the provisions, we actually think you will not have adulterated products. And so you shouldn't have more recalls.

If you don't agree, certainly let us no. If you think there will still be adulteration, let us know. But that's our premise.

And this questioner asks: can you describe a small operation with fewer than three people under the proposed rules?

And I guess what they're asking is: is it feasible to actually manufacture dietary supplements with only three people. And we do have survey evidence that there are firms with only three people.

MS. ACOSTA: [Off mike] Should I go through my questions, now?

One of the questions I have is: while not stating a size requirement for the quality control unit, it does appear you expect this unit to be a separate entity, not an [inaudible].

Oh--sorry--can you hear me now?

While not stating a size requirement for the quality control unit, it does appear you expect this unit to be a separate entity, not an added responsibility for existing employees. Is this a

correct assumption?

No. The quality control unit does not need to be a separate entity. It will be probably mostly added responsibilities for current employees. It doesn't have to be separate. And, also, the regulation doesn't say who can be in this unit, or if it has to be segregated from other functions. It can be anyone that you select, and any number that you select.

And another question--also regarding the quality control unit: can personnel who perform quality control procedures but report to manufacturing departments be considered part of the quality control unit?

Umm--there's no specification as to who can be part of the quality control unit. Any person can form part of that unit.

And another question--I'm sorry, is there any follow--up to the questions regarding quality control unit?

[No response.]

So, on to the next question. With the proposal, no product that has been rejected for microbe can be reworked? And that is correct for final product--finished product--that is detected

for microbe cannot be reworked.

And another question is: what about herbs that are sterilized high microbe count? If the sterilization of the raw ingredient or the raw material is part of the process, then you can--it can be incorporated into the batch production or master manufacturing records--the sterilization of the botanical product.

Then another question is: will foreign firms have to register with FDA and be inspected?

This is probably, in regards to the new registration for firms for bioterrorism. And, right now, I don't have an update for that information. So, probably look into the information that comes out when the bioterrorism is explained to the public.

Then, another question: there is no definition in the proposed GMPs for identity, purity, quality, strength and composition. Is the definition written somewhere?

And you can look for the interpretation for identity, purity, quality, strength and composition in the definition of a batch in the proposed regulations. That's what a batch--the description of what a batch should be.

The one more question: are practicing components to be tested to ensure conformance to the contact material requirements? The components need to be either tested or examined.

[Pause.]

Then I have one more question here: when you state a label copy or copies must be attached to the production papers, will private label companies be required to attach a copy of each label used? Or will a copy of the master label be acceptable?

I don't know if the person means someone who's producing something in bulk and sending it to someone else. But when you're producing your packaging under different kinds of labels, a copy of each of those labels needs to be in the batch record.

MS. STRAUSS: I'll answer a couple more questions.

This question says: how does the proposed rule address unsubstantiated label claims? If this question refers to structure/function claims, or health claims, the rule does not address those. Those are addressed by other regulations. If it refers to misbranding, as a label not including in

the--the product not including what is claimed on the label, that's called "misbranding." And it is covered in the regulation, and that's why we require testing, to ensure that the product is of the identity, purity, quality, strength and composition that's claimed on the label.

Another question here is regarding safety. It says if you are addressing consumer concerns, how does this proposed rule address your stated consumer concern regarding safety. And on the issues regarding safety, that the CGMP addresses are those that are related to manufacturing. And there are some safety issues that are of concern: too much, too little, contamination--those kinds of things. Maybe packaging that has some unhealthy leaching--or something like that.

But if it refers to the safety of a dietary ingredient itself, then that's the manufacturer's responsibility to start with an ingredient that is reasonably expected to be safe.

A related question is this: we are proposing to manufacturer a dietary supplement from transgenic rice extract. Do we need to obtain GRFs on the grain before the manufacture process, or can

we do the GRFs on extract, or do we not need to obtain GRFs? I think it's GRFs--its acronym is transposed.

The answer to this comment is that I suspect that this is a new dietary ingredient that this manufacturer is intending to use in a dietary supplement. And there is a separate regulation concerning new dietary ingredients, and there's a notification that is required to the agency that gives the evidence that the manufacturer relies on to assure that the new dietary ingredient is reasonably expected to be safe.

So, because the safety of the dietary ingredient is really, you know, something that the manufacturer deals with before manufacture, we've not addressed it in this rule. And that question was asked in ANPRM--something about substantiating safety of a dietary ingredient, and there is a question--I can't remember the number of the question--but it's one of the nine questions that was asked in the ANPRM that we answered in the preamble.

But this is a new dietary ingredient question--that transgenic rice--and there needs to be a notification to the agency. And it's in 21

CFR 190.6, I believe.

Another question regards the temperature and humidity controls: please clarify when temperature and humidity controls must be installed. Does FDA presume controls are required unless a manufacturer demonstrates through testing that they are not necessary?

And we haven't--if a control is necessary to prevent adulteration, to prevent microbe growth, then the manufacturer would be required to have those kinds of controls. And we've not specified what kind of documentation would be necessary to determine whether or not FDA would decided when the controls should be there or not. So this would be a good comment to send to the docket, to ask the agency this particular question--that could be considered in a final rule.

This question is related also to equipment and utensils: if that section is modeled after 21 CFR section 110, where in section 110 is there discussion of equipment calibration? And it's .40(f), and all it says is that it needs to be accurate. There's some other--"adequate" is another word that's used. And we thought, for clarity, we needed to give some additional

information there. And also there are some other food--specific food commodity manufacturing regulations that have other descriptions of calibration that we modeled that after.

Another question on instrument and controls--I don't see any hands, and I'm kind of going through these. I'm presuming that there aren't any needs for clarification. Did I miss some?

[No response.]

Okay. Can you describe the fundamental difference between a requirement for equipment calibration and the equipment requirements in proposed Section 111?

We've not required that equipment be calibrated, but that instruments and controls be calibrated--and there's a difference there. And I would interpret "equipment calibration" as more like equipment validation, which we've not required.

And I have some others--maybe I'll just turn to some other cards.

MR. MUSSER: Well, since I still have a significant pile here--if a dietary supplement manufacturer validates its manufacturing processes

and has adequate data to demonstrate these processes are operating and statistical control, will FDA consider allowing the manufacturer to perform finished product testing for label--claimed items at a frequency less than once per batch?

There's a note to this that this is not an arbitrary skip--lot testing program, which we understand is not allowed in the proposal, but one based on sound statistical principles, and only applies to validated processes.

Umm--as the rule is currently written that would not be allowed, however, we are still taking comments. And if you feel that this is something we should consider, we do consider these things and we would ask that you submit a comment to the docket.

Could FDA publish a list of approved FDA lab testing facilities for ingredients and final products?

FDA does not and does not intend to approve facilities for testing. So we would then not have a list of approved facilities for testing.

