ORIGINAL

PUBLIC MEETING

U.S. FOOD & DRUG ADMINISTRATION)
)
DIETARY SUPPLEMENT)
GOOD MANUFACTURING PRACTICES)
SMALL BUSINESS OUTREACH)
)
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REPORTER'S TRANSCRIPT OF PROCEEDINGS

Taken on Monday, July 12, 1999

At 7:05 p.m.

At Flamingo Hilton Hotel & Casino

Las Vegas, Nevada

Reported by: Deborah Ann Hines, CCR #473

96N-0417 TR1

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MR. VARDEN: My name is Peter Varden. I'm an economist with the Food and Drug Administration. I want to thank you all for coming this evening. I'm going to tell you a little about the purpose for this meeting and introduce our speakers. I'm going to tell you a little about the ground rules for the meeting and then I'll turn it over.

As I said, my name is Peter Varden. I'm an economist for the Food and Drug Administration. And the reason the Food and Drug Administration is having this meeting is because Congress has given the authority to FDA to promulgate good manufacturing practice regulations. And an aspect of those rule writing is that we do want to do a small business outreach, so we wanted to give the public an opportunity, those that might be affected by the proposed rule, to comment on the proposed rule.

The people who will be speaking tonight are Richard Williams. Dr. Williams has been with FDA for 20 years. He's the Director of the Division of Market Studies, and he'll talk for about five minutes on how we do a regulatory impact analysis, and in particular how we do our small

business analysis.

Following Richard, who will speak for about five minutes, Karen Strauss will speak for about fifteen minutes. Karen is our Consumer Safety Officer, and she's the one who is actually writing the proposed rule.

Following Karen's presentation we'll allow you to ask questions, and I should say following Richard's presentation we'll allow you to ask questions but not during his presentation. Then following Karen's presentation we'll allow you to ask questions but not during her presentation.

And then several of you have asked to present your comments, so we're going to allow those people who have already asked to speak. And the people who have asked to speak are Anthony Martinez, Beth Lambert, and Claudia Lewis-Eng. We'll allow them to speak for ten minutes, and after they've spoken then we'll just open it up for whoever else might have comments.

This is a public meeting, and so we are transcribing the public meeting, and Debbie Hines is our transcriber. And to help her in the transcribing, we'll ask you to announce your name and who you're with and to fill out a form that she

has. You can do that before you speak or after you speak, but we would like you to write your name and the firm you're with.

And we have the room rented until 9:00 o'clock. We hope we can accomplish what we want to accomplish in that two-hour period, but if by some chance we can't, we're willing to stay over. And so on that note I'll turn it over to Richard Williams.

MR. WILLIAMS: Thank you, Peter. I've never spoken for five minutes in my life. I elaborated on my wedding vows, I think I went on for about ten minutes.

Thank you all for coming here tonight. We are here tonight primarily because we're doing outreach for small businesses, that's the sole purpose of our being here. We're here tonight so that you out there who are members of small businesses can help us shape this regulation.

Right now is an excellent time for you to be providing input to the Food and Drug Administration. Everything is a blank slate, and I want to emphasize that. We are here to hear you. We are in the process of developing this regulation. Our minds are not made up about

anything.

Some of you may have participated in the industry petition that we received that talked about what they thought good manufacturing practices for your industry ought to be. As you know, we called this Advanced Notice of Proposed Rulemaking; however, we are not by any means wed to that. Advanced Notice of Proposed Rulemaking is like a question. It asked people, What do you think about this? It doesn't say, This is what FDA is proposing to do.

Okay, I don't think it's a stretch to say that we don't know a lot about your industry. We in the Center for Food Safety and Applied Nutrition have a long history of regulating the food industry. I think regulating the dietary supplement industry is something new for us.

We're just in the process of learning about you, so anything that you can tell us that will help us to shape a regulation that better fits your needs will certainly be encouraged. We want to know both about your particular firms, and if you care to do so, about your industry.

This is our first Small Business Outreach Meeting. We will hold at least one more. We're

planning to have one, for those of you that are interested, back on the East Coast in Baltimore in October.

We encourage you both to provide comments here, and if you'd like to submit comments in writing, I think we have a handout that you might have gotten that will tell you where to submit comments.

What I want to talk to you tonight about is what we're required to do under the law in terms of encouraging and asking small businesses for their input. Many of you may be aware that there's a law called a Regulatory Flexibility Act. That was passed way back in 1980.

In 1996 Congress decided it wasn't working as well it could have, and they passed the Small Business Regulatory Fairness and Enforcement Act, and that act gave the Regulatory Flexibility Act teeth. And what it did is it required us to actively seek out input from small businesses, who are often the people that we hear the least from, and it gave you certain rights.

One of the things it did is it gave you more influence in the development of regulations, not that we have to come out but we want to come

out and we want to hear from you. It also gives you some compliance help. It requires us, even though we do have a plain language requirement, it requires us to go further after we pass the regulation and we actually have to write out a small business compliance guide that tells you easily how to comply.

It also gives you the right to sue us. If we don't do a good job analyzing the impact on your industry, you can sue us. Well, you can sue Peter, don't sue me.

So you do have certain rights. Under the Small Business Regulatory Fairness and Enforcement Act the primary thing we are concerned with is what are the costs to your industry to comply with the potential regulations, and I'm going to talk a little bit more about that, and that's both on an individual firm level and also on the industry level.

We're also required under the executive order to consider what are the benefits of this regulation. What are the public health benefits that will be achieved by this regulation.

Finally, and I think this is one of the most important things, we're required to look at

flexible regulatory options. We have a public health mission that we want to accomplish. There is any number of ways that we can accomplish it, and we're required to look at as many as are practicable ways that might accomplish it so that we can achieve our public heath goal with the least possible burden.

Let me give you some idea of some things that have been suggested in the past. A lot of times small businesses will say to us, We need more time to comply. Often, if we have a regulation that goes throughout the industry and it won't promote sales in any way, it's hard for small businesses sometimes to get a loan to comply with the regulation. They want more time so that they can finance it out of retained earnings. If that's something that you think is important to you for particular aspects of the regulation or the entire regulation, please let us know.

