TRANSCRIPT OF PROCEEDINGS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

SMALL BUSINESS OUTREACH MEETING

"CURRENT GOOD MANUFACTURING PRACTICES

IN THE DIETARY SUPPLEMENT INDUSTRY"

Pages 1 thru 66

Baltimore, Maryland
October 21, 1999

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SMALL BUSINESS OUTREACH MEETING

"CURRENT GOOD MANUFACTURING PRACTICES IN THE DIETARY SUPPLEMENT INDUSTRY"

Thursday, October 21, 1999

7:00 p.m.

Chesapeake Room
Holiday Inn Inner Harbor
301 West Lombard Street
Baltimore, Maryland

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C O N T E N T S

P R O C E E D I N G S

MR. NARDINELLI: Let me welcome you to the Small Business Outreach Meeting for the current Good Manufacturing Practices in the dietary supplement industry. My name is Clark Nardinelli. I am with the Food and Drug Administration, the Center for Food Safety and Applied Nutrition.

I would like to tell you a little bit about our format for tonight. We're going to start with a couple of presentations from the Food and Drug Administration, and then we're going to ask for general comments. We have three people here who have already asked to comment: Michael McGuffin, Charles Raubicheck, and Jarrow Rogovin. Are you all here, three of you? One of them is. Okay.

MR. McGUFFIN: I can talk three times.

MR. NARDINELLI: Okay. We have a transcriber, and so if you have some general comments, we would appreciate you using the microphone in the center of the room. It is turned on. But after the general comments, we're going to break up and just have everybody talk at the tables, so this is why the table setup is as it is. Each table should have one person from the FDA who is there just as a facilitator, and we're really going to be here to listen.

So the purpose of the people at the table is just to listen to what you have to say. We have some handouts to

kind of guide the discussion, but many of the people here are not necessarily even experts on this particular rule, so we're not here to answer questions about the ANPR, but to hear what you have to say.

Also, we're scattered about a little bit, so perhaps if the room doesn't fill, when we do go to the discussion session, if we could combine some of the tables that are not quite full so that we have at least one FDA person sitting at each table.

And during the discussion session, we're going to ask each table to select somebody to be a recorder who will make notes of the five or six principle comments your table has, and then we would ask them just to talk about those comments briefly after the breakout session. We will also leave room at the end for another general discussion, for anybody who has further things to say or who perhaps had comments that didn't make it onto the list.

Any questions about the format?

[No response.]

MR. NARDINELLI: Okay, let's get underway, then. Richard Williams will be our first FDA presenter. He's from Division of Market Studies, Center for Food Safety and Applied Nutrition.

MR. WILLIAMS: Thank you for coming tonight. This is the third time we've done this, and let me elaborate a

little on what Clark said.

One of the things we found out was before when everybody was sitting and we said, "Please come up to the microphone and speak," we found out a lot of people don't like to come up to a microphone and speak in front of a lot of people, so we weren't getting a lot of comments. So we're trying this, and this is new for us and it's different.

I think the only table that we don't have an FDA'er at, because we would sort of like to, is that last table. Would you all mind moving up to this table? You know, this is one of the "move to the front of the class" things. Thanks.

This is our last session that we're going to do, and it really is important that we hear from you all tonight. It really is important that you express your opinion. One thing that Clark didn't say, when you do just speak at the tables, if you don't want to identify yourself and you don't want us--you know, you don't want to be on the record as "This is what my company says," that's fine. Just tell us what you think. Okay?

And that's really mostly what we're here for. We're not really here to talk a lot tonight. We're here to listen to you, and I think that's the most important thing. If you don't have a lot to say, we'll all go home early and

we'll watch the Ravens game. Okay?

But I think it's important that you should know that a potential regulation is in the work and it might have a considerable impact on your business, so it's important to us and I think it should be important to you that we hear from you.

What I'm going to talk about tonight a little bit is what the requirements are that we are under to listen to small business, and I'd like to think we would be here even if we didn't have those requirements; what the process of our regulations development is; and how you can make an impact on this rule through your comment.

So I'm going to start here. Sorry about the light in here. Clark, you want to see if you can do something with the lights? It isn't showing up very well. If you can just turn off the front ones and leave me in darkness here. None of them work? Great. That's all right. I'll just tell you what they are.

The first thing that we fell under was, in 1980 the Congress passed and the President signed the Regulatory Flexibility Act of 1980. That was really the first time that the government recognized the unique concerns of small businesses. Okay?

But it really was given teeth in 1996 with what we call SBREFA, the Small Business Regulatory Enforcement and

Fairness Act. I have to look at it to remember how to say it correctly. And that's the one that says that we have to go out and we have to listen to what you want to say, what you think about the regulation, and if we can, if we can still protect the public health, we can still accomplish our public health mission and minimize the burden on you, then we're required to do that. Okay?

So that, you want to keep that in your mind when you make your comments. And your comments I'll spend a little bit of time talking about. First let me talk about the process, though, and I want to talk about where we are.

You have on your table, most of you, I hope--if not, do we have any more copies?--the Advance Notice of Proposed Rulemaking. Did we get those done? Okay. That's the thing with the real tiny type that we published. And what this was, this was an industry proposal where industry came in and said, "FDA, if you're going to do Good Manufacturing Practices, this is an idea of what we think they should look like."

This has been published. We've already received some comments on that. Okay? The next thing that we're in the process of doing now is these small business meetings, and this is the third and last of those. Okay?

Oh, thank you. Is that better? Sorry. Well, don't put them in the dark back there if you can help it.

If we do go forward, the very next step that we'll have is a Notice of Proposed Rulemaking. The nice thing is, we're out here. We're talking to you now before we go to the proposed rulemaking, so this is an excellent time for you to get your comments in to the FDA, to say, "Look, this is something that works for us; this is something that doesn't."

It doesn't mean this is the last chance you'll get to comment, though. The Notice of Proposed Rulemaking, if it comes out, will come out, you'll get another chance. That's comments from the public. That's everybody, including small businesses. That's when we'll be soliciting written comments from the public.

Generally what happens is, after that we will go to a final rulemaking, and the final rulemaking will include in it a date at which you must comply.

Just some things that you can think about here: What are some things that you can comment on the rule? Obviously, you can comment on anything you want. One, you can say, what is the need for this rule? If you think there is a need for this rule. That's sort of a big comment, the general, global kind. Do you think that FDA really needs to have this rule? This is a really important one.

Okay, FDA has some public health goals and some identity goals in mind. What other ways can you think of

that FDA, you can accomplish your mission but do something perhaps that minimizes the burden on us? So that's a great thing to comment on.

We have here with us, I think most of the people from FDA here are economists, and they are responsible for analyzing your costs of the rule under SBREFA, and I'll speak a little bit more about this.

But one of the things that you know most about is your business and what your business costs are, and if you look at a set of regulations, what is it going to cost you? That's a really--that's something that you can really help us with. And under the law we have to consider, under SBREFA we have to consider your costs.

Maybe you can look at particular provisions and you say, "Well, would this provision accomplish what FDA is trying to accomplish?" If you have some ideas about how it might not, you can certainly tell us that.

Let me talk about costs again for a minute. You have on your table, I hope every one of you has something that's brand new for us. In fact, I think it's brand new for the government. And it says "Guidance for Small Businesses."

MR. NARDINELLI: Does anybody not have one? We have plenty.

MR. WILLIAMS: We have some more up here. Does

anybody not have one? Can we hand some of these out?

This just gives you some suggestive ideas about how you can comment on the rule. One of the things that you're going to see it's going to focus on is cost, and the reason it focuses on cost is because costs aren't necessarily the way that you might think about cost. Most of you have accountants, and the accountants sort of tell you what your costs are.