Are certain substances going to be required to be tested for certain toxins, or are all supplements going to be required to be tested

for a panel of toxins. The latter would be difficult, particular experience and not logical. If a toxin has never been found in a particular ingredient or product, why should it be tested for?

We are not going to specify a list of toxins that must be tested for. The rule, we believe, puts that requirement on the manufacturer, that the manufacturer is familiar with their product, is familiar with the kinds of toxins that they would encounter, and contaminants that they might encounter, and would have those specifications in its manufacturing record.

Now this is a good question: would certificates from the city water tests suffice, or do we test water in--house?

City water, interestingly enough, is generally tested to EPA standards for drinking water. And therefore, if you could get a copy of their test records for that, then that would be appropriate in this case.

Will electronic signatures be acceptable so paperless records can be maintained?

Yes, that is clearly pointed out in the proposed rule. And something else that I'd like to point out. You would, then, need to be in

compliance with CFR Part 11--the electronic signatures part of the food code, as well as other things that are not necessarily in the GMPs. You are required, for all aspect of the food code not just the GMPs.

I'll take this one and then we'll move on.

Will manufacturers be required to do pesticide or herbicide testing on all botanicals? And which specific contaminants would be required to be tested for?

Currently, EPA sets the allowable limits and allowed pesticides and herbicides that are present in those products, and they have not determined those levels for these particular products yet. And until they do, there wouldn't be an enforceable level at this point for GMPs. There may be for other items in the food code, but not for the GMPs as proposed.

MS. STRAUSS: Okay?

MR. VARDON: I have a few more questions.

What did FDA calculate as testing? Cost per batch or cost per dietary supplement?

And we estimated as cost per batch. And the question I'm asked--did that cost estimate take into account analytical testing, such as HPLC on

each ingredient, whether active or inactive, in multi--ingredient products, such as when there are 30 or more?

And, yes, we did. We summarize how we estimated the testing cost on page 427, Table 14. But just to give you some of the results, we did look at multi--ingredient products, and we used as a probability distribution a product with between one and 30, and we felt the mean would be somewhere in there. And we assumed that there would be about three tests per finished batch for product quality. And one test, per defect, per control point--there would be five defects that they would test for--as a mean estimator. But we recognize there is a wide uncertainty around that, and so we used Monte Carlo simulations for each of those numbers.

And: in the cost impact analysis, did you consider how much it will cost FDA taxpayers to enforce the GMPs?

And, no, we did not look at enforcement as a cost. And that's not required, and that's not done in accordance with Executive Order 12866.

But then the questioner asks: does FDA currently have adequate funds to vigorously enforce new GMPs?

And this question comes up quite a bit. And I think we're not really--we can't answer that at the table, but what we can say is that there are about 500,000 food manufacturers in the country, and only about 1,500 dietary supplement manufacturers, so the impact to FDA from this rule won't potentially be as significant as the impact to you yourselves. However large a rule this seems so you, to FDA it's not particularly overwhelming.

And another questioner asks: what time is spent, actually, by the consumer shopping for OTC drugs?

And out estimate, based on the methods that I mentioned, was about 3.75 minutes per unit.

And how dissimilar is this from shopping for dietary supplements?

And we think it's a close proxy. We don't have any other evidence to suggest otherwise. But we only used that model--we used this model in addition to the other two models--the grocery store model and use--of--time model, also. And, ironically, those models converged fairly closely to between, I think, three and five or six minutes. But we recognize, also, that shopping time is just a fraction of search time. And so our

total--okay--

MR. : Follow up question.

I guess what escapes me in the economic analysis is the "benefit'--in quotes--provided by GMPs applicable to dietary supplements in shopping habits, when GMPs which are already in place for OTC drugs have had no impact. That one just kind of escapes me. If the model is 3.7 minutes per OTC, they have GMPs--it's unclear to me how reduction of shopping time is going to occur for dietary supplements by the implementation of a rule on GMPs.

MR. VARDON: Well, you'd have to look at the drug OTCs without GMPs and with GMPs. And I'm not aware of any study without the GMPs. So you can't look at the difference.

MR. : So then I would suggest, then, that comparison is invalid, just as--you've officially compared an apple and an orange, and I don't think, therefore, there's validity to that. And I apologize for the harshness of the comment.

MR. VARDON: Can I ask you a question?

MR. : Please.

MR. VARDON: Now, do you believe consumer behavior will change, by adopting this? Do you

think they will have--

MR. : I don't have data one way or the other.

MR. VARDON: Uh--huh--just as a general principle, do you think that's true?

MR. : You know, personally--my personal belief--and this is just personal belief--

MR. VARDON: Uh--huh.

MR. : --is that I think that people who shop for dietary supplements are concerned about their health, number one. Number two, they're generally interested in those things that they take inside their body, and so, number three, it's not an inconvenience for them to look at a label, to read literature and information, because they are concerned and conscious about their health. They're not attempting to treat a disease--

MR. VARDON: Right.

MR. : --they're attempted to take better care of themselves.

MR. VARDON: Right. But the search time that we're looking at is the difference in product quality, so that they can compare--

MR. : Okay.

MR. VARDON: --different products. But they won't have a way of distinguishing one product quality from another product quality merely by looking at the label, or the brand name.

And so we're saying that if you adopt these rules, they'll have the assurance--they won't have to look. They can't look, but they won't have to look either.

MR. : I wholeheartedly concur. However, the shopper will continue to look for an appropriate combination of products, because these are not monographed items, with single indices mandated. They are, as of today, and as of the implementation of this final rule, a wealth of products across a panoply of dosages, encompassing a host of appropriate and completely safe dietary ingredients. It doesn't change their shopping pattern one iota.

MR. VARDON: Well, we do have evidence, though, that they do look at product quality, so that even if they're interested in one ingredient, they'll still want to know that the manufacturer actually has that ingredient in the product.

MR. : I concur that there is an issue of concern within the consumer's mind

concerning overall product quality, and that GMPs--regulatory GMPs are intended to address that. But to equate that as a cost benefit, in terms of shopping pattern and time saved by the American consumer, i.e. taxpayers, is a bit on the fallacious side, based on the comparison of one entity versus an entirely different entity as the model.

That's really the point of the dissertation.

MR. VARDON: Okay. Well, send your comment.

MR. : I do have one other point concerning the water quality issue.

Municipalities will, indeed, provide certification that their water is, in fact, in conformance, but they do not carry that guarantee inside your facility. Once it hits your door, they're done. And in many instances, once it leaves their facility, they're done.

So, in answer to the question of "do you have to test at your facility," you probably should, because that guarantee is only--unless you physically carried the water in a sterile bucket from their facility to your facility and then used

it, that certification's invalid.

MS. STRAUSS: That would be a good comment to send to the docket.

MS. ACOSTA: I have some more questions.

