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SIX YEARS AFTER THE ESTABLISHMENT OF DSHEA: THE STATUS OF NATIONAL AND INTERNATIONAL DIETARY SUPPLEMENT RESEARCH AND REGULATION

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

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SIX YEARS AFTER THE ESTABLISHMENT OF DSHEA: THE STATUS OF NATIONAL AND INTERNATIONAL DIETARY SUPPLEMENT RESEARCH AND REGULATION

TUESDAY, MARCH 20, 2001

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 1 p.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Present: Representatives Burton, Morella, Horn, LaTourette, Davis, Cannon, Waxman, Norton, Kucinich, Tierney, and Clay.

Staff present: David A. Kass, deputy counsel and parliamentarian; S. Elizabeth Clay, Nicole Petrosino, and John Rowe, professional staff members; Robert A. Briggs, chief clerk; Robin Butler, office manager; Michael Canty and Toni Lightle, legislative assistants; John Sare, deputy chief clerk; Sarah Despres, minority counsel; Ellen Rayner, minority chief clerk; and Jean Gosa and Early Green, minority assistant clerks.

Mr. BURTON. Good afternoon. A quorum being present, the Committee on Government Reform will come to order.

I ask unanimous consent that all Members' and witnesses written and opening statements be included in the record, and without objection, so ordered.

I ask unanimous consent that all articles, exhibits and extraneous or tabular material referred to be included in the record. And without objection, so ordered.

Seven years ago, the people of the United States raised their voices in unison and told Congress that we needed to give clear direction to the Food and Drug Administration, in regard to dietary supplement regulations. That cry from every State in the Union, every congressional district across the country, was heard in Washington and resulted in a unanimous vote to pass the Dietary Supplement Health and Education Act of 1994, commonly known as DSHEA.

Americans are passionate about their freedoms. We cherish our rights to free speech, religion, free press, our right to bear arms, and our right to make our own nutritional choices. Time and again, Americans have joined together across philosophical and political divides and demanded that the Federal Government not impede our access to dietary supplements.

The FDA, over time, has represented itself as having a clear bias against the marketing of dietary supplements under anything except the drug framework. Prior to DSHEA, they tried various ploys to restrict the market.

In the 1970's, the FDA issued a proposed rulemaking that would have allowed the agency to classify vitamins and minerals as drugs if they exceed levels of potency that the agency considered rational or useful. The American public was outraged, and rightfully so. Congress responded to this by enacting the Proxmire Amendment, thus stopping FDA dead in its tracks in its posturing to classify dietary supplements as drugs.

Our victories with the Proxmire Amendment and the passage of DSHEA were but individual battles won along the way. We have to remain ever vigilant in our oversight to ensure that the FDA properly implements the law. That's the role of congressional oversight and the Committee on Government Reform.

During the 106th Congress, this committee conducted two hearings. The first looked at the FDA's proposed structure function regulation in which they sought to use a definition of disease that had been considered and rejected by the Congress. The FDA's maneuvering would have created a climate where almost any structure function claim could have been considered an illegal disease claim.

The public once again came together as one voice and more than 170,000 individuals submitted statements to the FDA regarding the proposed Structure Function Rule. As a result of the public outcry and strong congressional oversight, the FDA made changes to the proposed rule so that it was in line with the DSHEA law.

The second hearing we conducted looked at the FDA's Adverse Events Reporting System for Special Nutritionals, using the dietary supplement ephedra as an example. The FDA admitted during the hearing that the system was problematic. That was almost 2 years ago, and Mr. Levitt is back today and will update us on whether or not the FDA has improved the system.

Additionally, the dietary supplement ephedra continues to be in the news. Used in traditional Chinese medicine for asthma, ephedra, or Ma Huang, as they call it, has been safely used for thousands of years. In the United States, it has been safely and effectively used for weight loss as well. With the health effects associated with obesity plaguing the Nation, there is a growing body of research evidence that verifies the effectiveness of this product to maintain a healthy weight.

Ephedra earned notoriety after reports of adverse events in Texas from a product called Nature's Formula One. It was a product represented as a dietary supplement containing ephedra. The product turned out to be illegally spiked with a synthetic ephedrine, and thus not a dietary supplement at all. Additionally, several "fringe" companies began illegally marketing high doses of ephedra or Ma Huang as natural alternatives to illicit street drugs. These two illegal actions have caused the FDA to spiral into a massive 4 year rulemaking process seeking to regulate an entire product category.

There have been legitimate adverse event reports about ephedra, and some of them have been serious. I think the industry has been very responsive to FDA's concerns, putting warnings on labels and

working to get the bad apples out of the supplement industry. Because ephedra is known to be a mild stimulant, consumers need to pay attention to product labels and not take the product if they have a medical condition listed in the warning. They also need to pay attention to dosing and not think that if two is good for them then four or six would be great.

It should also be noted that the FDA has not shown evidence of how often these events that have occurred are natural occurrences or product related events.

There are some that complain to us that the FDA was going to use the ephedra issue as a means of asking that DSHEA be overturned. I hope that's not the case. As a part of the executive branch, FDA employees, the same as those of us in the legislative branch, are public servants. That is, we serve the people of the United States. The people have spoken about how dietary supplements should be regulated. We in Washington heard their voices, and I hope the FDA is listening as well.

I hope the FDA staff will accept that DSHEA is the law and work earnestly to implement this 6 year old law appropriately. One of the issues that arises time and again with regard to the FDA's management of supplement regulation is that in 6 years, they have failed to establish good manufacturing practices for dietary supplements. They waited until the very end of the last administration to move their proposal forward, even though they had strong support from the industry to establish these guidelines.

It is our understanding that the new administration is currently reviewing the FDA proposal. We hope that it will be expedited very quickly.

Today we will hear from the Natural Nutritional Foods Association. They will explain their good manufacturing practices certification program. We repeatedly hear in the media that with DSHEA the FDA lost its power to regulate dietary supplements. This is absolutely false. As we have discussed in previous hearings, the FDA has seven points of authority to regulate dietary supplements, and they use them. A list of those points of authority is appended to this statement.

The hearing is about two topics today, the national and the international regulation of dietary supplements. I said earlier that the American public is passionate about their rights to make nutritional choices, and that they have become one voice regarding the FDA's handling of dietary supplement regulation.

Americans are also very passionate about our rights to retain American sovereignty. In 1961, in a desire to establish food safety standards, the United Nations Food and Agricultural Organization and the World Health Organization established a joint program, the CODEX Alimentarius. There are numerous commissions within the CODEX, including the Commission on Nutrition and Foods of Special Dietary Uses, through which 165 countries are discussing topics including dietary supplement regulation and the establishment of standards.

We have received a lot of complaints from citizens in this country. They are concerned that if countries who regulate dietary supplements more restrictively than the United States decide to vote en bloc at CODEX meetings that our views will be overridden.

Many Americans are afraid that eventually there will be restrictions placed on dietary supplement access. The FDA has stated previously that we are under no obligation to accept CODEX, but I have asked Congressional Research Services to review the CODEX agreements and to clarify our obligations.

Many of the 165 countries that participate in the CODEX look to the United States to take the lead in regulatory negotiations. We fail our citizens and the citizens of the world if we do not take a strong stand in supporting DSHEA internationally.

In addition to scientists, I suggest that the U.S. delegation to CODEX include representatives from the U.S. Government who are experts in international trade negotiations, and that FDA staff and all individuals representing the U.S. Government in negotiations regarding dietary supplements negotiate from the DSHEA perspective. It is important that we protect Americans' access to supplements, as well as ensure that trade barriers are not erected that will reduce U.S. manufacturers' access to the international marketplace.

Dietary supplements are an important factor in maintaining and improving health. My colleagues in Congress and I will continue to protect Americans' rights to access dietary supplements.

The record will remain open until April 2nd. I will now recognize my colleague, Mr. Waxman, for his opening statement.

[The prepared statement of Hon. Dan Burton follows:]

Opening Statement of

Chairman Dan Burton
Government Reform Committee

Six Years After the Enactment of DSHEA:

The Status of National and International Dietary Supplement Regulation and Research

March 20, 2000
1:00 pm
2154 Rayburn House Office Building
Washington, DC

Seven years ago, the people of the United States raised their voices in unison and told Congress that we needed to give clear direction to the Food and Drug Administration (FDA) in regard to dietary supplements regulations. That cry from every state -- every Congressional district across the country -- was heard in Washington and resulted in a unanimous vote to pass the Dietary Supplement Health and Education Act of 1994.

American's are passionate about their freedoms. We cherish our right to free speech, our right to practice our religion according to our own dictates and conscience. We are passionate about our right to a free press, our right to bear arms, and our right to make our own nutritional choices. Time and again, American's have joined together across philosophical and political divides and demanded that the Federal Government not impede our access to dietary supplements.

The FDA over time has represented itself as having a clear bias against the marketing of dietary supplements under anything except the drug framework. Prior to DSHEA, they tried various ploys to restrict the market.

In the 1970s, the FDA issued a proposed rule making that would have allowed the agency to classify vitamins and minerals as drugs if they exceeded levels of potency that the agency considered rational or useful. The American public was outraged - and rightfully so. Congress responded to this by enacting the Proxmire Amendment - thus stopping FDA dead

in its tracks in its posturing to classify dietary supplements as drugs.

Our victories with the Proxmire amendment and the passage of DSHEA were but individual battles won along the way. We have to remain ever vigilant in our oversight to ensure that the FDA properly implements the law. That is the role of Congressional oversight and the Government Reform Committee.