Sometimes small businesses particularly want more performance type rules. A performance rule says, Here's what you have to achieve, and it doesn't tell you exactly how you have to achieve it so we leave it to you to be flexible in how you can achieve something.

In some cases small businesses request an exemption from certain rules. Generally with health and safety rules that's a little bit harder for the agency to do; but nevertheless, if you think it's appropriate for your size of firm and your industry, please let us know.

Okay, so those are the things that we're going to consider under the Regulatory Flexibility Act.

Now, let me tell you about writing comments to us. As Peter said, I've been receiving comments for 20 years, and I'd say I get about one percent good comments and about 99 percent what I term bad comments. And the only reason I call them bad is because they don't make a difference.

Let me tell you what I mean by that. If you write us and say, My opinion of this regulation is it stinks, very nice to hear from you. Thank you. We'll take that into consideration, and we are required by law to respond to it, but that's all we'll do is we'll respond to it.

If you send us factual data, if you send us something that is bound in facts or bound in logic, that's something that we can actually use, and we can use it to help draft a regulation. I'm

going to be really specific tonight because I've received comments from small businesses and I know what works and what doesn't.

You can start, if all you want to comment about is how the regulation will affect your particular plant or your firm, that's good. That works very well. Even better, if you want to band together and do a survey of your firm, that would be nice also. It's whatever you want to send in, but try to make it as specific as possible.

Let me give you -- I want to walk through because mostly what we're concerned with under SBRFEA, the Small Business Regulatory and Fairness Enforcement Act, is cost. That's the thing that we're most concerned about. I want to go walk through, if I can, with you and just tell you some elements, if you put it in your comment we will find it extremely helpful.

One of the things that we have to know under SBRFEA, which we are required to actually find out, but it helps us if you tell us, is who would have to do something different. When I say "who," will the plant manager or owner have to do something different, not will you have to hire a new plant manager, but will the plant manager

that's doing something now stop what he's doing now, or what she is doing now, and she'll have to do something different.

Will the production line worker have to do something different? Will the quality control people have to do something different? Will the laboratory have to do something different? Again, I'm not just talking about hiring somebody new, I'm talking about stopping one activity and starting another.

Next, what will they have to do? What exactly will they have to do? How long will it -- for example, the manager may have to oversee taking samples, check incoming raw materials. If that's something the manager has been doing previously, you think the regulation might require him to do that, or her to do that, that would be something very specific, and lay it out as specifically as you can.

Next, how much time will it take? Will it take two minutes a day? Will it take five minutes a day? Will it take an hour a month? Will it take two hours a year? Whatever it takes, okay. And, incidentally, if you are going to send this kind of comment then tell us how many days you're open,

that allows us to calculate the impact that it will take. Are you open 260 days a year? Are you open 360 days a year?

Next, what is this person's annual salary? You don't have to give it to us exactly, you can give us this in a range. That's helpful in terms of calculating the cost impact. Those are the kinds of things that are labor-oriented. What changes will labor have to make in order to comply with this regulation?

You also may end up having to buy new equipment, and we'd like to know that. If you think this regulation might cause you to buy new, what kind of equipment will it cause you to buy? How much will it cost?

It may be that you have to contract with outside labs. There are potential testing requirements in this regulation. How many tests would you have to do? What will it cost you per test? Those are the kinds of things we would like to know. If you want to calculate the total cost, that's fine, but if you just send us the information that I just told you, we'll calculate them for you and that will be fine. That's on the cost side.

Of course, we're also required to estimate the benefits of this rule. Anything that you would like to say about that would also be fine. Why do you think the requirements may not work, why it might not achieve the public health benefit that it's intended to achieve. Is there something that's not helpful? Is there something that's not particularly applicable to your industry? All of those things will be helpful.

Finally, we'd like to know some other things, and again these are all optional on your part. Are you owned by a larger company? The Small Business Act basically is intended for small companies who are not owned by larger companies. So if you're owned by General Mills, even though you're very small, we would not count you as small.

What's the size of your firm? It can be either in number of employees or in annual sales. Some firms in the past, some food firms have actually sent us their average annual profits, and we will look at that kind of thing. We'll look to see what would be the cost on you for a year to comply relative to your annual profits. That's a very important figure that the Small Business Administration emphasizes for us. Again, if you'd

like to send us a range or something that you're comfortable with, that's fine.

What do you make? What kind of products do you make, okay, so that we can classify you. We are able, in a regulation, to carve the industry up literally in any way that makes sense, okay. For your industry you're considered a small business if you have less than 750 employees or if you make less than $100 million a year in annual sales.

That's a fairly, in my mind, that may be a fairly large company, and many of you may be thinking, I don't even play in that ball field. We're able to carve out requirements at different levels.

So, in other words, we can identify in the regulation very, very small firms and say they have one set of requirements, and middle small firms and they have another size requirement, and small firms that have another size requirement, and then large firms a completely different set of requirements. We are able to do that. It makes it a lot easier for us if we hear from you, if we hear the elements that I was just talking about, if you can come in and suggest those.

Okay, that's the kind of comments that we

would like to receive. And I'm going to turn it back over to Peter in a minute, and you're going to hear about what are some of the things that might be required in this regulation. So take those -- please take them home and please consider submitting comments to us, and we'd like to hear from you tonight as well. Thank you.

MR. VARDEN: Thank you, Richard.

Do any of you have any questions or comments at this point?

Okay. Our next speaker -- I'm sorry.

BETH LAMBERT: Can we get a copy of your remarks? Where are they going to be available?

MR. VARDEN: Yes, they are going to be available. We'll have the transcript available I think 15 days from today. And on the desk outside we've got --

MR. WILLIAMS: Let me also say we'll be here tonight. I'm in Caesar's Hotel, room 1390. I'll be there all day tomorrow. If anybody wants to talk to me, please just give me a call, okay.

MR. VARDEN: Yes?

MS. BARNETT: I just want to make a follow-up comment that although FDA is very interested in hearing specific information from you

all, the information that you submit in a comment is in a public docket, so please keep that in mind when you submit the comments.

