

te:

mc  
SH

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

GMP MODERNIZATION PUBLIC MEETING

Monday, July 19, 2004  
9:05 a.m.

Harvey W. Wiley Federal Building  
Auditorium  
College Park, Maryland

2004N-0230

MILLER REPORTING CO., INC.  
735 8th STREET, S.E.  
WASHINGTON, D.C. 20003-2802  
(202) 546-6666

TR 1

C O N T E N T S

<u>AGENDA ITEM</u>	<u>PAGE</u>
I. Introduction of Dr. Crawford - Ms. Janice Oliver, Deputy Director, Center for Food Safety and Applied Nutrition	3
II. Opening Remarks - Dr. Lester Crawford, Acting Commissioner of Food and Drugs	4
III. Introduction of Invited Speakers - Dr. Donald Zink	17
IV. Invited Speakers	
- FDA Research Related to Food GMPs, Dr. Richard Williams, CFSAN, FDA	21
- Industry Representative, Mr. William Sanders, VP-Quality, Nestle USA, Inc.	32
- Consumer Representative, Ms. Caroline Smith DeWaal, Center for Science in the Public Interest	40
- State Regulatory Representative, Mr. Joe Corby, Director, Division of Food Inspection, New York State Department of Agriculture & Markets	52
- FDA National Food Expert, Michael Ellison, Office of Regulatory Affairs, FDA	63
V. Question Period	69
VI. Break	77
VII. Small Business Outreach Presentation, Ms. Marie Falcone, Office of Regulatory Affairs, FDA and Dr. Clark Nardinelli, CFSAN, FDA	78 86
VIII. Public Comment Period	91
IX. Summary of Meeting by Moderator - Dr. Zink	132
X. Adjourn	138

P R O C E E D I N G S

MS. OLIVER: Good morning. I'm glad to see that a lot of you were able to make it even though the traffic is quite bad out there. I think we'll have some more people wandering in because we've got a lot of calls that people are stuck in traffic because of the Beltway.

My name is Janice Oliver. I'm Deputy Director of the Center for Food Safety and Applied Nutrition, for those of you who don't know me, and I'm pleased to welcome you all to the first of three public meetings that we're having on the modernization of good manufacturing practices for the food industry. It has been nearly 20 years since the food GMPs were last revised, and during the years since, the food industry has changed quite a bit, and we certainly are much more global than we were before.

As part of an agency-wide examination of good manufacturing practices, Dr. Lester Crawford, who is our Acting Commissioner, asked the Center for Food Safety and Applied Nutrition to examine

the food GMPs and determine what we could do to modernize these regulations. He emphasized the importance of stakeholder involvement, and that's why you're all here today.

The initiative is very important to the Center. It's also very important to Dr. Crawford. And as you all know, Dr. Crawford has played a major role in food safety in both the domestic and international arenas. He previously was Chair of the Department of Physiology and Pharmacology at the University of Georgia. He was Administrator for the Food Safety and Inspection Service at USDA. He was Deputy Commissioner of FDA. He was also Director of the Center for Veterinary Medicine. And from 1997 to 2002, he was Director of the Center for Food and Nutrition Policy at Georgetown University and at Virginia Tech where it moved in 2001.

I think nobody better could introduce this meeting and provide the tone for the meeting than Dr. Lester Crawford.

DR. CRAWFORD: Thank you very much,

Janice. It's a pleasure for me to be here.

When I was Acting Commissioner before, we began to have some major court cases and regulatory difficulties with the drug GMPs. And I remember when I first came in, in February of 2002, going over the briefs for those cases and trying to figure out what it is that we could do to improve that situation so that the drug GMPs were more effectively linked to the real public health problems.

An idea dawned on me, and that is that we would go through this comprehensive review, with a view towards modernizing the GMPs on the drug side. Then in the middle of trying to figure out where we would get the resources to do that with, it crossed my mind that we ought to do the same thing for the food GMPs. So I checked with Joe Levitt and Janice Oliver, as we were finalizing the drug initiative, and found out that they hadn't been modernized in some time either.

The reason they need to be modernized is not so much in my view that they're out of date.

It has to do with the fact that there is new instrumentation, new formulas, new models, much greater science, as they people to my right know far better than me, in terms of quality and safety assurance, that we might advantage by going forward with a review.

I also remembered another Commissioner, Jere Goyan, in 1981 determining that he wanted as a last event in his commissionership, which had been, unfortunately, brief because of the change in political parties, he wanted to modernize the food GMPs. And so he put together a small committee consisting of me and Sandy Miller, who is a legend in his own time, and will continue to be a legend after his own time. We were the committee to modernize, and we were given three weeks to do it before the inauguration of a new President and, therefore, a new Commissioner. And Dr. Miller never showed up for the meeting, so it was basically me. And I didn't get through on time. But in going back through those papers when I was asked--I wanted all the records in the

Commissioner's office that could be retrieved with respect to food GMPs. I found that in April of 1981 that Commissioner Goyan actually signed the report modernizing the GMPs. Well, he had been out of office then for three months, so I'm not sure how that happened. He must have sneaked back in the night and signed it.

[Laughter.]

DR. CRAWFORD: But it was like three pages' worth of modernizations, not nearly what we're thinking about here.

The food GMPs are off the ground, but I would report to you also on the progress on the drug side because I think both sides can learn something from each other. In fact, I am convinced of that.

The drug GMPs got started in August of 2002, and they're issuing a report the day after Labor Day of this year, after going through what was predicted to be a two-year process. And so proposed rules will come out for a variety of areas with respect to the drug GMPs. They presage to

some extent what we're considering doing here now, and I think there will be like three proposed rules for people to comment on and to learn from, I hope, and I hope we learn from them. And we hope to finalize those very quickly, sometime early next year, and those will be the first modernization of the drug GMPs since they started that actually result in a change in regulations.

So I think that will be a major development, and I congratulate the chairman of that committee, who is Janet Woodcock. And I also congratulate Don Zink for getting this show off the ground, and I understand there are going to be three of these meetings across the country. And I look forward to the results.

I also have to thank all of you for being here that are not necessarily with FDA. I thank the FDA people also. But we need stakeholder input. I know probably a little bit more about food GMPs than I do the drug GMPs, but I know in the drug GMPs, the expertise came to a great extent from the industry. As soon as we made the

announcement in August of 2002, we began getting calls, usually from vice presidents of quality assurance and safety assurance of various drug companies. Three of these people that eventually served as consultant members of the committees were persons who had previously served at FDA, like Greg Guyer, who is now vice president for quality assurance at Merck, who knew the GMPs, for drugs at least, from the inside of FDA and also from having spent now about eight years in industry in charge overall of that for a major pharmaceutical company. Those people, who once they had become cleared and could do this kind of thing, have been a great help in doing this, and we'll trot all them out in September for the commemoration ceremony.

Now, let me just talk about a few significant things. Our agency--and, in particular, the Center for Food Safety and Applied Nutrition; to a lesser extent, the Center for Veterinary medicine--regulates 80 percent of the food supply. We, therefore, must take a close look at how well the GMPs still ensure the safety and

wholesomeness of what we eat. We've conducted three studies focused on the types of hazards associated with the current manufacturing and processing practices and on the available controls to prevent these risks.

One of these studies reviewed the extensive scientific and technical literature on the issue. A second paper summarized views we had solicited from experts with extensive knowledge and experience in this area. And the third survey examined the food product recalls in the United States from 1999 to 2002.

I think this gives you an indication of how fundamentally deep and science-based we want this operation to be.

Let me give you the highlights of the survey. This included 842 recalls, 51 percent of which were Class I. As all of you in this room know, Class I recalls are hazards that can cause death or serious injury. And the rest were Class II, whose health consequences are reversible or temporary. The most striking finding, to me at

least, of this inquiry was that 715 of the recalls, 85 percent of the total, probably occurred due to GMP-related shortcomings.

Now, we know that on the drug side it's at least this much, probably a little bit more, virtually all of the regulatory actions we take, except for fraud and misleading claims, are related to GMP problems. And the court cases that result in fines are actually closer to 100 percent on both sides. So in terms of the real interchange with industry that turns out to be both disruptive, in some cases corrective, but, nonetheless, things that all of us would like to avoid, have to do with GMPs. This is the nexus between the regulatory agency that serves you and the industry itself. And this is what we're trying to make sure we're doing as well as we can possibly do.

We know that these kinds of interchanges are very often not going to be particularly pleasant, but we want them to be productive. Whatever action we take, we want there to be a useful public health outcome, and we also want the

connection between public health and the GMPs to be clear, unalloyed, and easily understood.

The results of these surveys and the information gathered in two other surveys make clear that we need updating. Now, what kind of changes and what do we want to accomplish at these meetings? There are two goals.

The first one is we want to explore the best, potentially most effective science-based measures and approaches that would help manufacturers reduce the likelihood of producing foods that can be injurious to consumers. Without ignoring the problems involving labeling, we want to primarily address the most serious risk of contamination with chemical, microbiological, or physical impurities.