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The public once again came together as one voice and more than 170,000 individuals submitted statements to the FDA regarding the proposed Structure Function Rule. As a result of the public outcry and strong Congressional oversight, the FDA made changes to the proposed rule so that it was in line with DSHEA.

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There have been legitimate adverse event reports about ephedra, some serious. I think the industry has been very responsive to FDA's concerns, putting warnings on labels and working to get the "bad apples" out of the supplement industry.

Because ephedra is known to be a mild stimulant, consumers need to pay attention to product labels and not take the product if they have a medical condition listed in the warning. They also need to pay attention to dosing and not think that if two is good then four or six would be great.

It should also be noted that the FDA has not shown evidence of how often these events that have occurred are natural occurrences or product-related events.

There are some that complain to us that the FDA was going to use the "ephedra issue" as a means of asking that DSHEA be overturned. I hope that this is not the case. As a part of the Executive Branch, FDA employees, the same as those of us in the Legislative Branch, are public servants. That is, we serve the people of the United States. The people have spoken about how dietary supplements should be regulated. We in Washington heard their voices, I hope the FDA is listening as well.

Today is the first day of Spring - the first Spring of our new Administration. I hope that the FDA staff will take the time to clear out the cobwebs of old thinking about supplement regulation, accept that DSHEA is the law, and work earnestly to implement this six year old law appropriately.

One of the issues that arises time and again with regard to the FDA's management of supplement regulation is that in six years they failed to establish Good Manufacturing Practices for dietary supplements. They waited until the very end of the last

Administration to move their proposal forward, even though they had strong support from the industry to establish these guidelines. It is our understanding that the new Administration is currently reviewing the FDA proposal. We hope that it will be expedited. Today we will hear from the National Nutritional Foods Association. They will explain their Good Manufacturing Practices certification program.

We repeatedly hear in the media that with DSHEA the FDA lost its power to regulate dietary supplements. This is absolutely false. As we have discussed in previous hearings, the FDA has seven points of authority to regulate dietary supplements and they use them. A list of those points of authority is appended to this statement.

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We have received a lot of complaints from citizens. They are concerned that if countries who regulate dietary supplements more restrictively than the US decide to vote *en bloc* at CODEX meetings, that our views will be overridden. Many Americans are afraid that eventually there will be restrictions placed on dietary supplement access.

The FDA has stated previously that we are under no obligation to adopt CODEX, but I have asked Congressional Research Services to review the CODEX agreements and clarify our obligations.

Many of the 165 countries that participate in the CODEX look to the United States to take the lead in regulatory negotiations. We fail our citizens and the citizens of the world if we do not take a strong stand in supporting DSHEA internationally. In addition to scientists, I suggest that the US Delegation include representatives from the U.S. Government who are experts in international trade negotiations and that FDA staff and all individuals representing the United States Government in negotiations regarding dietary supplements negotiate from the DSHEA perspective.

It is important that we protect American's access to supplements, as well as insure that trade barriers are not erected that will reduce US manufacturers' access to the international market place.

Dietary supplements are an important factor in maintaining and improving health. My colleagues in Congress and I will continue to protect American's rights to access dietary supplements.

The record will remain open until April 2. I now recognize the ranking minority member, Mr. Waxman for his opening statement.

Attachment

FDA Does Have the Power to Regulate Dietary Supplements

Since the passage of DSHEA, there has been a great deal of misrepresentation of the FDA's ability to regulate dietary supplements. During testimony in Senate confirmation hearings as well as in testimony presented before the Committee on Government Reform in 1999, FDA Commissioner, Jane Henney testified that she felt that FDA had adequate authority to regulate dietary supplements. In fact, the FDA has seven specific points of authority to regulate dietary supplements.

FDA has the power to:

- Refer for criminal action any company that sells a dietary supplement that is toxic or unsanitary [Section 402(a)]
- Obtain an injunction against the sale of a dietary supplement that has false or unsubstantiated claims [Section 403(a),(r6)]
- Seize dietary supplements that pose an" unreasonable or significant risk of illness or injury" [Section 402(f)]
- Sue any company making a claim that a product cures or treats a disease [Section 201(g)]
- Stop a new dietary ingredient from being marketed if FDA does not receive enough safety data in advance [Section 413]
- Stop the sale of an entire class of dietary supplements if they pose an imminent public health hazard [Section 402(f)]
- Require dietary supplements to meet strict manufacturing requirements (Good Manufacturing Practices), including potency, cleanliness and stability [Section 402(g)]

Mr. WAXMAN. Thank you very much, Mr. Chairman.

Today's hearing will examine the international and national regulation of dietary supplements since the passage of the Dietary Supplement Health and Education Act [DSHEA], in 1994. Supplements are more popular than ever. According to a recent article in U.S. News and World Report, supplement sales last year in the United States reached $16 billion. An estimated 23.5 million Americans use supplements sold in drug stores, grocery stores, malls, on the Internet and in gyms and sports clubs.

Dietary supplements can be very beneficial. For example, calcium can help prevent osteoporosis, and pregnant women should take folic acid in order to help prevent neural tube defects in the developing fetus. Unfortunately, there are also supplements that have safety risks. St. John's Wort, taken to treat certain kinds of depression, can interact negatively with a variety of drugs, including several classes of drugs taken to treat AIDS. The American Medical Association believes ephedrine supplements sold for weight loss should be removed from the market. According to a letter from the AMA to the FDA, "The evidence to support the benefit of these products for use in weight loss is outweighed by the risks."

The public expects FDA to act to weed out unsafe from safe products. But in fact, dietary supplements are largely unregulated in many important respects. This is due to FDA's lack of resources and the law itself, which took away much of FDA's authority to regulate supplements. Under DSHEA, FDA cannot require the supplement manufacturer to substantiate the claims they make on the labels nor require information beyond the labels about the dangers of interaction with other ingredients or pharmaceuticals. The burden of proof for safety problems is on the FDA, even when problems arise and are reported. And FDA cannot require supplement makers to report adverse events as it does with other products, such as drugs, devices and vaccines.

I have to say, even Members of Congress have difficulty in getting information they need. In the summer and fall of 1999, I sent out a letter to a number of dietary supplement manufacturers and distributors, as well as to manufacturers of dietary supplement ingredients. I asked for basic information regarding procedures for quality control, what research the company used to substantiate any claims that they make that their products are safe and effective, and for consumer complaint information.

Out of the 49 letters we sent out, only 10 companies responded, 6 of them by letter, 3 by phone and 1 through a meeting. One letter was returned by the post office. In total, only two companies sent the requested information. This is a very poor record. Many experts have suggested that we need to require adverse event reporting about supplements. The industry's failure to respond clearly suggests that we need to consider seriously this suggestion.

There are some things that the FDA can and should do under current law to regulate the supplement industry, and these are areas where I think we all agree. FDA has the authority to issue regulations for supplement good manufacturing practices [GMPs]. This would be an important step in protecting consumers. GMPs in theory could help ensure that products contain what the label says

they contain and help consumers make more educated choices about their supplements.

I believe that Americans need access to safe and effective supplements, but that does not mean we should permit misleading or unsupported claims to flourish or allow the public to be needlessly exposed to unsafe products. When it comes to our international concerns, I share the views that are going to be expressed today by a number of witnesses that I don't want to see, because of international trade agreements, our laws being reduced or being eliminated or superseded. That has been one of my ongoing concerns about the international trade agreements, that what we have decided in this country is best for our own people would be considered a trade barrier, and we would be forced to drop those laws and adopt some international standard, which may not be what the American people would like to have in its place.

So I want to express that concern, it's an ongoing one, and I look forward to hearing more about it from the witnesses. I think this is a hearing that should bring out a lot of information that will be useful to policymakers as we review the whole issue of dietary supplements and how they are handled both in this country on a national basis and in international forums.

I thank you for holding this hearing, Mr. Chairman.

Mr. BURTON. Thank you, Mr. Waxman.

Mrs. Morella, do you have an opening statement?

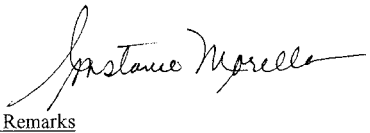
Mrs. MORELLA. Mr. Chairman, I'll make it very brief. I want to thank you and Ranking Member Waxman for holding this hearing today on the status of national and international dietary supplement regulation and research. Seven years ago, Congress passed the Dietary Supplement Health and Education Act, and in so doing, Congress recognized that many people believe dietary supplements offer health benefits and that consumers should have a greater opportunity in determining which supplements may best help them.

This law essentially gave dietary supplement manufacturers freedom to market more products as dietary supplements and provide information about their products' benefits. Consumers would have more responsibility for checking the safety of dietary supplements and determining the truthfulness of label claims.

This is a unique situation for consumers, manufacturers and the FDA, because most foods and drugs are regulated more before they hit the marketplace. Consequently, Congress and this committee has a responsibility to ensure that these dietary supplements are safe and that the FDA is disbursing the information that it does receive so that consumers can be sure that dietary supplements are not doing harm to them or their families.

So I look forward to the testimony, Mr. Chairman, from our expert panels and yield back the balance of my time.

[The prepared statement of Hon. Constance A. Morella follows:]



Opening Remarks

I want to thank Chairman Burton and Ranking Member Waxman for holding this hearing today on the status of national and international dietary supplement regulation and research. Seven years ago, Congress passed the Dietary Supplement Health and Education Act (DSHEA). Congress recognized that many people believe dietary supplements offer health benefits and that consumers should have a greater opportunity in determining whether supplements may help them. This law essentially gave dietary supplement manufacturers freedom to market more products as dietary supplements and provide information about their products' benefits. Consumers would have more responsibility for checking the safety of dietary supplements and determining the truthfulness of label claims. This is a unique situation for consumers, manufacturers, and the FDA because most foods and drugs are regulated more before they hit the marketplace. Consequently, Congress and this committee must ensure that these dietary supplements are safe and that the FDA is dispersing the information it does receive so consumers can be sure that dietary supplements are not doing harm to them or their families.

