave today.

21 Finally, I would encourage, especially since it
22 looks like we are only having a half-day today, to the
23 extent it is possible for people to stay not only for their
24 presentations, but for others, as well, because I think it
25 is important, as far as the overall priority setting, for

1 people to see what everybody else's priorities are, not just
2 their own.

3 With that, let us begin with Council for
4 Responsible Nutrition, Dr. Annette Dickinson.

5 Panel 3

6 Nutrition/Dietary Supplements

7 Council for Responsible Nutrition

8 DR. DICKINSON: Thank you, Mr. Levitt. We are
9 very pleased to be here to participate in this priority-
10 setting meeting.

11 The Council for Responsible Nutrition is a trade
12 association representing the dietary supplement industry.
13 We have about 100 member companies including suppliers of
14 vitamin, mineral, and botanical ingredients, as well as
15 finished product manufacturers whose products are sold in
16 the mass market, health food stores, direct sales, as well
17 as mail order.

18 We have a little trouble, Mr. Levitt, with your
19 pebble and boulder comparison because, in one sense, the
20 entire dietary supplement industry is only a pebble as
21 compared to the food industry. We had sales estimated in
22 1997 of about \$12 billion compared to over \$450 billion for
23 the entire food industry.

24 However, the interaction of FDA with dietary
25 supplement issues has presented some boulders of **issues** over

1 the years, and we serve a number of consumers, as well as
2 members of the industry, who have a certain tendency to
3 storm the barricades when they perceive that FDA is acting
4 in what they do not believe is their interest.

5 CRN's proposition to FDA is that the industry is
6 committed to be more proactive in the coming years in terms
7 of self-regulation in order to relieve some of the burden
8 that FDA currently suffers in terms of manpower and
9 resources in dealing with dietary supplement issues.
10 However, there are some basic FDA actions that need to be
11 put into place in order for an industry self-regulatory
12 system to thrive.

13 One of these is nutrition labeling, and that I am
14 happy to say is something that has already been done. Your
15 final rules were published in September of '97, we submitted
16 some petitions for reconsideration which FDA granted earlier
17 this month, and we appreciate FDA's receptiveness to those
18 petitions. So, we are ready to move forward with nutrition
19 labeling. You are already seeing those new labels on the
20 shelf.

21 A second issue has to do with Good Manufacturing
22 Practices. DSHEA authorizes FDA to establish GMPs for
23 dietary supplements. The industry is committed to helping
24 you do that, and has submitted a draft document which you
25 published as an ANPR in 1997, and a group of the Food

1 Advisory Committee is currently looking at this, CRN has
2 members represented on that, and we are prepared to do
3 anything else that you would suggest to us we can do to move
4 that process along because we think it is one of the
5 building blocks we need for action in the future.

6 Statements of nutritional support is another area
7 of controversy. DSHEA'S provisions on statements of
8 nutritional support were self-implementing. Companies began
9 using these statements immediately after the law passed.
10 FDA has three and some-odd years now of experience with
11 this, and, in general, our perception is that the fact that
12 FDA has only needed to respond to about 7 percent of the
13 notices indicates a fairly substantial degree of agreement
14 between industry and FDA about what the permissible scope of
15 these statements is.

16 In our view, this is not an area that required
17 rulemaking. In other words, it is not an area that we
18 believe has presented a problem of misunderstanding or of
19 lack of compliance that really required rulemaking.
20 Nevertheless, FDA has issued a proposed rule and we are
21 deeply studying that rule and will be submitting extensive
22 comments in October.

23 We do think that FDA made a couple of missteps in
24 that rule. The first we believe was to enter the discussion
25 by broadening the definition of disease, which we see as

1 highly problematic and which we see as necessarily limiting
2 the scope of statements of nutritional support.

3 We think the second problem area was to adopt
4 what, in our view, is very much a medical model of disease
5 as the basis of this presentation rather than the fully
6 emergent model of health promotion and disease prevention.
7 We think that it is true, as FDA observes in the notice,
8 that almost any structure/function statement at some
9 extension of its logical extension will have disease
10 prevention implications.

11 We believe that DSHEA clearly anticipated that
12 product labeling have this kind of information available to
13 consumers specifically so that they could use these products
14 for disease prevention and to help reduce health care costs,
15 so we think that this needs some major reconsideration on
16 the part of the agency and we will be submitting extensive
17 comments to assist in that reconsideration.

18 As much as any industry may object to the
19 existence of regulation, the fact is that an industry needs
20 a strong regulatory agency and consumers need FDA in place
21 and they need to be confident that if there are unexpected
22 problems that come up, FDA can respond to those.

23 That means that there needs to be swift
24 enforcement when unanticipated questions arise. For
25 example, last year we had an issue involving **plantain**

1 products which were contaminated with digitalis.

2 FDA notified the industry almost as soon as it
3 learned about this case and also issued a public health
4 alert . The industry and the agency were very productive in
5 working together to rapidly locate the source of the
6 problem, remove the contaminated material from the market,
7 and correct the situation. We believe this is a good model
8 for future cooperation between the industry and the agency
9 in resolving these kinds of problems, which ideally should
10 not occur, but which do occasionally happen.

11 An example of a safety issue that has come up that
12 has not received that kind of swift response either from the
13 agency or from the industry is the ephedra situation. This
14 is a situation that has been dragging on for a number of
15 years. CRN has repeatedly urged FDA to take action on this
16 issue, but no final action has yet occurred despite two
17 advisory committee meetings and a proposed rule.

18 There was at one time an industry coalition which
19 largely supported FDA action on this, but" it has largely
20 dissipated. At this point, it seems that almost anything
21 FDA does is likely to be subject to criticism from one side
22 or the other, but since criticism is inevitable, and since
23 this issue has been hanging a long time, CRN believes the
24 best course is for FDA to just face up to that, finalize a
25 rule with appropriate modifications based on **comments**, and

1 let's all try to put this matter to rest.

2 On a larger issue, we would like to suggest that
3 the agency improve its handling generally of adverse
4 reaction reports in order to involve the industry in early
5 response to problems that appear to be arising. We would
6 like to have the opportunity to illustrate our ability and
7 our willingness to respond to safety issues that may arise
8 by quickly removing the product, identifying the product,
9 working with FDA to identify whether indeed there is a
10 problem in the interest of consumer protection.

11 There are some other areas where I would like to
12 support some of the comments that were made yesterday about
13 the importance of FDA's continued involvement, active
14 involvement in the areas of risk assessment and in
15 international activities.

16 There are currently international activities
17 taking place within Codex Alimentarius and also in some
18 individual nations where there are proposals on the table to
19 place limits on vitamins and minerals that may be sold as
20 dietary supplements generally based on small multiples and
21 arbitrary multiples of the RDA.

22 CRN has been making the argument that if indeed
23 there are to be any limits placed under any of these
24 mechanisms on products, that they should be based on
25 scientific risk assessment, and not on some arbitrary

1 decisionmaking, and FDA has been supportive in making that
2 argument in the Codex meetings.

3 We are also facing some of these issues at a state
4 level where the State of California has had an initiative on
5 lead and calcium. We have submitted a petition to the
6 agency on this issue, and we encourage a response to that
7 petition, again based on scientific risk assessment.

8 Finally, I would close by encouraging further
9 cooperation between the dietary supplement industry and the
10 agency, possibly facilitated by occasional meetings between
11 the two groups, and in addition, we want to strongly
12 encourage the agency to establish a dietary supplement
13 advisory committee.

14 The Food Advisory Committee has spent three of its
15 last six meetings dealing with dietary supplement issues.
16 This distracts from its attention to conventional food
17 issues, and more importantly, from our own immediate point
18 of view, it fails to give FDA good guidance on dietary
19 supplement issues because most of the members of that
20 committee are not familiar with these products or with their
21 regulations.

22 Thank you again for the opportunity to participate
23 in this session.

24 MR. LEVITT: Thank you very much. Again, we will
25 do questions after everybody has had their turn. -

1 Let's move on to Ms. Charlene Rainey.

2 Nutrition Network, Inc.

3 MS. RAINEY: Thank you. Thank you for the
4 opportunity to make these presentations today. I prepared a
5 lovely slide presentation for you, but the slide projector
6 is not working, so I am going to wing it.

7 The Nutrition Network is a network of 650
8 dietitians across the United States and Canada. We monitor
9 the food supply by going out into the marketplace and
10 collecting samples and sending them into laboratories for
11 chemical analysis.

12 Our work is sponsored in whole by the food
13 industry, by mostly agricultural commodity boards, food
14 trade associations, food manufacturers, food industry
15 ingredient suppliers, and our reports are submitted to
16 government agencies.

17 Our reports to FDA are in the form of approval for
18 nutrient databases and petitions to change serving sizes.
19 We also send the same data into the USDA for inclusion in
20 agricultural handbook 8 for food composition and in to FTC
21 for substantiation on food claims and to EPA for re-
22 registration of chemicals and chemical residues.

23 Our goal here today is twofold, and that is, one,
24 to continue to encourage the FDA to hold approval and review
25 of nutrient databases in high priority and to convey the

1 economic importance to the food industry of having nutrient
2 databases.

3 Now , in my lovely slide presentation, you would
4 see excerpts from a short course that I received a
5 scientific lectureship from IFT, and the databases began
6 shortly after the implementation of nutrition labeling in
7 1973, so the food industry has been depending for over 20
8 years on nutrient databases.

9 The first was submitted on milk by the Dairy
10 Board, and I was involved in the second database that was
11 put together on potatoes for the National Potato Board. The
12 National Potato Board model was used as a model for now over
13 100 commodities and products from fresh produce commodities
14 to processed commodities, frozen, canned. There is a lot of
15 dependency on nutrient databases.

16 The three steps in creating nutrient databases are
17 dynamic. They are sample collection, laboratory analysis,
18 and the math used to summarize the results.

19 Sample collection is dynamic because it has to be
20 constantly changing to include the new variables of the
21 food . As new foods get imported, as foods change in the
22 fresh produce section, we have fresh cut and processed
23 carrots that did not exist 10 years ago, and as the products
24 change, as they are imported from new countries, the sample
25 collection has to be a monitoring process that **keeps** up with

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1 these changes.

2 The laboratory analysis methodologies change.
3 They are constantly being updated and improved through the
4 AOAC process, and sometimes the data gets old and the
5 laboratory data becomes outdated.

6 One example of an outdated laboratory analysis is
7 a product like papayas. We used to think there were 60
8 percent of vitamin A in papayas, but this was a gross old
9 colorimetric method where we counted every bit of the color
10 as vitamin A and beta carotene, but with new beta carotene
11 and carotenoid analysis, this vitamin A is found to be very,
12 very low in papayas, less than 8 percent.

13 Another change that is found in this dynamic
14 process, raisins are a good example. If you look up in
15 handbook 8, you will find that raisins have 28 percent of
16 daily requirement for iron, but the raisin industry changed
17 their processing equipment and they no longer use iron vats
18 for the processing of raisins, and they changed to stainless
19 steel. Now raisins have practically no iron.

20 so, as things like this come up as we are
21 monitoring, we find changes where we would least expect
22 them, which makes the constant ongoing process of continuing
23 to look at the nutrients in the food supply an important
24 step.

25 Now , the nutrient database approval program is the

1 math, and unfortunately, the math keeps changing, as well.
2 Since we started in 1973, the math of this process, that is,
3 now we summarize the results, the math was put into place
4 because some nutrients in some foods have a very wide
5 variation naturally occurring.

6 Milk has a 200 percent variation in calcium, and
7 this is beyond the 20 percent variation allowed, so we have
8 to have some math to take into account the wide variation of
9 some nutrients that are naturally occurring.

10 Potatoes at the early season might have 100
11 percent vitamin C, but by the very late season, have zero
12 vitamin C. Which number do we select to go on the nutrition
13 label? This is the importance of the math.

14 The math has changed only a few times since 1973,
15 and it has changed for good reasons. It has changed because
16 there was a new policy or there was an improvement to the
17 method, and I would encourage FDA, in their review process,
18 to not change math if it is not broken.

19 The changing of math has a lot of economic
20 implication. There are several food manufacturers that use
21 our software to create their own nutrient databases beyond
22 those which are submitted to you for review, and they are
23 all based on your guidelines and using your math.

24 You should understand that every time you change
25 math, if it is policy and if it is for a good reason and if

1 it is improving the process, then, we encourage it, but if
2 it is merely a careless mistake or something that does not
3 warrant the economic impact of having everyone reprogram
4 their computers and by updates to change all their nutrition
5 labeling, then, we would encourage you to make sure you have
6 thought about the economic impact to the food industry.

7 But as you can see, it helps a lot to have a
8 nutrient database rather than have every dairy in the
9 country provide their own analytical analysis.