MR. VARDEN: And, I'm sorry?

QUESTION: And since there's economic data, will it be shielded in the docket?

MS. BARNETT: No.

QUESTION: So it's not like other submissions where --

MS. BARNETT: No.

QUESTION: -- proprietary data can be shielded?

MS. BARNETT: No, because this is a public comment procedure.

MR. VARDEN: You could give hypothetical information.

Any other questions or comments?

Our next speaker will be Karen Strauss. Karen Strauss is the Consumer Safety Officer who is actually writing the proposed rule, and she'll tell us about that rule, what's actually in it at this point.

MS. STRAUSS: There were two handouts on the table outside the door; one is a copy of the ANPR, Advanced Notice of Proposed Rulemaking, and

the other is a copy of some slides that outline various elements in the ANPR.

And I want to tell you that those slides that you pick -- the copy that you picked up was first done as an outline for a presentation that actually is longer than the one I'm going to give, but because it was a pretty good outline, we thought we'd give it to you just for your information. But we'll tell you that the slides that we show on the screen will be different than the slides that you picked up. So if you're following along, I want to just alert you to that.

As Richard Williams mentioned, the purpose of this meeting is to receive your comments that will assist our Center for Food Safety and Applied Nutrition to understand the economic impact of that proposal to establish current good manufacturing practices, or GMPs, as we often call them affectionately, that dietary supplements may have on small businesses in the dietary supplement industry.

The Dietary Supplement Health and Education Act, or DSHEA, as we refer to it, gives FDA the authority to adopt GMP regulations. And a significant segment of the industry has told FDA

that GMP regulations would be helpful.

Before I go further, I wanted to just outline the five different categories of dietary supplements that DSHEA mentions, and these supplements would be recognized. Vitamins are the first; minerals; amino acids are the third; fourth group is other dietary substances used to supplement the diet; and the fifth is concentrates, metabolites, constituents, extracts, or combinations of these.

The FDA is, as was mentioned, in the process of developing GMPs for dietary supplements. And as a starting point, we are examining that proposal that was submitted by industry and published as the Advanced Notice of Proposed Rulemaking published February 6th, 1997. The ANPR is not something that FDA is bound by. It's not a regulation, but because we're examining it, we are going to use it tonight as the discussion framework at this meeting.

As Dr. Williams noted, we are interested in knowing about your firms' current manufacturing practices. We also want to know what you think about the elements included in the ANPR, and this is not as perhaps was mentioned by the proposed

regulation, but it's the industry outline and so we want to know what you think about these elements and what associated costs and time frames would be needed to meet such elements as those that are listed in the ANPR that was outlined by the industry.

Because small businesses may not have had an opportunity to review the Federal Register and the ANPR, I thought to give you some background for your comments, for those who don't know what's in the ANPR, my task is not very exciting, but it's to give you some of the basic -- some of the elements that are included in the ANPR.

The ANPR is based on the food GMPs, but the industry adapted, modified and expanded the food GMPs to meet some of the special manufacturing requirements of dietary supplements not addressed in the food GMP Act.

The purpose of GMPs is to ensure that customers are provided with dietary supplements which are not adulterated or misbranded. And the Food, Drug and Cosmetic Act prohibits the selling of adulterated products. In lay terms this adulteration means a product that contains contaminants. And misbranded, generally speaking,

means that the product is not what the label says it is.

The ANPR GMPs include requirements related to personnel that work in your dietary supplement firm. The sanitation and maintenance of the grounds that surround your physical plant or building used to manufacture dietary supplements, the building or physical plant design and construction are considered, and the design of the equipment and utensils as well as how they're installed, how they're used, the sanitation of equipment and utensils, and these are all addressed in the ANPR.

Production and process controls to ensure quality throughout the manufacturing process are included in the ANPR. And, finally, our identified GMP records that are needed during the manufacturing process and after distribution to ensure that a recall can been implemented as needed.

Over the next fifteen minutes I'll give you more information about each of these elements that are included in the ANPR. As I noted, FDA thought that the industry draft was an extremely useful starting point for proceeding to rulemaking

to adopt regulation.

The next slides and my remarks will include elements of the industry-suggested GMP that was published in 1997. And I'm going through these elements so that you will be aware of the types of issues that FDA is examining while we develop the GMP. At the conclusion of this presentation, we would like to hear from you about how these elements, or elements like these we're about to go through, will affect your business.

This is Personnel. All persons working in direct contact with dietary ingredients or dietary supplements must use hygienic practices and not have any disease that would adulterate a product. Employees should have the proper education, training and experience to perform their assigned functions. And also an appropriately trained and experienced supervisor should have the responsibility for ensuring that employees follow the appropriate hygienic practices and are capable of performing their assigned functions.

The grounds about a manufacturing plant must be kept in a condition than will protect against adulteration. This may involve storing equipment, removing litter and waste, cutting grass

and weeds within the immediate vicinity of the plant, and cutting these so that if they would attract or provide a breeding place or a home for pests.

Physical plant design and construction must be suitable in size and design to facilitate maintenance and cleaning and sanitation operations. They should be suitable in size and design for manufacturing purposes and to prevent mix-ups between different dietary ingredients, in-process materials, and finish dietary supplement products.

Also, I consider a plumbing, sewage disposal, rubbish disposal, toilet and hand washing facilities, these are also elements of the manufacturing physical plant that are addressed as measures that the dietary supplements produced are not adulterated.

Equipment and Utensils, this is a section in the ANPR. Equipment and utensils must be so designed and made of materials that are adequately cleanable and maintained.

The installation should facilitate maintenance and cleaning and sanitation and be positioned to allow for appropriate movement of

personnel during manufacturing.

The design, construction and materials used in the equipment, the calibration of instruments to maintain accuracy are all elements to protect against adulteration of the dietary supplements during the manufacturing process.

The ANPR addresses Production and Process Control, and here are some of the main headings that are in that section of the ANPR. The elements included include a quality control unit or quality control person, laboratory operations, manufacturing operations, packing and labeling operations, and holding and distributing dietary supplements.