One says: please describe what is mean by cross--referencing of receiving and batch production records. This is a requirement within the batch production record.

The cross--referencing means saying what lot of incoming raw material is used in your batch.

Another person asks: please clarify what the preamble refers to as "regulatory specifications." Are these required only for situations that safeguard against adulteration as the term is defined in Section 402 of the Food, Drug and Cosmetic Act? And, if so, how does the need for setting specifications for strength fit into this definition?

The requirement that a batch of product have the strength for an ingredient--for any given ingredient that it claims on the label--is that each ingredient should be what it's represented to be on the label. If there's way too much or way too little, in regarding--and that would be our definition, or what we interpret "strength"--too

much or too little of an ingredient versus the label claim, is that there could be health consequences to having too much or too little of that ingredient. And that's why it would be included under an adulterated product.

MR. : If I could just add a follow--up to that, in many places it says the specifications have to be set to safeguard against adulteration, and these other terms are used for purity, quality, etcetera, and strength. There seems to be a disconnect between adulteration and how it's defined in the statute. And then these other terms, including "strength." Strength, to me, seems to be more of a misbranding issue than it is an adulteration issue.

So, I don't quite understand how these tend to be used interchangeably.

MS. STRAUSS: I think we're relating to adulteration in two different ways. And if this is unclear, that would be--that's something we need to clear in any final rule.

Adulteration as it's used in foods is, you know, the filthy--you know, in 403, I think it is. Also, 402(g), that gives us authority to prescribe CGMPs also says if something is not manufactured in

accordance with the CGMP it's adulterated. So that's a different kind of adulteration that's related specifically to not following the CGMPs.

So in the CGMPs we indicate that dietary ingredient and dietary supplement must have specifications for identity, purity, quality, strength and composition. And it doesn't--our regulation says it must have those in a final rule. Then it would be adulterated if it doesn't have specifications for those in the testing to ensure that those specifications are met.

MR. : So, in the final analysis, then, we should really look at that longer list of identity, purity, quality, strength and so forth, rather than the definition of adulteration that appears elsewhere.

MS. STRAUSS: Right--not only that, but also the CGMP, so they're both important.

MR. : Thank you.

MS. ACOSTA: Another question says: are we allowed to make batches to better homogenize the final product; that is, if you have a sub--potent batch, can you mix them to change the composition of this batch?

And, pending that the firm does the

material review and disposition decision--yes, this is allowed.

Another question says: what does it mean, practically, about calibrations or checks and written records of them? For example, filling and counting equipment is checked during production by weighing or counting product in the bottle. Is that sufficient?

I think this is asking whether the filling and counting equipment needs to be calibrated and reviewed. I mean--you have to define a process on how to do the calibration and if weighing or counting the product that's in the machine to verify that the counter is working, then that would be your specification.

I have just a few more questions: if all components are required to be generally approved as safe, approval for food additive or color or dietary ingredients and materials not present in the finished dietary ingredient or dietary supplement or components, what if you use a particular solvent used in the manufacture, for example, of B--12 vitamins?

It is the ingredients that need to be approved, food additives or GRFs. The solvents are

not part of the ingredients, they're part of the components.

MR. : Perhaps it's an ambiguity within the preamble itself, but essentially what you have here is: if A equals B and B equals C, does A equal C-- question. Solvents used in dietary ingredient or dietary supplement are defined as being components.

MS. ACOSTA: Components.

MR. : A equals B. Components must be GRFs, approved food additives or food colors--

MS. ACOSTA: Ingredients.

MR. : --or dietary ingredients.

MS. ACOSTA: Ingredients. Not the components.

MR. : Not components.

MS. ACOSTA: The main heading is "components," and within components is dietary ingredients, ingredients and solvents.

MR. : Thank you.

MS. ACOSTA: Okay.

I just have a few more questions, and then Ill let other people that have a lot more questions than me go on with it.

If the quality control unit must not release a product unless all specifications are met, what purpose does the material review panel serve when it looks at products that are not in conformance for any reason?

I think, here, you need to look at the material review as part of the quality control unit. For a product to be released, there needs to be a series of steps that are performed, and material review is part of the functions of the quality control unit. And it's--again, the question says "a product will not be released unless all specifications are met." Then that material review is part of the--trying to--or determining if all specifications are met.

Does that answer the question?

[No response.]

And just a couple more questions: is finished product testing done before packaging or after packaging?

It can be done at any point that you choose.

Then, last question is: what specifically would the proposed regulation require be done as part of the material review and disposition

decision for returned products? Would it require complete testing for all specifications again?

This depends on the reason for return, but if it's returned for problem or failure, then you would need to test to make sure that all the specifications of this product are met.

MR. : I just want to follow up on the point that was just made before about component or ingredient--

MS. ACOSTA: Sure.

MR. : The reg--and it does talk about "any substance, other than the dietary ingredients--"--blah, blah, blah--"--which may reasonably be expected to result indirectly in its becoming a component, or otherwise affect the dietary ingredient or dietary supplement not [inaudible] authorized--"--blah, blah, blah.

So there may be an issue with how it's drafted, if that's not the intent.

MS. ACOSTA: Okay. Thank you.

MS. STRAUSS: If you'd point that out in a written comment to us.

I'll answer a few more.

The CGMP imply that records be kept for utensil cleaning, which would require excessive

documentation for cleaning numerous small items. Can you clarify the agency's position on this?

Umm--the records that would be required for maintenance, cleaning and sanitization are those for equipment and processing lines. And they're identified in the batch records. We don't--we've not required documentation of cleaning and sanitation of utensils. But it's equipment and processing lines.

Can you cite the legal authority to be granted access to written records for manufacturing dietary supplements.

I believe it's 701 of the Act, and it's for efficient enforcement. And there are other records that are required for other food commodities-- manufacturing regulations.

In what fundamental way do these regulations on in--process controls differ from HACCP?

I think perhaps they--as far as in--process--they're probably similar, in that in--process, in HACCP, the manufacturer decides what controls are necessary. And in our regulation, the manufacturer also decides what controls are necessary in--process to prevent an

alteration.

I would add, though, that HACCP has many, many steps, in an overall plan. And so there are many aspects and principles are HACCP that we've not addressed in our GMP.

Concerning complaint documentation and investigation--this would be consumer complaints--for U.S. manufacturing operations, are overseas complaints to be included, or only U.S.--originated complaints?

This--as we've written the rule, it would be all consumer complaints that come to the firm. If you think that foreign complaints--actually, the desire here is to see a trend, so that a manufacturer can identify whether there's a problem. And if the manufacturer doesn't think that overseas complaints are useful in trend analysis, then I guess they wouldn't need to be included, and you should send us a comment concerning that.

This is another question concerning foreign manufacturers. Due to the relative proximity of the United States manufacturers, will foreign manufacturers have an unfair advantage if they are not as accessible to regulatory agencies?