10 Thank you very much.

11 MR. LEVITT: Thank you very much. May I
12 compliment you on recovering from not having the slides
13 available. I sympathize. I gave a talk earlier in the week
14 down in Atlanta. It was a luncheon talk, and the time got
15 shift around, so I had to speak with slides just as the meal
16 was being served, so half of the people, because of the
17 round tables, they had to have their backs to the slides, so
18 I said when it is important, I will tell you to stop and
19 turn around. So, a very nice job. Thank you very much.

20 Our third presenter is Mr. Michael Ford from the
21 National Nutritional Foods Association.

22 National Nutritional Foods Association

23 MR. FORD: Thank you.

24 The NNFA is a trade association founded in 1936.
25 We represent about 2,500 health food stores throughout the

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1 country and about 800 manufacturers, distributors, and
2 suppliers of dietary supplements, health foods, and natural
3 ingredient cosmetics. I, like the others, very much
4 appreciate the opportunity to have input to your priority-
5 setting process. I am going to address five of the areas
6 mentioned in the letter I received.

7 First, in the area of consumer safety, we hear
8 protestations frequently that the FDA does not have the
9 regulatory might that it needs and the power to
10 appropriately regulate dietary supplements, and we feel this
11 is not really the case. Instead of enforcing DSHEA, the
12 Dietary Supplement Health and Education Act of 1994, many
13 times we hear FDA officials saying that their hands are tied
14 and that the agency is powerless to regulate.

15 We don't believe this is true, and need to stress
16 that the industry did not pass DSHEA, Congress did, and the
17 industry was not making the outcry for the passage of DSHEA.
18 That was from consumers.

19 As a result, the law sets labeling and potency
20 standards, the violations of which are crimes, and no one
21 likes to be read to, but I am going to recite the sections
22 in DSHEA which I believe underscore the point I am trying to
23 make.

24 FDA is empowered to do the following: to refer
25 for criminal action a company selling a toxic or unsanitary

1 dietary supplement. That is Section 402(a) . To obtain an
2 injunction against the sale of dietary supplement with false
3 or unsubstantiated claims. That is under Section
4 403(a) (r)(6). To seize dietary supplements posing an
5 unreasonable or significant risk of illness or injury. That
6 is Section 402(f) .

7 To sue a company claiming a dietary supplement
8 cures or treats a disease. That is Section 201(g) . To halt
9 the sale of a new dietary supplement with insufficient
10 advance safety data. That is Section 413. To stop the sale
11 of an entire class of dietary supplements posing an imminent
12 hazard to the public health, that is Section 402(f), and to
13 require dietary supplement manufacturers to meet strict
14 GMPs . That is Section 402(g) .

15 Incidentally, our association this fall will begin
16 inspecting the dietary supplement plants that are members
17 against the GMPs. That will be a prerequisite for
18 membership and a requirement for continuing membership in
19 our association.

20 In the area of international activities, we want
21 to commend U.S. Codex delegate Betty Campbell for her
22 efforts to keep the issue of health claims alive within
23 Codex. We believe countries should be devising their own
24 policies with respect to the regulation of dietary
25 supplements, but we also believe the United States has

1 something unique to offer with the utilization of
2 structure/function statements.

3 We would suggest this morning that you consider
4 issuing a regular invitation to the Codex briefings to the
5 U.S. Trade Representative Office which has a great deal of
6 interest in the export of American dietary supplements.

7 In the area of authoritative statements, you know
8 that the Modernization Act authorizes claims for
9 conventional foods based on authoritative statements from
10 governmental research agencies of the National Academy of
11 Sciences.

12 In your June 11th guidance statement, you say that
13 you intend to extend that to dietary supplements, and I want
14 to say on behalf of the association we appreciate that very
15 much and would be pleased to work with you toward that end
16 and hope that ultimately, the authoritative statement rules
17 for conventional foods and dietary supplements will be the
18 same.

19 In the area of adverse reaction monitoring, we
20 would like to see improvements in the system, and I think
21 you would too. We would like to see the data be more useful
22 in alerting the industry when there are problems with its
23 ingredients and products.

24 We have proposed in the past, and I propose again
25 this morning, I echo Dr. Dickinson's remarks, that there be

1 a partnership between CFSAN and the dietary supplement
2 industry in post-market product surveillance, as well as the
3 tracking of injury and adverse reaction reports

4 We believe that if the data were more consistent,
5 more readily available, more complete and more relevant, it
6 would likely eradicate the current problem that we have of
7 subjective interpretations which seem to forestall action.

8 Finally, in the area of safety of herbs, as I said
9 earlier, I believe that FDA currently has adequate
10 regulatory authority to ensure the safety of herbal and
11 botanical products under DSHEA, but we also support the
12 recommendation of the President's Commission on Dietary
13 Supplement Labels, that an additional option be made
14 available for dietary supplements to make a more direct
15 health claim through the OTC designation.

16 We would urge, though, as you consider this, that
17 you create an additional and discrete herbal review panel
18 comprising pharmacognosists and herbalists and other herbal
19 specialists, so that you can ensure a learned and specific
20 review process leading to the OTC approval.

21 That concludes my statement. Thank you very much
22 for having me here.

23 MR. LEVITT: Thank you and thank all of you.

24 I think just one thing that I would mention at the
25 outset, that I was educated, too, in terms of, you know, I

1 understand the feeling. You feel like you are. a pebble in
2 the world of boulders, all of us feel that, but the law did
3 in a way set out some of our priorities for us, for example,
4 the notification process does take a fair amount of
5 resources because it goes into effect if we don't do
6 anything, so we are very careful to try and look at those
7 letters within I guess it's 75 days--is that what it is--

8 DR. YETLEY: It depends on what it is.

9 MR. LEVITT: --whatever the different time frames
10 are--and so in a way, some of our priorities have been, you
11 know, set forth by the law and we do our best to accommodate
12 that.

13 I think the one question I would have, if you can
14 expand at all in the area of adverse event reporting, do you
15 have specific things, specifics you would like to see
16 specifically, or just, you know, it is an area we need to
17 start working on more together?

18 DR. DICKINSON: I think we do have some specific
19 things that we would like to see. For example, when FDA
20 first becomes aware of a serious adverse reaction, we would
21 like to be notified of that fairly promptly, and not find
22 out about it literally months or sometimes many months
23 later, when it becomes available in an adverse reaction
24 report .

25 We would like to have the opportunity to help FDA

1 with methods to help FDA determine what products were being
2 used, what other products are available with those same
3 ingredients, and if necessary, take some industry actions to
4 either remove the product or correct the situation.

5 The situation in the past has been that FDA has
6 been forthcoming at times in letting us know that some
7 problems seem to be emerging, but when we sought more
8 specific information, it was not available until there was a
9 Freedom of Information request and that sometimes took a
10 very long time.

11 There also is a significant lag between the time
12 that a report is generally received at the field and the
13 time it makes it to the official adverse reaction report, so
14 we are looking for some more flexibility in the ability of
15 FDA to notify the industry when a problem exists.

16 I understand from discussions with Beth and with
17 others that there are other industries who get involved in
18 the adverse reaction responses where maybe there is a more
19 efficient system for dealing with this, and we would like to
20 follow those models.

21 MR. LEVITT: Thank you. Let me just follow up on
22 that. There are a lot of other industries and a lot of
23 other models. Some of them are mandatory reporting by the
24 industry. Is that a model that you would be interested in?

25 DR. DICKINSON: No, we are not looking at

1 mandatory reporting. We are looking at the response
2 mechanism more than the reporting mechanism, and in
3 particular, I believe the infant formula industry has been
4 cited to us in the past as a group that is highly responsive
5 to any initial reports, but I think that begins with their
6 being notified at an early date of those reports.

7 MR. LEVITT: Thank you.

8 In the area of nutrition databases, are there
9 specific areas that we should be paying more attention to
10 than we are?

11 MS . RAINEY : Yes. I think one area is the
12 harmonization with Codex rules and with the international
13 scientific community. We have one technical amendment that
14 we have been waiting quite some time for, and that is the
15 changing of international units in vitamin A. The word
16 "international units, " we are the only country left in the
17 world using "international units. " Everyone else has
18 switched to retinol equivalence because of the obvious
19 technical error of using international units,

20 so, when I am giving you a database on carrots, I
21 know that I am stating on that database twice the vitamin A
22 that are in those carrots, twice the vitamin A that are in
23 those tomatoes, and this just isn't fresh produce, this is
24 every plant food labeled in the United States.

25 so, we have this Canadian retinol equivalence.

1 When my tomatoes are sitting in Canada, they have 8 percent
2 vitamin A. When they are sitting in the U.S., they have 16
3 percent vitamin A. It is a technical error. We would
4 really like this corrected.

5 MR. LEVITT: For my educational benefit, is that
6 something that requires that we change the regulation or
7 what would need to be done in order to correct that?

8 MS. RAINEY: Dr. Yetley told me it was a technical
9 error.

10 DR. YETLEY: We would have to amend the
11 regulations .

12 MR. LEVITT: We have to amend the regulations to
13 do that. Okay. Very good .

14 Dr. Yetley.

15 DR. YETLEY: I wanted to pick up also on the
16 adverse event reporting system. I think certainly we would
17 we 1 come cooperation with the industry. There are some areas
18 that from our perspective become rate limiting that I think
19 the industry could particularly help with, and I wondered
20 what your reaction would be.

21 One is the difficulty in getting information on
22 products, if we have only a product name and no other
23 information, we don't know the manufacturer and address or
24 ingredients necessarily, and I wondered if the industry
25 would be interested or had some mechanism for haviny

1 information on products that was more readily accessible.

2 DR. DICKINSON: We don't have a product database
3 that is immediately accessible. I think NNFA may have one
4 through true label to some extent, but we don't have one
5 that would cover all the products in the marketplace,
6 however, we have a very good network, and if we were
7 notified of a product name, we could certainly send out a
8 request for information on whose product that is and what it
9 contains.

10 DR. YETLEY: The other big area--and I think
11 Michael referred to it--is the methods development area, and
12 I wonder if you have any suggestions on how there could be
13 better collaboration and coordination between FDA and the
14 industry in terms of methods development, not only for bulk
15 products which are more generic, but also for finished
16 product.

17 MR. FORD: Are you talking about for testing
18 methodology?

19 DR. YETLEY: Methods of analysis to identify what
20 is in there and the quantitative amounts.

21 MR. FORD: We would be delighted to collaborate
22 with the agency in any way we could on that. As you know,
23 through our true label program, every product manufacturer
24 who are members submits the labels of all of their products
25 to us, and we take off of those labels the various -

1 ingredients and have them organized in a database, so when
2 we find out that there is a problem, for example, with the
3 plantain, we can pull up immediately on our screen all of
4 our members who have a plantain product, and we were able in
5 that instance to notify them very quickly, which was
6 terrific.

7 We would be very open, in fact, our Science
8 Committee will be meeting in about two weeks, and we would
9 be very open to cooperating on methodology on testing.

10 MR. LEVITT: Dr. Falci.

11 DR. FALCI: Dr. Dickinson, you mentioned a very
12 interesting term, self-regulation in the industry, and Mr.
13 Ford also mentioned a little bit about maybe what I would
14 term internal audits on GMP, for instance, in the industry,
15 and I was wondering, Dr. Dickinson, if you would maybe
16 expand on what you might mean, what the industry might do as
17 far as self-regulation was concerned.

18 DR. DICKINSON: For example, in the area of GMPs
19 and of product identity, we are considering at this time an
20 industry educational effort which would help to bring all
21 manufacturers in the industry up to at least the GMP
22 proposals that we have submitted to the agency and 'that were
23 submitted as a ANPR.

24 We think that this is one area where we could take
25 some action to both assure product identify because-some of

1 the adverse reactions that occur are due to errors in
2 identifying the product, and we think that through training
3 programs and through cooperation with the agency, we can
4 bring the products up to a higher quality standard.

5 We think most of the products are already at a
6 fairly high quality standard, but there is always a segment
7 that isn't quite up to speed with the rest of the industry,
8 and so we think that education and internal industry
9 activities to improve processing methods, to improve record-
10 keeping. We know that in the plantain/digitalis issue,
11 record-keeping was a barrier to some of the efforts to trace
12 the product to its origin, and those are the kinds of
13 problems that we think must, as a priority matter, be
14 corrected within the industry.

15 DR. FALCI: This focuses basically on the
16 manufacturers and producers, not necessarily on the public
17 per se?

18 DR. DICKINSON: Yes. Our membership is
19 manufacturers and producers, so what we have in mind is
20 primarily activities that would go to them. They then, in
21 turn, deal directly with consumers, however.

22 DR. YETLEY: I have a follow-up to that question.
23 Does self-regulation work best when FDA has policies and
24 guidelines out there, and regulations, or does it work best
25 when there is nothing out there?

1 DR. DICKINSON: There certainly needs something
2 out there. As we discussed, we need GMPs to go by.
3 Everybody in the industry isn't necessarily going to take
4 our word for what the GMPs ought to be, so we need some
5 superstructure to base that self-regulation on, but once
6 that is in place, we would offer the resources of the
7 associations, I am sure all of the associations, in helping
8 to improve compliance and assure compliance with those
9 underpinnings.