I'll give you a bit more information on each of those, but as we're really moving very quickly through these, if you want more detailed information on what's in the ANPR, you have it there for your reference.

There must be a quality control unit or quality control person that has the responsibility and authority to do the following things: In the ANPR it says that the quality control unit or person should have responsibility and authority to approve or reject all procedures, specifications,

controls, tests and examinations or deviations from them that impact the purity, quality and composition of a dietary ingredient or dietary supplement. The quality control unit or person must have the responsibility and authority to approve or reject all raw materials, packing materials and labeling, and to assure that completed production records are reviewed.

There should be adequate laboratory facilities with responsibilities and procedures established in writing and followed. And later on in our talk I'll outline more specifically what written procedures are included in the ANPR.

Holding and distributing elements include conditions under which ingredients and packing materials and labels are received and held, the holding of in-process and finished product and the distributing of dietary supplements.

The elements listed on this slide are found in the ANPR in several different places. I've taken some from the Production and Process Controls, some from Warehousing, Distribution and Post-Distribution Procedures.

Ingredients, in-process materials and the finished dietary supplements must be stored in a

manner that prevents adulteration and mix-up.

Ingredients, packing and labeling materials received must be examined and tested to determine if they meet specifications. Each lot of materials must undergo at least one test by the manufacturer to verify its identity and that it conforms to other specifications. Tests may include chemical and laboratory tests, gross organoleptic tests, microscopic identification, or analysis of constituent markers.

The ANPR says that in lieu of such testing by the manufacturer, a guarantee or certificate of analysis, or also referred to as a C of A, may be accepted from the supplier provided that the manufacturer establishes a reliability of the supplier's analysis.

At this point I wanted to tell you that a recently submitted draft report of an FDA Food Advisory Committee GMP working group that included dietary supplement industry members recommended in their draft report that multiple tests be conducted to confirm identity. So there is a difference there between the ANPR and another recommendation that was made, so this is a GMP element on which we would especially like to hear your comments.

Raw materials should be examined and tested for filth, insect infestation or extraneous material, microphyll contamination, aflatoxin and other natural toxins. And in-process materials must be tested during manufacturing to detect adulteration.

We're into Manufacturing Operations, and this is probably one of the briefest summarizations of the section. All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging and storing of dietary products must be conducted in accordance with adequate sanitation principles and conducted under conditions to minimize the growth of microorganisms.

Chemical, microbial or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible product adulteration.

Any product that has become adulterated within the meaning of the act shall be rejected, or, if permissible, treated or processed to eliminate the contamination.

The ANPR includes manufacturing operations elements such as ingredient and materials

specification, tests of ingredients, the use of a master and batch production records. Also included in the ANPR are various operations such as those that involve heat treatment, refrigeration, material grinding and so forth.

Filling and assembling, packaging and other operations are addressed in the ANPR. These must be performed in a way that protects against adulteration. The ANPR lists several methods to protect against adulteration, the section including cleaning and sanitizing measures, use of appropriate equipment and use of appropriate materials for packaging.

Dietary supplements, the ANPR says, must be identified with a lot number that permits the determination of the history of manufacture and control of each batch.

Production and packaging materials not meeting specifications must be rejected.

An ANPR element is that the finished product must be stored under conditions that will protect against adulteration.

Also in the distribution section the ANPR says that reserve samples of each batch of dietary supplements that is representative of each batch

should be retained and stored under conditions that are consistent with the label. And these reserve samples must consist of at least twice the quantity that's necessary to perform all the required tests.

Here's where I'll go over some of the written procedures and records that are noted in the ANPR.

In the ANPR, the industry identifies certain written procedures and records that the industry coalition thought were necessary to include in the GMPs. Under the ANPR outline, written procedures must be established and followed for the following:

For cleaning and maintaining equipment and utensils used in the manufacture of dietary supplements, written procedures for the responsibilities and authorities of the quality control unit, for processing batches including a master production record and batch production record.

Elements of each of these production records, the master and batch, are listed in the ANPR. For example, the master production record includes the names and amounts of ingredients that are in the batch, the steps of manufacturing,

quality controls, containers and closures used in that particular product and the labels. The batch record documents how the master record was followed. It documents any deviations that occurred and any investigation of those deviations.

The written procedures that are included in the ANPR also address appropriate laboratory tests or examinations to be conducted that may be necessary to assure the purity, composition and quality of the dietary supplement.

The ANPR also includes written procedures for the receipt, storage, handling, sampling, examination or testing that may be necessary to assure the identity of labeling and appropriate identity, cleanliness and quality characteristics of the packaging materials.

There should be written procedures to assure that correct labels, labeling and packaging materials are issued and used, and describing the handling of all written and oral complaints regarding the dietary product.

And the ANPR addresses how long records should be retained and which records should be retained, and the following are those that should

be retained: Raw material records, any laboratory, production, control or distribution record, the complaint records specifically associated with a batch of dietary supplements.

And how long must the records be retained? They must be retained for at least one year after the expiration date of the dietary supplement, or if there is no expiration identified on the product, for at least three years after the date of manufacture.

So there was a fairly quick and brief run-through of some of the elements that are included in the industry submitted ANPR GMP.

MR. VARDEN: Do we have any questions or comments at this point about Karen's presentation?

Yes?

CHIP MARSLAND: You addressed the complaint.

MR. VARDEN: Could you come up to the mike, please. And would you announce your name and who you're with. And also just let me repeat the rules that we'd like of you. After you've given your name and address, and after you've given your question or comment, if you could, come up here and fill out one of the forms so that we spell your

name correctly.

MR. WILLIAMS: I'll make it easy for you.

MR. VARDEN: We can do that before or after.

CHIP MARSLAND: I'm Chip Marsland. I'm the CEO of Betafoods. We're a functional foods company. I come out of the biologics industry and I've got about 15 years experience of drug manufacturing, and what I just heard here is that it does apply to my business directly, especially to my contract manufacturers.