In dealing with these issues, we will be careful to distinguish between practices that may directly impair food safety and those whose effects are likely to be marginal. Our guiding principles will be reliance on science-based systems that are guided by evidence both regarding problems and

their effective solutions. The outcome we seek is a set of targeted requirements that will enable manufacturers to focus their resources on strengthening the safety of their products.

Our corollary goal--and I want to emphasize this--is to elicit your ideas on just what should be changed in the GMPs and how.

Now, previously, in these remarks there was a sentence which said, "even if the GMPs need to be changed." I think virtually all of us agree that they would need to be changed after this amount of time. But the extent, the categories, and how is what we really need from you.

We'll be drawing on appropriate literature and on the experience of food technologists, microbiologists, and industry professionals, but extensive, thoughtful input from this group is very much solicited.

As a general background, I want to add also that updating the food GMPs is only one facet of a broad modernization process we've recently initiated with a similar reform of the

pharmaceutical GMPs.

Now, another major innovation we've recently launched is the development of standards and methods that would enable drug sponsors to better estimate whether their medications will qualify for marketing. This is an enormously important issue in drug manufacture where only 8 percent of new compounds eventually achieve FDA approval. This has been halving every few years over the last 12 years, even though we've tried everything we can to make the drug approval process both predictable and understandable. I have to say at this point that it's clear that we have failed.

Even as early as seven years ago, 13 percent of products that were patented eventually got FDA approval, and now it's down to 8 percent and going to decline by as much as half again if we don't soon get going.

Now, if you're a venture capitalist organization, then when you see this, you certainly would want to take your capital and flee the pharmaceutical industry. And that's what's

happening worldwide. That's an aside to this, but what we're doing with food GMPs is no less important. It just may not be quite as dramatic.

Now, in closing, let me welcome you again to this meeting. I wish you the very best, and be assured that my office and Bob Brackett's office and everything else that you can think of in FDA is fully and completely committed to this. We think this is the essence of public health. We know that FDA is a public health regulatory agency, and everything we ought to do ought to be directly linked to the improvement of public health and the prevention of disease. And if that is not clear about the GMPs or any part of the GMPs, then these ought to be reformed completely, maybe being reformed out of existence, because there is no way we succeed in the courts or in other forums that we get involved with with respect to enforcement and understanding of what regulatory actions we're trying to do unless there is this clear, understandable link.

So that's what we're trying to do here,

and you are people, without exception, that can help very much with that movement. As we moved in the other two meetings and then as we moved then to set a final game plan for getting this accomplished within as little time as possible but yet to thoroughly do the job, we will certainly need your input. And remember that with FDA, as with other federal agencies, your input is considered very, very carefully. And if you file a comment, it will be addressed. So whatever you ask for, you should be prepared to accept and also to up in lights somewhere.

So let's go about this seriously. The intentions, I can tell you, are honest, straightforward, and loyal to the American way of life. I know that because I'm the one that got all this started. And you might say, well, how come you picked on this kind of thing? And every Commissioner or Acting Commissioner has some sort of legacy. It always is something you don't plan. It's usually when you stole money or filled out something wrong or something like that. But if you

do have some sort of theme or plan, then maybe you can create something that won't be negative.

But I've thought about the GMPs; since the food GMPs hadn't been reformed in a quarter of a century and the drug GMPs hadn't been reformed in about 65 years, if you had a legacy, this would be an enduring one because probably no one will ever reform them again.

[Laughter.]

DR. CRAWFORD: So here we are. Congratulations to all of you for winning the traffic battle and being here, and thank you, Janice, for the introduction. Thanks to all of you for being at the table.

[Applause.]

DR. ZINK: I thank everybody again for coming, and thank you, Dr. Crawford, for getting us off to a good start.

I first have just a few housekeeping items. Restrooms are located in the hallway at the top of the stairs leading to the auditorium. We also have restrooms here at the bottom of the

stairs, if you go out this door and turn left. You have to be aware of some drainage hoses. We occasionally have a few flooding problems here. But both those doors have access.

When asking questions during the public comment period, please come to the microphone and clearly state your name and your affiliation. We're transcribing the meeting, and we want to be sure we correctly identify all of the commenters.

As pertains to questions, we're going to have some speakers start the meeting off, and I'd ask you to hold your questions until the last speaker. They'll return to the table here, and then we'll allow a period of time for any questions that you may wish to ask any of the speakers. We'll have people stationed with microphones in these little alcove areas here. If you'll just come down and take the microphone and ask your question from there, that I think will facilitate things moving smoothly.

I want to comment a little bit about what we mean when we use the phrase "good manufacturing

practices" or "GMPs." We're speaking in the broadest possible sense. GMPs certainly refer to the current GMPs in 21 CFR 110, but we're trying to think beyond that. One of the phrases that has come into use around the building here recently is "universal preventive controls." By "universal," we are thinking of the types of controls that are broadly applied across the entire food industry that we regulate. And by "preventive controls," that's really what we mean by GMPs. GMPs are what we intend to--the types of controls that a manufacturer should have that prevent adulteration of the product, prevent contamination with harmful microorganisms or toxic chemicals or foreign materials. We want you to think in this broadest possible sense.

What we're seeking is the current state of the art for preventive controls and how we can incorporate that into a meaningful regulation.

Finally, we don't come to this meeting with some preconceived regulatory agenda. Believe it or not, we don't have in our back pocket some

draft rule written. Obviously, we do have some idea of the kinds of things that we might use to modernize GMPs, but we genuinely do want to encourage some meaningful input and some fresh ideas. This really is a chance for stakeholders to become involved in developing the regulation, and we want the broadest possible participation from our stakeholders.

With that, I'm going to introduce our first speaker. Dr. Richard Williams joined the FDA in 1980 after getting a Ph.D. in economics from Virginia Tech. He's the Director of our Division of Market Studies in the Center for Food Safety and Applied Nutrition. Now, this division includes economists, statisticians, epidemiologists, physicians, psychologists, sociologists, nutritionists--basically all the people we don't want in any other division.

[Laughter.]

DR. ZINK: And his staff is responsible for diverse research, including consumer research related to First Amendment issues, estimating

benefits and risks and costs of regulations affecting food safety, labeling, and biosecurity, and they support, of course, our regulations development and enforcement actions. He's been responsible for the analysis of impacts of regulations implementing the Nutrition Labeling and Education Act. He's been involved in negotiating the U.S. position under the U.S.-Canada Free Trade Act, and he's currently responsible for developing a series of courses in risk analysis for food management as part of our relationship with JIFSAN.

Dr. Williams? Let me see if I can get your presentation up here.

DR. WILLIAMS: Good morning. This morning I'm going to talk to you about our research program that undergirds our GMP modernization effort. And as you see from the title, we are taking a broader look, as Don mentioned. We're really looking at this as preventive controls, which would include GMPs. I want to emphasize that this research is ongoing, and I'll talk a little bit about that in a few minutes.

So we always start by asking ourselves: What is the question that we as researchers are asked to answer? In this case, it is: What are the significant hazards associated with FDA-regulated food that can be addressed by preventive controls? And what are the most effective controls for preventing those hazards? And as Dr. Crawford mentioned, we are looking at the three major types of hazards that CFSAN regulates: microbial hazards, such as pathogenic bacteria and viruses; chemical hazards, allergens and cleaners; and physical hazards, such as glass and metal. And we are looking--I'm going to address most of my talk to the controls that we've looked at, and we're looking for things with demonstrated efficacy that are clearly not overly expensive.

So the types of evidence that we thought we would need for this mission really fall into two major camps. The first is: What are those things that are happening now as a result of problems in the food industry, current problems that are caused

by the absence of effective controls? And those are the things that we can see right now that lead to some of the outbreaks.

For example, there might be things that are happening because our good manufacturing practices aren't being followed. In addition, there may be practices that people ought to be following that we haven't capture in the good manufacturing practices. And either one of those things could cause an outbreak, for example, of foodborne disease.

In addition to that, we're also concerned that there may be--by just focusing on current problems we might miss something. There may be things that manufacturers are doing right now, either because they're in our GMPs or they're not in our GMPs, that if we fail to capture and carry on into our modernization efforts, we might see some resurgence of problems that are not happening now. So we're really looking for effective controls in both camps, those things that are causing problems now and those things that might

cause problems if we fail to capture them.

Now, I would say the second one is certainly sort of the more theoretical of the two. As Dr. Crawford mentioned, we are doing--we have ongoing research right now, and we have three studies that have been started right now, and I'm going to give you sort of a brief overview of what the findings are. And, again, these are addressing the current problems, things that are actually happening. And they are the literature search, an expert elicitation, a recall study, and finally, we regard all stakeholder input also as research, and we take into account everything that everybody says.

Let me just say that the three studies--the literature studies, expert elicitation, and recall study--we hope to have up on our Web in about a week or so. They won't be the final studies. The final studies should come around the end of September, but they will be--all of the significant findings should be up there. Again, I'm just going to give you a very brief

overview of those this morning.

Okay. In addition, I mentioned that we are concerned about making sure that we capture practices today that are effective. We are going to be starting sometime in the fall or the winter a survey of all of the existing practices of good manufacturing practices in the industry. And, again, we'll also be looking for stakeholder input. What are people doing right now that is effective?