That's not the way that the Federal Government thinks about costs. That's not the way that these Federal Government economists--and they're not all economists. and I'm sure that the ones will tell you that they're not economists--but that's what they're going to analyze.

For the accounting types of costs that you all generally think of, you say, "Am I going to have to buy something? Am I going to have to buy some new equipment, or is this going to make me buy more raw materials?" That is a cost, but it's not necessarily the only cost that you might have. "Am I going to have to hire somebody new to comply with this regulation?" Again, that's a cost but it's not the only type of cost that you might incur.

The way economists think about cost is, is anybody at your plant going to have to do something different from what they're doing now? So, for example, many of you in here are probably managers of your own plant. You run your

own plant.

If you have to stop focusing right now on perhaps some sort of quality improvements or cost-lowering function or hiring or something else, and you have to do something to comply with this rule, like for example you have to figure out what's in this rule and how to comply with it, you anticipate you'll have to figure out how to comply with it, what to do, that's a cost to an economist. Your account will tell you, "Well, it's no cost. You're still going to get your same salary," and so forth.

The economist will say, "No, the hours you spend figuring out what to do with that regulation is a cost," and the same is true for every single member of your plant. If they have to do something different, that's what we want to hear. What is it they'll have to do? What will they have to do different? How much time will it take? How much do you pay them? Okay?

All of that is in this. Okay? Which I wrote the first draft of, and like most things in the Federal Government, it only went through 100 revisions, but I still take credit for all the errors in it. And it can help you. There's a phone number in here. If you have any trouble figuring out what it's trying to say, please call the phone number and we'll be happy to talk to you about it.

Okay, so that walks you through that. These are

some of the things that we heard about from some of the other small businesses, both in the comments and the meetings, and Dr. Karen Strauss is going to talk to you about these.

But the written procedures, okay, that's standard operating procedures. There's a potential for some requirement for written procedures, for people to figure things out. Record-keeping, we've had some concerns raised by small businesses about how much record-keeping might be required. And finally, testing.

Those are kind of the big three things that I think we've heard from. And all I'm doing is pointing out, you know, that these are things we've heard from, these are things you might want to pay attention to, you might want to talk to us about.

Okay, that's all I have to say. Do you want to continue this, Karen?

MR. NARDINELLI: Karen Strauss will now talk about the ANPR, the industry submission, and that's the thing with all the little print. Karen is also from the Center for Food Safety and Applied Nutrition.

MS. STRAUSS: I'm going to speak from a chair. I feel it's less formal, and that's how I want this to be. It's less formal, so that's how I'll do it.

Before I begin, I wonder how many of you--because

I'm going to do a quick, brief, superficial walk-through of the ANPR--I wonder how many of you have reviewed the ANPR on a previous occasion before today?

[A show of hands.]

MS. STRAUSS: And so for the rest of you, you have not heard of or seen of it before? Okay. The purpose, as I mentioned, of my presentation is to introduce you to or, for some of you, to review the GNP sections included in the industry outline that was submitted to FDA.

Time tonight doesn't allow an in-depth review of the outline. Instead, for more information you have the ANPR, and there were a limited number of copies. If you didn't get one and you would like to get one, it's available through the FDA's Center for Food Safety and Applied Nutrition web site, or you could let one of us know and we could get a copy to you.

I refer you to the ANPR sections that also are listed on your table. There is a one-pager that has the various topics in the ANPR.

As I mentioned, we want to hear your comments on any proposal that FDA would make to establish GMPs, and your input will assist FDA to understand the economic impact that any proposal to establish GMPs might have on small businesses in the dietary supplement industry.

Just a bit of background on why FDA is developing

a GMP proposal. DSHEA, the Dietary Supplement Health and Education Act, gives FDA the authority to adopt GMP regulations, and by submitting an outline and in other ways, the industry has told FDA that GMP regulations would be helpful. DSHEA defines dietary supplements, and there are five categories, and this is what the proposed GMP regulation would cover, would be vitamins; minerals; amino acids; herbs and botanicals; other dietary substances used to supplement the diet; concentrates, metabolites, constituents, extracts, or combinations of these.

As a starting point in our drafting the proposal, we're looking at the outline submitted by the Dietary Supplement Industry Coalition, and this was published, as was mentioned, as an Advance Notice of Proposed Rulemaking. It was published February 6, 1997. And so what I want to do over the next few minutes is provide a brief overview of what's included in the ANPR.

The Food, Drug and Cosmetic Act prohibits the selling of adulterated products, and the purpose of GMPs is to ensure that customers are provided with dietary supplements which are not adulterated during the manufacturing process. The industry-submitted draft GMP was modeled after the food GMPs, but also adapted, modified and expanded to meet the special requirements of dietary supplements.

And this slide shows the GMP topics that are outlined in the industry outline, and my purpose in showing these is to inform you of the types of issues that FDA is examining while developing GMP regs. And, as I mentioned before, at the conclusion we would like to hear from you about elements like the ones that I'm about to go through.

There are personnel provisions in the ANPR, and these are directed towards disease control. Preventing adulteration by personnel working in your plant; hygienic practices; education and training of employees in maintaining hygienic practices and in performing their assigned functions, are some of the elements in the industry outline, and supervision of employees is also addressed.

Grounds, plant construction and design, there are procedures that are designed to prevent adulteration of dietary supplements caused by the grounds around the plant, by the plant size, by the design of the plant, the construction, maintenance, and these are all included in the ANPR, in that tiny print.

Equipment and utensils, there are procedures in the ANPR to prevent adulteration caused by these. The industry outline describes provisions for equipment design, equipment installation, cleaning and sanitation, and calibration, as measures to prevent adulteration.

This one is a little bit more involved. These

elements are included in the ANPR section on production and process controls. A quality control unit or a quality control person is included in the ANPR, as are laboratory operations, manufacturing operations, packing and labeling, and holding and distributing.

The industry outline includes a quality control unit or a quality control person, and this unit has the responsibility and authority to do the following, and I'll list them: to approve or reject all procedures, specifications, controls, tests and examinations, or any deviations from these that might impact on the purity, quality, and composition of a dietary ingredient or a dietary supplement.

The quality control unit would 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. A provision in the outline states that there should be adequate laboratory facilities, and that the responsibilities and procedures of the laboratory should be established in writing and followed.

And for holding and distributing, elements are included which describe conditions under which ingredients and packing materials and labels are received, are held, and the holding of in-process and finished product, and also the distributing of dietary supplements.

Elements that are listed on this slide are found in various places in the ANPR. Some of them are in production and process controls, some in warehousing, distribution and post-distribution procedures. The ANPR states that ingredients, in-process materials, and finished dietary supplements must be stored in a manner that prevents adulteration, and upon receipt, ingredients, packing materials and labeling materials must be examined and tested to determine if they meet specifications.

Each lot of raw materials must undergo at least one test by the manufacturer to verify its identity and to conform 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, a C of A or Certificate of Analysis may be accepted from a supplier, provided that the manufacturer establishes the reliability of the supplier's analyses.

The ANPR says that raw materials should be examined and tested for filth, insect infestation or extraneous material, microbiological contamination, aflatoxin and other natural toxins, and that in-process materials must be tested during manufacture to detect adulteration.

There is a section in the ANPR on packaging and

labeling operations, and these operations that are addressed include filling, assembling, packaging and other operations, and that these must be performed in a way that protects the dietary supplements against adulteration. The dietary supplements must be identified with a lot number that permits the determination of the history of manufacture and the control of each batch. Products and packaging materials not meeting specifications must be rejected.