I look forward to hearing the testimony today from our expert panel and I yield back the balance of my time.

Mr. BURTON. Thank you, Mrs. Morella. Mr. Tierney, no opening statement. Ms. Davis. Mr. Cannon.

Mr. CANNON. Thank you, Mr. Chairman. I want to thank you and the ranking member for holding this hearing also. I'm pleased that we will be examining the progress made in the area of dietary supplement regulation and research. Dietary supplements are quickly becoming a very large part of American health care. They're not just for weight loss and muscle building, but many of the supplements provide nutrients and minerals that humans need for a healthy life and healthy lifestyle.

I'm particularly interested in this industry because of its presence in my district. In fact, I like to think of my district in Utah generally as being sort of the heart of the dietary supplement industry. We have a very large number of folks there, many of whom are here today, and we want to welcome you all back to Washington.

The Dietary Supplement Health and Education Act was the first step in facilitating growth in the dietary supplement industry. It established a set of basic guidelines for marketing these products in an effort to inform consumers about the products they purchased. The Food and Drug Administration currently has in place loose guidelines for the regulation of dietary supplements. These regulations have been slow moving in comparison with the growth of the industry, which has been pretty phenomenal. I think currently we have many, many Americans who are using supplements in their daily diets.

It is important that we work to establish guidelines and regulations that will not hamper the growth of the industry, but will assure an individual the best possible information, so he can thoughtfully make decisions about his or her health. Such guidelines help to make dietary supplements a trusted part of our health care system, and I'm anxious to gather the information we'll hear in this hearing, Mr. Chairman.

I thank you and yield back the balance of my time.

[The prepared statement of Hon. Chris Cannon follows:]

Opening Statement for Congressman Chris Cannon 3/20/01

Mr. Chairman, I am pleased that today we will be examining the progress made in the area of dietary supplement regulation and research.

Dietary supplements are quickly becoming a large portion of American health care. Dietary supplements are not just weight loss and muscle building pills. Many of these supplements provide nutrients and minerals that humans need for a healthy lifestyle. I am particularly interested in this industry because of its presence in Utah. In fact, Utah is considered the heart of the dietary supplement industry.

The *Dietary Supplement Health and Education Act* (DHSEA) was the first step in facilitating growth in the dietary supplement industry. It established a set of basic guidelines for marketing these products in an effort to inform consumers about the products they purchase.

The Food and Drug Administration currently has in place loose guidelines for the regulation of dietary supplements. These regulations have been slow moving in comparison with the growth of the industry. It is important that we work to establish guidelines and regulations that will not hamper the growth of the industry, but will assure the individual the best information, so he can thoughtfully make decisions about his health. Such guidelines will help to make dietary supplements a trusted part of our health care system.

Mr. BURTON. Thank you, Mr. Cannon.

We are very fortunate today to have Representative Frank Pallone, Jr., with us from New Jersey. Although we have not always agreed on everything, I think we share the same views on the issue today, and we're very happy to welcome you to the committee, Mr. Pallone.

STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman and members of the committee, and thank you for extending me the opportunity to speak before you today.

I have to say I'm not a very good example of preventive medicine today, because I have a cold. But I'm going to continue with my testimony in any case.

Mr. Chairman, as you know, dietary supplement issues are a very important health care issue for my State and for my constituents. New Jersey is one of the States with a significant number of dietary supplement manufacturers and suppliers, employing thousands of people. In addition, we have among one of the most active consumer constituencies that support the use of dietary supplements in the context of complementary and alternative health care.

I wanted to commend you, Mr. Chairman, for your leadership in establishing the Complementary and Alternative Health Care and Natural Foods Congressional Caucus. I will be joining the caucus and I certainly urge others to join the caucus, because I think this is a very important issue.

Many Members of Congress serving today were not present in the 103d Congress when we passed DSHEA. I remember that debate well, as having been one of the original supporters of that legislation and having worked closely with the bill's author in the House, our former colleague, Bill Richardson.

I listened to what you said, Mr. Chairman, and I really want to commend you for holding this hearing today, because you basically laid out, as you said, my position, we basically share the same position, I think. And I think this important law deserves an evaluation and assistance from the Congress to make it an even better law for our citizens.

In the 6 short years since DSHEA, Americans have wholeheartedly embraced dietary supplements for the purpose of prevention, reduction of risk and health promotion. We've seen the establishment of terms like nutraceutials and functional foods for some of these products. I believe this is a good thing for the country as we transform our health care system.

We need to be moving away from a disease care only system and start promoting more wellness and optimal health care policies that include dietary supplements and functional foods. With open minds, we need to be looking at all the ways we can empower our citizens to make good health care choices.

Today your committee is examining several aspects of dietary supplement regulatory policy. I just wanted to share my views, because these issues will probably carry over to the House Energy and Commerce Subcommittee on Health, where I also serve. Mr. Chairman, as you know, and you mentioned, some who are opposed

to DSHEA would still call for its outright repeal. But I believe that would not make sense, nor would it be politically feasible, in my opinion. The firestorm that brewed in the Congress in the years of 1992 through 1994 would quickly return.

We need to be thoughtful of how we can resolve the issues and challenges faced by dietary supplement manufacturers and consumers and Congress can help generate mutually beneficial outcomes that protect and empower the public to better health. The FDA, I believe, has an obligation to fulfill the promises embodied in DSHEA, and our policy should be to strive to maintain DSHEA and it's time for the FDA to live up to the congressional findings we gave them that are contained in the act.

I think the most important thing is we have to enforce the law that is currently on the books, and let's make sure that the FDA has the resources to do a good job. That's an area of key concern to me, enforcement, that the FDA has not done a good job of enforcing the current law, because it has not allocated sufficient resources to do a timely execution of the law.

For example, we are still waiting for good manufacturing practice regulations for dietary supplements some 6 years after the passage of DSHEA. This is not satisfactory. It has placed the dietary supplement industry and consumers in an untenable position. People are confused what to buy, whether the product, what's contained on the label, is the consumer getting all the information he or she needs to make an informed decision on how to safely and beneficially use the product.

We need to call upon the new administration to promptly release these regulations and get to work on finalizing them.

I'm also disappointed that the FDA has not taken action against companies that are delivering products that do not contain what's stated on the label. If it's a question of sufficient resources, then we need to make sure adequate appropriations are made for the FDA to act effectively. And I compliment the trade associations that are making efforts to assure quality. I'm still concerned about the few companies out there that are taking advantage of and confusing the consumer.

I know you mentioned, Mr. Chairman, the concern that the United States will lose its sovereignty on trade matters concerning dietary supplements if it harmonizes U.S. laws with the laws of the European Union or the WTO under the CODEX Alimentarius. I believe that we ought to clearly state a position that indicates that we will not sacrifice our sovereignty. Where there are challenges on trade matters concerning dietary supplements, I urge that in a bipartisan manner we call upon the administration to send experts from the Department of Commerce and the Office of the U.S. Trade Representative to assist the current U.S. CODEX delegation.

I hope that the Congress will move progressively to improve dietary supplement regulatory policy. We could do this by working on ideas that both you, Mr. Chairman, and my colleague from California, Mr. Waxman, have championed before. One constant challenge we face is how we can improve the science and clinical research in the development of dietary supplements since they are not regulated as drugs.

Borrowing from ideas that were successfully led by Congressman Waxman in the 1980's when he co-authored the Hatch-Waxman amendments that gave us the Orphan Drug Act, I introduced H.R. 3001, the Nutraceutical Research and Education Act in the 106th Congress. This legislation attempted to create an orphan drug act incentive type of model to promote clinical R&D for dietary supplements. While my legislation did not pass, I remain committed as a member to explore all the ways we can create incentives and promote clinical research and development of dietary supplements.

I also want to commend you, Mr. Chairman, for introducing H.R. 3306 in the last Congress. This legislation would have amended the Internal Revenue Code to allow the creation of an insurance benefit to cover dietary supplements as a health benefit by an insurance company or employer sponsored insurance plan. Many of my constituents in New Jersey constantly ask me why dietary supplements and complementary and alternative health care are not always covered by insurance. One of the problems is the tax code. Bringing the tax code up to date with the realities of science and health care in the 21st century is an important step. This simple adjustment you propose will encourage our citizens to greater self care and wellness and decrease health care costs.

Furthermore, the integration of health insurance coverage for dietary supplements will promote and empower the dietary supplement industry to higher standards of quality in science, and recognize then as true partners in the health care product marketplace.

I want to end here, Mr. Chairman. I look forward to reviewing the testimony given today and working with you and my colleagues to ensure that the public can continue safely and beneficially using dietary supplements. I also recommend that your committee work closely, as I think they have, to assist the White House Commission on Complementary and Alterative Medicine Policy. This is a very complex area, but it needs a lot of attention, and I think it's really great that you're having this hearing today and trying to address it.

Thank you, Mr. Chairman and members of the committee.

[The prepared statement of Hon. Frank Pallone follows:]

Representative Frank Pallone Jr.
Government Reform Committee
Tuesday March 20, 2001

"Six Years After the Enactment of DSHEA: The Status of National and International Dietary Supplement Regulation"

Mr. Chairman, members of the Committee, thank you for extending me the opportunity to speak before your Committee today.

