Rec'd 10/20/99
jb

SEPTEMBER 28, 1999

MEETING FOR SMALL BUSINESS OUTREACH

FOR GOOD MANUFACTURING PRACTICES

ORIGINAL

96N-0417

TR 2

Rocky Mountain Reporting Service, Inc.
528 Newhouse Building
10 Exchange Place
Salt Lake City, Utah 84111
Phone (801) 531-0256

Statewide Reporting
National and Merit Certified Reporters
Expedited Delivery
Computerized Transcription
IBM Compatible Disks
Litigation Support Software
Video Depositions

SEPTEMBER 28, 1999

MR. VARDON: Welcome, everybody. My name is Peter Vardon. I'm an economist with the Food and Drug Administration. And we are here to introduce you to our food and drug administration small business outreach for proposed rule to require good manufacturing practices in the dietary supplement industry.

This is a public meeting, and so our comments will be recorded. Heather there will be transcribing our comments. And we're doing this because several years ago the industry submitted a proposal to us, the dietary industry submitted a proposal to us, suggesting that dietary supplement, the industry might benefit from a good manufacturing practice proposal. The FDA then submitted to the ANPR, which is there on the front desk and it's been out for a couple of years for public comment. Our stakeholders have also supported the initiative and that's led us here today in a nutshell.

Richard Williams, Dr. Williams will open the meeting by first telling you the regulatory process, how a rule goes into effect, and what sort of comments will help us write the best sort of rule especially as it regards to the impact on small businesses. Following Richard, Karen Strauss, our consumer safety officer, the one who is

actually writing the rule, will then talk about the provisions of the rule, then we'll open it up for public comments.

One reason we have done this small business outreach is because this industry perhaps uniquely is characterized by small businesses. Our estimate is that of the 2000 firms in the industry about 40 percent have fewer than 20 people, and the median firm has only 15 people. So the industry in character has been very small businesses. And also uniquely, the firm only has about six percent large businesses. And I'm defining large and small as the Small Business Administration defines them, as fewer than 500 employees.

Also, the industry has a large number of firms that are just unknown to us, about 40 percent of the industry is just unknown to us, the composition of the firm, and so because of that uncertainty, and because of how much we do -- what we do know about the industry being characterized by small firms, we wanted to endeavor to reach out to you as much as we can to get your comments about how this rule will impact your firms.

Because this is a public meeting, if you would like to make a comment, we ask that you go to the center of the room and state your name and the firm you're with, and so that Heather can record your name correctly, correct

spelling, if you would give her also your correct spelling of your name and your firm afterwards we'd appreciate it.

So without further ado, I'll turn it over to Richard.

MR. WILLIAMS: Thank you for coming. This is a nice small group, so I hope everybody will feel like it's okay to get up. I think Karen wants to go through her presentation all the way through without interruptions, that is not what I want. While I'm talking, if anything I say -- if I'm going too fast, which I have a tendency to do, or if there's just something that you don't understand, please stop me and ask a question, or make a comment, or whatever.

I would also like to thank you for coming. As Peter said, the Food and Drug Administration has announced through our advanced notice of proposed rule making, our intention to create a new rule, and I think that there is a possibility this rule will affect your business considerably.

And this morning, what I want to talk to you about is first of all about our process for creating rules, because I think many people in your industry may not be familiar with how the process goes, and then some suggestions for how you can play a part in helping make this rule better. And finally, I will lead into Karen's

discussion, which will be about the actual elements that were put forward in the advanced notice.

Typically, even though most of the firms that we in the Center for Food Safety and Applied Nutrition regulate are small, you are the people we hear the least from. I'm not as familiar with the dietary supplement industry as I am with the food industry, but when I talk to the food industry, they say the reason is because we're busy making payroll, we don't have time to pay much attention to what you do. But I think it's important that you're here, and I think it's important that you do play a role in this process.

Peter, can you start? You can just skip that one.

The first thing I just want to bring to your attention if you're not already aware of it are the two laws that affect what regulatory agency that basically create a lot of percussions for small businesses. And the first one was Regulatory Flexibility Act of 1980, and essentially that is the law that said that for significant rules we have to analyze what the impacts of small businesses are. That was really the meat of that rule. It was given a lot more teeth however in 1996 with the Small Business Regulatory Enforcement and Fairness Act. That rule requires us to reach out to small businesses to

solicit your comments, it requires us to analyze what the cost will be to your firms, and it requires us to look at flexible regulatory options. Where we can, while we're still accomplishing our public health and consumer information mission, if we can make the rule more flexible to lower your cost, then that's what we have to at least consider doing. However, it's very difficult for us to do that if we don't hear from you.

Here is generally how our analyzing process works, if you're not familiar with our rule making processes. We don't always start with advanced notice of proposed rule making, but we did in this case, and we did because your industry came forward and said here is some elements we would like to see in a good manufacturing practicing rule.

Right now we're holding not just small business meetings like this, but we're also holding general meetings for the entire industry to talk about some of these provisions.

The next step will be the notice of proposed rule making. What's important, though, is right here at this point in time if you want to give comments either in this meeting or in written comments to us, you can, and it's a good time to make your voice heard, I think.

Once we go through the notice of proposed rule

making, then we'll have a period, I think typically 90 days, I think, for public comments. Again, that's another opportunity for you to send your comments into the FDA after you actually see what's in the proposed rule making, then we will go to a final rule, and finally somewhere within that final rule will contain a date by which you have to comply with the provisions of that rule.

Some suggestions, you can comment on any aspect of this rule that you want. There's nothing that says -- but let me just suggest some areas that typically we see in the comments. Some people comment on whether or not there's any need for the rule at all. One important thing, I think, that you can comment on is other ways to accomplish goals. In other words, if we have a provision that we're suggesting might be a way to accomplish a goal and you know a better way to do it, after all, it's your industry, there's often more than one way to accomplish the mission.

This is the thing that I'm going to spend most of the time talking about, what it will cost you to comply with the rule. That is the thing you have intimate knowledge about, and that is that thing that here at SBREFA we are required by law to analyze.

Finally, you can look at specific provisions of the rule and say whether or not you think that that

particular provision of the rule will accomplish what it's intended to accomplish.

Mostly I want to talk about cost. The cost that we look at are your costs to doing new things, things that you haven't done before. And what I want to do is I want to take you through and describe to you how we analyze cost. Most of you are familiar with how accountants analyze cost, for economists like Peter, it's a different story. So the first thing that we're going to look at when we analyze cost is who in your industry will have to do something different? And if you want to submit -- if you would like to submit comments along these lines, what I've done is I've got some categories across the explanation of what I'm talking about, and some examples.

So in this case, for example, you might say if we have a GMP rule put in place, managers would have to do something different. They might have to start focussing on quality control and stop focussing on hiring. So the first thing we might like to know is who actually would have to do something different, and you would look through each one of the provisions of the rule and say, okay, I know that this kind of person in my plant will be affected.