Okay. Let me go right to the literature survey findings. This was done for us by a contractor, and, interestingly, three-quarters of the articles that were found in the literature address microbial hazards. About 25 percent address physical hazards, and very, very few address chemical hazards.

The number one and two findings, I would say, are: one, poor work hygiene was one of the leading problems that, at least in the literature, was found. The other thing--and this cuts across all three studies. We found this over and over again. Training was mentioned over and over again

and some of the barriers to training. Language barriers were huge. In my own county, in Fairfax County, there was a recent article that said we spoke 120 different languages in the retail institutions in Fairfax County. I'm sure it's even worse across the country for manufacturing plants.

There was a lot of discussion of whether or not you needed generic food safety training or specific training, plant training. And training was needed for hygiene, cleaning, pest control, and preventive maintenance.

I guess looking at these two things, too, I would say that in all three studies we sort of found two different types of good manufacturing practices were discussed. One would be sort of the direct kinds of good manufacturing practices that directly affect food safety, like such things as cleaning and hand washing. The others would be more like catalysts, things that made those practices happen, and those would be like training and enforcement.

Okay. Other things that our literature

survey found: contamination of raw ingredients, both at reception and in-plant contamination was discussed frequently in the literature. A very large literature has seemed to grow around allergens, allergen contamination by raw materials, a lot of articles on residues not being removed because of poor practices or insufficient frequency; and label review policy was something that struck us, that many plants did not have label review policies for allergens. And, finally, and sort of the more long-term problems, a lot of discussion about plant design, some plants weren't well designed to take care of food safety, and equipment design where some equipment was very difficult to clean because of niches in the equipment.

The second study that we did was an expert elicitation, and an expert elicitation is essentially a way of bringing together experts and trying to get answers to the same questions from all of the experts. This type of analysis was actually started in World War II and has been

adapted by risk analysis and we used it. We have--and we are just now in the process of completing it--four rounds of interviews with 17 national food safety experts. And by food safety, we have food technologists, we have microbiologists, and a number of other types of people. And their job was to identify the most important risks and the most important preventive controls for the overall food industry and also by sector. And I'll just give you a quick look at some of the top findings by the experts.

Again, notice that training is up there. In this case, the experts felt that the training was needed not just for employees but also for managers and suppliers, which we thought was interesting. They also addressed the fact that recordkeeping for standard operating procedures was a necessary requirement, they thought. They believed that cleaning should be validated. They suggested that we have periodic audits of facilities and raw materials, that we sanitation SOPs, and environmental sampling. We needed more

emphasis on preventive maintenance programs. Again, I'll mention label review and verification. I mentioned that respect with respect to allergens in the literature survey. And, finally, interestingly, they said somehow we need to create incentives for firms in order to do some of these things. Again, this is sort of a mix of direct controls and catalysts, if you will.

The third study we're doing is being done in-house by our epidemiologists, and in this study we reviewed Class I and Class II recall records from 1999 to 2002. I have actually a larger number here than the Commissioner noted, but that's because we have to work on weekends.

[Laughter.]

DR. WILLIAMS: So it's growing.

We are not quite finished, but as the Commissioner mentioned, 87 percent of the recalls were due to GMPs or labeling; 65 percent of those were incorrect packaging or labeling. Again, we see employee training, and note here these things were somewhat difficult to get at. We looked at

the recalls, and we had to actually go through them, and we had Don Zink and other of our CFSAN food safety experts try to get to the root causes of what was causing these recalls, and that's really what we're reporting here.

Ineffective employee training was the third. About a quarter of them, the standard operating procedures for processing actually failed. And smaller--10 percent were contamination of raw materials; 10 percent excess or mistaken addition of chemicals; and, finally, 8 percent ineffective use of sanitation principles. So that's just a big overview.

Okay. This is not all of the research that we planned to do. We do need other data and analysis, and we'll be working on this throughout this process. We will be taking some of the information that I've just mentioned and use it in a benefit/cost analysis where we will try to look at the benefits and costs of different regulatory options. We will be gathering other data as well. I think the survey that we're doing of

manufacturing plants on good manufacturing practices will fit right into that.

We also are going to need to gather information--and this will be mentioned later on by Dr. Nardinelli--to assess whether there are different provisions that are needed to address small businesses.

And, finally, we are looking for stakeholder input for any information that can help make these new rules easy to follow and effective.

And I will turn it over to Dr. Zink.

DR. ZINK: Our next speaker, to give us a perspective from the food industry, is William Sanders. I've known Bill for a long, long time. I guess you have been in the food industry 35-plus years. He's another one of these guys that can't hold a job very long, so he's worked for a number of firms: Nabisco, New Zealand Milk Processors. He's currently Vice President of Quality for Nestle. If you see a really large grin on his face, it's because he's retiring at the end of this month.

Bill was, as I said, one of the experts involved in our research on expert elicitation, and I can tell you, from having worked with him for about ten years myself, that GMPs are one of his passions. And he's somewhat legendary in the industry in his audit style for going through a plant.

I can tell you that at least one company, when Bill comes to audit the plant, it's a day they long prepare for.

He has been in hundreds of food manufacturing plants over many decades and has seen it all.

So with that, I am going to bring Bill up here and let him talk to you about his perspective on good manufacturing practices.

MR. SANDERS: I'm going to put a disclaimer up. I think that will do it. And the only other disclaimer that I think I need to put up here is a labeling piece. Yesterday I had peanuts on the plane.

[Laughter.]

MR. SANDERS: But I have been in the industry 30-plus years, and this is a passion of mine because if you're a quality professional in the food industry, this has got to be a passion of yours because you will deal with it every day of your life, one way or the other. There are very few days in my career that I didn't deal with GMPs, and many days, most days, that I dealt with them almost exclusively all day.

In my opinion, GMPs should equal common sense for the food industry. I would hate to see them get too scientific. I believe they need to be scientifically backed. They need to be scientifically studied. But the way they need to be published is they are our Bible out there, and they are known worldwide. And in factories worldwide, you can talk about GMPs and people understand reasonably well.

The problem then is they don't meet equal--I'm sorry. Gosh, I thought my voice--I thought they'd be able to hear me in Virginia.

[Laughter.]

MR. SANDERS: Okay. They do not equal common sense in many places and in many segments of the business.

I think that the GMPs--and, by the way, it's not often that I get to sit down and read the GMPs Part 110. I will refer to them. I will take pieces out. I have all my career. But just to sit down and read them, and this gave me an opportunity. They're well written. It's a lot of good information in there.

I do believe modernization is warranted, and in response to the Question 9 that came out on this, as far as how we should deal with different segments of the food industry, I would hate to see the GMPs diluted or watered down. Maybe we could deal with specific segments in some other format or some subset, but the GMPs are kind of our Bible out there in industry, and I would hate to see them diluted or watered down.

Some suggestions I have: I would say one in every three failures is management failure, if not higher, where management does not recognize the

importance of the GMP, does not allocate the proper capital; there are misinterpretations. But I think training is probably the key right now. And I would say cascade training. We better start at the top of the food industry and the food chain and cascade it down because there needs to be appreciation for this common sense and common language throughout.

Pest management is throughout in several locations of the GMPs, I noticed, but I would recommend an integrated pest management. That is a huge part of our problem, and if you get good pest management in a food factory, you will be good at food safety, because many times the same type of logic that applies to pest management also applies to microbiological controls and so on.

Allergen control needs to be talked about. Obviously that was not in the GMPs and was not a problem at that time, or at least not a recognized problem. And I would look at separation and cleaning as pieces to be reviewed.

Labeling verification--and, by the way, we

didn't collaborate on this. These are thoughts after 30 years, and having done my own recalls at times--and I have studied recalls, but the ones I've had to work with more closely, label verification certainly could help.

Cleaning of operations needs to be stressed. The food industry right now is under a lot of economic pressure, and it has been for years, and it continues to be. And as that economic pressure is applied, one of the areas we have to watch is to make sure the operations know how to clean or we get smarter in how to clean and do it better.

CIP validation. I have inspected factories around the world, and everywhere I go, CIPs are in place. They've spent the money in place, but they're not working properly and effectively. We really need to look at CIP validation: how to inspect a CIP, how to train on them; adequate facilities for cleaning out a place; written SSOPs I believe in.

Bioterrorism issues are not included, and

you can argue, well, traceability should be in, shouldn't be in. But this one I think we've found that control, particularly around critical food safety issues, CCPs as in HACCP, we need to make sure that people know what they're doing.

Zoning principles for microbiological control have been a major help, and recently we have worked on one particular problem in the food industry, and I was absolutely surprised that by better zoning and better work within those zones and controls, we were able to significantly reduce by a log the amount of problems we had in the area.

Now I'm going to talk about HACCP, and I know this is not a HACCP program. But it is a good program, and it is a good food safety program. But the GMPs have to work in harmony with HACCP. And I think they have to be a prerequisite program. And I don't see a problem with mentioning HACCP in there, but the prerequisite program, if you look at the recalls, they're more failures of the prerequisite programs than they are the HACCP or the CCP.