Dietary Supplement issues are an important healthcare issue for my constituents, my state, and our country. New Jersey is one of the states with a significant number of dietary supplement manufacturers and suppliers employing thousands of people in my state. In addition, we have among one of the most active consumer constituencies that support the use of dietary supplements in the context of Complementary & Alternative healthcare.

I commend you for your leadership in establishing the Complementary & Alternative Healthcare and Natural Foods Congressional Caucus. I am pleased to announce that I will be joining this caucus and urge other members with constituents who care about this issue to join as well.

Many members of Congress serving today were not present in the 103rd Congress when we passed the Dietary Supplement Health and Education Act of 1994 (DSHEA). I remember that debate well as having been one of the original supporters of that legislation and having worked closely with the bill's author in the House, our former colleague, Bill Richardson.

Mr. Chairman, I commend you for holding these hearings today. This important law deserves an evaluation and assistance from the Congress to make it an even better law for our citizens. In the six short years since DSHEA, Americans have wholeheartedly embraced dietary supplements for the purpose of prevention, reduction of risk, and health promotion. We have seen the establishment of terms like Nutraceuticals and Functional Foods for some of these products. I believe that this is a good thing for the country as we transform our healthcare system. We need to be moving away from a disease care only system and start promoting more wellness and optimal healthcare policies that include dietary supplements and functional foods. With open minds, we need to be looking at all the ways we can empower our citizens to make good healthcare choices.

Today your committee is examining several aspects of dietary supplement regulatory policy and I wanted to share my views with you as these issues will carry over to the House Energy & Commerce Subcommittee on Health, where I serve.

Dietary Supplement Safety & Quality – Mr. Chairman, today you will hear varying and diverse views on dietary supplements. I understand there are challenges and Congress can be instrumental in addressing them. Without getting into the technical or legal aspects of the controversies that may exist, I would like to state the following:

Some who are opposed to DSHEA would call for its outright repeal. That would not make sense nor would it be politically feasible in my opinion. The firestorm that brewed in the Congress in the years of 1992-1994 would quickly return. We need to be thoughtful on how we can resolve the issues and challenges faced by dietary supplement manufacturers and consumers. Congress can help generate mutually beneficial outcomes that protect and empower the public to better health. The FDA has an obligation to fulfill the promises embodied in DSHEA. Our policy should be to strive to maintain DSHEA. Its time for the FDA to live up to the Congressional

findings we gave them that are contained in the Act. Lets enforce the law that is currently on the books and lets make sure that the FDA has the resources to do a good job. I think that is an area of key concern, that the FDA has not done a good job of enforcing the current law because it has not allocated sufficient resources to do a timely execution of the law. For example, we are still waiting for Good Manufacturing Practice regulations for dietary supplements some six years after the passage of DSHEA. This is unsatisfactory. It has placed the dietary supplement industry and consumers in an untenable position. People are confused what to buy, will the product contain what's in the label, and is the consumer getting all the information he or she needs to make an informed decision on how to safely and beneficially use the product. We need to call upon the new Administration to promptly release these regulations and get to work on finalizing them. I am also disappointed that the FDA has not taken action against companies that are delivering products that do not contain what is stated on the label. If it is a question of sufficient resources, then we need to make sure adequate appropriations are made for the FDA to act effectively and efficiently. I compliment the trade associations that are making efforts to assure quality. I am still concerned about the few companies out there that are taking advantage of and confusing the consumer.

I also understand that there is a concern that the United States will lose its sovereignty on trade matters concerning dietary supplements if it harmonizes US laws with the laws of the European Union or World Trade Organization under the Codex Alimentarius. I believe that we ought to clearly state a position that indicates that we will not sacrifice our sovereignty. Where there are challenges on trade matters concerning dietary supplements, I urge that in a bipartisan manner we call upon the Administration to send experts from the Department of Commerce and the Office of the US Trade Representative to assist the current United States CODEX delegation.

I hope that the Congress will move progressively to improve dietary supplement regulatory policy. We can do this by working on ideas that both you Mr. Chairman, and my colleague from California, Mr. Waxman have championed before. One constant challenge we face is how we can improve the science and clinical research and development of dietary supplements since they are not regulated as drugs. Borrowing from an idea that was successfully led by Congressman Waxman in the 1980's when he co-authored the Hatch-Waxman Amendments that gave us the Orphan Drug Act, I introduced HR 3001, the Nutraceutical Research and Education Act in

the 106th Congress. This legislation attempted to create an orphan drug act incentive type of model to promote clinical R&D for dietary supplements. While my legislation did not pass, I remain committed as a member of Congress to explore all the ways we can create incentives and promote clinical research and development of dietary supplements. We need to be doing that now in the face of the challenges we are hearing about today.

For example, I would like to commend you Mr. Chairman for introducing HR 3306 in the last Congress. This legislation would have amended the internal revenue code to allow the creation of an insurance benefit to cover dietary supplements as a health benefit by an insurance company or employer sponsored insurance plan. Many of my constituents constantly ask me why dietary supplements and complementary and alternative healthcare are not always covered by insurance. One of the problems is the tax code. Bringing the tax code up to date with the realities of science and healthcare in the 21st century is an important step. This simple adjustment will encourage our citizens to greater self-care and wellness and decrease healthcare costs. Furthermore, the integration of health insurance coverage for dietary supplements will promote and empower the dietary supplement

industry to the highest standards of quality and science and recognize them as true partners in the healthcare product marketplace.

I look forward to reviewing the testimony given today and working with you and my colleagues to ensure that the public can continue safely and beneficially using dietary supplements. I also recommend that your committee work closely to assist the White House Commission on Complementary & Alternative Medicine Policy as I know they are reviewing these issues as well.

Mr. BURTON. Thank you, Mr. Pallone.

I don't know if you've ever tried echinacea or vitamin C—[laughter]—or products that contain zinc, like Cold-Eze. And I'm not touting that particular product, but if you've got a cold, that might help.

Mr. PALLONE. I didn't want to go into all the details, because I didn't want to suggest to anyone that what they were doing wasn't working.

Mr. BURTON. OK. [Laughter.]

Any questions of Representative Pallone? Any questions on our side?

Thank you very much. We really appreciate it. And we appreciate your support. I look forward to working with you on this subject. And I'd like to see your bill that you had in the last Congress. Thank you, sir.

Our next panel is Mr. Loren Israelsen, executive director of the Utah Natural Products Alliance; Mr. David Seckman, executive director of the National Nutritional Foods Association; Mr. Mark Blumenthal, executive director of the American Botanical Council; Mr. Karl Riedel, chief executive officer, Nature's Life, and member of U.S. delegation, CODEX Alimentarius Commission on Nutrition and Foods for Special Dietary Uses; Samuel Benjamin, a medical doctor, chairman of Invite Health; Sidney Wolfe, M.D., director of Health Research Group, Public Citizen; and Bruce Silverglade, director of Legal Affairs, Center for Science in the Public Interest.

Thank you all for being here. I know that a number of you probably have some opening statements. We have a procedure here where we swear in our witnesses on a regular basis, so would you please, stand and raise your right hands.

[Witnesses sworn.]

Mr. BURTON. I think we'll start at the left end there with Mr. Israelsen, and let you start off. If you would try to hold your comments to 5 minutes or less, I certainly would appreciate it. We have a lot of witnesses today and a lot of questions. We'd like to have you stick to that if you can.

STATEMENTS OF LOREN D. ISRAELSEN, EXECUTIVE DIRECTOR, UTAH NATURAL PRODUCTS ALLIANCE; DAVID R. SECKMAN, EXECUTIVE DIRECTOR AND CEO, NATIONAL NUTRITIONAL FOODS ASSOCIATION; MARK BLUMENTHAL, FOUNDER, EXECUTIVE DIRECTOR, AMERICAN BOTANICAL COUNCIL; KARL RIEDEL, CHIEF EXECUTIVE OFFICER, NATURE'S LIFE; SAMUEL D. BENJAMIN, M.D., M.D.(H), ASSOCIATE DIRECTOR OF PEDIATRICS, DIRECTOR OF THE CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE, STATE UNIVERSITY OF NEW YORK AT STONY BROOK SCHOOL OF MEDICINE; CHAIRMAN, INVITE HEALTH; SIDNEY M. WOLFE, M.D., DIRECTOR, PUBLIC CITIZEN HEALTH RESEARCH GROUP; AND BRUCE SILVERGLADE, DIRECTOR OF LEGAL AFFAIRS, CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Mr. ISRAELSEN. Thank you, Mr. Chairman and members of the committee.

My name is Loren Israelsen, I'm executive director of the Utah Natural Products Alliance and we're pleased to have Mr. Cannon on the committee. Utah is indeed the center of dietary supplement manufacturing in the United States.

The purpose of DSHEA was to establish a badly needed framework for the regulation and sale of dietary supplements in the United States. This was achieved in the following ways. Dietary supplements were defined for the first time as a special class of foods and not as food additives or as new drugs. The revised safety standard was created to distinguish new and old dietary ingredients.

A new class of benefit statements, commonly called structure function claims, was created. New ingredient labeling and nutrition information requirements for dietary supplements were established for labels and labeling. Good manufacturing practice regulations for dietary supplements were authorized. Section 13 of DSHEA created the Office of Dietary Supplements, to be housed in the National Institutes of Health.

Since the passage of DSHEA, FDA has initiated three major rulemakings. In September 1997, a final regulation on nutrition labeling for dietary supplements was published. This regulation mandated new label formats, declaration of ingredients and numerous other requirements to assist consumers in evaluating purchasing decisions with respect to dietary supplements.