Storing of finished product, the industry outlines provisions, says that finished product must be stored under conditions that will protect against adulteration, and that reserve samples of each batch of dietary supplements should be retained and stored under conditions with the product labeling.

Next one. This is the one on written procedures and records. The ANPR identified certain written procedures and records that the industry coalition thought were necessary to include in a GMP.

Under the ANPR outline, written procedures must be established and followed for: cleaning and maintaining equipment and utensils; for the receipt, storage, handling, examination or testing that may be necessary to assure the identity of labeling and the appropriate identity, cleanliness, and quality characteristics of packaging materials; written procedures for the responsibilities and

authorities of quality control; for the processing of batches, including a master production record and a batch production record; and the ANPR includes written procedures and records describing the handling of oral and written complaints regarding a dietary product.

Next one. The industry outline submitted identifies records as those to be retained, and they are listed here: raw material records; any lab record; production record; control record; distribution record; and any complaint record specifically associated with a batch of dietary supplement. And the outline submitted by the industry specifies that records must be retained for at least one year after an expiration date, if there is one; or if there is no expiration date identified on the product, for at least three years after the date of manufacture.

So there you have a quick run-through of some of the points that are in the ANPR. There is much more detail. My purpose is to just kind of quickly outline for you the items or the elements that are in the ANPR, so that you can have a framework for our later small group discussions. Thank you.

MR. WILLIAMS: One thing. Let's see. First off, would the people at this table move to some other tables, because we don't have anybody from FDA at this table, if you wouldn't mind. Just any of the other tables we've got

there. Thank you very much.

The second thing is, one of the things that we have to do, in order for any comment to be made--and again, you don't have to identify who you are if you don't want to, or what company you're from--but in order for us to take your comments and actually include them in our discussions about the proposed regulation, they've got to be on what we call the administrative record. So at your table, we want somebody to just--not the FDA but somebody else--to record the comments, and then after these sessions we want to sort of read these comments out, and we have a transcriber who will put them into the record, and that will be helpful to us. Okay? That's the only way we can include them.

MR. NARDINELLI: To go in the order I have, is Michael McGuffin here? Okay. You can be up first. Let me ask the speakers, those of you who have asked to speak, to please keep your remarks to 10 minutes or less, however, because we do want to leave room for the rest of the program. So, Michael McGuffin, do you want to speak?

MR. McGUFFIN: Do you want me to speak from here?

MR. NARDINELLI: Yes, please.

MR. McGUFFIN: Okay. I got almost everything done on my way here except printing this document, so I'm going to have to work from my laptop.

I want to start by saying thanks for the

opportunity. We do appreciate this forum. I'm here tonight on behalf of the American Herbal Products Association. AHPA is the national trade association and voice of the herbal products industry, and we will provide full written comments to the topic at hand at a later date, prior to the closing date.

As announced in the Federal Register notice of September 3rd, 1999, this meeting provides an opportunity to comment on the economic effects of a possible proposed regulation on CGMP for dietary supplements. This is the third such meeting, as you all have mentioned. We were represented at the first of these on July 12, 1999, by Beth Lambert of AHPA member company Herbalist and Alchemist. My comments will reiterate some of the points made in our earlier comments, and will be addressed to additional concerns of the herbal dietary supplements industry segment represented by AHPA.

I want to start with a little background. AHPA was one of the five trade associations that worked together to create the proposed CGMP for dietary supplements that were presented to FDA in November of '99, and that Dr. Strauss has referred to here tonight as the industry outline. Implicit in its role as a signatory to this industry draft CGMP, AHPA supported their adopting in 1995 and continues to support the adoption of these or

significantly similar CGMP for dietary supplements at this time.

I'd like to talk a little about the prevalence of small businesses. The majority of AHPA's manufacturer members, that is, those who would be affected by any CGMP established for dietary supplements, are small businesses. Annual dues for active members in our association are assessed on a sliding scale based on annual revenues. At this time, 85 percent of AHPA's members report annual sales of less than $10 million, and 95 percent pay dues in the categories defined by annual revenues below $25 million.

On April 29, 1998, FDA published in the Federal Register a proposed rule on related regulations, on the regulations for statements made for dietary supplements concerning the effect of the product on the structure or function of the body. In its analysis in that rule or proposed rule, the economic impact of that proposed rule, FDA presented a thorough review of the industry.

Their analysis included a discussion of the appropriate SIC codes, existing definitions for small businesses within each code, as well as an examination of authoritative estimates of the revenues of the businesses that make up the dietary supplements industry. The agency concluded that, and I quote, "Because virtually all firms affected by this rule will be classified as small under SBA

standards, FDA assumes that small entities will bear 100 percent of the costs."

We think the same estimation is true for any rules that have to do with dietary supplements, and any more specific analysis of the herbal dietary supplements industry would no doubt draw the same conclusions. We are an industry of small businesses, as shown by our internal documents as well as by FDA's own estimation. Any CGMP established for dietary supplements will be, by any measure, CGMP for small businesses.

With regard to minimizing the economic impact, I note in your earlier presentation you talked about the requirement to do so is established by Federal law, and we have defined, in order to minimize the economic impact, we proposed that at a minimum the following are included in the final draft:

Regarding time of implementation, based on communication with our members, we have tentatively concluded that small companies should be allowed an additional two years for implementation and manufacturing facilities of any final CGMP.

Training support: The agency should be prepared to develop an active training partnership with industry to provide training to small businesses in all elements of any CGMP established for dietary supplements. Further, the

agency should consider itself as a source of funding for such training, or alternately should assist industry in identifying alternate sources of funding.

And, finally, regulatory clarity: In order to minimize the financial burden on small businesses of legal review of any final rules, FDA should assure that these are clearly written.

I want to go off into a related topic with regard to the identification of dietary ingredients in CGMP. The industry draft addresses the issue of ingredient identification in quite straightforward language, and I quote, as Dr. Strauss did: "Each lot of raw materials shall undergo at least one test by the manufacturer to verify its identity."

The draft goes on to delineate specific appropriate tests by which such verification could be made. At no time does it state or imply that raw material for which identity is not verified can be used in the manufacture of a dietary supplement. At the same time, there is a need to provide good guidance to industry that can be used to accomplish such identity verification.

Dr. Forouz Ertl, AHPA's Standards Committee Chair, and I were active members of the GMP Working Group of FDA's Foods Advisory Committee. The efforts of the Working Group culminated in a report to the FAC, since forwarded to FDA,

that delineated recommendations toward the creation of a good guidance document for identification of dietary ingredients. The information provided by Dr. Ertl and me was specific to identification of botanical ingredients, as that is our field of experience.

As part of the process of managing the Working Group, FDA explained in detail the differences between a Federal regulation and a good guidance document. We were provided copies of the Federal Register notice dated February 27, 1997, which describes the agency's adoption of policies and procedures for the development, issuance and use of good guidance documents.

Our education on the agency's use of this excellent tool discussed the legal effect of guidance documents, and specifically the language in the notice that states that alternative methods that comply with the relevant regulation are acceptable. The requirement for any guidance to bear a statement of non-binding effect was also identified. Finally, we were informed that our work was addressed to the creation of a Level I guidance document. Such documents require that the agency in most cases solicit public input prior to implementation.

The implication of all this training, of course, was that our task was in the context of the development of just such defined good guidance document.

Now, why am I speaking about a good guidance document at a meeting that FDA has scheduled to discuss CGMP for dietary supplements? Why have I not kept my comments focused on the issue at hand, that is, the economic impact of any proposal to established CGMP?

I am speaking about this separate but related issue because significant confusion has apparently arisen over the work of the GMP Working Group. Others have appeared at earlier FDA public meetings to make statements in opposition to certain specific elements of the Working Group's recommendations.