10 MR. FORD: I agree. DSHEA and the guidelines that
11 you have been putting out, and some of the rules that we
12 agree with and some we don't, nonetheless, do create an
13 important benchmark I think for the industry and allow the
14 trade associations to educate their members.

15 In our case, we have both suppliers and retailers,
16 so we are able to educate our manufacturers about how to
17 comply and exceed some of the standards, and as well, make
18 sure that our retailers are aware of how they have to
19 perform with respect to the availability of literature and
20 what they say to their customers.

21 We are also able to provide information to the
22 public through the health food stores, through to the
23 customers of health food stores, and I think that has been
24 very positive for us, as well.

25 I want to just also, Dr. Falci, just quickly

1 mention that with our true label program, not only do we
2 gather the ingredients off of the label for the database,
3 but we also have a random testing program where we will go
4 to a health food store and buy product off the shelf and
5 test it.

6 Sometimes it is because of a complaint or a
7 concern that has been expressed, and sometimes it is just to
8 test like multiple vitamins to make sure they have what they
9 say they do. If we find there is a problem, we privately
10 contact the manufacturer and tell them that either the label
11 or the product has to change within a certain time frame or
12 they will not be able to remain members of the association,
13 and since we have a large and successful trade show, that
14 has been a pretty good hammer for us.

15 DR. FALCI: Thank you. One more question. Ms.
16 Rainey, you had mentioned that you wanted us to keep the
17 nutrition database reviews basically in a high priority. I
18 know that we get literally hundreds of them and have
19 reviewed hundreds of them, and I am sort of opening FDA up
20 now for potential criticism here, but as far as our reviews
21 are concerned, and the information that you got back that
22 the reviews were complete, how did you rate us as far as
23 that kind of service?

24 MS. RAINEY: Well, there has been a large turnover
25 of personnel. I have been submitting databases for review

1 for 18 years to the agency, and there is a little bit of a
2 training process that has to go on every time I get a new
3 person working on this project.

4 so, I have in my company, from my end, created a
5 checklist of what things need to be approved before samples
6 go into the laboratory and what things need to be approved
7 after you get the results from the laboratory, and I think
8 that if we sat down in some sort of a partnership way--and I
9 know that requires trust on both ends, you know, more trust
10 of industry on your part--but if we could go down and share
11 this checklist with you of what we need to know, because if
12 you disapprove of the way we are collecting our samples and
13 try to identify one variable or another, and we have already
14 spent money on laboratory analysis, that is not the time to
15 find out--submission of the plan ahead of time.

16 We would like to have the process not be a moving
17 target . We send in for proapproval and then after they have
18 had a chance to look at the results, then, there is new
19 criteria that are added on, and the new criteria, you know,
20 this is a dynamic process. We can make it better for
21 upcoming and future samples, but we need to have this
22 understanding that it needs to stabilize a little bit, and
23 not feel like a moving target that we can't possibly hit.

24 DR. FALCI: You want to go to completion at least
25 on one issue, and then improve it later on as the time goes

at

1 on.

2 MS. RAINEY: For the future, constantly improving
3 for the future, and the data is merely place card holders in
4 time of what we learned today.

5 DR. FALCI: I would agree with that. We should
6 meet more of that.

7 MR. LEVITT: Dr. Borsetti.

8 DR. BORSETTI: This is to pick up a little bit on
9 the famous phrase, "ask not what your country can do for
10 you, but what you can do for your country. " Ask not what
11 FDA can do for you, but how you can work with us to help us
12 to get an enormous job done, especially in this very
13 complicated area where there is not enough research, which
14 is what my question is coming to, to satisfy the needs in
15 order to develop the rules and the health claims, and the
16 other types of statements that we need to assure that
17 products are safe.

18 To the panel in general, would you please reflect
19 on how you might be able to work with us given the fact that
20 we now have a new joint institute for food safety and
21 applied nutrition, which I think is one mechanism where you
22 might be able to work with us to help divide the labor in
23 the area of research for dietary supplements. I think, Mr.
24 Ford, you alluded to some of these a few moments ago about
25 this development area.

1 MR. FORD: Yes. I think we could be very helpful
2 by providing some of the research to you, at least that
3 which would not be considered overly proprietary that is
4 going on with many of our companies despite the fact that
5 the way DSHEA is structured, the claims are not patentable,
6 nevertheless, there is a great deal of research going on in
7 our major companies, and a lot of it is quite good, and I
8 think that is something that I would be glad to talk to my
9 Science Committee and the Board of Directors, and the
10 membership broadly about being able to provide.

11 I also would suggest that you not overlook a
12 couple of resources available to you within government that
13 the National Institutes of Health, and that would be the
14 Office of Dietary Supplements and the Office of Alternative
15 Medicine, which have lot of resources--more resources than
16 they used to at least--and I know we would be very
17 interested in collaborating with the FDA and providing other
18 kinds of information you would need.

19 DR. DICKINSON: We have some collaborative methods
20 currently underway for method development with an
21 organization that is being established within the industry
22 under the industrial laboratories, which is a service
23 laboratory in Colorado, in which the effort is to establish
24 agreed-upon methods of analysis for a number of botanical
25 products and certain other ingredients, and get **those** into

1 at least peer-reviewed approved mechanism for AOAC, so that
2 these are publicly available methods.

3 We currently find that many of our companies have
4 developed proprietary methods which are probably very good,
5 but which are not generally available to the industry, so
6 this is an effort to break out of that kind of restricted
7 model and get to the point of publicly available methods,
8 and I know that many of our members have been working with
9 people at FDA in the analytical area to share information
10 and to facilitate that process.

11 MR. LEVITT: I have just one final question. One
12 of the issues dealing with the whole dietary supplements
13 area is that the law is still relatively new and a lot of
14 the basic framework is not yet in place, and so the number
15 of regulations we have in the dietary supplement areas is
16 clearly disproportionately high compared to what we would
17 have in other areas of larger impact.

18 The order we are doing them in I would describe in
19 terms of state of readiness is ephedra first, there has
20 already been a proposal out, the structure/function claim
21 proposal, which is out but more recently, the authoritative
22 statement, promise of a proposal which was made recently,
23 and the GMP, which is at advisory committee working group
24 for work.

25 Is that the right order, putting aside it-will

1 take longer than you would like, but at least is that the
2 right order of importance?

3 DR. DICKINSON: I would bump the GMP up higher
4 because I think we do have some identity and quality issues
5 that have come up which do have implications for public
6 health. The labeling issues also obviously have some
7 implications for health, but to a large extent, as I
8 mentioned, DSHEA is pretty much self-implementing on the
9 subject of the claims side, whereas, on the GMP side it
10 really is not. We really need an FDA model for GMPs for
11 this industry in order to improve the processes across the
12 board.

13 MR. LEVITT: Thank you very much. I thank all of
14 you .

15 [Applause.]

16 We can proceed I think straight away to the second
17 group. The second group is a group of three food trade
18 associations : the National Food Processors Association,
19 John Cady; the Society of Plastics Industries is Jerry
20 Heckman and Tom Brown; and the Apple Processors Association.

21 Mr. Cady, why don't you lead off, please.

22 Trade Associations

23 National Food Processors Association

24 MR. CADY: Thank you very much. Good morning. I
25 am John Cady, President and CEO of the National Food

1 Processors Association, and we appreciate this opportunity
2 to provide input on the priority-setting process for the
3 Center for Food Safety and Applied Nutrition.

4 As most of you know, NFPA serves as a scientific
5 and technical trade association for the \$430 billion U.S.
6 food processing industry. Our primary focus is on issues
7 related to food science and food safety, so it is highly
8 appropriate that we provide input on behalf of our broad-
9 based food industry at this meeting.

10 My comments today will briefly address the
11 administration's food safety initiative, as well as making
12 recommendations for priorities related to other food safety
13 issues and additional CFSAN activities. Our written
14 comments go into very specific detail on these points.

15 On the subject of the food safety initiative, let
16 me say at the outset that NFPA salutes the administration's
17 interest in food safety issues. We stand willing to work
18 with CFSAN on its endeavors related to the initiative,
19 especially those activities on which we believe the highest
20 priority should be placed, which is research, risk
21 assessment, and education, but NFPA remains concerned that
22 other equally important food-related programs, such as the
23 review process for new food and color additives or new uses
24 for approved ingredients or international trade issues may
25 not receive adequate agency attention or an adequate level

1 of funding from general revenues.

2 CFSAN and the administration must not divert
3 funding or attention from other important Center activities
4 to pay for food safety initiative related projects. I would
5 like now to address our views as to what a few of CFSAN's
6 top priorities should be outside of the food safety
7 initiatives in general.

8 It is our strong belief that FDA should take
9 action to require that all fruit and vegetable juices be
10 pasteurized to ensure their safety. FDA must mandate
11 pasteurization on an equivalent process for all juices or an
12 equivalent process for all juices, not just most juices as
13 the agency has proposed, or, we believe, juice safety
14 regulations will not be successful in advancing food safety
15 in this country, and E. coli will still be a major concern
16 for consumers of certain products.

17 Another priority for CFSAN should be the proper
18 implementation of HCCIP regulations for a variety of foods.
19 HCCIP is best used where there is evidence that rigorous
20 oversight is needed to control the food safety hazard and
21 where technology and processes exist to control that hazard,
22 however, the application of HCCIP where these considerations
23 do not apply will likely result in undue costs for
24 processors and higher food costs for consumers without
25 meaningful improvement in safety.

1 CFSAN should also place a high priority on
2 reforming of the food additive review process. It is no
3 secret that FDA regularly fails to act within its statutory
4 review periods for various applications and petitions.
5 Despite the fact that FDA is required to approve or deny
6 food additive petitions within six months, the average
7 petition lingers close to four years before FDA acts on it.

8 Timely action on food additive petitions is
9 necessary and we urge FDA to reform its review process, so
10 that the agency can comply with its statutory obligations.

11 International activities are becoming increasingly
12 important to the United States. Consequently, CFSAN should
13 place a much higher priority on efforts to improve
14 international food safety standards through cooperation in
15 Codex Alimentarius. Since 1962, the Codex process has
16 developed many guidance documents on food safety and
17 wholesomeness.

18 We urge CFSAN's continued strong participation in
19 the Codex process and other activities which strengthen
20 international food safety, and we emphasize the problems
21 that exist between the United States and Canada where
22 products have to be reformulated and labels have to be
23 redone because we can't ship them between on a uniform
24 basis, and I think we need to look at Canada specifically as
25 a good starting point.

1 National uniformity and harmonization among
2 federal and state agencies should also be a priority for
3 CFSAN . The efficiency of the food industry is greatly
4 impeded when it must deal with different regulations
5 established by federal and state agencies. This also
6 contributes to inefficient regulation and inspection.

7 Inspectors, be they state or FDA, should be able
8 to evaluate a plan's performance and the safety of a product
9 with respect to a single set of standards. Additional
10 programs which should also receive higher priority within
11 CFSAN include the continued maintenance and administration
12 of the food standards program, as well as ensuring consumer
13 confidence in the food supply through prevention of economic
14 fraud. Both are extremely important needs for the food
15 industry and for consumers.

16 CFSAN has a mandate to carry out a range of food-
17 related activities, however, to reiterate, the Center must
18 not rob Peter to pay Paul, nor can it continually cite lack
19 of resources and personnel to justify delay in important
20 activities . That answer does not pass muster.

21 Like industry, CFSAN will continue to be called
22 upon to do more with less, which is why we applaud this
23 effort to set priorities in order for the Center to meet its
24 obligations. We suggest a bold approach to establishing
25 Center priorities and an even bolder approach for addressing

1 an organizational structure that will reflect the public
2 health needs of the new century.

3 In closing, I would urge the administration and
4 HHS to make CFSAN funding a priority and to act much more
5 aggressively in obtaining the annual funding necessary for
6 CFSAN's mission to be properly accomplished. This funding
7 support by the administration at the highest levels cannot
8 be overemphasized.

9 Again, we appreciate the opportunity to present
10 these program priorities for consideration by the Center
11 and, as I said, our written extended documentation goes into
12 detail on each one of these subjects.

13 Thank you.

14 MR. LEVITT: Thank you very much.

15 Next, we will hear from The Society of Plastics
16 Industries. I am not sure who is going to be speaking. Mr.
17 Heckman?

18 The Society of Plastics Industries, Inc.

19 MR. HECKMAN: I am going to introduce Tom if I
20 may. On behalf of the Society of Plastics Industries, Inc.,
21 Tom Brown and I very much appreciate this opportunity to
22 tell you why we feel strongly that the Food and Drug
23 Administration should implement the notification system for
24 food contact substances created by the Food and Drug
25 Modernization Act of 1997.