In January 2000, FDA published the final regulation on structure function claims. However, there do remain significant areas of disagreement between industry and the agency with respect to what constitute appropriate structure function claims. This appears to be the subject of a new guidance document that the agency is now preparing.

In February 1997, FDA published for comment an advance notice of proposed rulemaking on GMPs for dietary supplements. This committee has already commented on the slowness of that process. This remains a major disappointment to us that this rulemaking is stalled. We urge the committee to encourage the administration to complete the current OMB review of this proposed regulation and to hasten its early publication. We view this as our No. 1 priority.

Adverse event reporting is becoming a very important issue, as you have already mentioned. Both the agency and the majority of the dietary supplement industry agree that a streamlined and improved adverse event reporting system is warranted and needed. We are anxious to see the current backlog of AER reports resolved, greater transparency brought to the system and an opportunity to assess real time reports to allow us, the industry, to evaluate consumer experience with dietary supplements.

Botanicals have become the fastest growing segment of the dietary supplement category, and also the most controversial. Many in our industry believe that a number of botanicals could and should be recognized as drug products, either as new drugs, old OTC drugs, or traditional medicines. At the moment, these avenues are largely closed to dietary supplement products.

The Presidential Commission on Dietary Supplement Labels created by DSHEA stated the following: Botanical products should

continue to be marketed as dietary supplements when properly labeled. The Commission strongly recommends that FDA promptly establish a review panel for OTC claims for botanical products that are proposed by manufacturers for drug uses. The panel should have appropriate representation of experts on such products. This in no way should limit the sale of such products as dietary supplements, but merely add an additional area of claims where science and research can be added to add value to consumer experience with these products.

Product safety is an issue of great concern to us, to the agency and to this committee. We understand that FDA has recently announced a contract with the Institute of Medicine to evaluate the safety of dietary supplements. We would very much like to be a part of that process, to assure that if a monograph system for the safety evaluation of supplements is developed, that it has the industry's full involvement and cooperation.

It may interest this committee to know that the U.S. Government is probably now one of the leading sources of dietary supplement research in the world. This is thanks to the funding and creation of the Office of Dietary Supplements and the National Center for Complementary and Alternative Medicine. These scientific and research investments will, I believe, pay great dividends in future health benefits to Americans.

I'm pleased to see Dr. Coates of the ODS present today.

A quick comment on international issues. I fully share Mr. Burton's and Mr. Waxman's concerns that U.S. laws not be trumped by international agreements. DSHEA has become an important regulatory model for many countries. They are looking to us for guidance with respect to the development and establishment of dietary supplement regulations in probably 30 to 40 countries worldwide. We will resist any efforts by CODEX or any other international body to limit the authority of DSHEA or any other U.S. law.

In summary, there is much work to be done to fully implement DSHEA. It is my view that the central issue is not whether FDA has authority to regulate this category of products. That was settled by DSHEA. Previous Commissioner Henney has noted in her testimony before this committee that DSHEA was enacted to assure access to dietary supplements. With that access now ensured, it is crucial that the necessary implementing regulations be fully completed, especially good manufacturing practices.

What we do not want to see is a repetition of misdirected enforcement policies and overzealous enforcement against dietary supplements. We would support additional funding for FDA to the extent that it supports programs and policies that bring guidance and proper regulation to the category of dietary supplements. We fully recognize that consumer confidence in this class of products is essential to their continued usage. Clearly, we are fully agreed with the agency on these issues.

My colleagues and I share these views and we also believe we can work closely with critics of this industry historically as we approach the issue of proper regulation. It is my deeply felt belief, having been involved heavily in DSHEA from the beginning, that we have found a structure that will work if proper regulation is

brought to bear, and proper funding for those regulations is brought to bear. To that extent, we very much want FDA to have the necessary funding for those assignments.

Thank you for allowing me this opportunity to speak before the committee. I'll be happy to respond to questions.

[The prepared statement of Mr. Israelsen follows:]

SIX YEARS AFTER THE ENACTMENT OF DSHEA: THE STATUS OF NATIONAL AND INTERNATIONAL DIETARY SUPPLEMENT REGULATION AND RESEARCH

Statement by Loren D. Israelsen
Executive Director, Utah Natural Products Alliance
Before the Committee on Government Reform
House of Representatives
March 20, 2001

Mr. Chairman and members of the Committee, thank you for this invitation to give a brief update with respect to important regulatory and scientific developments and issues related to dietary supplements since the passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA).

The purpose of DSHEA was to establish a badly needed framework for the regulation and sale of dietary supplements in the United States. This was achieved in the following ways:

1) DEFINITIONS. Dietary supplements were defined for the first time as a special class of foods, and not food additives or new drugs (Section 3).

2) SAFETY STANDARD. A revised safety standard was created distinguishing old and new dietary ingredients. Old dietary ingredients (ODI) were those dietary substances that had been used as supplements in the U.S. prior to October 15, 1994. New dietary ingredients (NDI) are any dietary ingredients new to the U.S. market after that date. Such ingredients require the seller to notify FDA at least 75 days before introduction of that dietary ingredient into interstate commerce and to provide FDA the basis on which that ingredient is believed to be reasonably expected to be safe under its conditions of use and labeling. FDA has received numerous NDI notices and has, on a number of occasions, advised that such NDI's either were not properly substantiated for safety or did not meet the standard set out by DSHEA. Prior to DSHEA, FDA had no way of knowing what new dietary ingredients were being introduced for sale; rather, FDA regarded most non-nutrient dietary ingredients as food additives and often took enforcement action against such products despite having little or no evidence that such ingredients were in fact unsafe. This, as you know, was a major point of conflict between the dietary supplement industry and FDA prior to the passage of DSHEA.

3) STRUCTURE/FUNCTION CLAIMS. A new class of benefit statements, technically called "statements of nutritional support" and commonly called "structure/function claims" (SFC's), was created by Section 6 of DSHEA. These claims may describe how a dietary ingredient is intended to affect the structure or function of the body or to characterize a documented mechanism by which a nutrient or dietary ingredient acts to maintain a bodily structure or function or to describe general well-being from consuming supplements. Companies

wishing to make structure/function claims must have substantiation that the statements are truthful and nonmisleading. Such statements must also be accompanied by a disclaimer which states: *"This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."*

Finally, such statements must be submitted to FDA no later than 30 days after the claim is first marketed. To date, thousands of SFC's have been submitted to FDA, and the agency has, on numerous occasions, advised companies that such claims are, in the agency's judgment, unapproved new drug claims or otherwise outside the scope of Section 6 of DSHEA. Most companies take this advice seriously and either amend or withdraw such claims. There are, however, several important claim areas about which the industry and FDA continue to disagree such as cholesterol lowering, allergies and cold/flu season statements.

4) INGREDIENT LABELING AND NUTRITION INFORMATION. DSHEA mandates that dietary supplement labels must list the name and quantity of each ingredient and identify any part of a plant used in a dietary supplement. Any dietary supplement label that fails to identify the product as a "dietary supplement" is misbranded. Further, a dietary supplement which purports to conform to a compendial standard and fails to do so or fails to have the identity and strength that it represents to have, or which fails to meet the quality, purity or compositional specifications that it claims to have is misbranded and mislabeled.

DSHEA authorized FDA to issue regulations establishing nutrition labeling for dietary supplements, including the format, content and layout of required information to be displayed on dietary supplement products.

5) GOOD MANUFACTURING PRACTICES. Section 9 of DSHEA authorized FDA to issue good manufacturing practice (GMP) regulations for dietary supplements, which must be modeled after current GMP regulations for foods.

6) COMMISSION ON DIETARY SUPPLEMENT LABELS. Section 12 of DSHEA created a Presidential Commission to study a range of issues of interest to both the Congress and the dietary supplement industry.

7) OFFICE OF DIETARY SUPPLEMENTS. Finally, Section 13 of DSHEA created the Office of Dietary Supplements (ODS) to be housed within the National Institutes of Health. The purpose of the ODS is to explore and study the potential role of dietary supplements

as a part of national efforts to improve health care and to promote scientific study of the benefits of dietary supplements to maintain health, prevent chronic disease and other health-related issues. This office is to serve as a principal advisor to the Secretary, the Director of the NIH, the Director of the CDC, and the Commissioner of FDA with respect to issues relating to dietary supplements.

THE POST-DSHEA ERA

The passage of DSHEA was the foundation on which a framework of regulations for dietary supplements could be built. Since DSHEA, FDA has initiated three major rule-makings:

1) In September of 1997, a final regulation on nutrition labeling for dietary supplements was published. This regulation mandated new label formats, declaration of ingredients and numerous other requirements. The principal feature of this rulemaking was the adoption of a Supplement Facts Box modeled after the Nutrition Facts Box found on conventional foods.

2) In January of 2000, FDA published a final regulation on structure/function claims. While there remain significant areas of disagreement between industry and the agency with respect to what constitutes appropriate structure/function claims, the agency made efforts to acknowledge the thousands of comments that took exception with FDA's proposed definition of "disease" and other rules that would have significantly narrowed what industry believes are appropriate statements with respect to how dietary supplements affect the structure and function of the body.

3) In February of 1997, FDA published for comment an advanced notice of proposed rule-making (ANPR), setting out GMP's for dietary supplements. This ANPR was heavily influenced by an industry task force, which developed a new and stricter set of GMP's for dietary supplements modeled on current food GMP's. It remains a major disappointment to us that this proposed rule has yet to be published, further delaying the implementation of final GMP regulations which the dietary supplement industry has urgently requested and believes are important to the public confidence in the quality of dietary supplements as well as confirmation of a national standard of manufacturing standards and procedures. I urge this committee to

encourage the administration to complete the current OMB review of this proposed regulation and to hasten its early publication.