The agency does look at imports. They have a history with certain manufacturers, and they also do testing when they suspect that there's need to do testing. So, realistically, they probably wouldn't have the same inspection periodicity that domestic would, but there still are measures to ensure that foreign manufacturers do comply. And if--with all of these comments and questions, you know, follow up with something to the docket--the address is up there--so that they're considered.

I'll take one more, and then I'll give it back to Steve for some.

Do you have a model for the education, training and experience necessary to handle, identify and segregate consumer complaints for adverse event reports?

Umm--really, I'm not sure I understand the question, but you wouldn't want to segregate--

MS. : CGMP versus ingredient--dependent--

MS. STRAUSS: Oh. Okay. So the question is, how would you separate consumer complaints that are related to a dietary ingredient pharmacologic activity, versus CGMPs?

MS. : That's--no. That's--

MS. STRAUSS: That would be related--I mean, that's a manufacturer's discretion. And it is a thorny issue.

MR. : The requirement is that the person who handles consumer complaints--if A equals B, B equals C--the person who handles consumer complaints be qualified by education, training and experience. And the curiosity was whether or not there was anything in mind as far as what that would be, because the duties include taking in the complaint, assessing whether or not the mico--toxin report from the consumer--how they determine that I'm unsure--is either related to a quality issue, as opposed to an adverse event.

And I was just curious as to whether or not the agency has given some thought to what those qualifications might be.

MS. STRAUSS: That mico--toxin might be related to an adverse event. I mean, we're not saying that CGMP complaints records should not be kept if an adverse event is related to it. That's not what we're saying.

We're saying that you get a consumer complaint, and somebody looks at it and says, "This one's GMP, this one's because of dietary ingredient

itself--there's something wrong." Like that. They make that decisions. Then the next step is looking at that quality complaint: is there an adverse event that's associated with it? And if the answer is yes, then the quality control unit would need to investigate that to see if there's a failure of a batch, or specification, or something else--so that they need to correct. That's what we're saying they need to do.

If that's not clear--

MR. : That's abundantly clear. The question was, whether or not you--

MS. STRAUSS: We have some ideas of what training--

MR. : --what that education, training and experience would look like to make a person qualified to perform this task, since you will be--you intend to look at the personnel records to verify that. I just--

MS. STRAUSS: That's a good point to be raised, because that holds true for anyone in the firm doing anything.

MR. : Right.

MS. STRAUSS: And I would imagine that once there's a final rule there will be guidance

documents. There will be training that will be, hopefully, going on for firms, that would be done jointly by industry and the agency. And I think--I don't think, I know, that somewhere in that preamble, that--

[Technical difficulty.]

MS. STRAUSS: Good question.

MR. MUSSER: I'd just like to address one--I have a whole pile of them here yet, but some are kind of comments, and others I feel I should at least address. And the one that I'm going to pick in the little bit of remaining time that I have here has to do with method validation and what we mean by method validation, and what is validation.

And validation is different things to different people. And, for example, validation is not instrument calibration. Instrument calibration just confirms that your instrument is reading the correct reading. It's not validation. What me mean by "method validation,' is that you conform to any number of what are now becoming internationally harmonized methods for analytical method validation. I would point you to a number of websites: the International Conference on Harmonization has a very nice website, with a very

nice summary of how you validate, what performance criteria are needed for method validation; what people mean by method validation.

The FDA also has guidance documents on its drugs website; that would be the Center for Drug Evaluation and Research--what would that be, that would be--yes, I'm trying to think of the website. Its www.--well, go to the FDA website, which is www.FDA.gov--FDA.com may take you to someplace that you don't want to be.

But the .gov website, within that, you would look at the Center for Drugs, and the Center for Drugs has a very complete section on guidance documents, and method validation is addressed in a guidance document in that particular website.

Let's see if there's anything else.

Oh, on stability requirements, the--I'm sorry--the proficiency testing--proficiency testing is not a measure of method validation, and so that is not included in the method; plus, I don't think the agency would have the resources to do proficiency testing.

There is also--stability requirements are not specified in the method. That goes to the expiration.

There were a number of comments on expiration dating. If you feel that we need to address that, once again, since there were a number of comments about expiration dating and shelf life, then we would ask that you send us those comments.

I guess we'll close.

MS. STRAUSS: I just want to thank you all for coming.

And your comments are really important to us. We did our best to kind of do the breadth and depth of what we thought should be in it. We want you to send your comments to the docket if there are some places where we've not been clear. I think wherever we tried to give real flexibility, we've created real confusion.

So if you could help us clarify that, that would be great.

This afternoon, Sara and Steve and I won't be here for that question and answer period that's on the agenda. We thank you for your questions this morning, and really want to ensure that you get them to the docket so we can consider theme in any final rule.

Do you have anything further to say?

MS. McDONALD: This is just for the

latecomers. This morning. We do have a restaurant list. The cafeteria on the fifth floor is one of your options, or you can go out the Clay Street entrance of the building. You do have to go back to the main bank of elevators and exit on the first floor. Go out the Clay Street side, cross the street, and in the City Center Plaza you'll see all sorts of choices of restaurants. But remember that you will have to have your photo ID, etcetera, to get back into the building through security.

I am going to babysit--but don't leave any valuables. You know, don't leave your wallet here. But--or your computer.

[Luncheon break.]

Regulatory Flexibility Act and How to Comment

MR. VARDON: Well, why don't we get started again. We're running a little late, but I know people are also waiting downstairs. And so we'll give you a chance to get to your seats.

[Pause.]

And thank you again for coming back this afternoon.

I mentioned this morning that the economic impact on small business is going to be quite great, and I characterized that as saying--or I

mentioned that several hundred firms are at risk of going out of business. At the break somebody didn't like that characterization, using "several hundred."

So let me be more precise. Our estimate is that 250 firms are at risk of going out of business. And, again, I don't want that 250 number to create a sort of a sense of false precision. It's just a mean estimator. But we recognize that many are at risk of going out of business. And so this session's particularly important if you're a small business owner, and commenting to improve the rule will be very important to you. And whatever the true number is, if our estimate is even remotely close, if 250 out of 1,500 firms are at risk of going out of business--how many?--15, 16, 17 percent of the industry is at risk of going out of business. So it's going to have a very large impact on this industry.

And so the importance of commenting, then, to improve the rule will be significant if you are one of those small business owners. And so this session is devoted to you.

And what I'm going to do in the next 15 or 20 minutes is give you more detail on how to

comment on the rule--the kind of information that we think will be most useful to help our economic analysis.

And two laws that require FDA to ask for and consider comments on these small business concerns: the Regulatory Flexibility Act of 1980, and the Small Business Regulatory Enforcement and Fairness Act of 1996--both require that we take your considerations into account in the development of the rule.