I would agree with such stated opposition if FDA has any intention whatsoever to include any part of the Working Group's recommendations for utilizing multiple tests to identify botanical dietary ingredients in CGMP regulations. In fact, if FDA has any such intention, I would consider this to be an abandonment of the trust that the agency and industry representatives placed in each other throughout the process of the development of the Working Group's recommendations. Further, the inclusion of the guidance intended by the Working Group into a regulatory scheme might significantly increase the financial burden on manufacturers, and especially on the smallest companies.

In conclusion, AHPA and its members, small and large, continue to support the establishment of CGMP

specific to dietary supplements that are significantly similar to the industry draft published in the Federal Register on February 6, 1997. We believe that the economic impact of these can be mitigated. We strongly believe that the efforts of the GMP Working Group should be used for the purpose for which its efforts were undertaken, that is, the development of a good guidance document or some similar non-regulatory document.

And, finally, we believe that if the agency intends to include anything in final rules for CGMP for dietary supplements that is not significantly similar to the industry draft identified here tonight, this should be communicated in the form of a proposed rule to allow for review of our members who would be affected by such a final rule. Thank you very much.

MR. NARDINELLI: The next name I have on my list is Charles Raubicheck. Okay, please take your 10 minutes.

MR. RAUBICHECK: I will endeavor to be brief so we can move on. My name is Charles Raubicheck. I am a member of the firm of Sibley & Austin. We are general counsel to the National Nutritional Foods Association, often referred to as NNFA. We are the largest trade association in the industry, as I am sure many if not all of you know.

NNFA did join with AHPA and other groups to support the publication of the ANPR as a starting point.

NNFA did not necessarily concur with each and every provision in this document, but the agency felt that it was appropriate under DSHEA for FDA to move forward and for the industry to move forward together to develop common ground on the subject of having Good Manufacturing Practice standards for supplements, to ensure and indeed raise the quality of product being sold within the industry.

However, the ANPR has been on the books now for almost three years and has not proceeded to a proposal. NNFA felt that, in the interest of its members, in the interest of retailers and consumers who are even outside its membership, it would be appropriate for NNFA to continue to explore this issue. And indeed the Association has adopted its own GMP program, which was formally launched this past July in Las Vegas, as I'm sure many of you know. These GMP standards have been submitted to FDA to help assist the agency in moving forward with the agency's own proposal that is expected.

The hallmark of the NNFA program is the fact that it is an independent third party certification program. NNFA does not send its own members to inspect its own facilities. We have an independent GMP Advisory Committee. We have independent auditors who go in and inspect member facilities to determine whether they are in compliance with the standards. If they are, they get a third party

certification. That certification is mandatory for NNFA membership. Furthermore, that certification is good only for a period of three years and must be renewed with follow-up audits.

Now, in adopting these GNP standards, NNFA used the ANPR as a starting point because the agency--excuse me--the Association agreed with the agency that the GMPs ought to be modeled on food GMPs with certain additional provisions that were appropriate to dietary supplements. Upon further reflection, in a process, a deliberative process that has been vetted over time within NNFA, it was determined that certain provisions of the ANPR were not necessarily appropriate to supplements, and they do not appear in our standards.

But I think if you look at our standards, you will see a valid, workable set of dietary supplement GMPs that we believe can be met not only by our members but by other companies within the industry, and we think that FDA will like this document when it is reviewed in toto. It has been submitted to Joe Levitt. It has been submitted to Beth Yetley. We are in the process of getting a copy to Bob Moore.

The hallmark of the GMPs, for purposes of this meeting, is that we believe that these dietary supplement GMPs can be met and satisfied by all companies within the

industry, not simply large companies. They are designed and intended to be broad enough and flexible enough that all companies within the industry can comply. We earnestly hope that FDA will take our standards into consideration when coming up with the agency's own proposal. We are open to dialogue with FDA in terms of the agency's own process, and look forward to the day when both government and industry can essentially have a workable set of GMPs that will apply across the board.

Thank you very much.

MR. NARDINELLI: The last person who has requested time before the meeting is Jarrow L. Rogovin. Is he here? Okay. How is your name pronounced?

MR. ROGOVIN: Jarrow Rogovin.

MR. NARDINELLI: Rogovin. Okay.

MR. ROGOVIN: Forgive me for reading this. I'll push it through a little faster.

I am president of Jarrow Formulas, Inc. We've been in business about 23 years. We're a Los Angeles company.

One, DSHEA standard of food for dietary supplements: The dietary supplement industry specifically sought and achieved statutory limitations on any GMPs for the category. The language of the statute states: "Such regulations shall be modeled after current Good

Manufacturing Practice regulations for food."

The agency's February 6, 1997 ANPR frankly states: "However, the agency recognizes that the first question that must be addressed is whether there is a need for such regulations, or whether Part 100, 21 C.F.R., continues to be adequate."

The ANPR does not attempt to answer this question. Am I right? Is it 100 or 110?

VOICE: 110.

MR. ROGOVIN: Thank you. Typo. "...continues to be adequate."

The ANPR does not attempt to answer this question, not to my knowledge has the agency done so to date in other documents. This is particularly disturbing in light of the apparent redundant testing requirements that are being proposed. More than any other issue, testing, including shelf life stability testing if an expiration date is used, is a more pharmaceutical than food GMP procedure, and will be exorbitantly expensive.

Threshold Distributors, the parent company of Source Naturals and Planetary Formulas, has authorized me to state that they have written the NNFA concerning the issue of shelf live testing twice and received no response nor acknowledgement of their letter. The company, and many others, are concerned about this issue because the NNFA's

new regulations require expiration dating which will trigger the FDA stability testing requirement.

The agency should also answer the following questions: Are GMPs necessary, or are current regulations adequate? Many companies, including Jarrow Formulas, believe current regulations are, for the most part, adequate but simply have not been enforced. We question whether failure to enforce a policy should become a self-justifying argument for a more rigorous regime. Second, the agency needs to state whether a particular policy or procedure exceeds food GMPs and state the justification for doing so, including the cost versus the benefit.

Two, statutory requirement for OMB review of economic impact, and the failure of the NNFA to consider economic impact. I see no figures out of anybody on what this is going to cost. It is just presumptively concluded, "Oh, it's affordable, it's reasonable." I haven't seen the numbers.

The agency understands its responsibility to report to the OMB on the economic impact of its proposed rules. While the agency states that it has been approached by elements of the industry, the fact is that a very substantial portion if not the majority of the NNFA membership feels that the organization's leadership acted unilaterally and without proper consultation with the

affected membership. Views presented were from large companies that conduct a substantial amount of their business in the mass market, and who have a substantial motivation to run up the cost to smaller companies with superfluous testing.

I asked Mr. Ford in Las Vegas, and also a supplier member of the NNFA board from a large company, why products such as Vitamin E from a GMP manufacturer such as Henkel needs to be revalidated every time. This seems to be the NNFA standards. Why a periodic check to give a statistical result would not be appropriate, as long as the manufacturer was GMP; that the chances of mislabeling a shipment were too rare to justify the ongoing collective expense throughout the country of such redundant testing, including the finished product.

Both made an ad hominem response which obviously did not answer the question. The question of revalidating materials from a GMP house appears to be an issue with the NNFA standards and not FDA, but both entities need to be addressed at this time, given their parallel tracks. Again, the agency, with the cooperation of the industry, needs to survey the reliability of the industry's products before such an enormously expensive and time-consuming project is undertaken.