These three rule-making procedures represent a significant portion of the administrative action mandated by DSHEA. However, there are a number of other important matters that remain to be addressed and about which both FDA and the dietary supplement industry seek additional guidance and clarity. These include the following:

1) ADVERSE EVENT REPORTING. Both the agency and the majority of the industry agree that a streamlined and improved AER system is needed. We are anxious to see the current backlog of AER reports at FDA resolved so that we will have opportunity to review and assess real-time reports concerning consumer experience with dietary supplements. Significant improvements can be made in data collection and management. To this point, the industry is in the process of developing and implementing a third party reporting system to complement the current FDA med-watch system.

2) NEW DIETARY INGREDIENTS. Industry would benefit from having a guidance document setting out FDA's views with respect to safety substantiation requirements for new dietary ingredients. We also believe the publication of a comprehensive database of new ingredients would be helpful.

3) STRUCTURE/FUNCTION CLAIM GUIDANCE. The agency recently published for comment a notice seeking advice and comment from industry regarding further definition with respect to the difference between disease claims and structure/function claims. We hope this will be a useful guidance to eliminate uncertainty and/or disagreement about important structure/function claim areas.

4) DEFINITION ISSUES. The agency is currently developing policy with regard to the distinction between dietary supplements and conventional foods as well as dietary supplements and drugs. This is a very important issue, specifically as it relates to the inclusion of non-GRAS dietary ingredients and whether such ingredients may be added to conventional foods and, if so, under what circumstances. The food industry has expressed great interest in offering value-added conventional foods, which contain one or more beneficial dietary ingredients, but feel constrained to do so by recent FDA correspondence to industry. A

streamlined system of evaluating old dietary ingredients that are appropriate for foods would be welcome.

5) BOTANICALS. Botanicals have been the fastest growing segment of the dietary supplement category and also the most controversial. Many in our industry believe that a number of botanicals could and should be recognized as new drugs, old OTC drugs and traditional medicines. At the moment, these avenues are either closed or virtually unattainable for the botanical dietary supplement industry. The Presidential Commission on Dietary Supplement Labels recommended that:

> "Botanical products should continue to be marketed as dietary supplements when properly labeled...The commission strongly recommends that FDA promptly establish a review panel for OTC claims for botanical products that are proposed by manufacturers for drug uses. The panel should have appropriate representation of experts on such products."

Those critical of the present labeling claims and usage of botanicals should recognize that most other countries have examined and resolved this issue by developing a multi-tiered system of regulation for botanical products, as I have described above. I would urge this committee to make this a high priority in advising the administration and the agency to develop alternative regulatory pathways for botanicals to be recognized as new drugs, OTC drugs and traditional medicines. This, in no way, should limit the availability of botanicals as dietary supplements, but as we have seen from other countries would create meaningful incentives for companies to conduct further research on the safety and utility of botanicals.

6) ANALYTICAL METHODS AND MONOGRAPH DEVELOPMENT. Since the passage of DSHEA, millions of dollars have been spent to develop industry-wide analytical methods for botanical and other dietary ingredients. This is widely recognized as an important process to clarify testing methods and techniques and to minimize unreliable and inaccurate test results. Unfortunately, a number of the media reports which criticize the quality and labeling of dietary supplements have used methods which are either different from, or not widely used or recognized, by industry. We are pleased to note that widely respected organizations such as the United States Pharmacopoeia and the AOAC have undertaken programs to establish quality and information monographs for botanicals and other dietary ingredients. I am also pleased to

inform this committee that the National Sanitation Foundation has expressed interest in establishing a certification program for the quality of dietary supplements, as has the USP. These are significant developments, which should be fully supported by everyone so that the public will have confidence in the quality and labeling of dietary supplements.

7) DIETARY SUPPLEMENT SAFETY. Since the passage of DSHEA, there have been controversies regarding the safety of some well-known dietary ingredients, including ephedra. The FDA recently announced that it has signed a contract with the Institute of Medicine entitled, "Framework for Evaluating the Role of Dietary Supplements in Health." This and other efforts are intended to establish a framework to assess the safety of a wide range of dietary ingredients. This effort complements the work of my sister trade associations who have been actively engaged in safety assessments and recommended label guidance for a range of dietary ingredients. This has largely been made possible because DSHEA allows us to include on the label or labeling any and all information which is necessary or helpful to the safe and appropriate use of a dietary supplement. Prior to DSHEA, FDA took a very narrow position as to what information could be communicated on a dietary supplement label, thus denying consumers the type of information required to make sensible buying and usage decisions.

8) FOOD ADVISORY COMMITTEE. FDA has, in consultation with the supplement industry, agreed to add additional expertise to the Food Advisory Committee specific to dietary supplements. This is a welcome development.

9) OFFICE OF DIETARY SUPPLEMENTS. The ODS was created by DSHEA and has become an important center of research on dietary supplements, is increasingly viewed as an important clearinghouse of information and has become an important advisor to other government agencies with interests in dietary supplements. The industry has enjoyed a cordial relationship with both the past and present directors of the ODS and hopes to continue supporting a range of research initiatives and public health care outreach programs sponsored by ODS.

It may interest the committee to know that the United States government is now one of the leading sources of dietary supplement research in the world, thanks to the ODS and the National Center for Complementary and Alternative Medicine. These scientific investments will, I believe, pay great dividends in future health benefits to Americans.

PRIORITIES

There is much work to be done to fully implement DSHEA. It is my view that the central issue surrounding dietary supplements is not whether FDA has adequate authority to regulate this class of products but whether the necessary resources exist to complete the regulatory framework as envisioned by DSHEA. As previous Commissioner Henney noted in her testimony before the House Committee on Government Reform on March 25, 1999, DSHEA was enacted to assure access to dietary supplements. With that access ensured, it is now crucial that the necessary implementing regulations be fully completed, especially good manufacturing practices, and that open issues which remain either contentious or confused be resolved, in order that the millions of Americans who use and rely on dietary supplements can continue to have full confidence in their safety, accurate labeling and quality. To the extent that additional funds are required by either CDER or CFSAN to complete the regulatory agendas noted above, most of the dietary supplement industry would support this. What we do not want to see is a repeat of misdirected enforcement policies or overzealous enforcement against benign dietary supplements. There is a growing spirit of cooperation between the supplement industry and FDA, and both sides recognize that the consuming public is served by this. It is my hope that the Congress will continue its oversight of the agency's regulation of dietary supplements to assure that the provisions of DSHEA are fully implemented as originally envisioned.

Again, thank you for allowing me this opportunity to speak before the committee. I will be happy to respond to any questions you may have.

Mr. BURTON. Thank you, Mr. Israelsen.

Mr. Seckman.

Mr. SECKMAN. Chairman Burton and honorable members of the Committee on Government Reform, I thank you for the opportunity to address the committee.

Specifically, I have been asked to discuss the issues and challenges that have arisen for the manufacturers and distributors and retailers of dietary supplements since the passage of the Dietary Supplement Health and Education Act of 1994. I am David Seckman, executive director and CEO of the National Nutritional Foods Association.

NNFA was founded in 1936, and it's the oldest and largest trade association in the natural products industry. We represent the interests of more than 3,000 health food stores and 1,000 manufacturers, suppliers and distributors of health foods, dietary supplements and related items.

For perspective, let me begin with some background information regarding DSHEA. Congress' intent in enacting DSHEA was to help ensure that safe and appropriately labeled products remained available to those who want to use them. In DSHEA, Congress acknowledged the potential for a positive relationship between dietary supplements and good health, and indicated the need for additional research to confirm this relationship.

As consumers educated themselves about the therapeutic benefits of supplements through a growing body of scientific research and other third party literature, their purchases of these products increased exponentially. Since the passage of DSHEA, sales of dietary supplements have nearly doubled, going from $8.6 billion in 1994 to more than $16 billion this past year.

In the 6-years since DSHEA's passage, the industry, such as those organizations represented by NNFA and others on this panel, have complied with the law by maintaining product safety substantiation and production safeguards to ensure consumers of high quality dietary supplements. NNFA's recently implemented Good Manufacturing Practices [GMPs], our GMP program, is an excellent example of an industry taking responsibility for its own products. I am very proud of NNFA's efforts to ensure dietary supplement quality and would like to tell a little about the programs that we have established.

NNFA's Good Manufacturing Practices Certification and TruLabel programs are representative of the dietary supplement industry's commitment to providing quality products. Since 1990, NNFA's TruLabel registration and random testing program has promoted quality assurance, label integrity and regulatory compliance to our dietary supplement supplier members. Under the TruLabel program, random tests are conducted to ensure that what's on the label is in the product.

Through the enactment of DSHEA, Congress encouraged the FDA to establish good manufacturing practices for dietary supplements. Today, more than 6 years later, the FDA has still not issued regulations for GMPs. It was our belief that if the industry established its own uniform GMPs in the absence of a Federal rule, it would better prepare manufacturers for the eventual establishment of the regulation.

So in 1999, NNFA launched a third party certification program for dietary supplement good manufacturing practices. The centerpiece of our Good Manufacturing Practices Certification program is inspections of the manufacturing facilities to determine whether NNFA's specified performance standards are being met. The NNFA's GMP program is designed to ensure that all elements of the manufacturing processes are reviewed. On-site inspections of manufacturing facilities cover the following areas and more: testing of raw ingredients and materials, sanitation controls, quality assurance, laboratory procedures and staff training and supervision. Only manufacturers who receive NNFA's highest compliance ratings are allowed to use GMP's seal on their products.