1 This is a case, using your analogy, where we feel
2 that you can get rid of a number of pebbles by just pushing
3 one boulder up the hill and avoiding the sisyphus effect
4 that we have been suffering under for many years. In a way
5 that we are saying is that we think we can help you to maybe
6 conserve or reorient the use of some resources, so that you
7 will have more to do with, with regard to the food safety
8 Initiative or whatever the other priorities are.

9 We recognize that the amount of additional funding
10 FDA will receive to carry out this program is uncertain at
11 this time. As I hope you will recall, the packaging
12 industry was, and remains, willing to pay reasonable fees to
13 help cover the cost of processing the notifications.
14 Congress, however, decided that the program should be funded
15 from FDA's budget and authorized the additional funding in
16 FDAMA . That is different than appropriating it and
17 authorized.

18 As you know, the appropriation of the funding
19 authorized in FDAMA presently is being considered by
20 Congress, and the packaging industry continues to work
21 diligently to obtain this appropriation. Here, we hope to
22 highlight the advantages of the food contact notification
23 system over the current indirect food additive petition
24 process, focusing on ways in which the new system will we
25 believe actually reduce the resources required from FDA.

1 We believe that the agency will be able to
2 implement the notification system without devoting
3 significant additional resources to the task. In fact,
4 there are efficiencies in the notification system that may
5 allow the redeployment of resources currently allocated to
6 the regulation of food contact materials to other FDA
7 responsibilities more critical to public health and safety.

8 The one thing we would like to help bring about,
9 to borrow a phrase that caught my attention and kept it,
10 used by Dr. Cheesman last week, is that we would like to
11 help you not continue spending a kilogram of energy on a
12 phenogram of risk. That seems to me to characterize our
13 problem completely and has for 40 years.

14 So that you will receive a very informed analysis
15 of why we believe moving to the food contact notification
16 model for substances now dealt with in the same way as
17 direct food additives can result in important pluses for a
18 more efficient operation of the Center, I have asked Tom,
19 who is experienced in the Office of Premarket Approval, and
20 before its existence, the Division of Food and Color
21 Additives, is well known, and he will make our presentation
22 in chief to you, I hope with some, specifics that you might
23 find challenging and interesting.

24 MR. BROWN: I would like to thank you very much
25 for permitting me a few minutes during this unique -

1 opportunity to comment on the CFSAN priorities and explain
2 why we urge CFSAN to include food contact premarket
3 notifications as a priority item in the upcoming plans for
4 Fiscal Year 1999 and beyond.

5 We believe that implementation of the notification
6 program will not require significant additional resources
7 from FDA. It could well permit current resources devoted to
8 petition reviews to be transferred to the food safety
9 Initiative.

10 As you know, the Food and Drug Administration
11 Modernization Act of 1997 sets forth a new procedure for
12 food contact items that would permit the use of notification
13 procedures in lieu of the current food additive petition
14 process now in use at FDA.

15 Under this procedure, the person wishing to use
16 the food contact material that is either new or not
17 currently regulated for such uses would submit a
18 notification to FDA containing the same quantity and quality
19 of data that would be submitted to the food additive
20 petition.

21 FDA would have 120 days to review the data and
22 determine if, in its opinion, the use has not been shown to
23 be safe. If FDA does not raise the safety issue, the
24 notification would be effective in 120 days with no further
25 action by the agency.

1 One of the unique features of the FDA
2 Modernization Act of 1997 is that the start-up of the
3 notification program is dependent upon FDA receiving a
4 special appropriation from Congress to fund the program. In
5 FDAMA, Congress authorized funding for the program of \$1.5
6 million for Fiscal Year 1999 and \$3 million beginning in FY
7 2000.

8 The packaging industry is exerting great efforts
9 to have Congress appropriate the authorized funding which
10 Congress substituted for the reasonable filing fees that the
11 industry is willing to pay, but I hope to show in this
12 presentation that the notification system will not demand
13 significant resources and may allow resources to be
14 allocated to more critical tasks.

15 Because I spent 29 years with FDA, 22 of which
16 were in the regulation of indirect additives, my aim here is
17 to offer some insight into the implementation of the
18 notification procedure and why we believe it will work for
19 the benefit of all, so the implementation of the program
20 should be prioritized.

21 Also, for many years I spent time developing
22 budgets for the entire food additive program and had reason
23 to pay special attention to how much time was actually being
24 spent working on petitions.

25 My main objective is to share with you my-thoughts

1 n resource allocation where food contact substances are
2 oncerned and thereby to persuade you that the new premarket
3 notification program will not require long-term additional
4 unding as compared to what is now being spent on dealing
5 with petitions for food contact applications.

6 To provide this analysis as coherently as
7 possible, I will first give you my analysis of how FDA
8 resources are now being expended on petition process and
9 indirect additives and how much of this expenditure can be
10 avoided with no adverse public health implications under the
11 premarket notification concept.

12 I will indicate to you how I feel FDA may best
13 implement the new premarket notification program to assure
14 that it is conducted in a way that will least strain the
15 resources of the agency and those who deal with them.

16 If you look at the current petition process, it is
17 understood that 85 percent of all the petitions, food
18 additive petitions that FDA receives are for what we call
19 indirect additives, but should probably better be called
20 Food contact substances since there is really no food
21 additive effect for a great majority of these substances,
22 and realizing that when the notification program is
23 implemented, perhaps 90 percent or more of these petitions
24 will no longer be necessary.

25 It would appear worthwhile to analyze resource

1 utilization differences between the two systems, in other
2 words, assuming as is intended, that the scientific reviews
3 under both systems will not differ substantially since the
4 same data will be submitted and same conclusions as to
5 safety assurance will be essential what differences might
6 there be, what reduced demands on agency resources might be
7 anticipated, because the need for writing, reviewing, and
8 publishing complex regulations must be understood by all and
9 will govern all, will no longer exist, we see this as a
10 definite area where there is a savings of time, not only at
11 OPA, but in other parts of the agency, CFSAN, Parklawn, too.

12 As I see it, the elimination of the burden of
13 issuing regulations is sufficiently significant, so that
14 even though we continue to believe that the food contact
15 notification program would best and most fairly be funded by
16 the sort of cost recovery fees Congress has thus far refused
17 to authorize, it is our basic belief that the program, once
18 launched and in place, may free some of the resources for
19 further agency activities, such as other programs with
20 greater potential for public health benefits like the food
21 safety initiative.

22 In passing we should note that we believe that the
23 commencement of the program will help provide data that
24 would enable us to try once again to make the system self-
25 sustaining on a cost recovery charge per notification basis.

1 We realize that the Congress has thus far rejected
2 the plan we proposed, and which FDA endorsed, but we think
3 that a demonstration of the effectiveness of the system and
4 an effort to further educate Congress and other industries
5 on its value and proprietary nature could affect the
6 turnaround at this point.

7 One good way of actually measuring the impact of
8 the notification program on the agency's resources would be
9 to conduct a pilot study. This is the procedure that we
10 used--I say "we," my time at FDA--on setting up the
11 threshold of regulation and the special project team, both
12 of which were proved to be quite successful and very time
13 saving.

14 This could easily be done by taking several
15 petitions or threshold of regulation requests from the
16 current backlog and processing them through the review
17 portions of the food contact notification program.

18 It would seem that this could be done with no real
19 disruption of the current petition review process and the
20 review times and subsequent administrative times. That is
21 the time involved with actually getting the regulation out,
22 which can easily surpass the--

23 MR. LEVITT: If you could just try to wrap up
24 quickly.

25 MR. BROWN: Okay. To summarize--it will be in

1 written testimony--but I have made a list of things that
2 don't happen, and people do not have to look at filing
3 notices and petition regulations.

4 Filing notices, that is not really all that great,
5 but there is about 15 people above the actual level of OPA
6 that will not have to be involved in this, and it is
7 probably a savings of 15 to 20 hours per petition, and in
8 the actual regulation area, I calculate is--again, this is
9 all detailed in the testimony--that 46 people handle each
10 petition on its way after it has been written by the CSO
11 before it is published.

12 MR. LEVITT: Thank you very much. Don't worry, we
13 will read the entire set of written comments. Thank you
14 very much.

15 Let us move to our third presenter, Mr. Paul
16 Weller, from the Apple Processors Association, a different
17 element of the food industry.

18 Apple Processors Association

19 MR. WELLER : Thank you, Mr. Levitt.

20 Let me preface my remarks by saying we very much
21 appreciate the opportunity to be here. We appreciate you
22 all putting this forum together, and we appreciate over the
23 years the opportunity to work with the Food and Drug
24 Administration.

25 I am Paul Weller. I am President of the Apple

1 Processors Association. We are a national association of
2 firms that manufacture quality apple products mainly from
3 the whole apple. Our member companies operate as apple
4 grower cooperatives or they grow a portion of the apples
5 processed in their plants. They produce the majority of the
6 nation's applesauce and much of the apple juice and
7 especially apple products in the nation.

8 Our member firms stress quality and safety in
9 their food processing operations. All of our member firms
10 pasteurize their juice products to ensure consumer safety
11 and with hot filter food containers as an added precaution,
12 and we are proud of our adherence to the strictest safety
13 standards.

14 We appreciate this opportunity for several
15 reasons. One is that several of the regulations that are
16 pending before the Food and Drug Administration and your
17 Center at this point give us great concern.

18 We are recommending today that FDA place its
19 priorities in three areas, three areas for regulation and
20 enforcement: Number one, that you focus on valid--and I say
21 "valid"--food safety problems; number two, that You assure
22 that consumers know what they are buying; and, number three,
23 that you adopt a science-based policy to define health
24 claims in labeling, and I would like to very quickly
25 elaborate on each of those three.

1 Number one, focus on valid food safety problems.
2 In cases of illness and death associated with microbial
3 contamination of food, we think that FDA should: one,
4 target the problem; two, find the most effective remedy;
5 and, three, act quickly to implement that remedy.

6 The current proposed HCCIP procedures for the safe
7 and sanitary processing in importing of juice is an
8 excellent example of FDA's failure to target the industry
9 that poses the greatest risk, this industry being the fresh
10 fruit juice processors that do not pasteurize their
11 products.

12 FDA should take immediate action to significantly
13 curtail hazards. Instead, FDA proposes a HCCIP proposal
14 that would require additional costly procedures and record-
15 keeping for the segment of the industry that already spends
16 significant resources to make juices safe through
17 pasteurization, while FDA proposes to exempt those
18 processors that arguably pose the greatest risk to
19 consumers, the small processors that make and sell less than
20 40,000 gallons of juice per year to consumers.

21 These small processors produce the bulk portion of
22 the 2 percent of juice products that are not pasteurized for
23 consumer safety. We understand that this issue was
24 addressed yesterday, and I think Mr. Cady addressed it
25 briefly this morning, as well. We urge that FDA carefully

1 reconsider its proposed regulations in this regard.

2 FDA should require fresh juice processors to use
3 full pasteurization or its equivalent in processing juices
4 for consumer use. Moreover, FDA should define the
5 temperature range and duration of effective pasteurization
6 or similarly effective technologies. Labeling of
7 unpasteurized juices should only be an interim fix until all
8 juice manufacturers adopt effective technologies to kill
9 microbes.

10 FDA has not acted quickly enough to implement a
11 strategy to effectively address the problem. It has been a
12 year and a half since the severe illnesses and death from E.
13 coli 0157 :H7-contaminated juice occurred in the Northwest.
14 It will be another two years before HCCIP will be
15 implemented. Even the interim labeling requirements will
16 not go into effect until the end of this summer, nearly two
17 years since the outbreak.

18 We understand FDA's political pressures. We were
19 part of the initial testimony a year and a half or so ago
20 when the pressures came from the small and from the
21 politicians. We think FDA should act now regardless of
22 these political pressures or concerns. No one--no one
23 should be exempt from sensible food safety measures that are
24 effective in protecting consumers.

25 Number two, assure that consumers know what they

1 are buying. It is FDA's mandate under the Food, Drug, and
2 Cosmetic Act to protect consumers from being misled on food
3 products. FDA should maintain a strict interpretation of
4 this law vis-a-vis food labels. FDA should also take the
5 necessary steps to enforce compliance with this law.

6 When a consumer issue is raised, labels need to be
7 modified and regulated accordingly. FDA's action several
8 years ago to require labeling a percentage of juice in
9 blended juice products is an excellent example of FDA
10 protecting the consumer's interests, and we appreciate that
11 very much.

12 We also commend FDA's actions to ensure that
13 adulterating substances, as in the case of sugar water, in
14 imported juice products, are clearly declared on ingredient
15 labels. When adulterating substances have not been properly
16 declared on labels, FDA has acted properly to remove those
17 products from the marketplace. Again, we appreciate that
18 action very much.

19 When FDA acts quickly and decisively in the public
20 interest, both FDA and private industry gain through
21 increased consumer confidence.

22 Finally, we think FDA should adopt a science-based
23 policy to define health claims in labeling. APA is
24 concerned that not all agency decisions are based on sound
25 science. Health claims must be based on sound science and

1 supported by statements made by federal agencies.