Next thing you want to do, is say, okay, well, if they have to do something different, what is it that they'd actually have to do? And that's not always

straightforward. You will have to look at the provisions of the rule and say in order to comply what will I do in my firm, what will these people do in my firm that's different from what they're doing now, what new duties will they take on? For example, again, I threw managers in there, managers may have to spend some time on implementation. Again, this is different than the way most people think about cost. Managers are still going to be paid what they're paid, so an accountant will say there's no cost here, but to an economist, if they have to stop doing one thing and do something different to comply with the rule, this is a cost, and the FDA wants to know how many hours will a manager have to spend, for example, on complying with a particular rule? How much time will they spend?

Okay, we've already looked at who's going to comply, what new duties do they have to take on, how much time will it take, is it in hours, days, weeks, months, or years, however you want, however, in fact, it makes sense for you to put it down. So for example you might say that quality control workers might have to now as a result of this rule spend two hours a day taking samples. Okay, so that's the third element. How much additional time per person will be spent?

In order for us to calculate costs, we have to figure out, basically, how you value their time. So, for

example, and, again, now that I'm getting into things like average salaries, I'm going to say this a couple of times, don't send anything to the FDA that you don't want in the public records. In other words, if you don't want the world to know, is all I'm suggesting, if you don't want the whole world to know it, don't send it into us, because everything that we get has to go in the public record. Generally we will try to guess what average salaries are, but if you would like to supply us that information for a group of people maybe like tell us what their hourly rate is or what their annual salary is. I have an example here that QC workers get 19 per hour which includes overhead.

It may be that for provisions of the ruling not only are you going to have labor costs and management costs, you may also have new material costs or equipment costs. So, for example, if in fact an element of this rule ended up testing for pesticide residue, I don't know the cost of pesticide residue, so don't pay attention to $40, I just threw it in there to put a number in there. Pesticide, you might have to buy a pesticide residue kit, and you might need, say, ten per month. Again, I'm just saying that as an example, I have no idea if that's the actual cost or whether or not that in fact that would be a provision of this rule.

So you could include actual cost of new equipment

in materials, whether or not you just have to buy something one time, or whether or not it's an annual expenditure.

Also, if you have equipment that would have to be tossed out, we might want to know what's the depreciated value of that equipment?

What's the size of your firm? As Peter said, the breakup is pretty specific about who is a small firm and who is not. If you have less than 500 employees, which, I think, includes virtually everybody in your industry, you are a small firm. We would like to know, you know, who is submitting the comments. It will matter to us if a firm is submitting comments and they have 15 employees or if they have 490 employees. So you might, for example, say our firm has 200 full-time employees and 20 part-time employees. I should also add that if you are a small entity, but you are owned by a large entity who is actually a large firm, you are, under the law, a large firm. Even if you operate entirely independently, if you are owned by a large company, you are a large firm, and you would not be under the SBREFA rules.

In order for us to think of this regulation in a sensible way, we want to know what kinds of products that you are submitting costs for. So if you're submitting costs for this is what it will cost me to make herbal supplements, that's one thing, and if it was vitamins and

minerals that would be another thing.

One of the things we are going to look at as we go about trying to structure this rule, is to see are they requirements that make sense for the entire dietary supplements industry across the board and are there some things that would apply only, for example, to vitamins and minerals and herbals and such. So what products do you make?

This probably is the most sensitive thing, we do get to talk to some firms because they're interested in telling us and the small business administration asks us to look for it, it's virtually impossible for us to get this information. I do want to point this out, it's sensitive information for you, you need not send this in, what are your average annual profits. However, if you want to send that in or you want to send it in as a range, I make between $20,000-50,000 a year, that's fine. That gives us some idea of what you have to operate with in order to basically spend money to comply with a new rule. Again, don't send it in if you don't want the whole world to know what it is, because it will become public information.

Again, this is the subsidiary question, if you are a subsidiary to a large firm you would not necessarily be a small business firm.

So those are the elements of cost that we look

for. Those are the things that we will try to analyze under SBREFA in order to see what the impact of a potential rule would have on your firm. The more information that we get from you, the more closely we can analyze what the actual impacts will be.

Let me go on to the next slide. Let me just start, just for a minute, and I'm not going to take a lot of time with this because Karen's going through it in detail, but let me tell you some of the things we've already heard from small firms in your industry that are concerned about them. These are some of the things that we have heard some concerns about.

There are concerns about any requirements that would require them for written procedures. In other words, standard operating procedures, if they had to write them down they felt that that would be quite a burden. There were suggested, and Karen will go through specifically, lots of record keeping requirements that were put in by the industry that we repeated in the advance notice of proposed rule making and there are testing requirements. These are the things that mostly, what we're hearing from small businesses they have some concerns about. So those I just want to alert you to these if you want to focus in on those when you hear them in the presentation, those might be things that you might want to comment on.

Here is an example, one of the things we had in the ANPR was creation of master batch records. Again, I just want to talk to you just in the cost perspective, master batch records you'd obviously have to develop them, there would be costs, I think, just to develop the system to keep them. If your people didn't know how to keep batch records, you might have to send them or give them in-house training or send them to training and then there would be the actual recording cost. Again, there is a frequency to these things, I expect you'd only have to deal with them one time, training cost if you had some turnover where you had to retrain people every couple of years, every other year, and, I think, recording costs will mostly be by batch.

Again, the master batch records, who would be involved in creating these? I mean, I don't know, I assume maybe it would be the quality control people, production people, management might be involved in setting it up. This is the formula that we use, basically we would say in order to calculate the cost of doing master batch records we would say how many people, okay, again, this is what kind of people, what's there wage, so we have a number of people and their wage, how many hours would it take, and what's the frequency, would this be once a batch, once a week, once a year? This is sort of a general formula that

we use to get costs, and it's this kind of information that we'll be looking for.

Another example, testing raw materials. There is a number of possible tests that could be included in this proposal. One would be tests for identity, to test to see that what you list on the ingredient label is actually what you have in the product. Possibly microbial tests to see if you have pathogens, or there are other possible tests that you can run for all sorts of contaminants, heavy metal contaminants like lead, or contaminants like aflatoxin, pesticides, or any other ones.

One of the things about ingredient testing that you might want to consider if you want to analyze this is you might want to tell us what is it you do now, for example, to identify ingredients, do you do organologic tests, or do you just do morphological plant structure tests? Do you use certificates of analysis, or some sort of certificate of guarantee? Do you do chemical or laboratory tests, or analysis of markets? What would be important if you use one thing now and then the rule comes out and says, okay, maybe you're using this now, we think it's important you use this, then that might create a cost to you that you would want to say, the difference between this and this for me is considerably more man hours.

So, again, cost items, you'd want to talk about

the hours that it would take people to take and prepare samples to run tests, you might want to talk about the material that you have to have to run tests, how many samples you have to take, obviously you lose product when you do this, you might have to buy new equipment, if you need space to store raw material while you're waiting for the results of the product, production time would be lost if, in fact, you had a period of time where you couldn't produce because you're waiting for the results of the test. And you would have to, undoubtedly any tests that you created you will have to retain the records that you create out of those, and you will have to -- and that's a cost also.

The kinds of factual information that I've been talking about, about costs, these are the kinds of comments that, I think personally, really help to make it a better rule, and they're -- it's the kinds of comments that I think will help you. It's definitely under your protections under SBREFA, it's the kind of thing that the federal government is required to look at, and I think it's probably in your best interest to submit those kinds of costs.