Mark is going to talk a little more about the guidance and assistance that FDA can offer you, but the important point to mention now is that FDA and the Federal government does require that we listen to your concerns, and we take that very seriously, and that's an enforceable requirement.

And what the two laws do that I just mentioned are to allow you to have more influence in the development of the regulations, and to create additional compliance assistance in the development of the Federal rules. And it also creates a new enforcement mechanism, but I won't go into that.

As I mentioned this morning, some suggested areas for your comments are the need for

the rule. Do you believe there's a market failure? Do you believe consumers are protected or are not protected now? The present state, under the present conditions?

Can the consumer distinguish an adulterated product from a non--adulterated product? And if they can't, is there abetter way of achieving that goal? And what will it cost for you to comply with this rule. It's very important to us, because the best way to influence the development of the rule is to show that the costs, in fact, exceed the benefits, and we've somehow underestimated or overestimated either one or the other.

And let us know whether you think this rule will actually accomplish the goal of preventing adulteration. Should we have a stronger rule? Or are there other ways--are there other regulatory options that we didn't address that can allow you, or allow manufacturers to accomplish these goals with a less significant compliance cost?

Let me begin by saying don't send sensitive information, proprietary information. We don't need to know the specific proprietary

information about your recipe, about your product. We don't want information that--about the impact on specific employees, for instance. But we do want to know what's going to happen to your firm. And the more specific and more detailed information you can send us, the more persuasive it will be. And so we'd be very interested in knowing what your before and after sales revenue will be, by this rule, if it's adopted as it's currently written.

We'd like to know what you think is going to happen to the price? Is it going to drive the price up? Is it--what is it going to do to the price of your products? And what is going to happen to your before and after profit? For several hundred, we think profitability will go below zero. And we'd like to know what you think this will do to your profitability.

But we recognize that's also very sensitive information, so we don't want tax forms. But if you can let us know within several hundred thousand, or several thousand dollars what your current revenues are and what your current profitability is going to be, that would be helpful to us.

And if you're an economist, or a business

analyst, or if you work with a trade group, we'd like you to comment on the overall analysis. One of the commenters this morning didn't like our estimate of change in consumer behavior. So if you can provide evidence that we've miscalculated, or we don't reflect what will really happen with consumer behavior, let us know that. We'd be very interested. And, as the questioner mentioned, we don't have specific evidence about the specific industry. We had to rely on other industries. We think they're closely related industries, but if you don't, let us know that. So always supply new data or additional literature sources for us.

This rule, we think, is going to have a big impact on the number of workers in your firm. And so we'd like you to let us know how many--what is this going to do to the number of workers you have. If you don't have people already doing quality control and now you have to hire somebody to do quality control, let us know that. Or if you're a manager, and now suddenly you have to wear two hats instead of just doing management, let us know that also.

We think record--keeping is going to have a significant impact. So let us know what it will

cost you to develop and store records, and let us know what it will do to you to train employees to use the records, and will this slow down your production? Do you have to stop production each time you have to maintain a record? And there's certainly a cost of that.

And let us know if you agree with us that there's going to be a benefit in the form of fewer recalls because you're maintaining records, or because you're complying with the rule in other ways.

And one way of showing the information--for instance, if you previously didn't use records, the cost to develop them will be the development cost for the individual records, and the frequency in which you have to develop them--if you have to change the master manufacturing record each year, then each year you're going to have a new development cost. And if you have to train employees to use those new manufacturing records, then the training costs are going to be a significant cost that you would incur that you otherwise wouldn't. And if you have to maintain a separate record for each batch, let us know what those recording costs will be--those

record--keeping costs will be for you. So the frequency is important--is as important as the actual cost per record.

So, for instance, although almost everybody does maintain master manufacturing records, we actually have survey evidence that show that some people don't. Some small firms don't maintain master manufacturing records. So to comply with this rule, they would have to develop those master manufacturing records, and that may involve shifting of the role of the quality control person, and it may involve changing the role of a production supervisor or management--all three may be affected by this new need to develop the master manufacturing records.

We want to know how many people are going to be affect, what their wage rate is, how many minutes or hours they're going to have to spend per record, and then the frequency of the record--keeping. And although the formula is very straightforward, very simple, if it's really not presented in this way, however simple it is, then it won't be as usable for us in really influencing and informing us about the total cost impact to you. So we'd like to know the number of people,

the wage rate, the hours, and then the frequency of record--keeping. It's a very straightforward formula, and if you can just follow this kind of thing in the development of your cost information, that would help us evaluate the economic impact.

We also think that finished product testing costs are going to be significant. So we'd like to know from you how many identity or product quality tests you think you'll have to incur--or how many tests you'll have to adopt to ensure compliance with this proposed rule. How many microbial tests will you have to do? How many other contamination tests will you have to do for lead or, alfatoxin or pesticides and others? What do you think this will do to you, and what frequency of those tests are you going to have to do? And how much are those tests going to cost?

And it would be helpful to know if there's a one--time development cost--for instance to validate the methods--and then, over time, those testing costs go down? Or what is that cost going to look like over time?

So let us know the number of tests per finished batch, the number of tests for contaminants per batch, the hours taking and

preparing samples and running the tests, and the costs for maintaining batch samples and for new equipment, and space for storing samples. Let us know if there's going to be lost production time, and what it's going to cost you to maintain the records for that. These are all potentially significant.

MS. : [Off mike] [inaudible].

MR. VARDON: Oh, sure.

MR. : [Off mike] [inaudible].

MR. VARDON: Oh, okay--it's static?

MR. VARDON: Yes?

MS. : [Off mike] Do you want this information as to what the costs are currently, compared to what it's going to cost to comply with the GMPs in the future?

MR. VARDON: Well, if you think there's a difference--if you think testing costs per batch are going to go up, we clearly want to know the difference in cost to you. So, in other words, if you're currently testing now--you're following some kind of periodic testing plan, and now you're going to have to test every finished product, then we'd want to know the difference.

You're currently incurring some cost

because you're complying with your own specification requirements. Now you've got a new requirement, and that difference is the cost that we would be most interested in. And that's an excellent question. Thank you for asking that.

Are you ready to go on?

MS. : [Off mike][inaudible].

MR. VARDON: Thank you, Janet. These slides will be available. I don't know how quickly, but my guess is probably a week or two from now. But I don't know.

But I would check the FDA website in the next couple of weeks.

Are we ready to move on?

Just one slide left.

As I mentioned this morning, there are five do's and don't's.

Do send specific numbers whenever possible.

Don't send unsupported opinions.

Do send comments in on time. Three's a little flexibility, but not a lot. The due date now--the end of the comment period--is June 11th, and keep that date in mind, although there is a request to extend that by 60 days.