In regards to research, a recent study indicated that more than 40 percent of the adult population in the United States is seeking alternative care. NNFA recognizes this as crucial for the health and security of all Americans, that objective, scientific research is done to determine the effectiveness of complementary and alternative therapies, including the use of dietary supplements.

For that reason, NNFA has always strongly supported increased funding for the National Institutes of Health Office of Dietary Supplements and National Center for Complementary and Alternative Medicine. We believe these additional funds will help to invest in additional scientific and clinically based research coordinated within NIH, educate practitioners and consumers through continued education and outreach programs, train additional investigators and invest in career development and publish scientifically peer reviewed fact sheets and compile research literature.

As for working with the FDA, clearly NNFA and the FDA share a desire to see DSHEA put to its best use. We have always welcomed outreach from the agency when an issue has arisen that jeopardizes the continued marketing of safe and effective natural products, including dietary supplements. For nearly a decade, in those rare instances where a potential safety issue has arisen, we have been able to draw upon our TruLabel data base of more than 25,000 product labels in order to provide the FDA with information and notify those members whose products may be involved.

We are appreciative that FDA is seeking the industry's assistance as a safety net and as a resource. As we look to the future, while it certainly may be true that the FDA is both underfunded and understaffed, it is not powerless to adequately regulate supplements. The all too familiar assertion that supplements are unregulated is patently untrue. Even the FDA's most recent Commissioner, Dr. Jane Henney, has testified before this committee that DSHEA provides enough regulatory authority for her agency to protect the public.

Our industry is rising to the occasion of its public responsibility with strict compliance with a good law and a meaningful self regulatory efforts to ensure the safety of its product and accuracy on its labels. With that in mind, it would be most helpful to ensure that FDA is given sufficient support to enforce against those who would take advantage of its inadequate funding. This would allow the FDA to work with Congress to get the resources necessary to fully implement DSHEA.

We at the NNFA look forward to continuing to work responsibly and cooperatively to ensure the safety and quality of dietary supplements.

I want to thank the chairman and the members of the committee for the opportunity to present our views here today.

[The prepared statement of Mr. Seckman follows:]

TESTIMONY OF DAVID R. SECKMAN

BEFORE

THE COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

MARCH 20, 2001

Chairman Burton and Honorable Members of the Committee on Government Reform, thank you for the opportunity to address the Committee with respect to the dietary supplement industry. I am David Seckman, executive director and CEO of the National Nutritional Foods Association (NNFA). NNFA was founded in 1936 and is the oldest and largest trade association in the natural products industry. We represent the interests of more than 3,000 health food stores and 1,000 manufacturers, suppliers and distributors of health foods, dietary supplements and related items.

The Committee has suggested that I address issues reflecting industry efforts to ensure the safety and quality of dietary supplements. Specifically, an outline of the issues and challenges that have arisen for the manufacturers, distributors, and retailers of dietary supplements since the passage of the Dietary Supplement Health and Education Act in 1994.

Background: From DSHEA to Today

DSHEA acknowledges that millions of consumers believe dietary supplements may help to augment daily diets and provide health benefits. Congress's intent in enacting DSHEA was to meet the concerns of consumers and manufacturers to help ensure that safe and appropriately labeled products remain available to those who want to use them. In the findings associated with DSHEA, Congress stated that there may be a positive relationship between sound dietary practice and good health, and that, although further scientific research is needed, there may be a connection between dietary supplement use, reduced health-care expenses, and disease prevention.

Since the passage of DSHEA, sales of dietary supplements have nearly doubled, going from $8.6 billion in 1994 to more than $16 billion this past year. For the first time DSHEA enabled consumers to access accurate information about supplements. As consumer's educated themselves about the therapeutic benefits of supplements, through a growing body of scientific research and other third party literature, their purchases of these products increased exponentially.

I would like to point out that with an increase in supplement use, a corresponding increase in adverse events would not be unexpected. Proportionately, however, adverse

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events related to supplements are down. But even assuming the worst-case scenario presented in a Washington Post article last year, annual adverse events related to supplements are less than one *one half of one percent* of the 106,000 deaths and 2.2 million injuries per year from prescription medication.

Since DSHEA's passage more than six years ago, the industry, such as those organizations represented by NNFA and others on this panel, has complied with the law by maintaining product safety substantiation and production safeguards to ensure consumers of wholesome, high-quality dietary supplements. NNFA's recently implemented Good Manufacturing Practices program is an excellent example of an industry taking responsibility for its own products. Let me tell you about that program and others the industry has established to further ensure the safety and integrity of dietary supplements.

The Present

Assuring Quality

I will begin by giving a brief overview of NNFA's Good Manufacturing Practices Certification and TruLabel programs, not just because I am understandably partial to these programs, but because they have also been around the longest and demonstrate the dietary supplement industry's commitment to providing quality products.

Since 1990, NNFA's TruLabel Registration and Random Testing program has promoted quality assurance, label integrity and regulatory compliance to our dietary supplement supplier members. Under the TruLabel program, random tests are conducted to ensure that what's on the label is in the product. Popular supplement products are selected and tested for label integrity. If the product contains less than 90 percent of the label claim, the manufacturer must recall the product lot.

Companies are given a brief period to remedy the situation by correcting the problem with the product or label. A company that fails to comply with this remediation process is expelled from NNFA membership. Currently, more than 25,000 product labels are registered as part of NNFA's TruLabel program. NNFA randomly tests six to 10 ingredients per year. Beginning early this summer, all testing methodology and results will be posted on NNFA's Web site, at www.nnfa.org.

NNFA's latest entry in the quality assurance area is our Good Manufacturing Practices Certification program. Through the enactment of DSHEA, Congress encouraged the FDA to establish good manufacturing practices for dietary supplements. Today, more than six years later, the FDA has still not issued regulations for GMPs, which I understand are still at the agency. It was also our belief that if the industry established its own uniform GMPs in the absence of a federal rule, it would better prepare manufacturers for the eventual establishment of the rule. So, in 1999, NNFA launched a third-party certification program for dietary supplement good manufacturing practices. The centerpiece of this program is inspections of manufacturing facilities to determine whether NNFA specified performance standards are being met.

NNFA's GMP program is designed to ensure that all elements of the manufacturing process are reviewed, providing a reasonable assurance that processes are sufficiently controlled so that products meet their purported quality. Onsite inspections of manufacturing facilities are cover the following areas:

- Disease control, cleanliness, education and training and supervision
- Plant and grounds maintenance, cleaning and disposal of waste
- Sanitation of facilities including pest control, sewage and water quality
- Cleaning, maintenance and calibration of equipment and utensils
- Establishment of a quality control unit that maintains lab records, test methods and expiration dating with supportive data
- Production and process controls including batch production and control records, handling and storage of raw, in-process, and rework materials
- Procedures for storage and distribution including customer complaints and returned product

Once certified, member manufacturers are given a compliance rating. A member supplier must receive an "A" rating in order to pass. Those that receive either a "B" or "C" compliance rating, must correct deficiencies and submit for a re-audit. Manufacturers that comply with NNFA standards are then allowed to use NNFA's GMP seal on their products.

Joining NNFA's efforts, within the last month are two new dietary supplement quality assurance programs from two established certifying organizations. As I understand it, the U.S. Pharmacopoeia's program will review manufacturer testing while the program from NSF International will conduct third-party inspections. Like NNFA's, both programs will establish testing standards for dietary supplements and will issue product seals that consumers can identify. Ensuring that products are safe, unadulterated, and meet the quality specifications that consumers expect is only the first step. NNFA also supports efforts to determine the effectiveness of dietary supplements and has been actively working with Congress to increase funding for research.

Support for Research

A landmark study published in the Journal of the American Medical Association in 1998 indicated that more than 40 percent of the adult population in the U.S. is seeking alternative care. NNFA recognizes that it is crucial for the health and security of all Americans that objective, scientific research is done to determine the effectiveness of complementary and alternative therapies, including the use of dietary supplements. For that reason, NNFA has always strongly supported increased funding for the National

Institutes of Health's Office of Dietary Supplements and National Center for Complementary and Alternative Medicine.

The Office of Dietary Supplements was established at the National Institutes of Health by the DSHEA to stimulate, coordinate and disseminate the results of research on the benefits and safety of dietary supplements in the treatment and prevention of chronic disease. NNFA agrees with the President's Commission on Dietary Supplement Labels that if fully-funded, "...ODS could play a valuable role in providing consumers with information about dietary supplements ...including [the] promotion of scientific studies on potential roles of dietary supplements in health promotion and disease prevention. Appropriations as authorized by DSHEA are essential if ODS is to meet [the] mandates of the Act."

The office, with NNFA's support, has begun funding research on botanical supplements through university-based research centers. Each of the ODS-funded centers will promote the scientific discourse and provide the critical scientific mass necessary for sound studies on the efficacy and safety of botanical supplements. With the support of NNFA and other industry associations, the ODS's budget has grown from $69,000 when it was first created in the mid1990s to $10 million in the Fiscal 2001 appropriations bill. For Fiscal 2002, NNFA supports additional increases in funding for ODS.