Again I want to caution you, the third time I think, don't send anything that you don't want in the public record. There's nothing that compels you to send

any of these things in, nothing at all. You don't have to comment at all. On the other hand, the more that we know about you and your products, the better the chance the agency can address your needs.

Okay, that's where I would like to stop and introduce Karen Strauss who is going to talk to you about some of the elements in the advanced notice of proposed rule making, unless there are any questions at this point?

GLEN PUTNAM (USANA): I have one question.

MR. WILLIAMS: If you would please stand up.

GLEN PUTNAM (USANA): You mentioned the size of the company was very important, saying how you seem to focus more on the small business entity, how are you going to factor the differences between a large corporation of about six percent that you talked about and the smaller business? If you get costs requirements from a very large corporation, they are going to be somewhat different than that of a small business, how do you take into consideration that compensation so you actually get the information you're looking for?

MR. WILLIAMS: Hopefully people identify the kind of firm they are when they send in the cost information, that will be very important. I mean, we need to know enough to know that a company is a small business. If they are a small business, that will be analyzed under the

Regulatory Flexibility Act. We then have to take that information and we have to say is there something different that we can do for small business? Sometimes it's a matter of they simply need more time to comply. Sometimes it's a matter of we can actually structure the rule differently. And it depends, we don't have all the answers, I think, for small businesses. A lot of the time the best suggestions come from the industry on ways we can make it more flexible, but under the law we can consider doing different things for small businesses and for large businesses.

I don't know if I've answered your question.

GLEN PUTNAM (USANA): That's all right. We'll see how the discussion goes.

MR. VARDON: Would you mind stating your name also?

GLEN PUTNAM (USANA): Glen Putnam, P-U-T-N-A-M.

MR. WILLIAMS: Anything else? Yes, sir.

MONZUR AHMED (Enrich International): My name is Monzur Ahmed from Enrich International. I wondered if you could explain a little bit more under what laws that large company that owns a small company subsidiary, subsidiary is not defined as a small business.

MR. WILLIAMS: Yeah. It's pretty straightforward. If you are an entity owned by a larger firm, even if you sort of feel like you're an independent

operation, if your employment combined, the large company and the smaller subsidiary, is over 500 employees under the law you are a large business, and that's just straightforward. You do not really qualify as a small business.

Karen.

MS. STRAUSS: I would like to say that I'm not going to be the only person writing the proposed rule, there is a team approach and I'm one of the team. And we will have on the team various kinds of experts within the scientific resources of FDA, so I didn't want anyone to think that I was going to go away in a room and write it all by myself.

As was mentioned before, the purpose of this meeting is to receive your comments that will help us, help us The Center for Food Safety and Applied Nutrition, to understand the economic impact that any proposal to establish current manufacturing practices for dietary supplements would have on a small business in the dietary supplement industry.

A little bit of background, you probably don't need this, but I'll just highlight it anyway, the Dietary Supplement Health and Education Act is the authority that gives FDA the authority to adopt GMP regulations. And a significant segment of the industry has told FDA that GMP

regulations would be helpful, and they did this by submitting the industry outline to us.

DSHEA defines dietary supplements as vitamins, minerals, amino acids, other dietary substances used to supplement a diet, and concentrates, metabolites, constituents, extracts, or combinations of these. And as was mentioned, FDA is in the process of developing good manufacturing practices and as a starting point we're examining the industry outline. If this was developed by a coalition and submitted to FDA, and then FDA published it as an Advanced Notice of Proposed Rule making. And as we've referred to this, we call it an ANPR. It was published February 6, 1997 in the Federal Register. An ANPR is not binding on the FDA, it's not a regulation, but because we are examining it and we need something to kind of get your comments as opposed to, we'll be using it as a framework at this meeting.

I'll provide an overview of the dietary supplement GMP proposed in the outline. And that's an unenviable task, it's not very interesting or exciting, it's not very interactive, it's kind of to give you a description of, in brief, what was in the ANPR.

I wonder if you would raise your hand if you have seen the ANPR before this meeting. Okay, so it's not that new. How many sent comments in during the comment period

to ANPR? A few. And how many were participants in the industry coalition? So some of you as well.

As Dr. Williams noted, we are interested in knowing about your firm's current manufacturing practices, because it's changed, that will be used in determining the economic analysis. We also want to know what you think about the elements included in the ANPR, what associated costs and time frames would be needed to meet these elements. The purpose of the GMP is to ensure that customers are provided with dietary supplements which are not adulterated during the manufacturing process. The Food, Drug, and Cosmetics Act prohibits the selling of adulterated products. In a lay person's terms this means a product contains contaminants. The industry submitted draft was modeled after the food GMPs, but it also adopted, modified, and extended to meet the special manufacturing requirements of dietary supplements not addressed in the food GMPs.

The ANPR includes the requirements that are related to personnel that work in the dietary supplement firm. The sanitation, maintenance of grounds that surround the physical plant or building used to manufacture dietary supplements are addressed. A building or physical plant design and construction are also considered, and the design of equipment utensils as well as their insulation, their

use, the sanitation of equipment and utensils, these are also addressed in the ANPR. Production and process controls that are designed to endure quality throughout the manufacturing process are included. And, finally, the ANPR identified GMP records that are needed during the manufacturing process and after distribution to ensure that a recall could be implemented if necessary.

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

Now, these are some personal concerns. All persons working in direct contact with dietary ingredients or dietary supplements must use hygienic practices and not have any diseases that will result in an adulterated product. And all employees should have the proper education, training, or experience to perform their assigned functions. Appropriately trained and experienced supervisory personnel should have the responsibility for insuring 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 that would protect against adulteration. This may involve storing equipment, removing litter, waste, cutting weeds or grass within the immediate vicinity of the plant that might attract or provide a breeding place or a home for pests.

Physical plant design and construction must be suitable in design and size, facilitate maintenance, cleaning, and sanitary operations, and also to prevent mix-ups between different ingredients and different materials, in processed materials, finished dietary supplement product. Plumbing, sewage disposal, rummage disposal, public handwashing facilities, all of these elements in the manufacturing plant are addressed as measures to insure that dietary supplement production are not adulterated.

Equipment and utensils are also addressed in the ANPR. And these are so designed and made of materials that are adequately cleanable and maintained. The installation should facilitate maintenance, cleaning, sanitation, and be positioned so that workers can move appropriately during manufacturing. Design, construction, materials, that are used in the equipment, the calibration of instruments to maintain accuracy, these are all elements to protect

against adulteration during the manufacturing process.

Production and process controls, these elements include a quality control unit or a quality control person. It includes laboratory operations, manufacturing operations, packing and labeling, and holding and distributing of dietary supplements.

I'll give a little information on each of these, but more detail on the type of control considered can be found in the ANPR.

There must be a quality control unit or quality control person that has a responsibility and authority to do the following: To approve or reject all procedures, specifications, controls, tests, examinations, or deviations from these examinations in specifications that impact the purity, quality, and composition of an ingredient or dietary supplement. You must have the authority and responsibility 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. There would also be an option for outside laboratory testing, but the laboratory tests are the control issue here.