2 FDA should continue to enforce and follow the
3 rules contained in the Nutrition Labeling Education Act, and
4 FDA should be also responsive to scientific consensus and
5 findings of your Dietary Guidelines Committee.

6 In summary, the Apple Processors Association is
7 pleased to work closely with the FDA and pledges its
8 resources and cooperation in establishing and enforcing
9 sound food safety rules and regulations.

10 Thank you.

11 MR. LEVITT: Thank you very much. May I just say
12 with respect to your first set of comments on the juice
13 HCCIP proposal, I trust that you will be submitting separate
14 comments to the docket on that, as I am sure others will.

15 MR. WELLER : We do indeed by the July 8th date.

16 MR. LEVITT : Let me start with a couple of
17 questions. I will start with Mr. Cady since he was the
18 first speaker.

19 HCCIP. A question was asked yesterday, so I will
20 give you a chance to reflect on it also, that in some other
21 countries, I think Europe, that they are adopting more what
22 was called a universal HCCIP.

23 Should we be thinking more in terms of a universal
24 HCCIP, does it help on trade, what are your thoughts on what
25 should be the right scope and applicability of the HCCIP

1 model?

2 MR. CADY : I think that even on the international
3 level, I think HCCIP has to be looked at from a food safety
4 risk perspective, and I think arbitrarily putting HCCIP
5 mandatorily or universally across the board for all food
6 products is not going to utilize the system, the HCCIP
7 system the way it should be, and doesn't allow it to focus
8 on where the risk is.

9 I think it is easy for people to say universal
10 HCCIP or mandatory or across-the-board HCCIP, but the fact
11 of the matter is, is that HCCIP is there in order to look at
12 risk and to identify it and to control it, and there are
13 just plenty of food products where that does not apply.

14 MR. LEVITT: Thank you. Let me ask you a more
15 specific question, having nothing to do with HCCIP, and this
16 is as much for my education as anything. You referenced
17 international, specifically, some issues dealing with
18 Canada. Could you just give a couple of specifics there?

19 MR. CADY: Well, the same product going into
20 Canada, the ingredients have to be changed, the formulation
21 of the product has to be changed, and that of course,
22 obviously, then, we get into the uniformity of labeling
23 between Canada and the United States.

24 It is interesting, as I go around and talk to our
25 member companies, the amount of people who bring up-problems

1 that they are having with Canada versus the rest of the
2 world that they ship to when they are so close.

3 The detail that we have in our written testimony I
4 think goes into that, and if you want us to provide more
5 information and examples, we have plenty of them that we can
6 give you.

7 MR. LEVITT: Those are general labeling issues,
8 not really safety issues?

9 MR. CADY: No, they are general labeling issues
10 and product formulation ingredient issues.

11 MR. LEVITT: Thank you very much.

12 If I could move down the table a little bit, to
13 Mr. Heckman and Mr. Brown, on food contact substances, one
14 of the concerns I have heard within staff at the agency is
15 while the concepts and the model developed is a very good
16 one, there is a concern that it will be such a good one,
17 that a lot of companies will try to utilize it.

18 Do you have any good estimates of what the volume
19 of usage might be with that in place?

20 MR. HECKMAN: The best model we have, the closest
21 thing to it that we know of is the way they do it in Canada,
22 and our experience of course in Canada is better than it is
23 in this country.

24 The Canadians are handling roughly 1,200--well, I
25 was told last week--1,267 requests in 1997. You have got to

1 remember a lot of these will be duplicative. The people
2 have looked at a lot of the things in the total, and will
3 know that they have passed on them recently and they are all
4 okay.

5 They handle 1,267 clearances and responded to them
6 with four and a half--the same as about four and a half
7 full-time equivalents. Now, what they don't have to do,
8 that we do have to do--and that is the biggest part of the
9 problem in our opinion, this is where the kilogram of energy
10 is used--is write regulations, have them reviewed by
11 everybody from here to Parklawn and back two or three times,
12 et cetera, et cetera.

13 They do this by giving it the same kind of
14 scientific review, chemistry, toxicology, and then out, and
15 when you are dealing with proprietary notifications, so that
16 you have all the facts in front of you including the precise
17 intended use, that should make it a lot easier to deal with
18 that issue, and you don't have to write a rule of general
19 application. That can, save a lot of time.

20 We know that many of those petitions are held up,
21 the current food additive petitions are held up. I think
22 Dr. Cheesman spoke at a meeting we had last week, and if I
23 understood him correctly--if I am mischaracterizing him, I
24 will find out and apologize--I think he indicated that a
25 threshold of regulation requests might require 150 days to

1 get out currently, but that doesn't include the time to log
2 it in and to write the letter, and things like that, and
3 that ends up taking eight months to a year.

4 So, we are spending a lot of time writing
5 complicated regulations and threshold responses that
6 probably don't have to be written.

7 Of course, we have been saying that--our problem
8 is that the original sin was committed in 1958, and that
9 original sin needs to be looked at and changed. It was
10 never a good idea to treat both direct and indirect
11 additives in the same way. That was the original sin. It
12 is time for us to rid us of it.

13 MR. LEVITT: A follow-up really, a more food
14 additive question. One thing, as we are talking about
15 priorities, what happens is certain activities do drive our
16 priorities whether we want them to or not. You know, that
17 is going to drive our priorities.

18 Yesterday, we heard a presentation on a coalition
19 of food industry on a user fee program for direct food
20 additives, which NFPA I believe is a part of. If that is
21 enacted, but not this, that will drive priorities.

22 We also heard testimony about GRAS affirmation and
23 how some GRAS affirmation issues, that ought to really be
24 where the priority is.

25 I tried yesterday to get people to rank **these**

1 different things and hopelessly failed. I will try to learn
2 from that experience. But do you see from an industry
3 perspective a way to pull all these together somehow,
4 because if it is becoming a race and one beats the other, it
5 will pull from the other whether it is intended to or not
6 just by the nature of our process and our limitations.

7 so, are there efforts to kind of link all these
8 together, food additives, GRAS affirmations, indirects, in
9 terms of wrap it up in one bow?

10 MR. HECKMAN: I can start if you want. We are
11 aware of the fact that people in the food industry are
12 attempting to find methodology to improve the processing of
13 direct food additive petitions, and we certainly are much in
14 favor of that, like we are in favor of uniformity as they
15 are and many other things.

16 By and large, we are together. I guess the only
17 place we have come apart in the past is on this matter of
18 fees for the service. We favor reasonable fees. We don't
19 favor fees for food additive petitions and probably never
20 will unless you make food additive petitions as simple as
21 indirect food additive notifications, but basically, I think
22 we are in the same place.

23 MR. LEVITT: And the reason for that is just out
24 of curiosity?

25 MR. HECKMAN: On why we don't? Well, we are

1 against food additive petitions per se as far as indirect
2 additives are concerned. As I said, I consider that
3 original sin, so we are certainly not in favor of it. On
4 the other hand, if they want food additive petitions, you
5 know, that is fine. If that is what the people who make
6 direct food additives want, we will not in any way oppose
7 that idea as long as we are not included in it.

8 Now, let me try to weave in the GRAS notification
9 concept. GRAS notification, GRAS affirmation petitions were
10 all extra-statutory. When the law was enacted, there wasn't
11 any provision for GRAS affirmation petitions. That was put
12 in, in 1973 or '74, if I recall correctly, and was an
13 initiative by the General Counsel's Office.

14 The fact that there is no priority put on it means
15 that I have got a couple of them that have been pending for
16 13 years, and there are probably more that maybe have been
17 pending longer.

18 If you put in the GRAS notification procedure, and
19 it works in some effective way, that is just another
20 alternative. There is no reason why, for example, indirect
21 additives could not be the subject of a GRAS notification
22 petition.

23 I don't think that is the right way to go for us,
24 but if you put in the GRAS notification procedure, or you
25 are trying to choose between GRAS notification and food

1 contact substance notification, we can do either one.

2 so, if you are going to prioritize, you might as
3 well, in my opinion, you might as well prioritize and get
4 rid of the 85 percent by putting in the food contact
5 notification. That should help make the GRAS notification
6 procedure work without as much difficulty, and if there is
7 also progress made on the food additive petition concept
8 that at least that alliance has, in due course, maybe there
9 will come a time when we are able to fund on a self-funding
10 basis anything that amounts to safety assurance as
11 distinguished from safety per se. These issues are safety
12 assurance issues.

13 The reason industry wants to have something that
14 shows that the substances it uses are okay is because that
15 increases public confidence or customer confidence. That is
16 a big part of the function they play.

17 MR. CADY: We just want to make a differentiation.
18 I guess I always try to do that between "user fees" for
19 public health inspections which we obviously are against and
20 can't see the benefit of that to the public or industry, but
21 in this particular case, where specific companies are
22 benefiting from this specific process, we firmly believe
23 that there is a way in which we can come up with some type
24 of fee arrangement in order to speed along the process, and
25 we intend to work with the legislature here in Washington to

1 try and figure out how to make that happen.

2 We realize the dollar limitations that are placed
3 on the Center. It is unfortunate how the pie is
4 distributed, so to speak, once the FDA budget is approved
5 regardless of what the total number is. We believe that the
6 Center needs more, a bigger part of the pie, and we are
7 going to continue to try to get that to happen, whether it
8 is through food additive petition fees or whatever.

9 MR. LEVITT: Thank you. I don't want our friend
10 from the Apple Processors Association to feel left out, so I
11 have on question for you, and then we will move down the
12 table.

13 Your second point was to the effect of ensure
14 consumers know what they are buying, and you gave a couple
15 of examples of things that you thought had gone well. Are
16 there specific medium-sized boulders that you think, if you
17 could look ahead a year from now, and say if FDA had done
18 this in that area, I would be really pleased? Are there any
19 specifics, or is that more on general principle?

20 MR. WELLER: Are you talking about labeling?

21 MR. LEVITT: Labeling.

22 MR. WELLER: For many years, Mr. Levitt, we have
23 tried to monitor the food shelves, and have brought to your
24 Center examples of food labeling of food products whose
25 labels do not meet your regulations, and find that FDA has

1 not been able to enforce those particular regulations. It
2 is always that we don't have the staff or we don't have the
3 budget.

4 so, to answer your question, I hope specifically,
5 what we would like to see is that the labeling standards
6 that are there now be enforced, because we think they are
7 good standards. We think that the percent of juice on the
8 front, we think that the nutritional labeling that we helped
9 put together, these are all good points, but we have to
10 monitor and enforce that labeling regulations.

11 If you can do that or come to us and say we need
12 more money from the Hill to do that, maybe we could help
13 you. That is what we would like to see, because we are all
14 for the consumer's right to know.

15 MR. LEVITT: Thank you. Let me move down the
16 table. Dr. Yetley.

17 DR. YETLEY: Thank you. I want to address a
18 question to both John Cady and Paul Weller. Both of you
19 gave us a number of issues in which you would like to see
20 the agency place higher priority or higher emphasis. If we
21 do that, we obviously then have to cut something else out.
22 What would you like us to drop that we are doing now?

23 MR. CADY: I know that we have tried to come up,
24 as Joe did, with numbers 1 to 10. It is always a good way
25 for that to work if it works that way. Unfortunately, my

1 experience in the government prior to coming into this part
2 of the world doesn't allow that to happen because it is a
3 public health center, it is a public health function. You
4 have a tremendous amount of requirements placed on you.

5 I do believe that the efficiency within house,
6 within the organization of this center has not been fully
7 reached yet in terms of not only people, but also in
8 process, and we talked a little bit about that here this
9 morning I think amongst us here.

10 I can't tell you go to give up indirects, I can't
11 tell you to give up whatever somebody else may feel is their
12 major thing in the world, but I can say that if the food
13 center is to be truly the food center, then, there are
14 groups of things that I think can be done on a quicker,
15 faster basis.

16 I think we take too much time. I think once the
17 science is established, I think the process ought to move
18 faster, and I think the whole notice and comment process, as
19 an example, needs to be totally revisited and totally
20 recalled as to who may, who should, and how long a comment
21 can be in order to move this process along.

22 I think we err too much in gathering data and then
23 mulling over the decision. I realize that, as good people
24 who run the center, you work in a Civil Service organization
25 that ultimately is directed, as in any administration, by

1 political appointees, and I think there has been an awful
2 lot of politics that have entered into a tremendous amount
3 of food center decisions, and I think that obviously extends
4 any decision process that is made by people who are trained
5 in science, et cetera, to come up with the right answer
6 based on their experience.

7 MR. WELLER: Dr. Yetley, you have gone in the
8 right direction by setting priorities and targeting your
9 resources to those priorities, and we certainly commend you
10 for that.

11 We think that you can reduce some of your
12 superfluous techniques, for example, if a company processes
13 at 180 or 190 degrees Fahrenheit for three to four minutes,
14 and it kills the microbes, why do we have to follow HCCIP?
15 You are requiring that, and yet all the paperwork that has
16 to go with that HCCIP comes back to you all. So, it seems
17 to us to be superfluous.