This has been an area--everybody I've met in the food industry is an expert on HACCP. I've never met anybody in the food industry who's not an expert on HACCP.

[Laughter.]

MR. SANDERS: They're all experts. But yet we're still arguing over what a CCP is. So it's very complicated. I'd hate to see us get the GMPs that way. We've got to be careful. We need to make sure that HACCP is focused and GMPs are focused on food safety.

I recently had an experience where an agent came into a factory and said, "You must have a CCP on this line." But there was no reason to have a CCP on that line. There was no valid reason to have a CCP on that line. So he was more interested in having the system in place than was it related to food safety. And we need to just keep it focused. I won't spend any more time on that.

This is, I believe, important. We need to modernize them. We need to be careful from the

industry standpoint as we modernize because these things are right now heavily recognized. They are followed. We need to do a better job. I will tell you, I have not--I cannot go into a factory that I will not find GMP violations. And it's the degree of violation as you go into a factory that concerns you. But it is a common language. You go anywhere in the world, and you talk to most of the manufacturing people, and they know exactly what a GMP is. So we just need to keep that clear.

Thank you.

[Applause.]

DR. ZINK: Thank you very much.

Our next speaker is Caroline Smith DeWaal. Caroline is director of the food safety program for the Center for Science in the Public Interest and co-author of "Is Our Food Safe: A Consumer's Guide to Protecting Your Health and the Environment." She represents CSPI in Congress and in the regulatory arena on such issues as meat and poultry safety, seafood safety, food additives, pesticides, and sustainable agriculture and animal drugs. She

is a leading consumer analyst on reform of laws and regulations governing food safety, and since 1999, she has maintained and annually published a listing of foodborne illness outbreaks organized by Food Source that now contains over ten years of outbreak reports. She has presented CSPI's outbreak database at numerous scientific conferences.

Prior to coming to CSPI, Ms. DeWaal was director of legal affairs for Public Voice for Food and Health Policy, where she spearheaded Public Voice's lobbying effort on seafood safety in Congress, at the FDA, and in the media. Ms. DeWaal graduated from the University of Vermont and the Antioch School of Law. She's a member of the Massachusetts bar.

MS. SMITH DeWAAL: I apologize for being a few minutes late. I was on the wrong side of an accident on the Beltway. It wasn't involving my car, but it's not where you want to be.

CSPI, for those of you who are unfamiliar, we represent about 900,000 consumer members. We're funded entirely by consumers and a small portion

from foundations. No money from industry, government, or even labor unions, I believe. And we certainly appreciate the opportunity to talk about good manufacturing practices.

I'm going to start with what we bring to the table, which is the outbreak database that CSPI has been maintaining since about 1997. We've been published it since 1999. We recently got our latest listing up on our website at [www.cspinet.org](http://www.cspinet.org). But basically we have a line listing of 3,500 food poisoning outbreaks, and we are the only source where they are organized by food. As you can see, a lot of FDA foods are included. In addition, there are many, many multi-ingredient food outbreaks.

Now, the difficulty with outbreak data generally is subject to reporting variabilities from the states, but also we can't always tell whether some of these hazards may have occurred in the retail portion of the equation or in the processor. But it is the best data we have available.

mc

Actually, I want to go back. I commend FDA for taking up the challenge of updating the good manufacturing practices. We urge you to do it well, but also to do it quickly. It has been several decades--25 years--since these regulations were adopted, and an updated approach is long overdue, not only because of the far greater diversity of manufactured food products today, but also due to the new potential hazards, such as bioterrorist threats to food.

The current manufacturing practices are general regulations that apply to all foods. They have many strengths that should be retained during this revision. For example, the section addressing the health of personnel is highly relevant today, in order to protect against hazards such as hepatitis A and Norwalk-like viruses. Daily assessment of employee health, cleanliness, and hand washing is a critical responsibility of the management and should be accompanied with multilingual training to ensure that individual employees understand the importance of these

requirements in protecting themselves and their customers.

In other areas as well, revised GMP regulations should require companies to develop written internal quality assurance/quality control programs that clearly state management's approach to fulfilling its food safety functions. Structural independence between the quality assurance and production departments of an establishment is essential. For example, it should be unacceptable for the QC personnel to be hired or fired by a production supervisor.

Revised GMP regulations should also incorporate enhanced enforcement systems, including progressive enforcement and criteria to rank the significance of violations. Additionally, it should adopt mandatory notification and traceback procedures for contaminated food and a program of comprehensive, periodic audits by qualified personnel free of conflicts of interest.

In addition to retaining and strengthening general requirements such as these, we recommend

that risk-based regulations for preventing specific hazards should be added to the general requirements applicable to all foods. For example, FDA should consider specifying refrigeration the panels or shelf life for foods that support the growth of specific foodborne pathogens, such as *Salmonella* or *Listeria monocytogenes*. Scientific understanding of the conditions affecting the growth rates of these common foodborne pathogens has progressed significantly in the past 20 years, and this greater knowledge should be incorporated in the revised GMPs.

Devices are now available that indicate if a package of food has been subjected to temperatures above a certain threshold. In addition to giving retailers an additional method to detect products that have been subject to temperature abuse, consumers would also be able to use the devices up to the time of their final use. And FDA should consider mandating these devices for refrigerated food products or those that have a shelf life that could be shortened with significant

temperature abuse.

More specificity is also needed in the area of sanitary operations. The current GMPs provide that food contact surfaces and utensils shall be cleaned as "frequently as necessary" to protect against food contamination. Improved knowledge about how *Listeria* and other hazards survive in the processing environment should be used to strengthen the sanitation sections of the GMPs.

Regarding all three categories of food contamination--microbial, chemical, and physical--GMPs should require HACCP-like procedures for the identification of hazards and interventions to control these hazards. Manufacturing operations should be required not only to manufacture their products--and I'm quoting from 110 now--"under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of food" but also to document these controls.

You have strong standards in the existing

GMPs. What's missing is the recordkeeping component.

In addition, the concept that process controls must be verified through a routine sampling program should be integrated wherever relevant throughout the regulations.

To help ensure that preventive controls are carried out, we endorse the use of all of these measures in the GMPs. This is what was included actually in the notice for this meeting, and we support all of these. I just wanted to get that on the record.

The current--but let me tell you what you're missing. The current GMPs largely exclude the area of harvesting and transportation, and we urge the agency to consider both of these additional areas. The recent hepatitis A outbreak linked to green onions clearly demonstrates that conditions at the harvesting level can greatly impact the safety of certain food products, especially produce and seafood. Today, consumers expect improved protection for hazards that are

foreseeable, even in raw ingredients. In addition, the successful introduction of food safety controls in USDA's organic regulations shows that motivated farmers can successfully control many agricultural inputs, such as manure, that are linked to food poisoning outbreaks. In fact, with the implementation of the manure requirements for organic produce, organic may surpass traditional varieties of produce in microbial safety. As food safety controls stretch from farm to fork, it makes sense to expand GMPs to include greater controls on the incoming ingredients, including harvesting conditions in the case of foods with minimal treatment or processing.

Additional transportation GMPs should be incorporated into the revised GMPs or considered as a separate document. These should include specific temperature requirements for transportation and storage, restrictions on back hauling to avoid cross-contamination, sanitation requirements, and basic inventory controls. And I don't need to remind this audience of the number of very large

outbreaks that have been linked to hazards that they believed were introduced in the truck, Schwann's ice cream being one of the largest. But there are also juice outbreaks and a number of other outbreaks that were linked to transportation problems.

The GMPs should apply to all entities--including both transporters and warehouses--that handle food items in transit between registered processing establishments--which FDA now has because all establishments have to be registered--and where the source of the material is also--and also where the material is going.

Safe temperature requirements should also be set for transportation of different food categories, and vehicles should be encouraged to carry recording thermometers that can accurately measure and record temperature within the vehicle compartments. And these devices are commonly used today, but they should be required as part of the GMPs, and the tracking devices should be monitored by the processors when they receive the food.

We also recommend that they address the issue of cross-contamination, specifically the use of mixed loads of trucks, including meat, poultry, or seafood, together with vegetables. Also, the whole issue of back hauling should be reviewed by FDA during this process.

I am down to my final recommendation. Our final recommendation is that revised GMPs must more formally integrate the concepts of product traceability, which is especially important for product recalls today, and ensure the agency access to production and distribution records. For example, inventory controls that identify the time and place of harvest or processing would greatly aid in product identification in the event of a recall and would additionally help to ensure that older food products are not mixed in with newer ones or otherwise languish for long periods of time in a vehicle or warehouse.

Product traceability and recordkeeping were both mandated as part of the Bioterrorism Act of 2002 and are included--or we anticipate will be

included in regulations that FDA will be implementing in the next year or so. Whether considering these issues in light of bioterrorism concerns or in order to manage existing food product recall and outbreak situations, ensuring traceability and agency access to distribution records are critical public health protections.

Thank you.

[Applause.]

DR. ZINK: Our next speaker is Joe Corby, and Joe is a guy who can hold a job. He has spent his entire career with the New York State Department of Ag and Markets, the Division of Food Safety and Inspection.