Holding and distributing elements include

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

The elements listed on this slide are found in the ANPR in various sections. They're in the production and process controls, they're in the warehousing, distribution, and post-distribution procedures sections. Ingredients in processed materials and finished dietary supplements must be stored in the manner that prevents adulteration or mix-up. When receiving ingredients, packing materials, and label materials they 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 to conform to other specifications. Tests may include chemical, laboratory tests, gross organoleptic analysis, microscopic identification, or analysis of constituent markers, these are what were mentioned in the ANPR. The ANPR says that in lieu of such testing by a manufacturer, a guarantee or certificate of analysis, or C of A, may be accepted from the supplier provided that the manufacturer establishes that that C of A is reliable.

A recently submitted draft report of an FDA food advisory committee, GMP working group, that included

dietary supplement industry members recommended something different than this and wanted you to know about what they recommended. This working group recommended that multiple tests be conducted to confirm identity. So this is a GMP element in which we would especially like to hear your comments.

Raw materials should be examined and tested for filth, infestation or extraneus material, microbiological contamination, aflatoxin and other natural toxins. In-process materials must be tested during manufacturing to detect adulteration.

These are manufacturing operations. All operations in receiving, inspecting, transporting, segregating, preparing, manufacturing, packing, storing, must be conducted in accordance with 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.

In the ANPR it says that any product that has been adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

The ANPR includes manufacturing operation

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

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

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

Products and packaging materials not meeting the specifications must be rejected.

Storing and distributing of finished products. An ANPR element says that the finished product must be stored in conditions that will protect against adulteration. It requires reserved samples of each batch of dietary supplement that is representative of the batch, or each batch of dietary supplement must be retained and stored under conditions consistent with product labeling. And the reserve sample must consist of an amount that would be available to test at least twice the quantity. Let me

say that again, the reserve sample must consist of at least twice the quantity that's needed to perform all required tests.

These are some elements concerning written procedures and records. In the ANPR the industry identified certain written procedures and records that the industry coalition thought were necessary to be included in the GMP. Under the ANPR outline, written procedures must be established and followed. Records would document the use of the written procedures. Written procedures were included for cleaning and maintaining equipment and utensils used in manufacturing, procedures for responsibilities and order of the quality control unit, written procedures for processing batches, including a master production record and a batch production record. Elements of the master and batch production record are identified in the ANPR and I'm not going to go through them all here, but, for example, the master production record includes the names and amounts of ingredients, steps in manufacturing, quality control, containers, closures, and labels that would be used in producing that product.

The batch record documents how the master record was followed and it documents any deviations from the master record and any investigations of those deviations.

Written procedures that describe appropriate

laboratory tests are mentioned in the ANPR. And these would be tests or examinations conducted to insure purity, composition, and quality of a dietary supplement. And records or written procedures for the receipt, storage, handling, sampling, examination, and testing that might be necessary to assure the identity of labeling. Appropriate identity, cleanliness and quality characteristics of packaging materials.

Written procedures to assure that correct labels, labeling, and packaging materials are issued and used, and the ANPR includes written procedures in reference to describing the handling of all written and oral complaints regarding a dietary product.

The industry submitted outline identifies these records as those to be retained: Records pertaining to raw materials, any laboratory, any production, any control, or any distribution record, and any complaint record specifically associated with a batch of dietary supplement. And how long must these records be retained? The ANPR noted that the records must be retained for at least one year after the expiration date of the dietary supplement, or if no expiration date is identified on the product for at least three years after the date of manufacture.

So there you have probably in brief the elements that were included in the ANPR, just an overview, with more

detail, of course, and in the ANPR. And as was mentioned earlier, we're in the process of drafting a proposal.

MR. WILLIAMS: I just want to add two more notes. One of the things you should know is we have been out visiting dietary supplement firms trying to get a handle on really what goes on in your plants. To date we have visited only very large plants and large operations. At some point I think if anyone's interested we might also like to visit a smaller operation to see what's going on.

The last note is we sent out, some of you may have received, a portion of what I talked about and there was a phone number on there. It is our intention ultimately to set up a small business hotline to help people in writing comments the way I suggested. That number will be ultimately (202) 401-4590. I think what was originally sent out and we had to stop it, we had 205 instead of 401, but that is the number.

Okay, I think we're ready to open it up for any comments at this point.

MR. VARDON: Glen Putnam wanted to speak first.

GLEN PUTNAM (USANA): Thank you, Peter. I said I only needed five minutes, but when you said I had more time I went ahead and elaborated a little bit here. Again, my name is Glen Putnam, that's G-L-E-N, P-U-T-N-A-M. I'm with a company known as USANA, U-S-A-N-A.

I appreciate the opportunity to address this body this afternoon. It is my hope that the information presented will be beneficial in your meeting your objectives in trying to establish GMP regulations for dietary supplements. First, I want to state for the record that the information and statements that I will make may or may not represent the opinions or views of other manufacturers or trade groups. I'm not acting as a spokesman in their behalf. I am representing, however, both my employer USANA, and myself as a consumer that advocates the need of high quality dietary ingredients and products. In this duel role, it is my opinion that the proposed GMP for dietary ingredients and supplements outline in the February 6, 1997 issue of the Federal Register is inadequate and does not provide both the safety and quality needed in this industry. Secondly, the difference between food and dietary supplement GMP are for the most part minor. The increased cost burden associated with the proposal in reality will represent mostly insignificant cost adjustments to most manufacturers. I hope that as I elaborate on several issues, I can identify why we do not see a large cost associated with the proposed program.

I am the quality assurance and regulatory affairs manager for USANA, Inc. We are a multi-level marketing

company that develops and manufactures a variety of nutritional products. Our dietary supplements are produced here locally in Salt Lake City, Utah with approximately 430,000,000 tablets manufactured annually. As a company we have tansitioned from a small Utah based company with a handful of employees, to approximately 500 employees throughout the world. Therefore, we have experienced the costs associated with small operations to that of our current size. Our product distribution is through independent distributors and not the usual retail outlet. Therefore, we have other costs not usually associated with the more traditional selling methods. For us we are very cost-minded and proactive to change particularly those that affect regulatory requirements.

We maintain an active pharmaceutical license with certain foreign countries to meet their regulatory position. Certain dietary supplements as defined under DSHEA are considered drugs in such countries as Canada and Australia. We have a quality system that reflects the highest drug standard in order to compete internationally. However, as we have transitioned from making dietary supplements as foods, then classified under DSHEA, and finally classified as drugs internationally, we have experienced what real costs are associated with that transition. Despite the growth phases or conditions of the

company, total quality and regulatory costs have been on average about one percent of our sales. For example, in fiscal 1998, total U.S. sales were approximately $70,000,000. The quality and regulatory costs were approximately $675,000. So we feel somewhat experienced in costs and controlling them to maintain compliance with regulations but keep our company profitable.