My company does currently between $15 and $25

million a year in sales. We are currently building a new facility, and intend to install an on-site analytical lab. However, I estimate the GMPs will cause us to hire an additional two persons, in addition to the lab personnel being planned. Additional costs will ripple through the company as our suppliers are required to do the same thing. The end benefit and increased cost to the consumer will be questionable.

Despite a lot of this, a company like mine is in something of the catbird's seat because we can change manufacturing vendors to supply our needs. However, there is a serious risk, as Mr. McGuffin pointed out, that smaller, traditional, older, quality tablet-making facilities will be put out of business.

Time frame: I would like to see phased-in GMPs beginning with ISO 9000 standards; basically, straighten out the paperwork. Sometimes cliches are also common sense: Walk before you run. The best approach to increasing quality control, and one that would save costs and give a sense of direction for the future, would be to implement ISO 9000 type standards first, raise the quality of paperwork, traceability and reproducibility of procedures. This will prepare an industry that is still growing and learning for the next stage.

In a sense, we are burdened by our own success.

Sine DSHEA, the industry has surged forward and is popular with the American people. Small, family-run businesses must now meet higher standards and compete with their newly interested competitors, mass marketers and pharmaceuticals. We have been a "last frontier" industry in many ways, the self-taught small entrepreneur with a passion for the subject. Now we must compete against multi-billion dollar companies who are also playing favorites with each other.

BASF has given favorable treatment to two large players for its sami product, and the natural foods industry has been hard-hit by this supplier's disregard for those who made this industry from the ground up. Now, to further burden us with a shortened time, particularly by the NNFA, to make even further substantial changes while we are being undercut by e-commerce and disloyal chemical suppliers, is problematic.

Accordingly, we ask to start with ISO 9000 procedures, a phased approach, while we adjust to the ongoing consolidation of our retail market into very large natural food quasi-supermarkets and an uncertain future with our chemical suppliers.

Fourth, overemphasis on manufacturing of capsules and tablets compared to raw materials: Phil Visiant, a vice president of Reliance Vitamin Company, has correctly pointed out that the real quality issue in our industry is the raw

materials, the raw materials supplier. He cites, for instance, the peaking l-tryptophan from Showadanka when they changed procedures, possibly violated a drug master file doing so; ginseng and the quinsazine contamination, the pesticide; creatine monohydrate and dihydrotriazine; alphapolyic acid contaminant if not purified, and others.

Now, if a raw material is not coming from a GMP certified house, in a sealed drum from a GMP certified distributor, the tableter should be required to do more checking, obviously. Again, I have asked the NNFA about this and not received an adequate response.

Five, impact of expiration dating due to shelf life study requirement, including costs and probable delays in product introduction. The question might presently be better addressed in the NNFA, which seems intent on not answering it, but the NNFA expiration dating requirement will trigger the FDA's shelf life study requirement.

Other than the cost of these studies due to their complexity, such as periodic testing through the study period of each ingredient for which there is a test method, the resulting delay will destroy the competitive ability of most companies. Companies will not be able to introduce their products into a market that often has a short market life for peak sales.

Also, this appears to be more pharmaceutical than

food in nature. Food generally has product category expiration periods. This will, the dietary supplement requirement will be product-by-product testing rather than by category. An effort should be made to establish ingredient life expectancies depending upon the dose form and packaging. I apologize for the word "dose," but having been an English major, "dose" happens to be the best word to convey the concept.

Six, need for industry-wide data on reliability of manufacturing tablets and capsules; with micronutrients, need for data on stability of inherently oxidizable compounds such as Vitamin A or carotinoids. This impacts clearly on expiration date data but also on manufacturing methods.

There probably should be industry-wide standards set for premixing micronutrients and dosing of oxidizable compounds. Currently this is a matter of trade secrets. However, some sort of industry process should be set. Products presently on the shelf could be studied for these issues and then an analysis made of these--determinations made of these manufacturing issues.

Seven, analytical methodology problems: The foremost problem of analyzing finished products is sample preparation. It is not uncommon to have virtually impossible sample preparation problems. For instance,

analyzing a finished ginkgo product versus the bulk material often yields very large differences, and my company has a lot of experience in this issue. Accordingly, verification manufacturing may often need to be done based upon input versus yield calculations.

Eight, need to develop reasonable statistically based analytical requirements. More reasonable cost is commensurate with low level of risk. The cost of analyzing difficult materials or multiple ingredients mitigates against universal testing of finished products, particularly considering the low risk to consumers and low payoff in quality assurance.

The agency and industry need to adopt a critical point assessment and analysis approach. For instance, if a multivitamin mineral formula is checked for its micronutrients or a certain number of them with good results, then little or no testing should be required on macronutrients. Also, in multinutrient products, higher priority should be given to RDR nutrients than to ingredients such as herbs where the cost of analysis is high and the benefit of such testing low.

Nine, GMP standards should be set by the FDA, not the NNFA, and the NNFA should stay out of marketing and not promote an NNFA GMP logo. For one, the logo of this health food retailer organization will be brought into the mass

market by brand names that sell to both. That disserves the NNFA's traditional and mandated health food retailer membership, who are being seriously impacted by the mass market. Any GMPs are an FDA issue, not a marketing issue for a trade organization.

Ten, in conclusion, there is an industry-wide concern that the drive for GMPs is being driven by mass marketing pharmaceutical companies who wish to drive out competition from smaller companies. In particular, Jarrow Formulas is concerned that GMPs will invite FDA inspections where companies simply get nit-picked.

Many agents remain hostile to the industry and still resent the passage of DSHEA. I have received such comments. I have noticed that five years after the fact, FDA field agents frequently still do not know the difference between a DSHEA authorized structure and function claim and a drug claim. Opening the door to overregulation of tableting and capsulating, while the greater issue is raw material integrity, does less to protect the consumer than the cost warrants.

Thank you very much.

MR. NARDINELLI: We have time for other general comments. Again, as Richard Williams said, if you wish the comment to be on the record, you'll have to identify yourself and please come to the middle--

MR. WILLIAMS: Up there, not necessarily at the table.

MR. NARDINELLI: No, not at the table, not in the small discussion groups but in this section.

MR. DEUS: Can I get some clarification? I didn't have time to put this off on a word processor, and so I just jotted down my thoughts. They're very rough and my handwriting is atrocious. There's no way I can give you a printed record tonight.

MR. NARDINELLI: No, no, no.

MR. DEUS: But I can when I get back to the office.

MR. NARDINELLI: If you'd like to stand up and talk about them, that would be fine.

MR. DEUS: Yes.

MR. NARDINELLI: Stand right over there.

MR. DEUS: Okay. Good evening. My name is Jim Deus. I'm the owner and general director of Deus Research Laboratories. My company specializes in developing, manufacturing, and packaging products for our customers to market on a worldwide basis, primarily in the nutroceutical and cosmeceutical fields. We do not market any of our products ourselves, but are a private label producer only. That's why I'm not at the health food store, because I don't go to trade shows; my customers do.

We have been in the business for over 25 years now, which probably makes us one of the oldest manufacturers specializing in these fields. After all, it was only passed in '94, that they recognized it.

In the early years of our existence, we produced pharmaceuticals only, so that when we decided to produce only nutroceutical and cosmeceutical products, we had a lot of experience in dealing with the CGMPs as they are promulgated, an old FDA word, by the FDA in the pharmaceutical industry.

Having done both, I can unequivocally state that due to the considerable difference in the nature of the two products or the two industries, that if you attempt to interpret the regulations exactly as they are stated in Part 211, we will have no trouble in passing. The problem has been with overzealous or inexperienced investigators who go far beyond what they say, and this has always been a problem. And we have done it, we have gone that extra mile, we have put it in place. We want to continue to do so.