The plant design, construction, equipment, utensils, process controls, the records retention, calibration, the SOPs, the validation of such, most of the people in this industry don't actually meet these specifications today, if I'm familiar with what you're trying to propose. They do have it for, perhaps the simplest and the most sturdy of all, which is the food industry. The, excuse me, it's been a long day. I've been talking for four days.

The industry here itself, I'm not sure, for example, my suppliers' contractors can meet all the actual requirements of this, but what are you trying to achieve? Are you trying to achieve

something equivalent to CBER or CDER or the device industry, because they're all different and you addressed everything here that's really more related to what I call CBER regulations.

MR. WILLIAMS: Okay. I think, for instance, it's fair to say that what was addressed here was in the Advanced Notice of Proposed Rulemaking. That was, I think, repeated pretty much verbatim from an industry submission of dietary supplement manufacturers. I don't believe it was necessarily the people represented here tonight, okay.

I think, and we want to make this very clear, it's a starting point. For us tonight it's talking points. In no way necessarily will that be what you'll see in a proposal. And I think it's very important that we hear from you just the kinds of things you said tonight, but perhaps with more specificity so that we can determine which of those elements are actually needed in this industry.

CHIP MARSLAND: The elements of design and construction of a plant are completely different than what exists today in industry. For example, you have -- usually you have raw materials coming in, you have manufacturing and you have product

going out. A lot of these companies here have cross flow, okay. A lot of this cannot be identified properly.

The other issue is that typically good manufacturing practices, especially for cleanliness of equipment, applies mostly to stainless steel. The utility -- the utensils and utilities, something you didn't address here, the utilities, they also apply to us directly as well, and the quality of our actual utilities such as water. The equipment that actually manufactures the water is also relevant.

I agree that we do need a specific regulation, but I audit all my vendors. But nonetheless, I think a lot of people -- my business is functional foods, all right. I don't know how many people here are in functional foods. Our functional foods are actually dietary supplements, so these particular products may include manufacturing plants.

Our products that we use are grass, except some of the particular materials that we use perhaps are not qualified under these regulations. For example, our feed stock, our materials that we select, our grass, our manufacturers may not be

able to meet some of the needs here stated because they're functional materials. They're made a little bit differently.

Plant design alone, you know, the regulations here, as I can see this, a typical biologics plant, when you finish everything, just building a plant, it's approximately a thousand dollars a square foot.

Validation of the plant, which essentially means making SOPs, keeping and maintaining SOPs, doing what are called IQ, OQ, PQ -- insulation qualification, operation qualification and process qualification and performance qualification -- it's very extensive, very extensive.

Most people here probably, unless you're in the drug industry, you actually don't know what that is. And most of our vendors, in my particular case, because we're a small company, subcontract out large products. I don't think any of these people are really going to be able to meet these qualifications. Is that what your objective is is to actually start implementing some of these such procedures?

MS. STRAUSS: Perhaps not to address the last question you asked, but I think rather than

looking at an industry and that would not meet these items or elements that were in the ANPR, it would be also be helpful to know of those elements that you think they would not be able to meet at this time.

CHIP MARSLAND: Most food vendors, for example, most people in this business don't use materials in construction that could be considered to be sanitary a hundred percent of the time.

MS. STRAUSS: What I was going to say further was which ones are with the special considerations, the special needs or concerns of dietary supplements would be appropriate?

CHIP MARSLAND: Do you want me to address that?

MR. WILLIAMS: Can I just add one more thing? I mentioned earlier that we certainly have the ability to carve this regulation out by size, but it's also true, and this is -- again, this is something where I think we may need a lot of help, that not all dietary supplements are manufactured in the same way. And there may be categories of dietary supplements that would perhaps need different requirements for good manufacturing practices. And again, we need to hear that from

the industry.

CHIP MARSLAND: Well, see, biologics, there's a whole platform for biologics, which I do agree because yeast can grow anywhere. There's all sorts of contamination. But in just addressing that, there's water systems that are specifically used in the pharmaceutical industry to address that issue. It's all very expensive. So if these things are implemented here for this industry, it's, you know, I know particularly my vendors are going to have a very hard time meeting that from a biologic standpoint.

But that's just a couple comments. I see that actually this is much more so than the drug, it's actually more like biologics, and CBER regulations, I don't know if you're familiar with those. Probably some of the better ones were written back in -- and they kept evolving, from like 1987, where they were really being implemented, to 1997.

They evolved tremendously, and they were quite dramatic. And it wasn't the intention, it just happened to the industry that it kept pushing in that direction that it became much more expensive. Initially everything, you know, it

didn't start off that way. It wasn't the goal, but it did -- it actually delayed, for example, the introduction of products in particular cases, manufacturing products.

MR. VARDEN: Okay. Well, that's helpful. Thank you.

Why don't I turn it over to those three people who've already announced that they would like to make a public presentation. I've asked Anthony Martinez to speak first. And again, we've agreed that we'll just speak for ten minutes and then we'll move on to the next speaker. And as you approach the ten-minute mark, I'll raise my hand.

TONY MARTINEZ: Okay. I hope not to take up ten minutes, but for the record my name is Tony Martinez. I'm an attorney specializing in food drug law, and I also lobby before the United States Congress. My address is P.O. 2069, Wayne, New Jersey 07474.

I'm here on behalf of American Specialty Health Plans, San Diego, California. And just a little bit of background about myself, I was one of the principal individuals involved with the creation and the passage of the Dietary Supplement Health and Education Act, and it was a little bit

of a watershed moment that I'm actually seeing here a public meeting here about the GMPs.

I think it's a bit of a frustration that it's taken this long to get this implemented, because there are a great many controversies still out there about dietary supplements, and many of these controversies will be resolved once we have workable GMPs.

My client is an insurance company, and it's offering supplement products, and in the future envisions a time that it would like to cover it. Many insurance companies are getting into this business. This is why good manufacturing practices are critical at a stage where it's very difficult for the companies to know who to buy from, where to buy from, etc., because of the lack of the standards.

This void has even forced -- maybe the industry now has gone into a self-regulation mode. The NFA just announced its own version of a compliance for good manufacturing practices. I think that's good.