When reviewing the proposed GMP language, we compared it to the current food GMP model as mandated by Congress under section 9 of DSHEA. We wanted to compare current methodologies with proposed new ones to determine a relative cost. We took the position that we had a basic system, with adequate staff, procedures and equipment for full compliance to food GMP. A significant change from food GMP to dietary GMP was noted and assessed for needed tasks, manpower, and equipment. This was then reviewed and assigned as either a cost addition or reduction. For the most part, we found minor wording and format changes when making this comparison with no added costs. The more significant additions that we also viewed as insignificant because of the vague nature of the wording. Let me illustrate our review.

Under the definition section, eleven new terms were added and seven were removed from the basic list found under the food GMP. There would be no additional costs or

savings with this section.

The personnel section for the most part is similar to food with a minor addition that required the retention of training records. Again, it was viewed to have no additional -- no cost burden to the company.

Both of the plant and grounds and sanitation of building and facilities remained so similar to current methods that costs were unaffected.

Under equipment and utensil, two new additions were noted, the cleaning procedures and records. Again, both requirements are considered to be very minor with no additional costs associated with their implementation.

Under quality control and laboratory operations section, the first major change was presented. We noted an addition of five major tasks with potential manpower and equipment requirements would be needed depending upon the operation. However, after careful consideration of the requirements, it was realized that the terms were vague. Because of the loose language we could rationalize sharing the tasks with others, and avoid additional costs in manpower and equipment. This is our interpretation of the rational:

The QC unit could be manufacturing, warehouse, or even accounting personnel given some added responsibilities. Neither the definition nor this section

speaks in terms or takes into consideration potential conflicts of interest. Unlike the language in drug or medical device GMP programs, the needed clear and distinct separation of this unit from all other company units does not exist. Therefore, the QC unit could be a shared responsibility with others in the company to incur no additional costs.

The wording, and I quote, "Adequate laboratory facilities should be available as needed," close quote, can also be interpreted as not needed. Because testing requirements throughout the proposed GMP are vague, a laboratory can be viewed as not a necessary item for compliance to this regulation. For example, the minimum one identity test required on raw material can be done with no facility needed. Most manufacturers will verify identity with a visual comparison of the receipt sample to their internal standard test. If any test is needed, it can be sent to an outside contract-testing lab to save costs.

Dietary data is only required when a, and I quote, "dietary ingredient and dietary supplement bears an expired date," close quote. With no additional requirements for mandatory expiry dating, companies can choose never to place an indication on the label and avoid this requirement. Again no additional costs are incurred.

With the production and process controls section, several new paragraphs were added, but again, these were viewed as a standard among the industry. Master batch formulas and records are commonly used to produce dietary supplements. Procedures for the receipt, rotation, storage, control, identity, and traceability are all common practice. Those that may need to implement these processes will experience very little cost to their overhead. The only potential cost addition was the raw material and finished product testing. However, as stated earlier the requirements are still vague. Most manufacturers will simplify this process to minimize costs. They will continue to perform this function by comparing raw material received with the internal standard. The same will be true for finished product. If additional costs are incurred, they will be minimal at best.

The last section on warehousing, distribution, and post-distribution presents some new ideas not as common as most would believe. Sample and record retention, complaint files, investigation, and rework procedures are not difficult to implement. However, those that are familiar with these practices can testify that it represents a small cost initially and is a minimal cost long-term.

Therefore, we concluded that the associated cost

adjustment needed for full compliance to the proposed GMP was minimal and insignificant. The larger and more reputable companies have better quality programs than that proposed. However, let us be honest and realistic with how most companies will implement the proposed regulations. Both as an employee and a private consultant in this industry, I can tell you that most will do the least possible. In boardrooms and departmental meetings, more time and effort will be used to find ways to avoid any large expense for compliance purposes. I have already alluded to this with examples of how the loose language of the proposal will be used in a company's best interest, not the consumer's. So to truly assess the economical impact on business, the language needs to be clarified.

We found the vagueness of terms and requirements to even be somewhat in contradiction to some of the wording in DSHEA. For example, section 7 of DSHEA amended section 403 of the FD and C to add conditions of misbranding of dietary supplements. If the label or labeling of the supplement fails to list an ingredient by name and quantity, it was to be considered misbranded. Now I will not claim to interpret the intent of Congress, but the term quantity can be viewed in two different ways. One is the theoretical amount added to the formula and the other is the real quantity or potency. Under the proposed GMP

regulations, it appears that it has been interpreted as the theoretical amount. It is our opinion that many in the industry want this interpretation, because it's easier and will not cost them very much. However, we disagree with this viewpoint and interpretation. I will illustrate with two real examples, and these are examples I know personally.

I have two samples of Cyanocobalamin, vitamin B12. It's in a one percent concentration. Both claim to use USP grade vitamin B12 that is diluted with Dicalcium Phosphate. Both come from major well-known suppliers in this industry. They always supply a Certificate of Analysis. As you can see, they're both very different. As I have already stated, most manufacturers will examine the material upon receipt, if it matches their internal standard it will be used. No other tests will be performed, and this is perfectly acceptable under the proposed GMP. However, upon chemical analysis, one of these samples proved to be sub-potent at .076 percent. The products that contain this material will not have the real quantity of B12 represented on the label. The manufacturer will not be aware of this condition because it is not required under the proposed GMP and would cost money to find out. When we questioned this with the supplier, their comments to us were not surprising, that they had never

heard from their customers that it was sub-potent, and they probably never would have heard because of the language, the way it was written.

A local company was selling a multivitamin tablet with folic acid. They used a local contract manufacturer to make their product. The folic acid was received with a C of A from a well-known and reliable source. Again, it matched their internal standard, so it was used to make product. Lot after lot after lot, this process was repeated. Batch records and other process controlled records confirmed that folic acid was added to the batch in the right quantity. Everything was processed in accordance with the proposed GMP requirements.

Eventually a consumer of the product complained to the FDA because her child was born with neural tube defect or spina bifida. The woman was educated and knew she needed folic acid for her developing child. She relied on the label that gave a quantity that was not realistic. From the investigation it was discovered that the product was sub-potent for folic acid. A recall order was issued with very little product being returned due to the consumption rate. Even though strict compliance to GMP was followed, the product was sub-potent for folic acid and a consumer was not protected.

The conflict in the term quantity poses a

significant risk to consumers. Many of you are aware of the Los Angeles Times article that reported the results of independent laboratory tests on ten products labeled with a quantity of St John's Wort. Even conflicts within the regulations need to be reviewed. For example, compare the finished product testing requirement and that of product salvage. The wording is not shared evidence from laboratory testing.

Therefore, we restate our original opinion that the proposed GMP does not have the muscle to prevent such a situation from occurring again. We feel that it will continue to defraud the American public of safe and high quality dietary products. In section two of DSHEA, Congress stated that improving the health status of the United States citizens ranks at the top of the national priorities of the Federal Government. If this is true, why are the regulations so watered-down? Why is not quality defined as potency or some other term to assure consumers receive what's on the label?

Consumers do not view food labels the same way they view dietary supplements. Industry only confuses the issue by making health claims. If the industry wants to use health claims to help market their product, then they should be required to do more to prove the safety and quality of the products they sell.

Inasmuch as FDA representatives are visiting supplement manufacturers and suppliers, USANA would also like to extend an invitation to visit our facility. We have transitioned from a local small source to a large international competitor. Our quality system offers potency guaranteed products economically. This system enhances consumer safety and product quality. We would be supportive in providing methods, systems, alternatives, and the economical impact of our company with you. Thank you.