18 I think if you look at these priorities and say
19 how can we protect the consumer, how can we protect the
20 public health, let's do one or the other. So, I think you
21 are going in the right direction. Let's just keep it slim
22 and trim.

23 MR. CADY: I think the choices have to be made
24 within the Center as to the definition of safety, and there
25 is a risk basis associated with this. That has to go into

1 your decision process and where you put your emphasis. I
2 think in most cases, we have tried to be so sure in your job
3 to protect the public that that just takes up too much time
4 and too much energy on the part of the limited staff.

5 DR. YETLEY: I just had one other question for
6 Paul Weller. You indicated that the agency should base its
7 labeling decisions on sound science and consult with other
8 federal agencies. Do you have specific examples on where
9 that has failed or has not been the case?

10 MR. WELLER: Where they have not used sound
11 science? There is a lot of politics that have entered into,
12 and I don't know if you want to go back to the whole alar
13 situation, but we in the apple industry have been hit time
14 and time again with some of this unsound science, and found
15 that our best ally, the people sitting across from me, the
16 Food and Drug Administration, have not come up to our
17 defense. It took you 17 days to come to our defense on
18 alar, until our industry was decimated.

19 There is examples of unsound science that are in
20 the media literally every day, if FDA could help us build
21 that case, in other words, use your public information
22 capabilities a little bit better, and let us knock down this
23 unsound science that is out there. There are groups in this
24 town that make a very good living just trying to destroy
25 parts of our industry here on this side of the table, and

1 you are our allies and we need your help.

2 MR. LEVITT: Dr. Falci.

3 DR. FALCI: Two things for Mr. Cady, one, a
4 clarification, and the second, a question. The
5 clarification, you mentioned organizational structure that
6 should be changed, and you mentioned people and process, and
7 I supposed you meant in CFSAN.

8 Were you also talking about organizational
9 structural change in CFSAN, the way the offices are set up?

10 MR. CADY: Yes, I was. I think that that needs to
11 be really looked at in depth. Under the current procedures
12 where you are not filling people who retire, et cetera, I
13 think that keeps pecking away at different things, and I
14 think there should be a way to put people together in teams
15 and to address specific general areas.

16 I also think that the Center needs to come up with
17 what I would call a food safety scheme, food safety
18 management system that encompasses a new way of looking at a
19 lot of different things that I think would help you from a
20 resource perspective and be able to do things on a more
21 efficient and still effective and protective basis.

22 DR. FALCI: And this is outlined in your comments,
23 as well?

24 MR. CADY: It is mentioned in there, but we can
25 detail it more if it is not. There is some ~~direction~~ in

1 there.

2 DR. FALCI: Then, we talked a little bit about
3 HCCIP, and it didn't sound like you were in favor of general
4 HCCIP, you were more in favor of a risk-based HCCIP
5 approach. You can imagine that the agency has taken, and
6 will take in the future, some actions on HCCIP. We have
7 looked at seafood, we are looking at juice. We are probably
8 going to look at other things.

9 Would you like to suggest some commodities where
10 the agency should go and maybe correct our movement in
11 looking at future HCCIP?

12 MR. CADY: I think the industry has commented on
13 that before when we were doing HCCIP, and we have done the
14 HCCIP pilot plants, and we went into great depth on trying
15 to define areas, levels of risks. I am not going to get
16 into products or commodities at this point here, but I would
17 say that the seafood HCCIP program, as an example, is in
18 being now. Nobody ever realized the cost impact on the
19 seafood processor that the HCCIP system has placed on them,
20 which is going to be seen in price rises in the seafood
21 industry.

22 While somebody may define risk in the seafood
23 industry, maybe there is portions of the seafood industry
24 that need to be prioritized versus across the board, and I
25 think that that applies to normal packaged food products.

1 There is hundred of thousands of products in
2 packaged foods that should never even be looked at by this
3 agency because they do not carry any type of a food safety
4 risk. There are some where, for purposes of the consumer,
5 and in your mission they probably need to be looked at, but
6 I don't believe that you can say HCCIP is the silver bullet
7 and it should be applied across the venue of all food
8 products, because that is going to hurt industry, it is
9 going to hurt the FDA someday, and I think it is a total
10 waste of resources that you don't have.

11 DR. FALCI: Thank you.

12 DR. BORSETTI: A topic that has come up, and it
13 has come up over the past two days, yesterday and today, and
14 I guess it was a bit of a surprise to me and I think some of
15 us sitting here on panels that were up here yesterday, and
16 that is the issue of economic adulteration.

17 What I am coming at is the question of priority
18 and how we address this, which in many cases is not a real
19 safety problem, but an economic problem. 'So, my question I
20 guess to John would be, across the industry, if you have any
21 idea, first, what percentage of the industry might be
22 affected by this? I know that is a very difficult question.

23 MR. CADY: You have to look at the product in some
24 cases. I mean Paul is a juice guy, as an example, there is
25 an awful lot of adulteration that goes on in that particular

1 area. His members are a lot of my members, and we talk on
2 these issues jointly, but when you say that it is the
3 consumer's right to get what they are paying for, and it is
4 the industry's right, who puts up with the processes and the
5 regulations and the labeling requirements, to get their due
6 in terms of their competitive position in the marketplace
7 versus somebody who wants to put something out and says it
8 is high in vitamin C, and you find out there is no vitamin C
9 in it, or whatever the case may happen to be, and that
10 exists out there.

11 I would say that 98 percent of the food industry
12 is abiding by the regulations and putting out quality
13 product and identifying it properly on the labels, but there
14 are people out there who do not do that, and they don't do
15 it in juice, is predominate as I said, and there is other
16 product areas, packaged areas, and people know it is not
17 enforced.

18 That makes consumers nervous when they find out
19 about it obviously. It creates animosity from the consumer
20 groups who try to protect the consumer, and it makes
21 industry look bad when 98 percent of the industry is in
22 total compliance.

23 so, I think that is a big area that needs to be
24 looked at also.

25 MR. WELLER: There is a lot of reconstituting of

1 apple juice from concentrate in garages, literally, in
2 garages, in backyards, in our industry, which those of us
3 who crush apples and to make a pure juice, 100 percent juice
4 product, take the brunt of the consequences of that.

5 We find that some of this goes into the private
6 school systems, a lot of these juices right in this area--I
7 won't mention any names--but right in this area that go into
8 the archdiocese of Catholic schools, that are real problems,
9 and so there is a lot of adulteration, especially in the
10 juice area.

11 DR. BORSETTI: For us, it is a tradeoff, because
12 the amount of resources we have got, how do we allocate
13 those resources, but the message is fairly clear, and it
14 keeps coming through to us, and I am trying to understand.

15 MR. CADY: I think this resource issue, if I could
16 just comment on this because I know the constraints that you
17 are under, we don't like it, and I know you like it even
18 less, but it all comes down from the top, and I am going to
19 just say if HHS can't go to bat for the Center, then, you
20 are never going to fix this dilemma that you are talking
21 about in terms of resources.

22 It is one thing to continue to put out political
23 statements about food safety, about things that are needed
24 for the consumer, but if you don't fund it correctly, that
25 is all it is, is hollow statements, and you are ~~where~~ the

1 rubber meets the road, and you can't implement it unless you
2 have the proper people and the proper funding to do it.

3 so, I share your concern, I am not asking for a
4 response because I know that is not your business, but I
5 will tell you that I do not believe that FDA has properly
6 given the Center the resources that it needs to do its job,
7 and it hasn't done so in a long time because they have
8 decided to use it for other priorities.

9 So, our goal from my industry is try to help fix
10 that.

11 MR. LEVITT: Thank you. Let me ask John just one
12 last question. In a way I have already asked the other two
13 this question, which is looking shorter term, if you could
14 look a year from now, and we really got together next year,
15 in July 25th, whatever the date is today, and said a year
16 from now I would like to see these two or three things done,
17 what would they be?

18 MR. CADY: I would like the food additive process
19 fixed, and I would like to have the juice pasteurization
20 issue settled with mandatory pasteurization. Do you want
21 two?

22 MR. LEVITT: That is good. Jerry, I think I know
23 what yours is.

24 MR. HECKMAN: Well, I just wanted to comment on
25 that. We have already submitted proposed regulations for

1 you to consider, We would like you to go forward with that
2 process, and if at the end of the year, we have got new
3 regulations pretty much agreed upon for food contact
4 notification, I think that would be a pretty major
5 achievement and one that would be worthwhile.

6 MR. LEVITT: Thank you for that suggestion. As
7 you know, the system built into it a prerequisite of
8 funding, and one theme I take away from all of this is,
9 while everybody wants their priorities, nobody wants to take
10 it away from anything, and so at some point we need to
11 balance that out.

12 MR. HECKMAN: We think with that system we will be
13 putting back, not taking out, so I hope that will be taken
14 into account.

15 MR. LEVITT: If you get the food additive guys to
16 line up and say I can take away time from their work to do
17 that, then, I will. If I were to have one global kind of
18 reaction, which is at some point--I mean we are talking
19 about funding over years and years, and that's fine and that
20 is important obviously--but at some point, life is a zero
21 sum game, and yes, we will look for efficiencies, but we
22 struggle with the problem of everybody wanting their pebble
23 pushed, everybody wanting their pebble pushed at the
24 requisite speed, and what we are hoping to try to get a
25 sense of is, you know, there is different kinds of -

1 priorities. Sometimes they are based on readiness, is it
2 ready to be done, is it almost done already. Yesterday,
3 people were talking about things that were old.

4 Sometimes it is risk because it is just so urgent
5 as opposed to readiness or just kind of global impact, and
6 so forth, but what people say to me in my center is give me
7 focus , we are spread so thin we know we are not getting the
8 job done we need, we need to get clear direction on this,
9 that, and the other.

10 This meeting I think is giving us some very good
11 input into that.

12 MR. CADY: In conclusion, maybe the agency and the
13 Center need to look at the yard in which all the pebbles lie
14 and decide how big the yard has to be, and maybe the growth
15 that has been put into the Center year after year of
16 requirement and et cetera, maybe it has got to be revisited
17 and maybe you have to look at it.

18 If you want to call it a zero sum game, and you
19 want the focus, maybe in the end it requires a judgment and
20 final decision by the Center and by the agency, and the rest
21 of us are going to have to live with whatever that answer
22 happens to be.

23 I can't give you the 10 top priorities because he
24 has got 10 more, so maybe it is time that the agency and the
25 Center have to make some decisions as to what they -think

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1 they are capable of doing and what their priorities are in
2 terms of carrying out their mission, and the rest of us then
3 have to fall in line.

4 MR. LEVITT: Thank you, and thank you for
5 everybody's participation today.

6 [Applause.]

7 MR. LEVITT: We have taken a quick poll up here on
8 whether we need a short break, and our consensus is, no, we
9 are having a good time, so I think we will just proceed
10 straight to our next panel.

11 We have two health professional organizations, the
12 American Heart Association, the American Dietetic
13 Association, Carole McGeehan Johnson and Tracey Fox.

14 Before we get going, I have been given a note on a
15 couple of questions, common questions people are asking.
16 One is when will the executive summary be available on the
17 web. That is a good question. I think we have talked in
18 terms of a couple of weeks. Let me agree to by July 15th we
19 will have a summary available on the web for that.

20 Second, just to let you know that additional
21 copies of the slides are available at the registration desk
22 on your way out, and I think there is enough that people
23 don't have to rush out to get them now.

24 Let's turn to our next group. Let's start with
25 the American Heart Association. - .

1 Health Professional Organizations

2 American Heart Association

3 MS. JOHNSON: Good morning or I guess it is early
4 afternoon by now, right?

5 MR. LEVITT: You still get the good morning. Your
6 colleague will get to say good afternoon.

7 MS. JOHNSON: I am Carole Johnson, legislative
8 representative for the American Heart Association. I am
9 joining today with Tracey Fox of the American Dietetic
10 Association to present a brief overview of some key issues
11 of interest to our organizations as CFSAN works to set
12 priorities.

13 I support the comments Tracey will offer
14 highlighting dietary supplement issues. My comments will
15 focus particularly on the implementation of the FDA
16 Modernization Act.

17 Over 4.2 million American Heart Association
18 volunteers work each day in communities throughout America
19 to fight America's leading cause of death" - cardiovascular
20 disease. Essential to our mission is the dissemination of
21 scientifically sound nutritional advice to the public. Poor
22 nutrition is among the major modifiable risk factors for
23 heart disease and stroke, as identified by American Heart
24 Association's scientific authorities.

25 We are therefore grateful that the Center has

1 convened this meeting to solicit our views and those of our
2 colleagues in the nutrition community in the priority-
3 setting process for CFSAN.