Do send the comments to the dockets and do, if possible, send combined comments through your association. Having eight questions or comments about the same topic won't influence us any more than one would.

And don't send sensitive information.

And now, I think Mark is going to tell you about some of the things that FDA can offer you.

MR. ROH: Thank you. I'm actually filling in for Marcia Madrigal, the Small Business Representative, who can't be here today because she's sick. And they asked me to fill in for her because I used to be a Small Business Representative at one point.

And it's a very important program, and it's a very little known program--I think particularly in your industry. It's very well known in the medical device industry and the drug industry. In the food industry it's not so well known.

But basically this could be your salvation to compliance--if I could put it so boldly.

The Small Business Program--it was developed as a result of small--the Medical Device Act of 1976, and Congress required that FDA have

people to assist the medical device industry in complying with the new regulations at that time. And so an office was created in headquarters, in the Center for Devices, but also offices were created in the field in 1978 to help the medical device industry come into compliance with the medical device regulations that were new at that time.

Subsequently, the Small Business Assistance Program has expanded to cover all programs, not only medical devices.

The medical devices, as you can see--or the Small Business Program, as you can see from this slide, is really a voluntary program to help the industry comply with the rules and regulations. The best thing about the program is that it's confidential. I was a Small Business Rep for eight years. I was an investigator for 12 years before that. The best thing about being a Small Business Rep is companies invited me out--they wanted me to come out--and look at their products. They wanted me to come out and look at their process and give them advice.

The Small Business Reps still do that. So when you find yourself in a situation where this

regulation in some form gets published, and you have to comply with this regulation, you really have three alternatives. You can try and do it yourself. You can hire a consultant that I can almost guarantee is not going to be cheap. Or you can call the Small Business Representative.

And I was looking at the list of attendees, and we have attendees here, mostly from California and Washington and Oregon, but we have some from Iowa, one from Georgia, Alabama--and every region has a Small Business Representative.

Well, that's the products that they cover--they cover everything.

We don't really define small business in the Small Business Program. We figured anybody who requests--voluntarily requests assistance--probably needs it. So you would get--if there was a list of people who needed it, and the companies varied in size from 2 to 2,000, the two--person company would get the assistance before the 2,000--person company would get the assistance.

Now, what does this Small Business Rep do? Well, the Small Business Rep--and I just really want to focus on how the Small Business Rep can assist you--mostly inquiries. This person can

answer your question in a confidential manner, and can help you walk through the regulations, evaluate your predicament--if you will--and give you advice on how to comply. And it's totally confidential. You don't have to worry about any reprisals. It's a very helpful program.

Also--can conduct training in your facility. I used to do a lot of training programs in firms--which might come in handy in the future. If you've got a crew of people who don't understand GMPs, you might consider having the Small Business Rep give a GMP training course in your facility, and get the employees thinking in terms of GMP product control.

It says "on--site inspections" here. What these inspections are are voluntary, confidential consulting visits. What we used to call them is "on--site visits." I think Marcia Still calls them on--site visits.

Now, it might be a bit premature for you, since it's not a regulation yet--although, if you want to get a jump on the regulation, because you do know it is coming--and you want your facility evaluated, you might call Marcia up and say, you know, "Come on out here and look at the way we

operate." You can have her evaluate you against the current food good manufacturing practices, or against the proposed GMPs for dietary supplements. It may be a bit premature for that. You may want to wait until they're actually published, and then have her evaluate. The nice thing about this is she can--or any Small Business Rep, if you're located in a different region--can come out and look at your process, look at your record--keeping, look at the training of your employees, evaluate it from a compliance standpoint, and it remains totally confidential between that Small Business Rep and you, the firm. Nothing gets written down. No report gets made. Nothing gets turned in to anyone. It's totally confidential between you and the Small Business Rep.

It can be very, very valuable, depending on how much that Small Business Rep knows about that particular industry.

Again, these are courtesy on--sites. They're at your request. So you would have to orally--and I used to ask for a written request, only for my files. You request that the Small Business Rep come out and look at your facility. And you can talk about anything you want. You can

talk about--if you just are concerned with record--keeping, or manufacturing, or raw materials--you know, whatever it is you're concerned about. It's your visit. This is--I don't want to make it--sad little joke about this--this is your tax dollars at work. But it really is your tax dollars at work. It's something that the agency puts money aside to pay for this program to help you out.

So I would take advantage of this program. It's really a very good program. And like the second bullet says: it is confidential. Nothing gets written down.

There's only one little caveat: in the Small Business Program--and it's in all the small business literature--in fact, when Marcia called me this morning and said she was going to be ill, I ran to her office and grabbed a bunch of brochures, and her business cards. And by the time I got down here, you guys were pretty much all in here. So what I did was I put them on the table out there. So I would encourage you to pick up one of these brochures and her business card. And there is some contact information in this presentation later. I don't know if this presentation will be on the web.

I kind of doubt it. But give her a call, and see if she can help you out.

The one little caveat is--which I never used in my eight years, eight--and--a--half years of being a Small Business Rep, is if the Small Business Rep sees anything during the walk--through of your firm that he or she would think that it is an immediate threat to health, then that situation would be discussed with the Health Hazard Evaluation Committee at the center for whoever governed your product--whether it was foods, or drugs or devices--and the Health Hazard Evaluation Committee would determine whether or not it was, indeed, an immediate threat to health. And if the Health Hazard Evaluation Committee did determine it was an immediate threat to health, then they would notify the district director of the district in which your firm sat, and the district director would initiate an inspection of that facility.

But that never happened in the nine years I was a Small Business Rep, and I never heard it happening anywhere else. I did see some pretty nasty situations when I was out there and asked them to clean them up right away. But it never got as far as the Heath Hazard Evaluation Committee.

So it truly is a confidential program.

Again, the Small Business Rep can help you with a lot of things. And I'm not going to go through--but basically, what it's all about is helping the industry to achieve voluntary compliance. Because in doing so, we help each other. You save us a lot of time and money by doing inspections and taking regulatory action. We help you out, hopefully, by preventing recalls and helping you to produce a good product.

So--I mean, there are ways to approach the agency in a sort of a friendly manner and get advice and help back, where, when you get inspected by an inspector, they cannot give you advice. If an investigator comes out to give you a formal inspection, they are only there to evaluate your compliance with the regulations--to say yea or nay, this appears to be in compliance, this does not appear to be. They cannot give you advice, whereas the Small Business advisor can give you advice. Now the Small Business advisor won't tell you how to do it, but they can tell you what they've seen in other facilities that works--that is--how do I say--accepting to the FDA. So there's a difference there between the Small Business person and the

investigator.