MR. VARDON: Thank you, Glen.

MR. WILLIAMS: Thanks very much for those comments. I just want to point out one thing, and I think, Karen, I don't know if you want to respond to it also, but before you do I want to point out where we are in this process again, because you kept using the term proposed rule making. We're not there yet. All we have so far is an advanced notice of proposed rule making and what that was, was our reflection of what the industry submitted. We are in the process of developing an FDA proposed rule making now, and this is part of that process. So the things that you read in there are not necessarily what we would go with. That's what we're in the process of developing now.

Karen, do you want to take it from there?

MS. STRAUSS: I just want to say what was in the

ANPR was the industry submitted outline.

GLEN PUTNAM (USANA): I realize that.

MR. WILLIAMS: Do you have any other --

MS. STRAUSS: I just wanted to back up a little bit. I appreciate the invitation to visit and thought it might be helpful to tell you that in deciding which sights to visit, FDA received invitations through industry groups. We made known our interest in visiting sites so that we can learn more about manufacturing practices, and then through the industry organizations they made their members aware of our interest, and then the invitations came in that way. So if you are a small business and you would like us to visit, an invitation would be well received.

MR. VARDON: Would anyone else like to make a comment or do you have any questions so far of any proposal, any of the provisions? Yes, sir.

IRA PORTERFIELD (Porterfield Enterprises, Inc.): My name is Ira Porterfield. I am a consultant out of Denver, Colorado, and I just have several questions that I'd like to get out on the table.

Number one, given the fact that the FDA has a limited budget and certainly as it addresses certain parts of its mandate, those limitations have restricted the number of audits and the auditing techniques or instruction techniques that have been changing. And with that in mind,

I guess, one question is what's your reaction to the ability to keep up with the regulation as it may be promulgated here sometime in the future?

Will you -- as a second question, will you consider third-party contractors in this process, whether that be industry association driven? GMP compliance programs, I understand there is at least one that is being developed or just an independent qualification of consultants and contractors.

I guess another question along those lines is whether or not -- and I know this would be a departure from tradition, but some kind of a seal, a GMP seal, is being proposed through one industry association, is that something that FDA would consider as a way of branding products that, in fact, do comply?

And, I guess, the last question I have, have you actually inspected? You've indicated that you visited several larger dietary supplement manufacturers, has there been any attempt to assess the quality systems that are there today given the DSHEA mandate that food GMPs would likely be the standard? So, in other words, do you have a good sense from a compliance perspective of how well the industry is currently doing, large and small, and how they can through that mechanism how you might discover for yourself the impact that it may have on this industry?

And the last question I have, I guess, is more in line with the process that you're going through. Do you have any preconceived notions, any threshold of -- in your cost analysis as to where it will impact both timing of the promulgation as well as the content? In other words, I know you're in the fact gathering process, but do you have any -- I use the term preconceived notions not negatively necessarily, but just as a guidance to the industry at this point as to where and when and how you might react to the data and the information you're gathering during these sessions?

MR. WILLIAMS: I'll take the first couple of them. I think I got them all down, there goes that feedback again. How will we keep up was your first question. I guess, I'd like to say that anybody who would like to write to Congress and say that FDA needs more money for inspectors, I applaud you, but if that doesn't happen --

The second question was about third-party contractors. We actually are looking into that in some other areas, not dietary supplements, but I think it's something that the agency is looking at right now. We have no idea how this will work or if it will work, but I think it's an interesting suggestion.

What else, how -- well, I'm going to skip the GMP

seal one and I am going to leave it to our general counsel.

Attempt to assess how well the industry is doing now. That is what we're in the process of doing, and Peter Vardon up here, that's primarily his job. He's doing it by a number of methods, not the least of which is some of these industry visits that we've had. We're not necessarily getting that information through inspections, but we are doing everything we can. We're always hamstrung in our ability in terms of how we go about gathering data, we have rules for that as well. But we rely a lot on what the industry tells us, that's just the way it is. And like I said at the outset of my talk, the people we usually hear the least from is particularly the really small businesses. And that's why we are coming out in this session. We've had a previous one and we've got another small business outreach in Baltimore scheduled for next month. We're trying to get small businesses to come forward and tell us more about where they are now and what their potential costs would be.

I'm going to leave the process question to across the way here and the GMP seal.

MS. BARNETT: My name is Alexa Barnett, and I'm from the office of chief counsel at FDA.

As far as the question on the FDA seal, that's something that stakeholders have raised at our public

meetings and it's certainly something that the agency is aware that people are interested in. But I think all I can say is that we hear you and you've raised it and it's under review.

On the last one, I believe, correct me if I'm wrong, I think you're asking for when can you expect the rule?

IRA PORTERFIELD (Porterfield Enterprises, Inc.): The proposal.

MS. BARNETT: The proposal. All I can say is that both the commissioner and Joe Leavitt, who is the director of center for foods, this is on their top and high priority list. I mean, I'd say top three, top five. So we're under a lot of pressure to get it out, but we're also under pressure to put out a proposed rule that makes sense and takes into consideration all the things we have to like the small business concerns. So I apologize, all I can say is we're working on it.

IRA PORTERFIELD (Porterfield Enterprises, Inc.): Is it possible to put it into some rough time frame?

MR. WILLIAMS: Next year.

IRA PORTERFIELD (Porterfield Enterprises, Inc.): Next year, okay.

MS. BARNETT: Can I just follow up on one last thing? On your first question on inspections I think Rich

addressed that, but I just wanted to follow up and say that, you know, the people sitting here don't set the priorities for the agency on what we do inspections on, so we're just doing our part and hopefully we'll follow up with inspections later on. But certainly I can't commit the agency's resources to doing anything.

IRA PORTERFIELD (Porterfield Enterprises, Inc.): I guess I recognize that's necessarily not your mandate, but I wondered if that would be helpful to you to actually conduct given the fact that DSHEA set the food GMP up as a standard. And during this process would it make sense to actually employ the uses of some of your food inspectors to evaluate a sampling of these companies to see just how well they're doing. Maybe they're not doing well even against food standards, so adding to that standard would be the added requirements may, in fact, further complicate and it may not be necessary.

MR. WILLIAMS: I think it's a great suggestion, and we need to take it back and talk to our field people about it. Obviously we have to compete with all the other inspection priorities in the agency. Thank you.

MR. VARDON: Thank you, Ira. Does anyone else have any comments, we have plenty of time?

Well, I think, unless -- oh, here we go.

ANGELO CONTINO (Neutraceutical Corp.): My name

is Angelo Contino from Neutraceutical Corporation, and I just have one question. I just wanted to read the statement in the proposed rule making, but it states that the Food and Drug Administration establishes national levels for these defects in dietary products produced under current GMP and uses these levels in deciding whether or not to recommend regulatory action. And it's in reference to the defect action levels, and my question is what are the FDA's plans as to how those max levels will be determined?