4 We believe that CFSAN plays a vital role in
5 influencing public understanding and perceptions of a
6 healthful diet. We continue to encourage the agency to make
7 public understanding of the value of a total overall healthy
8 diet rather than a diet of magic bullet foods a priority.

9 The AHA urges Americans to enjoy a diet consisting
10 of a variety of foods, low in fat, low in saturated fatty
11 acids, and low in cholesterol, balanced with regular
12 physical activity. CFSAN public leadership when nutrition
13 is used can help advance this message.

14 While we recognize the breadth of issues on
15 CFSAN'S agenda, including important work in food safety, we
16 want to ensure that proper attention is given to
17 implementing the FDA Modernization Act sections related to
18 health and nutrient content claims.

19 There are many issues on CFSAN'S plate that are of
20 interest to the American Heart Association's Nutrition
21 Committee, and we will attempt to address those in more
22 detail in written comments. However, today, we simply want
23 to emphasize the importance of getting it right with regard
24 to health and nutrient content claims.

25 We applaud the agency's recently issued **guidance**

1 on this issue. We are among many in the nutrition community
2 who encourage the agency to move quickly in response to the
3 Modernization Act to ensure that the consensus developed in
4 the implementation of the NLEA was not endangered.

5 Clearly, we think the agency is correct in its
6 conclusion that authoritative statements used to support
7 health claims must reflect significant scientific agreement.
8 The final regulation ought to continue to reflect this
9 conclusion.

10 However, among the best means of determining when
11 an authoritative statement meets the significant scientific
12 agreement standard is to allow scientists, like those who
13 sit on the AHA Nutrition Committee, and the respective
14 membership of the American Dietetic Association, the
15 opportunity to even be aware that the FDA is even
16 considering a proposed health claim.

17 The FDA must place notifications for health claims
18 in a public docket. The ability of interested parties like
19 us to review the docket and comment to the agency on the
20 scientific validity of the claim may, in fact, help
21 alleviate some of the resource burdens CFSAN is sure to feel
22 as a result of the expedited approval process established by
23 the Act.

24 In fact, in setting priorities, CFSAN must take
25 into account the resources needed to review notifications in

1 the limited time frame defined by the Act. Minus
2 appropriate resources to properly review notifications, FDA
3 may very well be overwhelmed with requests that cannot be
4 properly met.

5 It will then become the task of the American Heart
6 association, the American Dietetic Association, the American
7 Cancer Society, and other prominent health information
8 sources to discern for the public the growing number of
9 claims, some of which may, in fact, be conflicting, that
10 begin to flood their supermarket shelves.

11 This was not Congress' intention and from the
12 interim guidance you have issued, it certainly does not seem
13 to be the agency's intention, and we in the public health
14 community would rather be on the front end of these
15 decisions than on the back end.

16 Therefore, it is of the utmost importance that FDA
17 put their resources in place to protect the integrity of the
18 review process; first, by publicly disclosing the
19 notification filings, and second, by ensuring adequate
20 staffing for thorough review.

21 As I mentioned, we will look more fully at
22 priority areas and attempting to craft written comments. We
23 wanted to be here today, however, to point out the
24 importance of the Nutrition Labeling and Education Act to
25 the American Heart Association's mission of fighting heart

1 disease and stroke, and to emphasize our strong concern that
2 the agency include among its priorities a careful focus on
3 balancing the requirement to expedite health claims review
4 with the importance of ensuring that the public receive
5 accurate and scientifically reliable information about food
6 products.

7 Thank you again for the opportunity to be here.

8 MR. LEVITT: Thank you very much. Please .

9 American Dietetic Association

10 MS. FOX: Good afternoon now, and also I am very
11 glad to hear you are having such a good time up here.

12 Hello. My name is Tracey Fox. I am a registered
13 dietitian and a senior federal regulatory manager with the
14 American Dietetic Association's government affairs office
15 here in Washington.

16 Like AHA and others who have talked before me, we
17 really appreciate having the opportunity to share with FDA
18 our ideas and concerns about areas under the jurisdiction of
19 the Center for Food Safety and Applied Nutrition, and thanks
20 the agency for soliciting our input.

21 ADA is the world's largest organization of food
22 and nutrition professionals with nearly 70,000 members who
23 are dedicated to improving the nutritional health and well-
24 being of Americans.

25 We support the comments made by the **Carole** Johnson

1 of the American Heart Association, which highlighted health
2 and nutrient content claim issues. My comments today here
3 will be focusing on dietary supplements, but our written
4 comments will address a number of areas.

5 Consumer safety should continue to be the top
6 priority at the Center. Direct consumer safety, such as
7 activities related to the President's food safety
8 initiative, clearly deserve and are receiving significant
9 attention at this Center and other federal agencies,
10 however, consumer safety is also a factor in other FDA-
11 related activities.

12 ADA urges FDA to continue and strengthen efforts
13 surrounding dietary supplements. Areas needing specific
14 attention include regulations addressing Good Manufacturing
15 Practices for dietary supplements, as well as critically
16 important labeling issues. Consumers deserve scientifically
17 based information in order to make appropriate and safe
18 choices regarding dietary supplements.

19 Health care professionals need accessible and
20 balanced information about supplements. Over the past
21 several years, we have seen shifts in the health care
22 **setting**, and consumers are seeking medical advice, not from
23 their physicians, but from other health care providers.

24 Registered dietitians, experts in the area of
25 **nutrition-related** sciences are seeing a major significant

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1 .ncrease in clients seeking nutritional advice and expertise
2 n the use of dietary supplements.

3 In order for trained professionals, such as
4 L.D.'s, to provide sound information about the appropriate
5 use of supplements, they must have access to both current
6 and emerging sciences, and there is no efficient and
7 effective system in place today to provide such information.

8 ADA urges FDA to optimize its limited resources
9 and work with others, such as NIH's Office of Dietary
10 Supplements and other NIH entities, to supplement industry
11 and organizations like ADA, American Heart, American Cancer,
12 other professional organizations and associations to develop
13 an effective communication strategy about dietary
14 supplements.

15 Such a strategy must include the need for
16 accessible scientifically-based information for health care
17 professionals and consumers. Only then can we hope to reach
18 a balance among all those parties truly concerned about the
19 health of this nation.

20 FDA specifically asked for information on future
21 research directions. While ADA recognizes the limitations
22 in resources the agency faces, there is a great and growing
23 need for more research in the consumer arena. Specifically,
24 more data is needed regarding consumer perception of
25 labeling information on foods and on dietary supplements.

1 With more and more products in the marketplace,
2 and limited control on what information is placed on the
3 label, good consumer data is essential. Without such data,
4 FDA's limited resources will be even less targeted and
5 potentially wasteful.

6 There has been some interesting research conducted
7 by FDA regarding consumer perception of health and nutrient
8 content claims on the food label. This research clearly
9 points to the need for a more consistent mechanism to gather
10 similar data across the board including consumer perception
11 of nutritional support statements and dietary supplements.

12 ADA recognizes that it should not be the total
13 responsibility of FDA to continually gather data on consumer
14 attitudes and understanding. We therefore recommend that
15 consumer research be a shared responsibility with several
16 entities including FDA, the food and dietary supplement
17 industry, and other organizations.

18 Such efforts must be continuous and results should
19 form the basis for policy enhancements. ADA also urges FDA
20 to look at the issue of consumer research being a required
21 component of substantiation files for dietary supplements.
22 While health care professionals, federal regulators, and
23 industry experts can debate the merits of a
24 structure/function claim or a health or nutrient content
25 claim, the real decision regarding such claims rests with

1 the consumer, and until we know how consumers interpret and
2 understanding information, an effective solution cannot
3 really be reached.

4 Again, ADA's written comments will address a
5 number of the priority areas outlined in the Federal
6 Register notice. Thanks for the opportunity to provide
7 comments today.

8 MR. LEVITT: Thank you. Let me begin with the
9 American Heart Association.

10 In terms of the new health claim notification
11 process and your desire to have input, part of the question,
12 of course, is how much time there is. We know we will find
13 it a struggle to do out work in the 120 days provided. If
14 we get comments from you after 118 days, that is not
15 something that will be useful, and a lot of work for you,
16 that will not be productive either.

17 How much time do you need to provide such input
18 because we have to start figuring out--the system wasn't set
19 up with that in mind, but if that is what you want to do--
20 you don't have to answer now, but roughly what is your
21 capacity for turnaround?

22 MS. JOHNSON: Time is always beneficial to us
23 because our members are volunteers and have full-time jobs,
24 and so we try to get the benefit of their knowledge when we
25 can and when we can convene them, but we can move quickly

1 when we need to.

2 You issued an interim document on the 10th, and we
3 have comments from our Nutrition Committee ready to submit
4 this week on that. So, when we need to, and that is the
5 circumstance, and that is the congressional intention is to
6 move the process more quickly, we will have to adapt, but we
7 would rather adapt at the front end than have the
8 information out there later and try to sort it out for the
9 public .

10 MR. LEVITT: Thank you. A question on dietary
11 supplements . Are there current safety issues out there that
12 you are worried about?

13 MS . FOX : I think there are probably a lot of
14 potential safety concerns that won't be highlighted given
15 the current structure and system until there is a major
16 concern. In terms of specific supplements, I think FDA
17 certainly has moved to address the ephedra issue.

18 We would like to see some more movement on that in
19 terms of finalizing regulations, but in terms of specific
20 nutrient supplements, no, I am not aware of a particular
21 safety issue, but I think the overriding concern is just the
22 multitude of supplements and new products being developed
23 every day.

24 Eventually, there is going to be a problem, and if
25 there isn't a good system in place, like good manufacturing

1 practices that are standard across the board, then, the
2 potential for a problem down the road is huge.

3 MR. LEVITT: Thank you. Dr. Yetley.

4 DR. YETLEY: You mentioned that health
5 professionals want to be more involved, but they sometimes
6 need more heads-up or more information from the agency.

7 Certainly, I think in terms of your associations,
8 you do provide comments on most of the major rules, and we
9 appreciate those, but oftentimes we would like to have more
10 individual comments from individual members of your
11 associations, particularly when they have particular
12 scientific expertise in the topic that is of interest at the
13 time.

14 Do you have any suggestions on how you can or we
15 can work with you to mobilize health professional
16 communities or health professionals as individuals to be
17 more involved in the rulemaking process?

18 MS. FOX: I think certainly from ADA's standpoint,
19 we certainly heartily agree. We clearly 'comment as an
20 association, but also encourage our members to, on their own
21 comment, because we know numbers do sometimes speak volumes,
22 as well as just finding that particular issue that might be
23 addressed by an expert, so we **will continue** to do everything
24 we can to try to encourage our members to get involved in
25 the important regulatory process, which eventually will

1 result in a decision that will impact consumers.

2 I think also just continuing to get information
3 from your office. I have noticed an increase in the amount
4 of information I am getting from your office regarding
5 different issues that are happening regarding food safety or
6 dietary supplements, and I think to continue that flow and
7 to give us as much of a heads-up on those issues will then
8 allow us to notify our members, so they have the time
9 element to be able to provide useful comments to you, but we
10 will continue to work in that area and we will make sure we
11 try to get those who are experts in that area to not only
12 help us in developing our comments, but to individually
13 provide comments, as well.

14 MS. JOHNSON: I may take that back to our
15 scientists your interest in that because what we try to do
16 is develop some consensus, bring the experts to the table
17 ourselves and develop some consensus among them to offer a
18 unified AHA position. So, if you would like individualized
19 comments in addition rather than something like that, we
20 need to look at that.

21 DR. YETLEY: Certainly, I don't want to suggest
22 rather than, but certainly where your members have
23 scientific expertise, it is also useful to hear from them.

24 My second question has to do with a comment I
25 think Tracey made, that health professionals want more

1 reliable information in dietary supplements and other label
2 issues, and also you were interested in having more consumer
3 research.

4 This is a common request or these are common
5 requests that we give, and they really do exceed what we
6 have resources to do, but is there some mechanism that we
7 could implement that would facilitate meeting those goals,
8 whether it is a partnership or whatever, so that we could
9 get more reliable information packets available, and could
10 get more consumer research, well-done consumer research?

11 MS. FOX : I think one of the recommendations or at
12 least an area to look at would be to have some consumer
13 research be part of substantiation for dietary supplements
14 when it comes to structure/function claims because I think
15 that is a very potentially confusing area for consumers, and
16 if there is a way to establish certain criteria, just as
17 perhaps there might be some unwritten guidance or guidance,
18 not regulations, regarding health claims and consumer
19 Perception, that might be one area to look at.

20 There are also a lot of surveys that go on, on a
21 regular basis, and it might be worthwhile to enter into some
22 kind of discussion about some elements to capture on
23 existing surveys that wouldn't require your resources other
24 than some recommendations and guidance on data elements to
25 capture, whether it be--ADA does a survey every two years, I

1 know FMI does a survey, as well--there are existing
2 mechanisms to capture data, which might be beneficial, they
3 happen on a regular basis, and they are consistent and
4 fairly worthwhile in terms of getting consumer perception.