I'm going to go ahead and give you a little background on the company because you asked for that, and I'm certainly what you would call a very small business. Unlike many other companies, we not only press tablets, fill capsules, and produce liquids, powders, lotions or gels, but we also do extractions of herbs. We do produce some of the

raw materials ourselves, when we cannot find the specifications we need to meet the requirements of our customers, so we synthesize chemicals occasionally, when we have to.

We are a small business. We have approximately 50,000 square feet in our facility. Our employment averages around 30 people year-round, goes to a maximum of 40, and maybe a little lower at times. Our sales last year were a little over $1 million, and we will do half again more than that this year, so we'll be just under $2 million.

I've always predicted that you'll attempt to introduce, as closely as possible, GMPs into the nutroceutical field, similar to what you have had in the pharmaceutical field, and since we originally set up to follow those GMPs, I maintain much of the same procedures I used when I produced pharmaceuticals. However, I quickly learned that due to certain basic differences, we had to make some differences in the way we do them, and I would love to show you what those differences are if you're interested, particularly in herbs.

Most FDA inspectors want to see all stainless steel. They want to see all brand new stainless steel every year or two. And when you're grinding herbs that come in from all over the world, particularly from Third World countries, this is not always feasible. We do that in a

different--we have five and a half acres where we're located in a rural area in Texas, as you can tell from my accent.

So that area where we do the first processing is separate from, and most of it is outside because we don't want that dust in the plant, airborne contamination. As I said, my background was ethical pharmaceuticals. I worked for the major companies before I started my own company. So this is something I worry about. This is how we found to solve that problem.

Then as it moves through the phases, then we go to much more stainless steel, the whole bit, but the initial grinding has to be done in a different, different way, and that doesn't match up anything with what you do in the pharmaceutical field.

In keeping up with the demands in the manufacturing process of my customers, I have over the last five years or so invested approximately 80 percent of my profits back into facilities and equipment to expand our capabilities to meet our customers' needs. In the last year or so I have shifted gears somewhat by earmarking the bulk of that investment into our quality control and quality assurance departments.

I'm surprised, you talk about quality control, I don't hear anything much about quality assurance. They are two different things, although they are related.

To this end, I have expanded our QC laboratory by 300 percent, added new equipment, where we have a complete microbiology laboratory now. We have ability for colormetric analysis of finished products and raw materials, and I put in a completely automated Farr UV scanning spectrophotometer. By the way, I used to sell medical diagnostics, so I used to teach it, so I know how to run this equipment.

I have spent roughly $75,000 in the last year. Also, I have added two full-time employees and have placed additional duties on my existing employees, incurring overtime salaries in many instances. All this represents a major investment for a small company like mine.

My greatest fear is that I hope that I have not done all this in vain. My concerns are directed in three primary areas, although I could probably think of a lot more.

Number one, all this investment without question requires me to raise prices to cover these additional costs. I want to be certain that my competitors are required to do the same, if this is what I must do, so that we can all play from a level playing field.

I know from experience that industry self-regulation does not always meet the goals that it was intended to do, but it does make the end user, the customer

who buys the product, a little bit more comfortable with it. I would like to see minimum national licensing requirements which could be put in place as follows:

All manufacturers are required to be State licensed, usually as food manufacturers. That's the way we do it in Texas already. Why not put in place certain nationwide licensing requirements for a new classification of nutroceutical and cosmeceutical State licenses that must follow these requirements? Nothing would change, except the standard nationwide licensing programs would be an extension of the existing State licensing regulations that are already in place.

Number two, I've heard from many in the university/academic fields that call for all herbal extract supplements to undergo Phase I and Phase II testing for safety. Such a program would be unnecessary in most instances, as monographs for essentially all these extracts have already been done overseas and the information is in the public domain. I know. I manufacture for them. Such testing would only increase the income of those people who would do the unnecessary testing, in my opinion.

Number three, others have proposed an approval process for all nutritional and cosmeceutical products similar to NDAs and ANDAs, with some protection for the companies who spend the hundreds of millions of dollars to

do the submissions--and I know what it costs, I work with them all the time, that's one of the things I consult on--similar to what is used in the orphan drug programs. Again, this is totally unnecessary due to the fact that this work has already been done by foreign governments and the information is readily available.

Under the international harmonization process, which is rapidly ongoing at this time, such an arrangement as I have described is going to happen anyway, so that any money spent on safety testing of herbal supplements or approval process of products, such as an NDA or an ANDA, will be done in vain except for those who will be more than amply paid for doing this unnecessary work. There is no need to reinvent the wheels which already have been working for years in the rest of the world.

Whether we want to acknowledge it or not, we are not an island unto ourselves but are part of the world market. Introducing Phase I and Phase II herbal testing and NDA approval requirements would only increase prices to the end user, completely out of reason in relation to the expected benefits, and such products are not in the best interest of the public. Thank you.

MR. NARDINELLI: Somebody else? Please go ahead.

MR. COVEN: Mitch Coven from Vitality Works. I'm president of a small liquid extract company in Albuquerque,

New Mexico, and I also chair the Small Business Committee of the American Herbal Products Association.

First of all, I would like to thank the FDA for the opportunity to speak and give feedback as a small business member in the herbal industry, and I do want the FDA to know that most small companies are already doing most of what is already proposed in the GMPs, as far as I understand it, as are we, and it seems at this point there is just some tightening that needs to be done.

In the spirit of the attempt that was trying to happen today, we were trying to assess the cost impact, the economic impact of small businesses. I would like to address that most directly.

First of all, it seems like there were some attempts to find out from the small businesses what the financial impact would be, should the CGMPs go through, and I just want you to know that it's a difficult assessment for small businesses to project what that impact might be based on some of the aspects that we're not doing, some we are. And we're attempting to do that.

And information that was given us earlier today at the breakfast meeting of the American Herbal Products Association from Karen--I don't know your last name.

MS. STRAUSS: Strauss.

MR. COVEN: Strauss. It came to, it's the first

time I had heard that some visits were done to some manufacturing sites to assess how well some manufacturers were currently implementing Good Manufacturing Procedures. If the attempt is being done to assess the impact on small businesses, a question was brought up as to how many of the site visits that occurred were to small businesses as defined by the FDA, and the response was none.

We are wondering why no smaller businesses, as the FDA defines it, were visited to assess what kind of impact this may be on site. The American Herbal Products Association defines a small business member for committee purposes as revenues of $5 million or less gross revenue, which at our last count comprised approximately two-thirds of the AHPA membership. As Mr. McGuffin stated, $10 million or less were about 85 percent of the AHPA membership.

So I would like to ask, if possible, as the FDA tries to assess the economic impact to small business, if they can visit a smaller manufacturer in the herbal trade, I would like to invite them to do so. And at the meeting there were approximately four or six companies which volunteered to have their sites visited, which might provide some further education on the impact.

One other point. So we're looking for guidance as to any kind of economic information that currently exists, that FDA may have, as to what they project the economic

impact might be, should they have such numbers.

Another issue that I would like, as a point of clarification, one of the points that we see could have severe economic impact is the issue of botanical identification, how many kinds of tests need to be done. In the GMP it states that from a raw materials supplier, that we can accept a Certificate of Analysis if we can establish the reliability of a supplier.

As many know, there may be some importers or growers that may have container loads of raw material. If they can do testing once and spread out the economic impact on that through the whole crop, maybe the purchasers of such raw material may not have to duplicate the tests over many times. I'm looking for guidance on what does it mean, and can FDA define how one would establish the reliability of such a supplier to satisfy the FDA? So I'm looking for guidance on that as well.

Thank you.