MS. STRAUSS: I'll try to answer your question. It's unlikely that defect action limits would be considered along with or at the same time or proposed at the same time as the GMP proposal. They would come sometime later. And at present there isn't, you know, a set plan for timing of those, but the same kinds of considerations that go into determine any kind of defect action limits, you know, the scientific background, that kind of information would be used for dietary supplement action as well.

ANGELO CONTINO (Neutraceutical Corp.): Would there be any involvement with the industry?

MS. STRAUSS: I would imagine, yes.

MR. WILLIAMS: Can I ask you to elaborate, do you have any suggestions for how the industry would like to participate in setting defect action levels?

ANGELO CONTINO (Neutraceutical Corp.): I think that's a question we all need to kind of go back and research, but I would assume that it would be very similar, that we look at scientific data and make sure there's adequate data to be able to make an assessment. If there wasn't we should find more or not set those limits. But I would assume it would be very similar to what you described.

MR. VARDON: Actually, last Friday we had a discussion about defect action limits, and I think our scientists felt there wasn't a lot of science available right now.

IRA PORTERFIELD (Porterfield Enterprises, Inc.): Forgive me for my ignorance in this material, but what -- certainly like, for example, in the medical device industry, the issue of addressing defects is handled through a number of different mechanisms, and they start with regard to nonconforming material reports, et cetera, manufacturing processes, all the way to corrective and preventive action techniques that are applied throughout and as well their complaint handling side. Are those provisions -- are they missing in this proposed rule making and if not, how are they being addressed or how is that being integrated? Because some of this is a learning process, is it not, and that's a very dynamic closed-loop

approach to addressing defects depending on where they occur. Could you comment on that?

MS. BARNETT: I think the kinds of defects that you're talking about are the kinds of things that we envision catching here, like manufacturing failures. From my understanding of defect action levels, they're really product specific and not only product, but like foods you have them for a certain kind of fungus that grows on peanuts, you know. And so you set a defect action level for those peanuts for that level. And, of course, the scientists are involved in, you know, figuring out what's an appropriate level for that.

And I think with the GMP certainly we're really concerned with at least initially getting out a broad regulation out there, and then later on if necessary defect action levels would be developed for specific products.

IRA PORTERFIELD (Porterfield Enterprises, Inc.): So this would be a formally published, kind of a generally regarded as safe level for a given contaminate, or whatever?

MS. BARNETT: Well, I can't really speak for it. I know for foods there is a whole book with defect action levels for certain types of products.

MR. WILLIAMS: Yes. Those are published for our inspectors, and they are available to the public.

Obviously you need to know what the defect action levels are, and that's how it's done.

IRA PORTERFIELD (Porterfield Enterprises, Inc.): I had one additional question here. I think in some point in your presentation you mentioned that there's been a recommendation for multiple tests to confirm identification or identity, can you tell us what the basis for that was?

MS. STRAUSS: That one test would not be sufficient. For example, viewing a root in a botanical would not be sufficient to confirm identity. Typically a botanist would want to have the whole plant and parts of it wouldn't be there, and may be microscopic, wouldn't be yet enough to confirm. Maybe some chemical tests for fingerprinting would be needed to show that you had the right substance there in the right amount, and that there wouldn't be something there that was not expected to be there. So that multiple tests, not just one visual test, was recommended.

MR. VARDON: Loren?

UNIDENTIFIED SPEAKER: That was actually my question as well, that identity for botanicals is probably going to be probably the most expensive element for many small companies. And as it relates to finished raw material from a certified vendor, which is, say, a finished extract, with clear ratio markers and percentage level

markers, and this is a vendor that is absolutely qualified, clearly it seems to me there is no need to have multiple confirming tests. Certainly one chemical identity test makes sense, but you're not going to see a lot of raw material botanicals in the future, it's going to become far more sophisticated. And small businesses are really in a struggle with this.

MS. BARNETT: Could I just get a clarification? You said they're from qualified vendors, could you explain that?

UNIDENTIFIED SPEAKER: There's certainly vendors who are in the world marketplace who are producing pharmaceutical standards in a domestic market, and they are selling those products in this country as dietary supplements. And they have been audited, they have been inspected very carefully at various levels, governmental and by U.S. companies who they work with here.

I have absolutely no question about the confirmation of those analytical tests that they would send with their finished goods. And small companies need to rely more and more on other vendors and the valuated process. They're going to get stuck with multiple tests that seem to be truly redundant and yet add a significant amount of cost in the process.

Having said that, that the raw material testing

element is going to be very difficult as well for small companies, because of the small lot size but the relative cost of testing remains relatively constant. You have to run an HPLC or a GC, and that's a lot of money. And if you've got a 50 kilo lot, it's pretty hard to make a profit on that, frankly.

MR. VARDON: Would you state your name and --

IDENTIFIED SPEAKER: Executive director, Utah Natural Products Alliance.

MR. WILLIAMS: I just missed something you said. You said something about there was something changing, and I just missed what you said at the very end of your first comment.

MS. BARNETT: I believe you were saying that the market was changing and you're not seeing --

UNIDENTIFIED SPEAKER: Commercial relationships are changing a lot between vendors and companies, either marketing companies or in-process manufacturers.

MR. WILLIAMS: How would you describe that change? I mean, what's actually changing?

UNIDENTIFIED SPEAKER: Well, for one thing the average cost of raw materials has gone up probably actually tenfold over the last ten years. So whereas people use to pay say $10 a kilo, they're now paying $100 a kilo. That's because the type of -- nature of products being sold has

changed dramatically.

So we're talking about thousands of dollars a kilo now, instead of tens or hundreds of dollars a kilo. So that complicates things for small businesses, because they're buying quantities that are relatively small, but it's whole raw material, but they're still small lots. But you're expected to burden that with very expensive tests that are normally associated with much, much larger lots, where you can advertise the costs of those tests over thousands of pounds per lot, then that could be absorbable but for small businesses, this is going to be a real problem.

MR. VARDON: Thank you.

MIKE ROSE (Celestial Seasonings): My name is Mike Rose with Celestial Seasonings. I would like to make one comment that was brought up about an FDA seal of approval or something like that. On the surface that seems like it would be a really good quality attribute to have for companies to have that on their package. In essence, it creates a real what I call, dummying-down effect.

We just recently went through an experience with something similar where we have an organic seal for our product. We have a very high quality, relatively expensive product that's out there. A competitor of ours came out with another same seal, same organic trade association with

their seal on it. Unfortunately they had a much lower quality product, but the consumers did not perceive that. What happened is the consumer turns the product around, sees the same seals, sees two different price points, purchases the lower quality product.

So, in essence, you're really not bringing the quality of the industry up by doing that, you're actually dummying it down to the very base price.

MR. VARDON: Thank you.

LINDA HAMMONS (Natures Sunshine Products): I'm Linda Hammons with Natures Sunshine Products. It seems like there's been a lot of questions about the reporting of adverse reactions with nutritional supplements. And do you feel that this is one area that's going to be closer to the pharmaceutical regulations? And how do you think the FDA is going to handle everybody reporting these reactions?

MS. STRAUSS: Because we're in the developmental process, I would actually be more interested in what you have to say or what your comments would be, what you think it should be?

MR. VARDON: Is it costly to develop that information?