After receiving his environmental health degree in 1970, he became a food inspector with the department in the Syracuse, New York, area, and he was over the years promoted up the chain to senior food inspector, supervising inspector, director of field operations, assistant director, and finally director in 1999. And his service with the department includes the development of numerous

food safety and training programs for regulators in the industry, the design of the division's HACCP-based inspection protocol, and authoring the state's smoked fish regulations. He was nominated four consecutive years for the Governor's Productivity Award.

He is a commissioned officer, FDA-commissioned officer, and Cornell University certified instructor for human resources development, and he served as a faculty adviser for food processing and technology at the State University of New York, Morrisville. He's a member of Cornell University's Institute of Food Science Advisory Council and a frequent speaker at Food and Drug Administration's State Training Branch's seafood safety, vacuum packaging, and retail and food protection courses.

Joe has been a member and associated with the Association of Food and Drug Officials since 1985, and he was the chairperson for the Food Committee, where he spearheaded the development of model codes, food processing guidelines, training

programs, and AFDO's Food Code Pocket Guide and official AFDO responses to national food issues.

I think very notably, too, he has been awarded AFDO's Distinguished Service Award in 1995 and 2000, became president of AFDO in 1998, and he has received the prestigious Harvey Wiley Award on June 19th of 2001, the namesake of this building.

Joe?

MR. CORBY: Thank you. It is true that the only job I've ever had has been as a regulator with New York State. I do consider myself fortunate that I have seen an awful lot of different types of food processing, and as Bill said, there really hasn't been a day that has gone by that I have not been impacted in some way--is that better? So there have probably been no days that have gone by that I have not in some way been impacted by the GMPs. And I'm pleased to be here today to comment for FDA on behalf of New York Agriculture and Markets.

My agency, my state, just like many other states, have been privileged to work very closely

with FDA on many food safety issues throughout the years. Together, we've formed partnerships together. We share resource. We share intelligence. We share information. We continue a tradition for addressing public health matters in an integrated fashion.

In New York, we currently are modeling an integrated food safety partnership where we pretty much share everything with the New York FDA District. And it goes beyond inspection and investigation. It includes recalls, it includes working on imported foods, and also doing some work on food allergens.

In our efforts with FDA, we oftentimes rely on the strengths, the tools, and the authorities which we both have. And, furthermore, we are guided in all of our efforts through a regulatory foundation of rule, much of which can be found in Part 110. This regulation as it is written and crafted can be broadly interpreted by regulatory agencies, and we view that as something that is very, very favorable that it can be

interpreted very broadly. We find that to be a very true strength of the regulation.

As a result of this, we have a history in New York State associated with the interpretation of these GMPs, particular in Section 110.80 as it relates to processes and controls. This section allowed us to require food plant--requires that food plants take all reasonable precautions to assure manufacturing practices do not contribute to contamination. When, in our opinion, there is an absence of reasonable precaution, we are able to take enforcement actions against food plants until compliance can be obtained.

Additionally, Section 110.80(b)(2), which requires manufacturing, packaging, and storage to be conducted under controlled conditions, has permitted New York Ag and Markets to take appropriate intervention steps when and where we believe these controlled conditions do not exist and the health of consumers may be impacted.

To be specific, this section allowed us to prohibit the processing of uneviscerated fish in

New York State following several botulism outbreaks which occurred in the late 1980s and early 1990s and prior to us promulgating new regulations that specifically prohibited that type of processing.

This section also allowed us to require the refrigeration of shell eggs following a large number of salmonellosis outbreaks that were associated with those products in the Northeast. And, again, we were able to do that until we were able to promulgate specific regulations to require that.

But perhaps most importantly to us, this particular section of the GMPs allowed us to require food manufacturers to obtain from a recognized food processing authority a scheduled process prior to a manufacturer of any food product which may have food safety risks associated with it. These scheduled food processes are filed for food manufacturers or small entrepreneurs, and they identify critical control points within the manufacturing process; they identify monitoring methods, labeling requirements, and records that

should be kept by the manufacturer.

As we believe HACCP is systematic and should be employed in all food manufacturing, we will routinely rely on Section 110.80 to allow us to require HACCP concepts through a scheduled process in food plants where HACCP plan requirements are not mandated. I'll give you some examples of this:

Tomato sauce manufacturers, they are not acidified food manufacturers, but because of the GMPs, we can require them to pasteurize the product and to do pH testing on the product. And from a food safety perspective, I can't think of anything more important for them to do than to check the pH of those products. If it's a product that may contain a food allergen, we can require them to make sure that the label is labeled properly. And from a food safety perspective, I can't think of anything more important for them to do.

We have certain products that are vacuum-packaged, such as tofu, that are manufactured in New York. While there may not have

been any botulism outbreaks associated with that product, we know the risk is there. And so we are able to require them to employ certain HACCP concepts to make sure that that product is manufactured safely. We do it also with condiments. We do it with dressings, and also with some fermented, dried, and semi-dried sausages.

Food safety is always evolving as a result of emerging pathogens, because of new control technologies, and challenges that are created from a globally influenced economy. Additionally, many new issues and concerns, such as food allergens, remind us of how critically important sanitation, labeling, and proper manufacturing practices in food plants are. We believe Part 110 must also evolve, and updating this regulation is very appropriate, in our view, and we would like to offer the following specific recommendations:

As Part 110 is a regulation and not a guideline, we believe any requirements within this document must be mandated in the context of a "shall" and not through a "should." This, in our

view, would have a much greater impact on strengthening this regulation and creating better uniformity between state and federal regulatory agencies.

Two, the GMPs serve as a prerequisite foundation for HACCP systems. We know that HACCP cannot work well without manufacturing firms following GMPs. We would like to see the GMPs evolve from a quality control system to more of a public health strategy and intervention program. Frankly, much of what we find weak in Part 110 is it's focused in certain areas on quality issues rather than food safety issues.

And as an example, number three, definitions for batter, blanching, and quality control operations are specific examples of this, and they seem somewhat outdated and out of place to us. Whereas definitions of ready-to-eat foods, HACCP plans, food allergens, sanitation standards operating procedures, SSOPs, would to us seem a more modernized food safety focus and appropriate for this regulation.

Fourth, food plants that manufacture or handle high-risk foods, in our opinion, should be required to meet a higher standard. For those identified as posing the high risk of *Listeria monocytogenes*, for example, we believe an action plan to effectively control or minimize the potential for this pathogen contaminating finished product should be developed and implemented by them. We have experienced some success with the use of these action plans with our smoked fish industry in New York State.

Number five, FDA should not be reluctant to require food safety competency and food safety training for select personnel in food plants, particularly where high-risk foods are handled and where food plants seem unable to gain compliance. To do otherwise, in our view, is inconsistent when compared to certain other food establishment types. There is precedent with this with low-acid canned foods, with acidified foods, and even with retail food establishments. Please understand that education has become a major enforcement mechanism

for state agencies to utilize, and we have had some great success by employing education rather than penalties, injunctions, or license revocations.

Number six, bare-hand contact of ready-to-eat foods, in our view, should not just be a retail food issue and should be addressed in Part 110.

Incidentally, in New York State, we apply 110 not only with food manufacturers, but also with retail food establishments. To us, they're all food processors, and we do apply bare-hand contact not only at retail but at wholesale manufacturers.

Number seven, Section 110.21 identified specific requirements for outdoor bulk fermentation vessels, but the section does not address the more high-risk matters such as indoor precautions for ready-to-eat foods. Again, this is an area we believe is in dire need of being updated.

And, number eight, Section 110.33 outlined equipment cleaning and sanitation requirements for low-moisture food and wet processing, but nothing for allergen cross-contamination concern.

We believe that updating Part 110 is really a great opportunity for FDA to finally address food allergens in the food industry. Some of the surveillance that we have done with our manufacturing plants and with our retail stores indicates that this truly needs to be done.

Most states have adopted Part 110, in part or in whole. Clearly, it is one regulation that is uniformly supported and employed. We believe FDA's desire to update this regulation is commendable and appropriate. Quite frankly, it is that important of a document to state food safety regulatory agencies, and we recognize updating it will fundamentally change very much of what we do.

And I thank you for the opportunity to present these comments.

[Applause.]

DR. ZINK: I'd like to introduce our next speaker, Mike Ellison. Mike is from the FDA. He's one of our national food experts from the Office of Regulatory Affairs out of the Salisbury, Maryland, resident post. Mr. Ellison started his career with

FDA in the Kansas City District in 1972. In 1973, he transferred to Omaha, Nebraska, resident post, and in 1978, he was selected as the resident in charge of the Salisbury, Maryland, resident post.

He joined the International Investigations Cadre in 1986. In 1989, he was selected as one of three FDA investigators to receive long-term training in low-acid canned foods, and following that training, he was promoted to the position of regional LACF specialist and later to national LACF expert. He's a recognized agency expert in LACF and HACCP, and he has been involved in numerous FDA national training courses, including basic LACF, advanced LACF, food microbiology, HACCP and orientation to international inspections. He's the principal author of a number of FDA's investigators' guides to inspectors, including the guides on LACF, acidified foods, computerized systems used in the food industry, and aseptic processing of foods.