I just found out this morning the program's changed a little bit in the couple years I haven't been doing it--that now there is this top line--this top website is an on--line magazine kind of thing for food labeling. And it's also a listserve. So you can sign up--go to this website, the top one, sign up, get on the listserve, whenever this labeling--electronic labeling newsletter comes out, you get an electronic copy. And, of course, there's other websites you can go to to visit to see about FDA. Probably if you just went to the FDA--do you know about this on--line labeling newsletter? If they just went to the FDA website, is it easy to click to?

MR. VARDON: I don't know that.

MS. : [Off mike] It's probably easier to go to the homepage and click on "Food and Dietary Supplements" homepage, which is actually on the bottom,[inaudible] and then it's on that page.

MR. ROH: Okay. So if you go to the homepage, click on "Dietary Supplements," then you get the bottom link, and then you click on that, and you'll get a whole bunch of other links. Okay. Good.

Okay. Now, there's still one limitation that the SBRs cannot do, and that is--remember, this is a voluntary program. It's preventive in nature. And--but once you're already in trouble, it's too late. So I advise you to call the SBR before you get an inspection rather than after you get an inspection. Because after you get an inspection, the SBR can't help you--another reason to call the SBR early, and see what sort of assistance they can provide you.

And more websites.

Okay. This is the Small Business Representative--Marcia--she can't make it today. She's ill. But her business card, like I say, it's out there on the table. There's a whole stack of them, as well as this pamphlet that sort of describes the program. I really encourage you to pick these up and give her a call--particularly in your situation. You may have been complying with the food GMPs, Part 110, but these new GMPs are going to be specific to your industry. It may be a whole new realm for you. There may be instances that you have never dealt with FDA before, and this would be a good introduction to working with FDA, rather than dealing with FDA, is to start out with

this Small Business program.

And those are the Small Business Reps around the country. We won't go there.

This is, of course, the CFSAN website, if you need more help. But if you got to the regular FDA website, you can click on the little food icon and get to the CFSAN icon.

And let's go industry.

Okay. So I'm going to turn it back over to Janet, who will take it away for this afternoon--oh, let Peter take it away.

Small Business Questions on Proposed Requirements

MR. VARDON: I'll take it away--although we do have a few minutes for questions, also.

Do you have any questions?

[No response.]

Otherwise, we were going to devote the next portion of this program to the breakout sessions. And, as I mentioned this morning, the breakout sessions are intended for you, the small--business owner. We believe you might be impacted by this rule--just to sit down together with your peers and talk about this rule. And unlike other breakout sessions that we've held in the past, we're going to ask you to actually try to

develop a specific comment: what is the single issue that you think is the greatest--that you think is going to have the greatest impact on you, or the issue that you think--that needs the most reform, or most improvement--or whatever comes to mind for you. What is the most important thing on your mind right now, and try to formulate a comment around that at the breakout session.

And the session's originally scheduled to run about an hour, although we're running early, and there are fewer people than I expected.

So--it's a little after 2:00. I'm going to suggest that we meet back here at 3:15 if we can. And then what we would like is--we would have a facilitator at each breakout session to take notes; somebody from your group who could take notes about the general discussion and then could come back here and report to the general group what your thoughts were; what comments you want to report into the record, so that it can be transcribed.

And there will be--I'll be running around between groups to see that they're focused, and on the topic. And we have other FDA people also who will go from room to room.

But to get down to the breakout session rooms, just go to the elevator right out here, out the door, and then--which is on your left--and then go down to the second floor. And I think there are five conference rooms that are available as breakout sessions. And we just ask that you fill up each breakout room--or have 10 to 12 people in each breakout room, and as you see them being filled, you just go to one room or another, until you find a seat for yourself.

And then we'll just meet back here at 3:15, if that's okay.

[Meeting recessed for breakout sessions, to reconvene at 3:15 p.m.]

Breakout Session Summaries and Discussion

MR. VARDON: Let's just allow one representative of each of the three groups just to summarize for the record what you discussed, what you think the most important issue is that we should be thinking about now.

And so--do we have a representative from any of the groups who'd like to go first?

Okay. Great.

Yes--why don't you go to the podium? And

give us your name. And if you could spell your name.

MR. FLORES: Hello. I'm Ray Flores--F--L--O--R--E--S, is the last name. Ray. And I'm from California Marketing, I'm a natural foods broker in southern California. I also do some consulting, and I'm also a law student.

I'm very pleased--I'd like to thank you very much for allowing me this opportunity.

Our group had some specific concerns. And I do hope that I do them justice with regard to everything that it is that they wanted to express.

To start off with comment we started with-- 80 percent of the herbs than many manufacturers are purchasing are imported. And therefore it's going to cost quite a bit of money, and quite a bit of trouble for them to get CAs from those manufacturers; and that if product shipments are going to be held up, in addition to--when you include the Bioterrorism Act that's going to take effect toward the end of this year, things will be rather difficult for them and could inhibit schedules.

We were also very concerned that some of the comments this morning regarding the approximate

1,500 businesses that are dietary supplement business, that several hundred of them--which we now know is between 250, 350--and I've heard also that that may be a conservative estimate--may be forced to go out of business. And that, of course, is of great concern to us in the natural foods trade.

Also of particular concern was that they considered large industries to be 596,000 square feet and over. And in the natural foods trade, I really don't know of too many manufacturers that are that large.

MR. VARDON: No, we defined as large as being 500 employees or more.

MR. FLORES: Okay--there were different parts there. And still, 500 employees or more--still, for the natural foods trade, that's considerable.

Now, there are large businesses that already have many of these steps in place. And they probably won't have to add on additional costs, because they're already complying in so many ways with this already. It's the smaller firms that are going to suffer the most, and the ones that are also in the natural foods trade are also

of concern to us as well.

Another comment that I made in particular: that if DSHEA is not being enforced to its fullest extent, then why add on the GMPs which, in a way, will be even harder to monitor?

And then, also, why is it that if dietary supplements have such a great track record of efficacy and safety, then why is it that many of the ingredients, the raw materials, need to be tested at more strict standards than many pharmaceuticals? And so that was a concern.

The idea of batch--to--batch testing seems to be over broad; day--to--day too often--were some of the comments--every lot, every single item. It needs to be more friendly and flexible.

And we also had another comment here that the idea of GMPs is a great idea, and the execution, however, needs to be fine tuned. And, once again, we thank you for the opportunity to express our concerns.

Really, what we figured out was that the most efficacious way of handling this, according to some people from the NMFA, was that what we really needed was to test ingredients a the raw material stage, because that is the opportunity when the

contamination could occur; that's the greatest likelihood. Then some in--processing monitoring as well, and then finally, finished product testing--perhaps not on every batch; perhaps a skip--lot, perhaps at different stages.

There was also concerns, too, just within our own industry, that self--policing would be difficult, since the quality assurance person, or quality control person, could be just a production manager. And that person has to keep their job. So they may not be ready to say that there is a problem.