LINDA HAMMONS (Natures Sunshine Products): As far as the reporting, yeah. I think it's more -- maybe not so much the cost because we are a $300 million company, and

right now we have a lot -- you know, we have staff to do these types of things. I think it's more of a question what should be reported? I mean, we do get reports from everything like this caused a stomach ache, and, you know, that it probably isn't the herb. You know, after you do the investigation it's just maybe that person couldn't take that or maybe they didn't take it with food, that type of thing, or that reaction based upon an efedron reaction.

It's like -- it seems like you're going to be inundated with all these little types of reactions, and I think that's going to be more of how it's going to be handled, and is it going to cause a reaction in the industry and with people in taking a nutritional supplement. So I think it's more what should be reported and how that's going to be handled.

MR. VARDON: Can we also ask how you handle those now?

LINDA HAMMONS (Natures Sunshine Products): As far as reporting those?

MR. VARDON: Yes.

LINDA HAMMONS (Natures Sunshine Products): We do some reports. We have a health scientist department that reviews those reactions, and we do investigation follow-up, you know, by testing retentions and going through that type of things. So we right now we look at what the reaction

is, what the product is, and that -- before we do, you know, reporting, so we would not just report everything.

MR. VARDON: But you would report some to the FDA?

LINDA HAMMONS (Natures Sunshine Products): Yeah. Just depends on what the reaction is and what the product is and that type --

MR. VARDON: Thank you. Yes, sir.

JERRY ARENO (Modern Health Strategies): Yeah. I'm Jerry Areno from Modern Health Strategies. I'm interested in knowing about the other folks here in the room that have read the -- if I use the term correctly, advanced noticed for the proposed ruling. We have read it, and we believe that it's more towards the pharmaceutical side than it is towards the food side.

Now, obviously, USANA doesn't believe that, because they believe that it's a long ways away from pharmaceutical, but we believe it's very close to pharmaceutical, and it's not close to DSHEA regulations which is modeled after food.

MR. WILLIAMS: I guess I would point out that the reason we publish the ANPR is because it did come from your industry, and we put it out for comments like that essentially. I mean, what we really want to know from you, are what are the actual elements in it that you will find

burdensome and you think are perhaps not worthwhile for dietary supplements? Those are the kinds of things that -- that's what we're in the process of doing now, trying to get those comments from you. But I would also like to hear about it from other people about that.

MR. VARDON: Does anyone else have any comments or questions? This certainly has been very helpful to us.

Well, if no one else -- yes, sir.

UNIDENTIFIED SPEAKER: Sorry about cutting you off. I just have a couple of follow-up comments in regards to the GMP seal, just so you know, I know that with the medical device, because I have been in that industry for some time, the same proposal was raised but the general counsel said that that would be an announcement that they could not give because that would be a conflict of interest and I think the same would hold true here.

Now with regard to the adverse reaction reporting or that particular part of the proposal, those things that are being debated, I know that within the pharmaceutical industry they have the same problem that you're going to find here. One of the problems that you have first is substantiation of the claim. You know, someone calls in, it is merely an allegation until you can prove otherwise. Now you have doctors and medical staff that are also in the reporting system that talk about bad reactions with drugs

that they may have encountered, but it's more along the severe injury and/or death terminology. A stomach ache, for example, would not be one from my standpoint that we would even report, because it is an incidental.

MR. VARDON: Okay.

DENNIS HAGAN (Nutraceutical): My name is Dennis Hagan. I too am from Nutraceutical, and I wanted to comment on some of the things, particularly that was raised about whether this is pharmaceutical. I come from a medical device background, and there's a lot of overlap that I see and I think much of it's going to come down to how it's enforced and how these particular GMPs are interpreted by auditors, by inspectors, who come into plants.

And one thing that comes to mind in particular, for example, in the C of A case and the analytical results example that Mr. Putnam from USANA brought up, I think that if an inspector were to come in and ask the manufacturer how they validated a vendor's C of A or how they validated the tests that were used, you look for appropriate documentation, possibly some audits, on-site audits of your supplier, and then maybe do some of your own additional redundant testing using your own laboratory or an outside laboratory. That may be enough to justify those results. A lot of companies just accept a vendor's C of A without

any further inspection, and if that's the way it's interpreted and audited then I think there's some risk there.

So, again, much of it's going to come down to how auditors and inspectors interpret the rule and how they hold manufacturers responsible for really challenging under certain things.

MR. VARDON: Anyone else like to make a comment or ask a question? Yes, sir.

KEN DRISSAN (American Laboratories): Ken Drissan with American Laboratories. I wonder if what -- all that's going on here implies that all these dietary supplement manufacturers will then become registered with FDA, would have, you know, identification and traceability?

MS. BARNETT: Could you explain the last part, traceability?

KEN DRISSAN (American Laboratories): Well, we are an FDA registered company and we have our inspections. Would this situation imply that the dietary supplement manufacturers also would then be registered with FDA and subject to FDA inspections and all that goes on?

MS. BARNETT: Yes. I mean, registered, I can't speak to, I don't know about that. But certainly if you're putting out a dietary supplement and we have -- in the future, you know, we have a final rule out there putting

down the GMPs, then, yes, when an inspector showed up at your facility they would expect to go in and make sure you're complying with the law.

UNIDENTIFIED SPEAKER: But how are you going to know who is making dietary supplements and who isn't if they're not listed like a drug manufacturer?

MR. WILLIAMS: We have -- our field keeps a list of who makes dietary supplements and has -- they get those lists from various sources, but there's no requirement right now that dietary supplements manufacturers register with the FDA, nor food companies, for that matter, but we'll find you.

IRA PORTERFIELD (Porterfield Enterprises, Inc.): I think the question may be, is that going to change? Is it likely that the industry will be required to register?

MR. WILLIAMS: I think it would require, we would have to have new legal authority in order to do that.

MS. BARNETT: I don't want to speak to the legal authority, because that's not something I was prepared to speak on today, but we put the ANPR out there to hear from you, and it's not part of the ANPR but if you're interested in registering for inspections, I can take your name down. I'm just kidding.

MR. VARDON: Okay. Well, if no one else would like to speak, I think we can wish you all well and thank

you for coming. And we will have another public meeting in October in Baltimore, October 21st. And I've already gotten a number of registrations, a number of you have registered for that also and we're looking forward to that. And we're very eager to hear your written comments also. Thank you.

(The meeting was concluded.)

STATE OF UTAH)
) ss.
COUNTY OF SALT LAKE)

I, HEATHER WHITE, Registered Professional Reporter and Notary Public in and for the State of Utah, do hereby certify:

That said public meeting was taken down by me in shorthand on September 28, 1999, at the place therein named and thereafter pages 2 through 62 were reduced to transcription under my direction.

I further certify that I am not of kin or otherwise associated with any of the parties to said cause of action and that I am not interested in the outcome thereof.

WITNESS MY HAND AND SEAL this 5th day of October, 1999.

Notary Public
HEATHER WHITE
8399 Snow Basin Drive
Sandy, Utah 84093
My Commission Expires
June 23, 2002
State of Utah

HEATHER WHITE, RPR/CSR
Notary Public
Residing in Salt Lake County

My Commission Expires:
June 23, 2002