He's a member of the Institute for Thermal Processing Specialists and serves as a co-chairman

of the Committee on Temperature Distribution. He is also a member of the Association of Food and Drug Officials and a professional member of the IFT.

Mike?

MR. ELLISON: Good morning. I'm glad to have the opportunity to speak to you this morning concerning the good manufacturing practices, and as a representative of FDA's Office of Regulatory Affairs, Division of Field Investigations, I'm going to speak from the perspective of the food regulator.

Our Division of Field Investigations has tried to put together these comments, so it's not only my comments, but we tried to think as an organization of some changes we'd like to see in the regulations and why we need to make some of those changes.

Now, good sanitation is mandatory for all foods. We're all aware of that. And Section 402(a)(4) of the Food, Drug and Cosmetic Act deems food to be adulterated if processed under

unsanitary conditions. The current good manufacturing practice regulations, 21 CFR Part 110, articulate the kinds of conditions and practices that need to be followed in order to avoid producing an adulterated product.

Nevertheless, while FDA has been enforcing the sanitation standards for years, it has not completely succeeded in developing a culture throughout the food industry where processors assume an operative role in controlling sanitation in their plants.

The statistics relating to the incidence of insanitation cited in the preamble to the seafood HACCP regulation and observations from USDA's HACCP rules for beef and poultry clearly demonstrate that such a culture was not in place in 1995. And, further, the requirement of standard sanitation operating procedures, sanitation monitoring, and recordkeeping in the more recent juice HACCP regulation further highlights the significant need to motivate a portion of the industry to comply with sanitation requirements.

As previously mentioned by Dr. Richard Williams, an FDA/CFSAN/Division of Market Studies examination of food recalls from 1999 to 2002 found that a majority of the food recalls were related to good manufacturing practice problems. Some of those good manufacturing practice issues outlined in the study were: incorrect labeling, which in most cases related to allergens; ineffective training of employees; product cross-contamination; lack of routine maintenance of equipment; poor equipment and plant design; lack of temperature control; and ineffective employee hygiene.

Now, all of these things except allergens are addressed in the current good manufacturing practice regulations, but evidently we need to address them in a different way with a different emphasis to make sure that everyone understands what they need to do.

Although the number of food recalls relating to sanitation seems high, it makes sense, as FDA's own database shows, that the top 30 food inspection observations relate exactly to these

types of current good manufacturing practice deficiencies.

Now, every time we see one of these deficiencies, it doesn't necessarily mean that the product is adulterated. But when they occur over and over and over again, it can lead to adulteration, and sooner or later that's generally what happens.

Taking a look at the current good manufacturing practice regulations is long overdue. FDA, consumers, and the regulated food industry, and other interested parties need to take the time to evaluate these regulations and make suggestions for revisions. If successful, these revisions would help FDA assure that firms take full responsibility for sanitation in their plants, which, of course, relates to the production of safe and wholesome food.

Revision of the current regulations should attempt to strengthen the current regulations in the following ways, and I'm going to mention a few of the things that we as good regulators think need

to be changed, and most of these things have already been mentioned by one or the other speakers.

We need to require some specific daily sanitation regimes that incorporate features such as monitoring, corrective actions, and recordkeeping to help the processor track sanitation in their plants. Statistics from the seafood HACCP program as it relates to sanitation have shown that this type of requirement has helped with compliance. In 1998, the percent of firms that had adequate sanitation controls, including good manufacturing practice sanitation and recordkeeping, was 21 percent in the seafood industry, and in 2003, it had come up to 54 percent. That is a 100-percent improvement in five years, and this statistic continues to improve.

We need to include some additional definitions for terms used in the food industry. An example would be the term "pasteurization" where the definition varies depending upon the application.

People talk about pasteurization. Most people will think of pasteurization of milk products and the specific times and temperatures for different milk products. But pasteurization is also used in the industry for treating vegetable products, for treating seafood, and further applications, and it is not always heat that is used for pasteurization of products. In today's world, we have other processes which are now being used.

We need to require specific records for verification activities such as the calibration of monitoring equipment to ensure that accurate instruments are used to measure and control process parameters.

We need to have documented validation for equipment design, process establishment, and process delivery to ensure that the process is designed and delivered to control or eliminate the specific targeted hazard.

We need to address more stringently the training requirements for food plant operators as

well as employees and documentation of that training to ensure that the food plant operators and employees understand their responsibilities for producing safe food products.

We need to define allergens and require monitoring and recordkeeping to ensure that products are properly labeled.

And, finally, we need to require each food processor to determine hazards that are associated with their product and manufacturing process and control those hazards throughout the process.

That is just a few. Today, the purpose of the meeting is to elicit responses from you for other suggestions to help FDA foster a culture of and a commitment to good manufacturing practices that may well have been lacking in a significant portion of the food industry.

I thank you for your time.

[Applause.]

DR. ZINK: What I'd like to do now is open it up for a question-and-answer period. If there are those in the audience who would like to ask

questions of our speakers, then if you would come forward, we'll get a microphone into your hand. And, again, please identify yourself and your affiliation, and we'll give you--let's say we'll have up to 15 minutes here for questions if we need it.

Don't everybody come forward at once.

MR. SHIRE: Good morning. My name is Bernie Shire. I'm with the American Association of Meat Processors. And the question I have, I'm well aware how the current 21 CFR Part 110 affects people in that industry. For anybody who would like to answer this, how would these new regulations affect food manufacturers that operate under the stringent USDA regulations?

DR. ZINK: Our regulations would not apply to a USDA-regulated establishment. They would apply only to those FDA-regulated industries.

MR. SHIRE: Okay. So, in other words, establishments that would have, say--and some of our members are regulated by both agencies. Then it would apply to the ones that have FDA

regulations.

DR. ZINK: That's correct.

MR. SHIRE: Thank you.

MS. WILKEN: My name is Edith Wilken. I'm with Leprino Foods. The gentleman talked about verification, recordkeeping on calibrations. Could you elaborate on that, please?

DR. ZINK: Are you talking about the last speaker?

MS. WILKEN: Yes, the gentleman from the Office of Regulatory Affairs.

DR. ZINK: Okay.

MR. ELLISON: I'll give you an example. There are requirements in the regulations to use accurate instruments to monitor food operations. So if you're using something like a thermometer to monitor temperature, then there should be some assurance that the monitor is accurate. There is no requirement in the regulations that there's any record made of any check of that thermometer to assure that it is accurate. So that kind of puts the firm and the regulator both in a spot where you

have to check the thermometer while the regulator is in the firm. If the thermometer is accurate, then you can--you only can then assume that it has always been accurate. If it's not accurate, then you have no way of knowing when was the last time it was accurate. And that puts the firm in a bad spot because then they have to assume that all their food is suspect back to the time that it was last checked for accuracy, which may have been when they brought it brand new.

So most of the pertinent firms, most of the firms that use good manufacturing practices, they do have those records, although there's a large number of firms out there that do not have that type of record.

MR. SAYLER: Allen Sayler with the International Dairy Foods Association. Thank you. I think this is excellent information. Two questions, and certainly to anybody that may want to address it.

Number one, different industries have in themselves done a lot of work with GMPs and got the

industry up to speed. Is there ever going to be any effort or outreach to try and incorporate some of those programs or learn about them and maybe gain from them as you develop these?

And, second--well, let me stop there. We'll get that question first.

DR. ZINK: I think what we're looking for is universality here. So, yes, I think we would like to incorporate any new learnings or state-of-the-art types of controls that have been developed by industry for segments of the industry to the extent that they can be broadly applicable.

For example, if there is a control that's identified that's very, very specific to the chocolate industry, that might not be something we'd incorporate into a modernized 110. But if it's a control which can be crafted in a way that it relates more broadly to the food industry and would be helpful, then we would.

And I would encourage you to submit written comments detailing those specific sorts of controls or include, you know, a copy of industry

GMPs to us so that we can have a look at it.

MR. SAYLER: Thank you, Don. That almost answered my second question, and that is, would you see, as you develop this in more detail, things where you might be more specific to certain industries or, I think as Caroline had said, where there's high-risk plants versus maybe lower-risk foods? Would there be some differentiation or is there no thought of that at this time?

Thank you.

DR. ZINK: That's one that, amazingly, hadn't popped into our head, and that's an interesting idea that we would make some differentiation between higher-risk and lower-risk types of processes and the controls applied to them. I think that is intriguing and something we need to consider further.

A question here?

MS. VITALE: Good morning. Thank you for your recommendations. My name is Linda Vitale. I work for Ross Products Division, Abbott Laboratories.

I am involved in the infant formula GMPs in terms of at our company, and also the dietary supplement GMPs that are also on the forefront. My question is: Is your committee or are the people working on food GMPs working in combination with those other committees or people for the other GMPs? Or are they totally separate?

DR. ZINK: They're different working groups, but we are certainly aware of the implications that one might have for the other. And we are communicating with one another. I think it's likely that the dietary supplements GMPs would be out before the food GMPs are. But other than that, Janice, do you have anything to--no. Okay.