MR. WILLIAMS: Let me just address a couple of points that were raised.

MR. NARDINELLI: Sure.

MR. WILLIAMS: The first thing, you are absolutely correct, except under FDA guidelines a small company is defined as a company, they have defined it by employment, it's less than 500 employees. We actually did visit some,

let's say "large" defined small companies, but up until I guess it has only been a few weeks ago, we didn't have any invitations at all from small companies, so this is good to hear.

We need to take that, we need to go back and look at our budget, okay, because we have exhausted quite a bit of money on some of these other visits, and see if we can do that. But we certainly appreciate the invitation, so we'll take a look at that.

The second thing you asked about was our projections of cost. Basically, our projections of cost are done within the executive branch and they have received clearance, and the first projections that you'll see of ours will be--will accompany the proposal, if we have one. Okay? So we're in the data gathering stage now. We want to learn from you what your projections are, and then we'll put all those together if we go forward with the proposal.

MR. NARDINELLI: Would someone else like to speak to the group as a whole?

[No response.]

MR. NARDINELLI: Okay. Well, for those of you who came in a little late, let me explain the next part of the meeting. We are going to engage in discussions at each individual table. There will be one FDA facilitator at each table, except there is nobody at that last table. Would it

be possible for you four ladies to find a seat somewhere? there are at least four more seats.

And the format here is just going to be open discussion. The FDA facilitator will be there not to answer questions but just to listen. Everything said at these tables will be anonymous. We would, however, like someone to volunteer to be the recorder, and the only not anonymous will be the five or six comments, main comments you might have after the discussion.

We'll try to organize the discussion around the one-page description here of the ANPR. Here is the ANPR itself, and if anybody does not have either of these documents, we've got some extras made, so we can start by making sure everybody has got them. If you're ready to go, you can start.

[Meeting recessed for roundtable discussion groups.]

MR. NARDINELLI: May I have your attention? I would like to reconvene the general session. All right. let's reconvene the general session, and the format for this next section is, we will begin by asking a representative from each table to briefly talk about the five or six comments, the most important comments that they would like to make, and then we'll just open up again for any general comments, discussion that anybody else would like to offer.

So, let me see. Does any table wish to volunteer to start, or do you want me to just pick one? Well, let's see. This is the biggest table. We'll start here. Oh, you're not ready? Okay, who's ready, then? We'll start there. Okay, this is also a big table. We'll start with them. Please, the microphone, so that our transcriber can get this down. Thank you.

MR. COVEN: Mitch Coven, Vitality Works. Hopefully I can do justice to the good conversation we just had. We have six points that we came up with that we would like to address on the GMPs.

Number one, we have concern that the FDA still does not have enough economic data from small businesses, i.e., companies well under 500 employees, to make an educated decision on the small business impact financially, and we request that the FDA make more attempts to gain more concrete information from small businesses, especially site visits to smaller businesses, so that the end result of the GMP may be more informed as to the impact so that the expense to small businesses may be more thought out.

Two, we hope that FDA keeps the section on botanical identification as it is current written, to avoid excessive economic burden for small businesses, and we fully back comments made earlier by Michael McGuffin on perspectives on the guidance document. We want to state

that raw material testing should be appropriate to the form of the raw material.

For instance, whole ginkgo leaf can be morphologically, organoleptically, and visually identified, and where it would be appropriate, if one has a powdered product called echinacea, then probably some kind of chromatography would be appropriate to distinguish echinacea angustifolia from echinacea purpurea. An inappropriate test would be any kind of chromatography on distinguishing whole herbs when visual, organoleptic, and morphological testing would suffice.

Three, document control maintenance is significant, and control of such costs is an issue. Maintenance of GMPs may be more significant costs than implementation costs. The proportionate cost to a small company who have no GMPs in place may be cost-prohibitive to such companies.

Four, these GMPs may reduce small raw material supplier selection. The GMPs will increase the business of suppliers who can produce a Certificate of Analysis and afford to provide appropriate documentation. The small harvesters or wildcrafters or growers cannot compete, the ones who supply 50 pounds of a raw material, versus a company that supplies 10,000 pounds of a lot, who can average the costs of testing over a larger lot, gives them

an economic advantage, and that the smaller companies who provide smaller lots may go out of business, thus reducing the choices in supply of raw materials. Commonly, it is thought that the smaller batches from smaller harvesters may be of a superior quality to some of the larger lots of some botanicals, although that is arguable.

Number five, defect action levels could have significant compliance costs to monitor the defect action levels per crop. Depending on what we need to do to be compliant, this may be expensive. It will also reduce raw materials suppliers, again, to those who can provide documentation that defect action levels are in compliance, and again those companies who can produce defect action level testing and average the costs over a large lot will have an economic advantage over those who harvest smaller lots and have to average it over a smaller lot, thus limiting raw materials supply from the smaller companies.

Six, the GMP states that we can accept a Certificate of Analysis on a raw material from a raw material supplier if we can establish the reliability of a supplier. As I asked earlier, and it hasn't really been answered at this point, we would like guidance on how to establish such reliability to help keep costs down as a small business. So if we can establish what it means to establish reliability of a raw materials supplier who

provides a Certificate of Analysis, that could help control our costs as a small business dramatically.

Thank you.

MR. NARDINELLI: Are you ready now? Okay.

MR. : I'm sure I'm not going to do our table justice, and I apologize for that. Not being herbs at all, this is an education day for me, and I appreciate it, my table. Thank you.

We also would like to see the tests that must be appropriate for the particular product or product form and company size. We also agree with that. The expiration testing, we had a comment on that. The table does not support that with respect to herbal products, because sometimes there is no one test to test for a herbal product, and so we do not support that.

Most importantly, the regs need to be clear and size-appropriate. In herbal products, again I'm learning today, and I appreciate it, the traditional knowledge needs to be respected along with modern science. There's a lot of knowledge I just learned that is not so well accepted outside of the herbal field, and it's interesting.

Training and guidance will also be very helpful when they're developing, when the companies develop their particular SOPs and meet the GMPs.

Was there anything else that we should bring up?

That's it? Okay. Thank you.

MR. NARDINELLI: Let's see. Richard, is your table ready?

MR. WILLIAMS: I have no clue. Are you ready?

MS. : we had some extremely educated people at our table that should really be giving this, but I volunteered, I don't know why, to do it. Just because I like to be in front of the microphone.

One thing I think that was interesting that was raised for some people who--I think one thing that was raised was that the learning curve on any education within the industry is varied, so one important thing I think that was pointed out was that there is this gap in the industry.

And the understanding is that these proposed GMPs, the baseline is really already there because the baseline for the GMPs was required in the food GMPs, and the proposed GMPS that we see now are really not that more significant. And, as a matter of fact, I guess there were some companies that were contacted, and the feedback from them in certain areas was, "Hey, you know, we're already doing this."

There was feedback from some of the companies that were contacted, and there are two areas of potential cost concern, and that was with identification and date labeling. As it relates to positive feedback, the no requirement for the expiration date, that was good, that was some positive

feedback. And also positive feedback was that the agricultural products are not subject to the GMPs, and that was some very positive feedback within our group.

We also talked about the Certificates of Analysis and questioning the reliability, and we had a discussion about raw materials. We learned that some--that there are some companies who do test and visit their suppliers, but we had concern that that's not true across the board. And I think our table in general believed that the Certificates of Analysis were a good thing.

In general, we talked about whether the GMPs were going to help, and I think our table agreed that the GMPs will help. They will raise the thresholds of reliability and responsiveness within the industry.