Ultimately I want to also suggest as you craft these regulations with the Congressional intent, one of the things that we want to avoid

from ever happening again was an L-Tryptophan -- the L-Tryptophan contamination episode, which really goes back to the heart of the GMP issue.

In that particular matter where it was the altering of the manufacturing process which led to the creation of a new compound that caused the contamination of the L-Tryptophan, got into the United States, and as many people that were -- consumers that were harmed by it, also the companies that relied on the supplier to supply them safe and well-manufactured L-Tryptophan.

Even though the industry is doing its self-regulation, and I said earlier that that's good, we still need government standards. And we are going to need different types of standards for different aspects.

For example, raw material manufacturers will need a different set of good manufacturing practices than someone who's doing finish product manufacturing. And I know this is of great concern to many small businesses, because I also represent smaller companies, and there's a little bit of trepidation on their part.

It's important that the agency who has crafted this regulation has a program in place to

give guidance and assistance needed so that we don't drive business -- we don't drive companies out of business but we allow them and we facilitate their getting up to the standards that are in place as much as possible.

The days of garage formulation of dietary supplement products are over. Health insurance companies are going -- and consumers want these kinds of products, and they also want them to be covered and included and contribute against a shift from a disease pirating health care system to a prevention, wellness, anti-aging type of health care system.

We're going to need to have good standards in place. It's not to say we -- they should not be -- manufacturing practices should not all -- should not stifle innovation but at some level guarantee a minimum level of safety that the public and various businesses, because these GMPs are not only for the manufacturers, they're for the consumers and also the distributors, and, as I said now, the health insurance industry.

It's also my suggestion and hope that the FDA will see to it in its budget allocation that there is enough resources given so that way these

GMPs get completed in a timely manner as quickly as possible. And that's basically it for our suggestions. We intend to submit more detailed submission in writing. I thank you very much for your time.

MR. VARDEN: I appreciate it. And Beth Lambert has asked to speak.

BETH LAMBERT: Good evening. Thanks a lot. My name is Beth Lambert. I'm representing the American Herbal Products Association, it's Small Business Committee and my own company, Herbalist & Alchemist.

For those who do not know of the American Herbal Products Association, it's the trade association of herbal products, growers, manufacturers and marketers. We're part of the industry trade group that developed and submitted to the FDA the industry GMPs that were published in '97.

The Small Business Committee represents about 70 percent of the AHPA members. These are companies that are under five million in sales. This corresponds to the SBA's definition of a small business.

And let me add that under the definition

that you quoted tonight, small businesses under a hundred million will be a much higher percentage of the folks in AHPA. We've estimated under 20 million, or probably 85 percent.

Many of our companies provide employment in rural areas as well as purchase plant material from small farms and businesses.

Herbalist & Alchemist, my own company, is located in Washington, New Jersey. We're in rural Warren County, which is in the northwest corner of New Jersey. We've been in business over 18 years, and we make over 300 different types of herbal products from organically grown or ethically wild crafted plant materials.

Our commitment is to produce the highest quality, traditional herbal extracts. We have developed relationships with several areas of Rutgers University, to that end in which at the time I was an adjunct professor, including The Center for Advanced Food Technology and Extension Growing Areas.

We employ fifteen people, ten of whom are women, and two are from a Native American heritage. We've developed farmer programs with several local organic growers and employ regional

marketing groups to help us market our products. And our sales are just under a million dollars.

Approximately 90 percent of our business, which are wholesale sales, with over half of that to health care practitioners.

A bit about me. I'm the chief executive officer of Herbalist & Alchemist. I have a B.A. in political science and economics from Wellesley and an M.B.A. from Harvard. I spent 14 years in the financial services industry, and I retired to pursue an entrepreneurial career that reflected my own deep concerns about the state of the environment.

I have found that calling in joining up with my business partner, David Winston, and is now co-owner in our business. I also, as I said, do teach at Rutgers University.

First of all, let me address the issue of timing. We really appreciate the opportunity to address you and that the FDA is continuing communication and willingness to confer with industry as it implements DSHEA; however, the short notice that we received about this meeting made it impossible for many of my colleagues from The Small Business Committee to be here and express their

views. I've spoken with several of them, including Mitch Coven from Vitality Works, Daniel Gagnon from Herbs, Etc., Tierney Salter from The Herbalist, Linda Batcha from Green Mountain Herbs, just to name a few.

Linda told me that prior to her going to the NFA show she actually just received a notice on Tuesday, the day she was leaving. I left Tuesday so I didn't even get notice. The only reason I knew was because my trade association asked me to extend my stay here to be able to talk to you this evening. I had to give up family plans this weekend, and that was extremely inconvenient.

I do appreciate that you've told us that there is going to be another session in October. I will make sure that many members of The Small Business Committee are there, and I would suggest that you reserve quite a bit of time to hear everybody's interests.

As an overview, AHPA and The Small Business Committee and our company, Herbalist & Alchemist, continue to endorse the concept of GMPs relative to dietary supplements. We currently have many of the industry GMPs in place in our company, but our procedures are tailored to our size of our

operation.

All of the companies have a commitment to quality, but the methods by which we achieved that quality must be appropriately tailored for our size and scale of businesses.

The GMPs were drafted by industry reps to try to accommodate these differences, but small businesses only had a chance to review them after they were published.

The documentation procedures, two of the major areas where I see as costs for our particular business, are documentation of procedures and the equipment needs that we will need to upgrade to get ourselves to the level of those procedures.

With respect to the botanical ID issue that you raised tonight, I'm aware that the GMP working group, The Food Advisory Committee, did submit a report on June 26th. The industry reps on the working group actively sought the views of The Small Business Committee members and they realized that some of the recommendations of the report went beyond what are published as the industry GMP suggestions.

Michael McGuffon and Fran Ertl are very aware of the differences of how large and small

companies operate. For example, as a small business we receive shipments of anywhere between one and 500 pounds of a given herb, depending on the size of the market for that herb. We get them from growers that we know personally and have had long-term relationships with.