But, expressing other industry concerns that have been expressed at the Natural Foods Expo in Anaheim recently, many people in our trade consider this a necessary part of what--it is what we need to do, and we would like to be able to trust what's being sold ourselves. And if we in the natural foods trade, as consumers, can't trust 100 percent of what's out there in the market, then what's a consumer going to believe.

So--Thank you very much.

MR. VARDON: Thank you.

Do we have a second volunteer?

MR. CHANG: My name is Michael

Chang--C--H--A--N--G. I'm Active Drug Products.

Our group is also grateful for this opportunity to have input. And most of us were manufacturers. And most of our concerns center around the testing methodology issues. I mean, everything related to this whole big issue; from the development end, who exactly is the final arbiter? And the lab certification issues--you know, which labs are qualified to do these tests?

We have a few questions about testing, at which stage? You know, whether it's the raw material vendor? Is it the grower? Is it the manufacturer? And, you know, there may be duplication of testing.

We have issues also with skip--lot testing--you know, we felt that it's more stringent than the pharmaceutical industry.

Also, we have issues concerning the education and training of personnel. Earlier, they were saying the qualifications--the QC units can be anyone. I guess you also addressed issues such as, you know, the education, the training, the experience--that aspect--so it doesn't quite jibe.

We had questions concerning reprocessing--what is allowed in reprocssing of a

product, and what is not. And we have issues with definition of adverse events; how do we define that?

And, of course, the cost issues of the tests, we found absolutely absurd, in the analysis. We expect that to be much, much higher. And even the number of tests to be done. I think there's a lot of ambiguity in that aspect.

And, I guess, that's the gist of it. Basically a lot of questions with the--you know, overemphasis on testing, and almost not enough in the actual production procedure aspects. So, again, some inconsistencies. Those kinds of things.

Did I skip anything from my group? Does anybody want to add anything to that?

I think those are our main concerns.

MR. VARDON: Great. Thank you very much.

And do we have a third person?

MR. MANOUSAKIS: My name is George Manousakis. I'm from Salt Lake City. Want me to spell that? M--A--N--O--U--S--A--K--I--S. And I work for Nutriceutical Solutions. We're a contract manufacturer.

Our group consisted mainly of--well, of

both raw material manufacturers and finished product dietary supplement manufacturers. And most of our discussion centered around the cost of implementing all these changes, and the required testing that would be necessary to comply with these changes.

Our panel strongly felt that the cost for small businesses to incorporate these regulations was grossly underestimated. You know, our panel came up with some small figures, and we didn't have all the numbers and research that you guys, I'm sure used. But for someone who is--who doesn't have--let's say that company does not have a QA unit, they have no way to analyze for minerals or vitamins, a company such as this would have to purchase an ICP--let's say an ICPMS at $150,000, HPOC at $65,000, and then hire an analyst at $50,000 a year, which would be an ongoing expense. And if they had a tremendous volume, they may need two analysts.

So, if you look at those costs alone--and it appears that--you know, it appears to be a lot more expensive than was discussed previously today.

Second, there was a lot of discussion regarding C of A's. This was touched upon earlier

today, but we felt that it wasn't answered definitively what would be acceptable and what wouldn't be. And "let's just not call it a C of A, let's just use an alternative word for it." So let's just call it a raw material analysis. Same thing. But anyhow, just to get away from the stagmatism of C and A's, which a lot of us agree they don't seem to be up to snuff a hundred percent of the time.

But what our question was: if a raw materials supplier gives us an analysis, with the appropriate supporting documents, will this be sufficient as a raw material identity and potency test? As a stand--alone test? Or will this have to be re--tested by the manufacturer by an outside party, or through their own in--house lab. We didn't feel that that question was answered today--definitively.

Also, some of our group members had some concerns, based on the municipalities that they live in, whether or not those cities or counties would allow the chemicals that they may need to conduct these certain tests that are required.

Fourth--our panel--most of our panel felt that the response--well, I think all of our panel

felt that the response regarding foreign manufacturing firms, and the advantages that they may have over manufacturing firms in the U.S.--we felt that response wasn't really--it wasn't really adequate. I'm trying to be nice here.

There's no way that a foreign firm that's overseas--there's no way that anybody here in FDA can make sure that they are producing products under the same conditions that we are supposed to be producing them under. I mean, someone could send out a clean product that tests out good, that gives you high potency numbers, but who knows what kind of conditions they are operating under? There's absolutely no way to know. And that puts them at an unfair advantage, because they have--they may have lower operating costs, lower overhead, lower capital equipment costs, and that can make it hard for some people here, when they have to compete against that.

The last discussion--the last topic of discussion for our panel centered around what needed to be tested in the final product. In our panel it was stated that in a meeting that was held up at Washington, a meeting similar to this, it was stated that the final product had to be

quantitatively tested for every component that was added. And there was a lot of discussion regarding this; whether that was, in fact, the case, or whether it was--or whether the final product only had to be tested for items, or claims, that were in the fact box. For example, would the final product have to be quantitatively tested for flavoring, acidulence, thickeners, or hardening agents--things of that nature? If that's the case, what's the logic there, if there's not any specific quantitative claim, why should you have to test for it. For example, why would you have to test for the quantity of citric acid that you're going to add to your product, when what you really care about is the pH of the final product, not the quantity of citric acid.

And, I guess specifically the section that we were discussing was 111.35(g)(1), and it talks about testing all--well, do you have the document there?

[Pause.]

It states, "You must test each finished batch of the dietary ingredient or dietary supplement produced before releasing for distribution, to determine whether the established

specifications for identity, purity, quality, strength and composition are met; provided there are scientifically valid analytical methods available to conduct such testing."

Well, one of the questions that we had centered around this paragraph was: what is--what do they mean by "established specifications?" Do they mean master batch specifications, or do we mean supplemental fact--box specifications? Or do they mean batch recipe specifications?

You know--so it just seems like it's a little ambiguous or unclear, as to what we're supposed to be testing.

And that's pretty much what we discussed. Does anybody have anything to add?

MR. : [Off mike] In that same section [inaudible].

MR. MANOUSAKIS: Okay--so, in addition to what we just discussed in regard to 111.35(g)(1)--well, that comes back to this--where is that here?--"Establish specifications." Well, when we say "establish specifications," are they talking about component specifications, or establish specifications would be a collection of components, basically--right?

That's all I have to say. Thanks for your time.

MR. VARDON: Okay. Thank you very much.

Does anybody have any final thoughts? Anything else you'd like to add to the record, or that we should know about?

[No response.]

If not, we can certainly adjourn early.

Thank you. Thank you for coming. Your comments were very helpful.

[Applause.]

[Whereupon, at 3:39 p.m., the proceedings were adjourned.]

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CERTIFICATE

I, hereby certify that the tape recording represented by the foregoing pages were transcribed by me; that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

CLAIRE COHEN

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