One of the things that we talked about as it relates to in addition to the GMPs was education, and we felt that education in addition to the GMPs is really key, and it was raised that perhaps the FDA should play a role in that education. We know that industry can provide education, but we think that it would be helpful for the FDA to get involved in that education, as well.

I guess that's it.

MR. NARDINELLI: Thank you. Pat, your table is ready? We have a volunteer.

MR. : A few of the points at our table,

number one, if GMPs are in fact appropriate, let's start slowly, phase in the GMPs by first beginning with raw materials, use that as a foundation and then move forward from there, because most of the quality problems happen at the beginning of the process.

Number two, and this really applies to dietary supplements, many issues of dietary supplements as well as GMPs, FDA needs to train its agents to be sensitive to the needs of the dietary supplement industry. Five years after the passage of DSHEA, some agents remain prejudiced against the industry and don't understand even the basic definition of a structure function claim.

Another comment at our table was that the FDA needs to teach in-house the difference between pharmaceutical models and nutritional models, regarding the law, procedure, and again the attitude of the agents.

Also, with respect to GMPs, phase in the requirement for expiration dating and stability testing, because those are the most expensive items. Also regarding costs, GMP supervisors are more expensive, and there's a lot of concern about soft costs, additional computers and software and training and a lot of expenses, particularly in large city companies, in training costs in connection with those issues.

And, finally, a comment that NNFA does not speak

for the industry. GMPs are an issue that will require more time to develop, and this process should not be rushed.

Thank you.

MR. NARDINELLI: Thank you. Next?

MR. : Speaking briefly, so we can all go home, as far as the outline, no one at the table had any particular disagreements with the concept of GMPs or controlling processes. I don't think anybody argued with the format there.

However, one of the effects on small business, we felt, was the fear of inspection and enforcement. I think the fear is that the quality of the inspectors could be inconsistent and that the training may be inconsistent. Experience indicates that inspectors that are out inspecting in the field are often one- and two-year employees, and possibly in the training process.

Also, it is noted that FDA inspectors often turn over. They either, if they are particularly good, they rise up through the organization, or if they are particularly good, they leave the agency and go to outside business. Therefore, the quality of inspectors for the inspecting of facilities is a fear, I think, of small businesses.

Another fear in the inspection and enforcement process is the "no liability" policy of the FDA. And what I mean by "no liability" policy, FDA inspectors cannot help or

suggest how to improve an operation. When they make an inspection, they're basically there to make an observation. Upon making the observation, if you ask them how you can improve or how you can do something, like how they can help, they are not allowed to, basically. They are not allowed to voice an opinion or to give any direction to the company.

And therefore there is a fear when an FDA inspector comes in, basically, when he does his exit interview, that you're basically a part of a legal process, and you almost don't know whether you need to have your lawyer there, because anything that you can say can be held against you. So I think a small business in particular is fearful of that FDA inspection, and therefore does not look very eagerly towards an FDA inspection.

Also, I think the small businesses are afraid of uneven enforcement across the country through the various districts. In the past, particularly in the drug area, while it is certainly far more unified today, there has been--the industry has classified enforcement as reasonably uneven from district to district, and so there's a fear that in New Jersey or California or Texas it may be particularly tough, but in Kansas City or St. Louis it may be a fairly lax enforcement.

I think there are some possible answers to this. First of all, I think we could, with industry-FDA

cooperation, let industry somewhat self-police itself through a program like the NNFA, which is an independent third party inspection program with supervision by another independent advisory committee which coordinates policy with the board of directors of the NNFA. The reason for this is that private inspections are more likely to be more helpful, offering suggestions and guidelines.

For example, in the NNFA program, the two current auditors are both ex-FDA employees. One is Jeff Hewen in California, with 10 years of experience, who has gone into the outside field and represents the NNFA's inspector. When Jeff does an inspection, he doesn't just leave the company with some observations or a pass/fail. Jeff reaches out to the company, and at some point where he sees they are not making the grade, offers suggestions or help, and will come back to reinspect at a later date rather than just giving them a blanket failure. People in the industry that have gone through that process find that very helpful.

I think also an independent third party person is less threatening to a supplier or manufacturer because he does not represent the formal government agency. I think third party independent inspectors can be more experienced than many of the current FDA inspectors. As I say, Jeff has got 10 years. The person that the NNFA has in Michigan has multiple years with the agency before going into private

practice. And they are familiar with the problems of private practices.

The fourth thing, I think, is it's an opportunity for the agency and the industry to work together on a program. The NNFA looks at approximately or a potential of some 530 manufacturers, suppliers, distributors or co-packers, that could be inspected by its program. And with that large number of people, those are people that the Food and Drug Administration would, if they implement a CGMP program, inspection program, are going to have to get out and visit.

One of the suggestions we came up with at the table is that maybe there is a possibility of some sort of--I don't know how you want to say it--but maybe the FDA could inspect, or if they would accept a third party inspection agency such as the NNFA program or State agencies or something else, that the certification by the third party or a State agency or some other group could be the equivalent of an FDA agency, and the FDA, while not giving up their authority certainly to go in and to inspect anybody, could accept that as an inspection. And, therefore, having that certification would be an alternative to the FDA coming in for a biannual or every two or three year type of inspection.

I think that was pretty much the comments that we

wrote down. Thank you.

MR. NARDINELLI: Has your table been heard from?

VOICE: Yes.

MR. NARDINELLI: Okay, so each table has been heard from. Would someone like to make some additional-- this is a quiet table. Yes, do we have additional comments?

MR. ROGOVIN: Yes, Mr. Rogovin from Jarrow Formulas. It would help if I had my glasses. Okay, a couple of things here.

Our otherwise thorough reporter did leave out the stated desire of a couple of companies to have ISO 9000 first and phase into GMP. Again, it's the small company issue. This will really help small companies get organized, and then once they get used to the paper chase, it will be easier to implement further procedures.

As to the NNFA role, three issues. NNFA standards should not exceed FDA requirements. I don't see why the organization should take it upon itself to go beyond the statutory authority of even the FDA. And this is not something that has been agreed to by the affected membership. We see it as an imposition.

The other thing is, is to stay out of marketing. No go to the logo. I am getting 100 percent response of retailers as to this logo. They see it going into their competition. Something like 90 percent of the suppliers, on

being polled, oppose the logo.

The third issue is alternative auditors, for two reasons. If I can't stop the NNFA, I may pull out of the organization. And if I still want to do second party auditing or third party auditing, whatever, there should be other recognized auditors, not only because I'm not the only company that is at its wits end with the NNFA. There are a number of very large companies that have pulled out.

But I think that to be fair to our competition who are not NNFA members, maybe because they don't qualify, you know, they're involved in the mass market, whatever, they should be allowed, if the NNFA is going to function as an independent auditor recognized by the FDA, there ought to be some way to have some sort of other auditors also for these companies.

MR. NARDINELLI: Are there any other general comments? Somebody who didn't hear their concern or their comment mentioned previously? Here's your chance.

MR. McGUFFIN: Yes, let me just clarify, to make certain that the point that I was trying to make is that the industry draft GMP specifically exempts raw agricultural commodities from these GMPs, and I think that that's a good point in these GMPs that should be maintained, that raw agricultural commodities should be exempt from CGMP for the manufacturer of dietary supplements.

MR. NARDINELLI: Okay. Well, if there are no further comments, let me thank you very much for coming here at the end of what i know has been a very long day. We have a few more copies of all three handouts. If you would like to take some for friends or family, please, it will save me from dragging them home.

[Whereupon, at 9:31 p.m., the meeting was concluded.]

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CERTIFICATE

I, **ELIZABETH L. WASSERMAN,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

Elizabeth L. Wasserman

ELIZABETH L. WASSERMAN