We receive these plants many times in their fresh, whole form. What we do is we have two professional members of the American Herbalist Guild on staff and a trained botanist in our lab. And our procedure is that one of those folks have to examine every plant shipment that comes into our operation.

These professionals, as I said, review all the plant material and identify it. We have a herbarium with specimens that have been set up by our own ethnic botanist and reviewed by others for comparison. The entire shipment of our plant material is inspected by our lab staff in a process we call garbling. That is every piece of plant material is gone through by hand. All foreign material is removed by hand.

Large companies simply do not have the staff or time to follow that type of procedure. They have to rely on statistical sampling to test

and ID their plant materials; two different approach but both result in a high quality product.

Given our level of scrutiny, we, and many other small manufacturers, felt that to add the level of testing needed by large companies would be redundant and to only add cost for the consumer; so therefore, we counselled with those industry reps to suggest a 500-pound exemption for multiple testing.

The plant materials we receive also are in fresh form, because we believe in many cases that makes a superior product. To have to send this out for chemical testing and wait for those tests would obviously degrade the plant material.

So hiring, you know, that would result in us having to hire in-house folks which would be probably at a cost of probably 40 to $50,000 plus the cost of the equipment, if we were to establish our own in-house lab. We would have to test every batch, according to these new standards, whole plant material, and we believe that that would needlessly subject our own personnel to working with highly toxic solvents, such as hexane and benzene, which are needed for this process. As a company committed to preserving our environment, we

find this inappropriate.

We believe in testing when there is a question of plant identity. We send things out when our botanists have a question about plant identity. But it is, we believe, redundant to try to confirm what you already have exceptional personnel and staff to ID.

MR. VARDEN: You have a minute left.

BETH LAMBERT: Okay. Let's see, what does it take for small businesses to implement good manufacturing practices? Oh, we believe it's essential to our survival to have that 500-pound limit.

The key for small business is to make changes meaningful and integrative to our business process. Time -- we need at least two years to get all our people trained in areas like documentation of procedures, expiration studies, and documentation and training.

And we need courses that are appropriate for these opportunities. The FDA has held some very helpful microscopy classes, which we have sent our lab manager to. The New Jersey Department of Labor funds an ISO 9000 two-year course in which we were enrolled to help bring up our level of

documentation.

The USDA has a small business innovation research grant that we've been awarded and help us answer some research questions. But in working on that we will also get our personnel trained at Rutgers University.

But some of these things we found just by chance, and it's not fair to the rest of our colleagues. We really would hope that some kind of a centralized listing of all these opportunities would be set up for people. We would like partnerships in training. We'd like to see an active partnership with the FDA and the industry in bringing up these issues.

Centralized information -- where all these opportunities would be listed.

You spoke tonight about plain language. We believe that you have a responsibility to issue your information in the manner that does not require us to extend funds for legal review.

I consider myself a fairly sophisticated reader, but, for example, this question on controls of computer operations, we thought that basically meant that if you have a good computer operation, that was fine. If you review things, we go to a

trade meeting and we find out from our larger colleagues that it would take a main frame to run this. And the interpretation of the fellow -- of Michael McGuffon to me the other day is basically what this says to him, a high level of understanding of The Small Business Committee is either we have to buy a huge computer operation that would put us out of business or not allow us to use computers. So it's real important to get it clear so that we understand what it is that you're asking us.

In closing I just want to say that we are all committed to putting in place and continuing our good manufacturing practices, but it's important to make them meaningful to our scale of business.

What I have presented is a few of those issues. We'll present more in writing to you and be happy to work with you on any of those things. The Small Business Committee of the American Herbal Products Association is a strong and active group and we would, you know, again welcome a dialogue and discussion with you.

MR. VARDEN: Great. Thank you, very much.

(Applause.)

MR. WILLIAMS: Thank you. That was really helpful. First of all, let me apologize for the late notice that we had. This really was for us somewhat of a last minute decision to come out here to Las Vegas. And the idea to send you all letters was even more of a last minute decision.

But, however, I think that's a good idea. We really need to send a listing. I think the best place for us to do that is the FDA website. And so we will -- any future meetings we'll have on the FDA website and we will try to get it out, perhaps in industry publications, or whatever we can do to try to get the word out as soon as possible, so again, I apologize for that.

One more thing I just want to say, and this is about the plain language, we are required to write a plain language small business guide to compliance. That's in the law, in the SBRFEA law. In addition to which, as you may know, the vice president has a major push on to get all regulations, not just our small business compliance guide, but all regulations written in plain English, and I can tell you that FDA is extremely committed to that goal.

MR. VARDEN: Okay. And Claudia Lewis-Eng

has asked to speak also.

CLAUDIA LEWIS-ENG: Good evening. My name is Claudia Lewis-Eng, and I'm an attorney with Emord & Associates. We're a Washington, DC based law firm, and I'm here on behalf of Pure Encapsulations, they are a dietary supplement manufacturer and distributor. They're based in Southborough, Massachusetts. I'm also here on behalf of Weider Nutrition. They're out of Salt Lake City, Utah. I'm here on behalf of Durk Pearson and Sandy Shaw. They're out of Nevada, Tonopah; and American Nutrition Corporation, and they're a center located right here in Las Vegas, Nevada, and they're also a dietary supplement manufacturer.

And I'm here to say today that my clients object to any adoption of GMPs for dietary supplements. They firmly believe that dietary supplements are safe when you look at them and compare them to food and drugs.

And we specifically have experts, and we'll submit that with our comments that are due, I believe August 4th. Also, we also feel that the FDCA and DSHEA also has in place mechanisms to protect against adulteration and misbranding and

that those are sufficient to mitigate against any health concerns that you might have within the agency.

I guess our foremost concern would be the economic impact that such regulations would have on small businesses. Many of our clients at our firm are medium to small businesses, and it would be overwhelming and very expensive to get do all the procedure and reporting, the record keeping and the personnel. It would just be absolutely overwhelming.

We also feel that it would sort of concentrate the industry. It would sort of push out the smaller guys and allow the big players in the industry to take over.