MR. PEARCE: Good morning, and thank you. This has been very informative. My name is Bill Pearce. I'm with Proprietary Processing Associates, Pacific Rim Crab. I'm the importer-exporter. We also produce in this country and out of this country. Of course, in a political year, it's always very hard to say something about exporting jobs, but in essence, my question evolves

around that is that, yes, these regulations are needed, I highly recommend them, and as an industry manufacturer, we look forward to new regulations to be assured that they are going to assist us in providing our customer the best product.

My question to you is: When are we going to enforce them overseas? When are we going to take this beautiful race car that the FDA has developed and painted it beautiful and now put gas in it and enforce it? Because one of the problems that we're having right now is if a manufacturing factory can't meet these guidelines and is not doing a very good job, what do they do next? They move overseas because they know they're not going to be inspected there. I do international audits all over the world six months a year, write HACCP plans for these people. They are trying, but there is no enforcement at all.

So what I'm asking is--and we just had a recent disaster out of Venezuela just two weeks ago, where a couple of order came in on a fresh product with a seven-day shelf life, and it took so

long to get the product inspected that the whole crop for a whole month from Venezuela was wasted, totally wasted, because there wasn't enough staff in Miami to run the tests and inspect the product.

Our industry as importers are requesting and inviting inspection to assure that this country gets the best product.

DR. ZINK: I think that's one of the things that occurred to us, is now that we've become more global, how well do our trading partners globally understand our regulations? Do they, for example, understand what we mean by Part 110?

You know, we're mindful of the need to craft regulations that will be more clearly understood by our trading partners and can be implemented by our trading partners.

Any more questions?

[No response.]

DR. ZINK: Very well. If we have no more questions, I'm sure everybody could use about, let's say, a ten-minute break. That won't let you

wander very far, but we'll get back together here at 15 minutes before the hour.

[Recess.]

DR. ZINK: I'd like to introduce Marie Falcone. Maria is with FDA, Office of Regulatory Affairs. She's the regional small business representative for the FDA's 15-state Central Region. Before that, for five years she ran the FDA's Southwest Region Industry Outreach Program, which was headquartered in Dallas, Texas, and she draws on her career knowledge and experience as an FDA investigator and investigations supervisor to assist those regulated by FDA in understanding and, therefore, complying with FDA requirements.

Ms. Falcone has received several FDA Commendable Service Awards and the FDA Award of Merit for Leadership in promoting FDA's mission.

Marie?

MS. FALCONE: Thank you, Don. I'm very happy to be here, and there's a distinct advantage to being among the last to speak because I got to hear all the other speakers and time to compare

what I was going to say with what they said about the advantages and disadvantages of the current GMP so as to modify my remarks.

I did some research of my own during the break. I looked around to see how many people has picked up the small business brochure. And I'd like a little help in that research. For those of you who represent small businesses, could you give an indication so I can see the representation here? A few. I'm very glad you're here. I think it's important for small businesses to have a say in the review and recreation of this GMP.

The FDA regional small business representatives assist entrepreneurs, consultants, owners, operators, and employees to understand FDA requirements. We answer questions. We provide guidance and explain the intricacies of dealing with the FDA. When new regulations issue, we contribute to the general FDA effort to explain them, and we make referrals to other FDA offices for those inquiries which require more technical expertise and so smooth the regulatory process for

the small business.

About 40 percent of my inquiries come from food firms, and many of these questions range from the general to the very specific. Some are addressed by 21 CFR 110, the current GMP for good manufacturing practice for manufacturing, packaging, or holding human food. And I'd like to give you an example of some of them.

Entrepreneurs ask if they can manufacture in the home. They ask if shelf-life studies must be done, whether an expiration date or use-by date must be on the food package. They ask for standards and test methods, how often and how much to clean their equipment, and how to assure that suppliers provide compliant ingredients in packaging.

They ask how they can select safe food-contact surfaces. Concerns range from tamper-evident packaging to employee health certificates. They ask when they will be inspected and what records must be kept and whether the records have to show lot numbers. They ask what

acceptable chlorine limits are in sprout washes and what kind of processing is needed for bottled iced tea or salsa.

They want to know whether food manufacturing equipment must have installation, operation, and performance qualifications. They ask how GMPs apply to commercial kitchens used by a variety of small manufacturers, and whether a specific cleaning compound is acceptable on a food-contact surface.

While the current GMP was written in general terms so it remains a flexible standard as technology changes, the generality of its language at times creates more questions or the need for more investigation and research to locate information required in order to comply. Small businesses in particular may not have the time or money to perform this research.

For example, 21 CFR 110.40, Equipment and Utensils, mandates that the design, construction, and use of equipment and utensils shall preclude adulteration of food. It also states that they

shall be made of non-toxic material.

21 CFR 110.80 states that appropriate quality control operations shall be employed to ensure that food packaging materials are safe and suit. The indirect additive regulations and the FDA food contact notification website exists, but together do not provide a usable, well-organized listing or reference for small business to select materials with confidence that are compliant with FDA requirements and do not present a health hazard.

Think of all the food products in the past 20 years that are now packaged in plastics, polymers of some kind or another, from cheese to highly acidic juice drinks and many other products, some microwaveable and some not.

In my 12 years of dealing with the concerns of small businesses, my impression is that they could benefit from a review of 110, as well as how FDA organizes and presents information needed to comply with the generalities of 110, to the goal of developing a more accessible, specific,

understandable, and integrated system of requirements and supporting information. FDA is capable of doing this and has taken steps to meet specific needs of the regulated community for information in a variety of arenas. The steps taken have resulted in smoothing the pathway to compliance while eliminating the need for redundant research from business to business. And I'd like to give a couple of examples of that in the many arenas that FDA regulates.

First, in the food arena, 21 CFR 110.110, immediately following the food GMP, addresses defect action levels or those low levels of natural or unavoidable food defects that are not hazardous to health. And the food code itself for retail food service sanitation contains in some areas much more specificity than the GMP.

The Center for Drug Evaluation and Research's post-approval changes program was enhanced by creation by a trade association called ISPE of an equivalent equipment list which was adopted by FDA. The list facilitates meeting FDA

requirements regarding equipment changes by drug manufacturers.

The Center for Devices and Radiological Health recognized a series of standards by non-FDA organizations which device developers can select from when developing data and tests to show that their products work. They also integrated the 21 CFR 803 and 804 medical device reporting requirement into the 820 quality system regulation by specifying under complaint handling that manufacturers must make a determination whether a medical device report should be filed according to those regulations. And the cosmetic regulations incorporate by reference the Cosmetic, Toiletry, and Fragrance Association dictionary that provides cosmetic manufacturers a list of official ingredient names that meet FDA ingredient naming requirements.

So FDA has many examples and has taken many steps in other areas that help to unify and integrate the approach to regulation that makes it easier for businesses to find out what they need to

do.

I've heard so often from small businesses that they want to comply. They just want to know what to do. But the FDA needs to hear more from small businesses directly about how the current GMP affects their ability to comply and what the FDA might do to clarify its regulatory requirements and integrate them with practical information that facilitates compliance.

We small business representatives have worked in cooperation with the Center for Food Safety and Applied Nutrition, particularly Peter Bardon, who is sitting here in the audience, to make small food firms aware of this public discussion and to invite them to participate in this process. And I believe the next speaker is going to elaborate more on how small businesses and everyone can participate.

Thank you.

[Applause.]

DR. ZINK: Thank you, Marie.

Our next speaker, as Marie said, is going

to talk about how small businesses can comment. But I want to say, having only recently joined the FDA and having had an opportunity to look at comments submitted on other regulations from both large firms and small firms, I think everybody could get a good lesson in how to comment to FDA and make your comments as impactful and useful as possible.

Our next speaker, Dr. Clark Nardinelli, has been with FDA since 1995. He's an economist and serves as a team leader for economics within the agency. He has worked on cost/benefit and small business effects for CFSAN regulations, which included foods, dietary supplements, infant formula, and others. Prior to joining FDA, he taught economics at Tulane, University of Virginia, Clemson, and University of Maryland.

Clark?

DR. NARDINELLI: I'm here to tell you a little bit about how to comment. As Don said, we particularly want to give this advice to small businesses but, of course, much of this applies for

any comments submitted to the agency.

Two laws require FDA to ask for comments from small businesses and to consider small business concerns in developing policies and regulations. These are the Regulatory Flexibility Act of 1980 and the Small Business Regulatory Enforcement Fairness Act of 1996, commonly called SBREFA.

These laws are intended to give small businesses more influence over the development of regulations, create additional compliance assistance, and new mechanisms for addressing enforcement actions by federal agencies. And something else that I think is very important and needs to be emphasized is that the laws require agencies to consider different regulatory requirements for small businesses. So we are asked to look at the possibility that perhaps the regulations could be tailored so that the requirements for small businesses differ from those of large businesses.

Now, in submitting comments to the agency,

there are some questions that you might want to consider answering or addressing in your comments. The first is: Is there a need for a requirement or a provision? What will you have to do to comply with the requirement? And I'll say a little bit about that in a moment. Do you think that a provision or requirement will accomplish the stated goals? So, for example, with the modernization of food GMPs, our goals are fewer recalls and illnesses associated with microbiological, physical, and chemical hazards in foods. And are there other ways to accomplish these goals?