5 DR. FALCI: This is for Ms. Tracey. I was taken a
6 little bit by your comment about trying to get information
7 to the health care professionals and the registered
8 dietitians who are dispensing nutrition information
9 throughout the nation.

10 One of the things we are doing in the food safety
11 initiative is to develop a food **safety.gov**. It is a way of
12 developing a list server, if you like, or an education net
13 is also part of that system, and it is an interactive way of
14 getting information out to, for instance, what I would think
15 could be registered dietitians and have it back and forth.

16 I would like to get your thoughts on that. Do you
17 think by doing something like that, it would reach all of
18 the people and you wouldn't have a problem anymore?

19 MS. FOX: I wish the solution were that simple.
20 That is an excellent first step in terms of communicating.
21 ADA has a list serve that I think has close to 1,000
22 members. Of course, we have 70,000 members, so in terms of
23 that being a large percentage of our association, it is not,
24 but there are a number of mechanisms that I think we could
25 use, that being one of them.

1 I think the Office of Dietary Supplements really
2 needs to be active in this area. They are trying to get
3 some information now and building a database of information
4 that is out there on dietary supplements, but I think
5 between the resources that are being spent now in a number
6 of different areas, that if those resources were pooled with
7 some recommendations from outside organizations on ways that
8 we can help to get the message out, then, I think there
9 might be a fairly cost effective solution, but I think a
10 list serve or some kind of a web page, like the Fightback
11 Campaign, or other food safety areas, might be a very
12 resource-smart mechanism for getting information out, and
13 then it would be up to our offices, in the association role,
14 to make sure our members know of that information, but right
15 now there is really not one place or even just a few places
16 to look.

17 There is a whole lot of information out there, and
18 some of it is good, and some of it isn't.

19 DR. BORSETTI: A couple of questions. In terms of
20 getting information out, the FDA puts out a Medical
21 Bulletin. It goes to health professionals. I assume that
22 you are both aware of that.

23 My question here is do you have any thoughts on
24 how effective that bulletin has been in reaching the health
25 professionals, or is it something that is not **working** very

1 well? That is my first question.

2 MS. FOX: I think perhaps for some of the health
3 care professionals who are in the clinical arena, it is
4 probably fairly effective. For a lot of the other
5 dietitians out there who are either hospital-based or long-
6 term care-based dietitians in nursing homes, dietitians who
7 are in private practice and consulting, it is not. That
8 information is certainly not getting to them at all.

9 Should it all? I am not sure it needs to, but I
10 think there is probably a lot of information that does come
11 out of FDA that a lot more people would be interested in
12 knowing about.

13 DR. BORSETTI: My second question related to a
14 topic that has come up over the past days of accident
15 reporting, and injury reporting I think as Dr. Friedman
16 referred to it yesterday. My question is how could your
17 associations be able to work better with us in this arena if
18 we were to centralize such a system at the agency level?

19 MS. FOX: That is a good question that at this
20 time I am not prepared to answer, but I would certainly be
21 glad to take that back to others and get their ideas on
22 adverse event reporting. We certainly had a lot of
23 discussion with it when we were dealing with the medical
24 foods regulation, so I know there are some people out there
25 with some very specific thoughts on this issue, and- I would

1 be glad to provide that to you in writing.

2 MR. LEVITT: There being no further questions, I
3 would like to thank both of you very much. Again, we are
4 happy to have written submissions for the record.

5 [Applause.]

6 MR. LEVITT: Let us now welcome our final
7 presenter from the Viskase Corporation, Mr. Tom Higgins. If
8 I didn't say that correctly, please correct me.

9 Mr. Higgins, as you are coming up, let me also
10 thank you for your patience. Somebody has to go last. I
11 suppose with a V in your name, maybe you are used to it, but
12 nevertheless, we thank you very much for your patience and
13 sorry you had to wait until the end.

14 Companies

15 Viskase Corporation

16 MR. HIGGINS: Thank you. You did get it correct,
17 it is Viskase Corporation.

18 My name is Tom Higgins, and I am Manager of
19 Regulatory Affairs for Viskase Corporation with headquarters
20 in Chicago. Viskase appreciates and thanks you for the
21 opportunity to comment on program priorities. Viskase will
22 submit written comments.

23 I want to thank you also for your openness, this
24 open meeting and the openness of your staff. Just an
25 example of the openness of your staff, which I hope-would

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1 retinue, is that three weeks ago, Ed Machuga returned a
2 Viskase call within 30 minutes. He took the time to answer
3 a technical question completely including his reasoning. It
4 all made sense to us, and we are still running with his
5 answer. He made us more responsive and more efficient.

6 The phone call had nothing to do with the
7 President's food safety initiative. In fact, when was the
8 last time that food packaging was the cause of food-borne
9 illness or death? I don't think there was a last time, and
10 I think we are still waiting for the first time.

11 Viskase is regulated by the USDA and by the FDA.
12 It follows, then, that there are program areas and
13 activities that are extremely important to Viskase that are
14 outside the President's food safety initiative.

15 In the area of programs, there are two that are
16 important to Viskase - threshold of regulation
17 determinations for food packaging, under the current system
18 can mean millions to our company. Certificates of free
19 sale, 35 percent of Viskase's sales revenue is outside of
20 the United States, comes from outside the United States.
21 Certificates of free sale are essential often for this
22 export business.

23 In the area of activities, I would **class**
24 activities in three types that are crucial to us, and these
25 may seem trivial to you, but the opinion letters that you

1 supply, that currently take 12 months, we would like to see
2 4 months.

3 You have meetings, both these open meetings, and
4 you will have short, face-to-face focused meetings on
5 technical issues with us, and we can get answers to your
6 questions in one to two days to maybe three weeks in that
7 setting.

8 With phone calls, sometimes we can get an answer
9 immediately. Sometimes it is 30 minutes, and sometimes it
10 is a day or two . We appreciate having the choice of these
11 three, what I will call activities to decide what we need
12 from you to answer the questions that we have, and we would
13 encourage you to cut the time for opinion letters.

14 Why is it important that these areas be given
15 attention in your priority settings? Well, Viskase
16 Corporation is a packaging company. We are the world's
17 leading producer of cellulosic food casings. We also make
18 specialty films for meat, poultry, and cheese. Our sales
19 are 1 percent of the total U.S. food packaging sales.

20 To give you one example, Viskase's largest product
21 line is a sausage casing for the hot dog. Sausage casing is
22 about 10 percent of the cost of making a package of hot
23 dogs . In fact, speaking of hot dogs, I would like to show
24 you this ad. This ad, to me, is unbelievable.

25 It appeared in the Chicago suburbs last week, and

1 I call your attention to the upper righthand corner. The
2 price of hot dogs. Hot dogs for 39 cents. Is that 39 cents
3 each? No. This is 39 cents for 12 ounces of franks. That
4 to me is simply incredible.

5 You can't buy 12 ounces of anything for 39 cents,
6 but it is a fact that U.S. hot dog makers are efficient.
7 They produce hot dogs in the U.S., they ship them to China
8 and to Russia where they are sold at a lower price than if
9 they were made by the Chinese and the Russians.

10 Viskase is proud to contribute to the hot dog
11 makers productivity, and you, as regulators, are part of
12 this story, as well. You have, and you must continue to
13 regulate efficiently and well.

14 In your regulation, you have a responsibility to
15 do no gratuitous harm to those that you regulate. By
16 providing rapid answers, by cutting response times, by
17 keeping resources where they must be kept in critical areas,
18 not just for food safety, but for the economic well-being of
19 the United States and for providing **customers** a choice, a
20 choice to buy 12 ounces of franks for 39 cents is something
21 that you really must consider, and if you do your work
22 wisely, the result will continue to be the safest, most
23 abundant, and varied meat and poultry products in the world.

24 Consumers will have more choices, and exports will
25 continue.

1 Thank you.

2 MR. LEVITT: Thank you. What kinds of products
3 does your company make, or what product line to you sell?

4 MR. HIGGINS: We sell cellulosic sausage casings
5 for the meat and poultry industry, the sausage casing that
6 hot dogs are made in is one of those products, the sausage
7 casings for baloney and larger products that you see in the
8 deli case, and these casings are all stripped off before the
9 product is eaten.

10 Those are our products. We make specialty films
11 for the meat and poultry industry primarily, that are used,
12 next of our products, before retail sale, packaging primal
13 cuts of meat, cook-in bags for cooked roast beef. We also
14 make and sell pouches for the retail display of cheese, and
15 the bags that frozen turkeys are in is one of our products.

16 MR. LEVITT : Thank you. Certificates of free
17 sale, what is your experience in turnaround time?

18 MR. HIGGINS: We get them within a month.

19 MR. LEVITT : Is that an okay time for you?

20 MR. HIGGINS: That is an okay time for us, and we
21 would encourage you not to lengthen that time in your
22 allocation of resources, but you will always hear that from
23 someone like me.

24 MR. LEVITT: I think I will ask the others if they
25 questions. Dr. Yetley.

1 DR. YETLEY: I just discovered that I can buy hot
2 dogs for less than I can buy bottled water, so I guess I
3 know where the bargain is now.

4 I appreciate your point about FDA responsiveness,
5 particularly when industry has questions. Certainly in the
6 office that I am in, we have numerous, numerous telephone
7 questions on a daily basis, 50 to 100 a day probably. This
8 becomes a very critical use of staff resources.

9 My question to you is, number one, is there a way
10 to make this more efficient in terms of having information
11 available in other forms, or if not, what should we cut out
12 to take care of the telephone inquiries?

13 MR. HIGGINS: Well, I would submit to you that
14 responding to these telephone requests, although it seems
15 like a drag to you, it avoids problems down the way. It is
16 very similar to consultations that people who might be
17 involved in submitting petitions do up-front.

18 It is not important that we speak to a particular
19 person, but that a person has authority to answer for the
20 agency. For example, Ed Machuga says he gets 60 telephone
21 calls a day, and that to me is overwhelming, I can't imagine
22 being able to respond to that many, so that I could see that
23 you have a problem there, but I would submit that it is also
24 responding to these telephone calls that can avoid
25 additional problems, or not problems, but ~~telephone-calls~~ or

1 meetings in the future.

2 DR. YETLEY: How useful would be a section on the
3 web page that would have commonly asked questions and
4 answers to those commonly asked questions?

5 MR. HIGGINS: I think the more and varied types of
6 communication that you can use, the better, and I don't
7 think any particular one is the answer any more than I think
8 responding to telephone calls is the answer. I think that
9 would be useful, yes.

10 DR. FALCI: Mr. Higgins, I think you just answered
11 my question, but you had mentioned telephone calls, opinion
12 letters, open meetings, and technical meetings, and I was
13 wondering how they rank in priority with you. It sounded
14 like they are all about the same. Was there one that was
15 more valuable than the other?

16 MR. HIGGINS: From an immediate standpoint,
17 telephone calls have to be up there on the top. Open
18 meetings, I know require a lot of your resources to conduct
19 those. I find them to be very educational, and I did attend
20 every session, although sometimes when there wasn't a break,
21 I had to take a few minutes, but I attended the entire
22 sessions and found them to be very informative and very
23 educational .

24 The face-to-face meetings we have used less. So,
25 [would guess I would rank them in that order. -

1 DR. BORSETTI: As complimentary as you have been,
2 I think I am ready to take the rest of the day off. I am
3 used to standing up here and receiving some form of
4 criticism. I appreciate, we all do, your kind comments.

5 Is there anything that we are not doing right that
6 maybe we could do better?

7 MR. HIGGINS: I haven't had a lot of experience
8 with getting caught up in your web of threshold of
9 regulation. We had a submission that we thought was a
10 simple opinion letter, that turned out to be threshold of
11 reg, maybe because the product was so much different than--
12 it was different in the area of what this packaging product
13 had in it in the way of contaminants that it was in the
14 range of threshold of regulation, and we were almost shocked
15 to discover that it was in the threshold of regulation
16 committee, it wouldn't be quite as simple a subject as we
17 thought, and that the time would be extended.

18 I would say the length of time that it takes to
19 get these deliberations done is a shock to me--I shouldn't
20 say a shock--but I am amazed that it requires that much
21 deliberation. If a petition is deficient in some way, we
22 would prefer that you toss it back to us, explaining to use
23 how it is deficient, so that the ball is in our court and we
24 must provide you with something.

25 Maybe it needs a system that allows ~~much more~~ give

1 and take would be able to cut down that total time.

2 MR. LEVITT: With that, let me thank you very much
3 for coming and again for your patience.

4 Let me thank everybody in the audience that has
5 been here with us listening.

6 This will conclude our day and a half of priority-
7 setting meeting. Again, let me thank everybody for
8 participating. Let me thank the staff again who worked hard
9 for putting it together, and we will look forward to seeing
10 additional comments in the public record.

11 [Whereupon, at 12:35 p.m., the meeting was
12 adjourned.]

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CERTIFICATE

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