I've talked to several clients before I came here, and specifically Pure Encapsulations stated that they would have to forgo some of their research and development. Instead of developing new products they would have to move that money over into coming into regulatory compliance, and they're much more interested in their consumer base, much more interested in having more new and better products as opposed to complying with regulations that they don't deem to be necessary.

And I guess my final comment, and I suppose it would be a question to you, is I know the FDA right now, and it's government-wide, has limited resource, I'm just wondering how does the agency intend to enforce these GMPs? Once you have the GMPs in place, consumers will assume that the government has taken the steps necessary to -- that the dietary supplements themselves are safe. Well, that might not necessarily be so, and I think that it will be a disservice to the consumers to make that representation.

And we will submit comments to you in greater length with our expert reports attached to it.

MR. VARDEN: Great. Thank you, very much.

At this point why don't we open it up for whoever would like to speak at the mike, and again announce your name and the firm you're with.

JEFFREY REINHARDT: Jeffrey Reinhardt, People for Pure Foods, a national consumer public interest networking group. I have a question. You mentioned an advisory report of the industry member or GMP committee or subcommittee. Is that report available?

MS. STRAUSS: The draft report is

available. It was presented to The Food Advisory Committee June 25th, and The Food Advisory Committee took it under advisement along with some suggestions and an opportunity for small comments from The Food Advisory Committee up until July 23rd.

JEFFREY REINHARDT: Is The Food Advisory Committee an external committee or an FDA in-house?

MS. STRAUSS: It's an FDA committee.

JEFFREY REINHARDT: Made up of FDA employees?

MS. STRAUSS: Right. And then the working group was established by The Food Advisory Committee to address a couple of particular questions regarding the GMPs.

JEFFREY REINHARDT: Again, all in-house?

MS. STRAUSS: No.

JEFFREY REINHARDT: Could you --

MS. STRAUSS: Surely. The Food Advisory Committee members, some of them are on the working group as well as industry members. The representatives from industry included Mike McGuffon, Bruce Earl, Paul Bowlard and -- I'm blocking on -- as well as industry -- as well as

university academic scientists. The FDA was merely a facilitator.

JEFFREY REINHARDT: Okay. Thank you. And then I have a comment. I believe you said under the handling and storage of raw and in-process materials section that with regard to certificates of analysis and one identity test for each lot of ingredients that there was a discretionary option for the manufacturer to use a C of A from an ingredient supplier; is that correct?

MS. STRAUSS: If the purchaser or manufacturer checked the reliability of the C of A, established the reliability of the C of A.

JEFFREY REINHARDT: With all the constraints and practical aspects of your responsibilities, I think it's accurate to say that current standards, C of A's sometimes are, I really see why it is, and if you give -- what strikes me as greater discretion that that situation could only get looser, and certainly with the spirit and intent, not only of the industry activities, as Tony Martinez described, and the NFA announced, but also the legislative GMP situation, that needs, I think, greater thought, greater scrutiny to really make within the industry the C of A's more

meaningful and valid with regard to what they attempt to represent.

But particularly my concern is that that then translates to the consumer, and although the consumer would never see it, certainly if this particular situation is addressed meaningfully and thoughtfully it will give consumers a much greater likelihood and higher probability of getting higher quality products batch to batch to batch, getting value for money in essence. Thank you.

MS. STRAUSS: And if you have comments on how meaningfully and thoughtfully to address that, those would be very, very helpful, if you can write written comments.

JEFFREY REINHARDT: So the consumers benefit --

MS. STRAUSS: No.

JEFFREY REINHARDT: -- or procedurally?

MS. STRAUSS: Procedurally for the GMP.

MR. VARDEN: Okay. Would anyone else like to speak?

I.S. NEWTON: I.S. Newton from Roche Vitamins, New Jersey. Just a question, would you happen to know if these GMPs were compared against the GMPs for those and carried out by HPB in Canada

to see if there's any harmonization between what was carried out there and what is proposed here?

MS. STRAUSS: I don't think so, but that's a good idea.

MR. VARDEN: Any other questions or comments?

Yes, sir?

TONY McKELVEY: My name is Tony McKelvey from Captek Softgel. I was just wondering if, Karen, did you write a lot of these -- the thing that we're seeing, the ANPR?

MS. STRAUSS: No, not at all.

TONY McKELVEY: Okay. Did any of the authors go out and actually visit any of the manufacturing sites?

MS. STRAUSS: The authors -- it was a coalition from industry. There wasn't anyone on FDA on that --

TONY McKELVEY: Okay.

MS. STRAUSS: -- writing.

TONY McKELVEY: Is the FDA going to also look at label claims or try to discern that for some of the supplements or vitamins? I know that's an issue. I'm sure testing for that too would also be a very costly aspect too for some. I'm

wondering if the FDA is also going to look at the label claims.

MS. BARNETT: What kind of claims are you talking about?

TONY McKELVEY: Claims that certain products would do certain things, help in certain ways.

MS. BARNETT: That's not within the scope of this rule.

MR. WILLIAMS: We're talking about the ingredient list. Also let me just say that it is our intention, actually, before we promulgate this regulation, to visit some plants and look at their manufacturing operations.

MR. VARDEN: Anyone else?

Well, I guess we can close the meeting earlier, I guess, unless anyone else has any last thoughts.

MR. WILLIAMS: Let me just reiterate, if anybody does have anything they would like to say over the next day or so, please contact me. Again, I'm across the street in 1390, Richard Williams.

(Thereupon the proceedings were concluded at 8:14 p.m.)

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CERTIFICATE OF REPORTER

STATE OF NEVADA)
SS:
COUNTY OF CLARK)

I, Deborah Ann Hines, certified shorthand reporter, do hereby certify that I took down in shorthand (Stenotype) all of the proceedings had in the before-entitled matter at the time and place indicated; and that thereafter said shorthand notes were transcribed into typewriting at and under my direction and supervision and the foregoing transcript constitutes a full, true and accurate record of the proceedings had.

IN WITNESS WHEREOF, I have hereunto affixed my hand this 27th day of July, 1999.

Deborah Ann Hines

Deborah Ann Hines, CCR #473