Now, when you submit a comment, it's very, very helpful for us if you describe how a provision or a suggested regulation will affect you. How will it change how you carry out your business? What will you have to do? And remember also that comments and information submitted are available to the public, usually on our website. So please do not submit any private, sensitive information.

Now, the sorts of data we look for as economists when we do our cost analysis are the

following things: what changes are going to be required--this could be what more or less will you have to do; the number of employees affected; how long it takes to do things; then the type of employees whose activities will change. Will this affect primarily managers and quality control personnel, or will production workers and others be affected as well?

So let me give you an example. Let's suppose that as part of GMP modernization training becomes necessary, either as a requirement or as a way to bring about the regulation.

It would be helpful for us if comments came in telling us who's going to be involved in the training, the type of people, and other information that is useful for analyzing costs includes the numbers involved--wages, time, frequency of training.

So, for example, if you need to train workers in a new procedure, we think there are likely to be two types of costs: there's the one-time development cost, learning about the

provision, and planning, deciding how the training will have to be carried out; and then, of course, there's the training itself, the ongoing training. It might be weekly, monthly, annual, or it might be some combination. Tell us about that. Tell us what you think will be required to bring about to get the training done.

Just to try to clarify that, I've got a very simple numerical example here. Suppose that this type of training you think will be necessary for regulation will require two days' time for two managers, and we'll say with some kind of management time cost, we come up with a \$500 one-time cost. And then in ongoing training for eight production workers, again, just as an example, one hour per worker per month, and suppose that comes out to about \$1,500 per year. Show us how you get this number and work through the calculation as I've done here.

Finally, let me just conclude with four things, four do's and two don'ts.

Do send specific numbers, if possible, if

you can do so without compromising your sensitive information.

Send comments in on time. The sooner we get them, the better.

Send comments to the docket. All of our requests for comments have the specific docket number for this rulemaking listed.

Do, if possible, send combined comments through associations. Surveys from association members are particularly valuable to us.

Do not send sensitive information because, again, as I said, this will all be publicly available.

And do not send unsupported opinions. Everybody is going to like or dislike provisions or suggestions, but just telling us you like it or don't like it doesn't really help. Please be specific. Give us examples and numbers.

Thank you. I look forward to getting comments from everybody.

[Applause.]

DR. ZINK: We now enter that phase of the

meeting when those who have asked to make public comments will have an opportunity to do so. I have a list of those who have registered to present a statement. I am just going to start at the top of our list and work my way down, unless there is someone that has a pressing scheduling need and needs to go early.

What I will ask you to do is I'll call off your name or organization, and if you would, you can either come down here to the microphone, if you'd like, to make your presentation. I think that would be what we would prefer. I should also tell you there's this ominous panel that has gathered here. Very often we find in these kinds of public comments there is a need to clarify some points that a commenter may make or to ask further questions. So when you make your statement, I'd ask that you consider and take an opportunity to take any questions from our panel that might arise.

I believe our first commenter is Anne Munoz-Furlong from the Food Allergy and Anaphylaxis Network.

MS. MUNOZ-FURLONG: Thank you. I'm the founder and CEO of the Food Allergy and Anaphylaxis Network, a nonprofit organization. I'd like to begin with some statistics about food allergy.

First of all, food allergy affects 11 million Americans; 6.5 million are allergic to seafood. Peanut allergy in children has doubled in this country between 1997 and 2002, and there is no way to know if food allergy has peaked in our country. We know that trace amounts of allergens can cause fatal reactions. There is no cure for food allergy. Strict avoidance of the allergen is the only way to prevent a reaction.

Severe reactions to food result in 30,000 emergency room visits and up to 200 deaths per year in the United States. It is safe to say that food allergy is now a food safety and public health issue. There is no doubt in my mind that the FDA must do more to protect Americans with food allergies.

My comments are going to be directed to Question No. 7 regarding cross-contact. Some

companies have embraced the food allergy issues; others have not and are putting consumers at risk. I'm going to address three areas that are causing allergic reactions or putting individuals with food allergies at risk: undeclared allergens from cross-contact, precautionary allergen statements, and rework.

We know that some products in the marketplace contain undeclared allergens. Of 659 food products classified for recall during fiscal year 1999, 36 percent were recalled because they contained undeclared allergens. Three principal factors contributed to these recalls: ingredient statement omissions and errors, cross-contact from shared equipment, and human error.

A study reported at the American Academy of Allergy, Asthma, and Immunology's annual meeting showed 177 food samples suspected of causing allergic reactions by consumers and/or allergists were submitted for testing to the Food Allergy Research and Resource Program, or FARRP, of the University of Nebraska. FARRP found one or more

hidden allergens, including milk, peanut, almond, walnut, or egg, in the products they tested.

I'm going to take a few minutes to provide examples of how cross-contact with undeclared allergens impacts the millions of American with food allergies. One FAAN member informed us that his daughter had had a reaction to a cookie product. When he called the manufacturer, he was told that the item was made on shared equipment with nuts. The company acknowledged that cross-contact was the problem.

Another member reported that her 16-month-old son had had a reaction to a frozen fudge product. When she called the company, she was told there was a possibility it contained milk because it was made on the same equipment as milk products and, quote the company, "employees aren't careful these days."

Another FAAN member reported a product indicating it contains traces of peanuts. Her daughter, allergic to tree nuts, had a reaction. When she called the company, she was told that the

product is made on the same line as a product containing walnuts. There was no warning of this on the label.

Another FAAN member purchased half a gallon of ice cream the label stated contains milk, but no mention was made of peanuts or tree nuts. Halfway through ingesting the ice cream, she found a sliver of a nut. The company informed her that, oh, yes, all our ice creams are made on shared equipment.

Regarding precautionary allergen statements, precautionary advisory statements or "may contain" statements were developed by the food industry as a way to communicate additional allergen information to those with allergies. The statements are voluntary, and as a result, there is no standardization of messages and no rules for when these messages can or should be used. Some companies use them, some don't. Some use them sparingly, others put them on all products.

In 1996, the FDA issued a letter to the industry warning them that "may contain" statements

cannot be used in place of good manufacturing practices. Unfortunately, we have seen an increase in both the types of messages and the number of products that contain them. The increase has made label reading even more confusing and consuming for our members.

One FAAN member asked: Is there a big difference between "may contain traces of peanuts" and "manufactured in a facility that uses peanuts"? Should we follow the same precautions for both of these warnings?

FAAN has good reason to believe that in lieu of proper equipment cleanup, some companies are merely placing "may contain" statements on all their products. After acknowledging cross-contact as a result of an allergic reaction, one company told our member that when they order new packaging, they would have a new warning on the label. However, that won't happen for a few weeks.

A FAAN member reported that a chocolate bunny product listed no peanut or tree nut ingredients and featured no allergy warning.

However, other identical products had "may contain peanut" warnings on them. She called the manufacturer and was told that all the bunnies are processed on shared equipment and that all of them should have had a warning.

Our data shows that consumers sometimes don't read the ingredient statement if a product has a precautionary allergen statement. Unfortunately, these statements are inconsistent, thereby increasing the chances of a reaction. I'll give you two examples.

Some companies think that peanuts are the only allergen that warrant advisory labeling. Some have "contains peanuts" statements on the products even though other major allergens, such as milk or eggs, are listed in the ingredients.

Some companies think that peanuts and tree nuts are interchangeable. As an example, one company put "contains traces of peanuts" on the label of a product that is manufactured on shared equipment with walnut-containing food.

Another company uses "may contain peanuts

or other allergens not listed on the label," leaving the consumer to try and figure out what those might be.

Regarding rework, currently there are no regulations regarding rework as it applies to allergens, although it is mentioned in the compliance guidelines. Experience has shown us that some companies do nothing until they're required to do so by federal regulations. The result of a company not taking food allergy seriously or keeping like into like when handling rework can be deadly.

A 21-year-old with a known peanut allergy died after ingesting chocolate chip cookies. The cookies contained no allergen warning. When several packages were tested, we learned that they contained 3,000 ppms peanut. This individual paid the price for a company's ignorance.

A prominent allergist with a known peanut allergy nearly died after eating ginger snap cookies with undeclared peanuts from rework. If he hadn't been allergist, recognized the symptoms, and

had access to multiple doses of epinephrine, he would not have survived.

In conclusion, food-allergic consumers depend on the FDA to protect them. The agency must take the lead in food allergen control, particularly as it relates to labeling and good manufacturing practices. We applaud the efforts that we're here today to discuss. In the ideal world, food manufacturers would use separate equipment for allergen- and non-allergen-containing products, but this is not reality. We must work to put a stop to the practice of some companies who are putting their energy into protecting themselves from liability from undeclared allergens by using precautionary labeling. They should be putting their energy toward developing GMPs and using GMPs for allergens.

The FDA must provide regulations regarding GMPs, including rework and labeling of food allergens, so that all companies who are doing the best they can regarding separating, cleaning, packaging, and labeling of products that contain