In 1992 Congress directed the National Institutes of Health to establish the Office of Alternative Medicine with the expressed task of assuring objective, rigorous review of alternative therapies to provide consumers reliable information. In fiscal 1999 the Office of Alternative Medicine elevated to a Center with its own grant making capabilities. Funding for the Center has grown along with its increased authority from $2 million in fiscal 1992 to $50 million in fiscal 1999 to $89 million in fiscal 2001. NNFA supports increased funding of $100 million for NCCAM in fiscal 2002. We believe that NIH has the best infrastructure to clinically examine the science of dietary supplements.

We believe these additional funds will help to:

- Invest in additional scientific and clinically based research, coordinated within NIH
- Educate practitioners and consumers through continuing education and outreach programs
- Train additional investigators and invest in career development, and
- Publish scientifically peer-reviewed fact sheets and compile research literature.

Working with the FDA

Clearly, NNFA and the FDA share a desire to see DSHEA put to its best use. We have always welcomed outreach from the agency when an issue has arisen that jeopardized the continued marketing of safe and effective natural products, including dietary supplements. For nearly a decade, in those rare instances where a potential safety issue has arisen, we have been able to draw upon our TruLabel database of more than 25,000 product labels in order to provide the FDA with information and notify those members

whose products may be involved. We are appreciative that the FDA is seeking industry's assistance as a safety net and a resource or even in regard to administrative matters.

Most recently and notably, we have been working closely with the FDA on the issue of dietary supplements and bovine spongiform encephalopathy (BSE), widely known as "mad cow" disease. In addressing the agency's questions on this issue, we were able to not only utilize our TruLabel database to obtain a snapshot of this niche market, we also leveraged our unique ability to reach retail members, and through them, consumers. In addition, we reminded our members of the of the FDA's guidelines to ensure BSE-free supplements and augmented these guidelines with our own "standard operating procedures" to further ensure this disease does not manifest itself our industry's products. Although we developed these guidelines specifically for our members, we have made them available to any manufacturer by posting them on our Web site.

We are appreciative that the FDA is seeking industry's assistance when there is a potential safety issue or even in regard to administrative matters. For instance, last year the FDA sought industry comments regarding the program priorities at the Center for Food Safety and Applied Nutrition.

The Future

While it certainly may be true that the FDA is both under funded and understaffed, it is not powerless to adequately regulate supplements. The all to familiar assertion that supplements are unregulated is patently untrue. Even the FDA's most recent commissioner, Dr. Jane Henney has testified before this committee that DSHEA provides enough regulatory authority for her agency to protect the public. Our industry is rising to the occasion of its public responsibility with strict compliance with a good law and meaningful self-regulatory efforts to ensure the safety of its products and accuracy on its labels.

With that in mind, it would be most helpful to ensure that FDA is given sufficient support to enforce against those who would take advantage of its inadequate funding. This would allow the FDA to work with Congress to get the resources necessary to fully implement DSHEA. We at the NNFA look forward to continuing to work responsibly and cooperatively to ensure the safety and quality of dietary supplements.

* * * *

I wish to thank Mr. Burton and the other members of the Committee for the opportunity to present these views.

National Nutritional Foods Association GMP Certification Program

Overview

Program Objectives:
The NNFA GMP Certification Program is designed to verify compliance of member suppliers of dietary supplements with a standardized set of good manufacturing practices (GMPs) developed by NNFA. This program is based upon third party inspections of member suppliers and comprehensive audits of their GMP programs in the areas of Personnel, Plant and Grounds, Sanitation, Equipment, Quality Operations, Production and Process Controls, and Warehouse, Distribution, and Post-Distribution Practices. This program ensures that all elements of the manufacturing process are reviewed to provide reasonable assurance that processes are sufficiently controlled so that products meet their purported quality.

Member suppliers that meet minimum NNFA GMPs standards and have received an "A" compliance rating after an NNFA GMP audit will be entitled to apply for certification and use of the NNFA GMP seal. NNFA certification and display of the GMP seal demonstrate to retailers, consumers and the public-at-large that products have been manufactured using good manufacturing practices and bring a means of self-assessment to the dietary supplement industry.

Organization:
NNFA:
The NNFA, the largest dietary supplement trade association in the United States, has developed GMP standards based upon dialogs with member suppliers, other trade associations, and the FDA. Compliance with NNFA GMPs is a requirement of membership for suppliers beginning in 1999, with a 3-year implementation allowance. The NNFA GMPs are a living document and will be updated periodically based upon feedback from consultants, member companies, best quality practices and the FDA. NNFA will facilitate certification of member suppliers by providing education and training upon request.

GMP Advisory Committee:
The GMP Advisory Committee, under the direct supervision of NNFA, is comprised of three experts selected for their expertise and training in GMPs. Whenever possible, the Committee members will have a diverse background, including food, dietary supplements, pharmaceuticals, and botanicals, representing the needs of the membership.

The functions of the Advisory Committee include:

- Periodic review of the NNFA GMPs
- Review and revision of suggested programs, procedures and records, necessary to meet GMPs

- Review and revision of the Audit Checklist and Performance Rating System
- Selection of auditing companies and assessment of their performance
- Resolution of any disagreements between auditors and member suppliers

Third Party Auditors:
Several agencies are selected to conduct audits of supplier members utilizing the NNFA GMPs and associated performance standards.

Auditing companies are selected by the Advisory Committee, based upon geographical location, resources, and prior experience conducting audits and inspections of food or dietary supplement manufacturers.

Auditing companies must be independent, with no known or potential conflict of interest, for each company for which they are contracted to complete an audit review. Auditors have agreed and been trained to conduct GMP audits only according to the audit checklist and performance rating system developed by NNFA.

Arrangements for initial audit, resolution of any findings, and any follow-up audits, are to be made jointly by the auditing company and the member supplier, but must follow the protocol developed by the NNFA.

Auditing companies are limited to the determination of compliance of a member supplier to NNFA GMPs, and any decision with regard to certification is at the sole discretion of NNFA. It is a conflict of interest for an auditing company to currently consult with any member supplier for which it conducts an audit; or to have consulted with that member supplier for a three year period prior to the audit.

Auditing companies shall provide NNFA with copies of all audit and corrective action reports. They must also agree to the accompaniment of members of the NNFA GMP Advisory Committee on a specified number of audits each year so that the NNFA may assess the quality of audits and the need for revision of the audit checklist and/or performance rating system.

On-Site Audits:
The purpose of the audit is to verify compliance of a member supplier's GMPs with the requirements of the NNFA GMPs. It also provides for an exchange of information between the company and the auditor that will identify areas for improvement required to meet minimum NNFA GMP standards.

The member supplier must allow access to all facilities, which are involved with the manufacture, packaging, testing, and/or distribution of dietary supplements. The member supplier must also have a qualified representative available to answer the auditor's questions.

Audits will be conducted by experienced auditors that have been trained in the NNFA GMPs and performance rating system, and have the required education, experience and training to conduct on-site audits. Typical education and experience of auditors is:

- A four year college degree in biology, chemistry, or food science
- Expertise in food or pharmaceutical GMPs
- Experience in the manufacturing processes for foods or dietary supplements
- Successful completion of training in the NNFA GMPs

Auditors are responsible for all phases of the audits, including completion of the audit checklist, the audit report, follow-up on corrective actions, and any secondary audits.

A fee will be charged for the audit according to fee schedules submitted by the auditing companies. There will be additional charges to cover the auditor's travel and lodging expenses; these expenses are to be determined by the company and auditing company in advance of the audit.

Communication will occur directly between the auditing company and the member supplier during all aspects of the auditing process following guidelines developed by NNFA. Any disputes that cannot be resolved within these guidelines shall be referred to the GMP Advisory Committee for resolution.

Performance Rating System:
The levels of compliance are as follows:
A. A member supplier has excellent compliance with NNFA GMPs, with few deficiencies noted
B. A member supplier has good compliance with NNFA GMPs, but several significant deficiencies were noted
C. A member supplier has fair or poor compliance with NNFA GMPs, many deficiencies noted; a re-audit of the facility required

The compliance ratings determine need for corrective actions and follow-up inspections. Member suppliers earning an "A" rating may immediately apply to NNFA for certification and the right to use the NNFA GMP seal. Member suppliers earning a "B" rating may apply to NNFA for certification and use of the seal once there is written verification that the outstanding deficiencies have been corrected. Member suppliers earning a "C" rating may apply to the NNFA for certification and use of the seal after successful completion of a second audit and once there is written verification that outstanding deficiencies have been corrected.

Appeal Procedure:
A member supplier has the ability to appeal an assigned compliance rating. The

appeal must be in writing and must address each of the deficiencies and the reasons for the appeal. The written appeal must be submitted directly the GMP Advisory Committee c/o NNFA along with the required appeal fees.

The GMP Advisory Committee will review the appeal within 30 working days and attempt to resolve the issue through discussion with the member supplier and auditing company. If this is not possible, a site visitation will be arranged.

The Advisory Committee's review of any appeal is contingent upon prior payment of a fee to offset the expenses associated with appeal process.

Certification Procedure:
Once a member company has documented compliance with NNFA GMPs, they may apply to NNFA for certification and the right to use the GMP seal. The application will be reviewed together with the audit and corrective action reports. Upon successful completion of certification, the official NNFA GMP seal may be used on the member supplier's labels, marketing and advertisements. Certification will be valid for a period of no more than three years from the date of the award.

Note: To obtain certification, a member company must be audited under the NNFA audit process described above. Compliance with other programs (e.g., ISO) will not be accepted as a substitute for the NNFA audit process.

Fees:
The certification program is self-funded through the assessment of fees for services rendered. Fees will be of three types: a. Registration fees: $100, includes all materials and referral to approved auditors. b. Certification and Use of Seal fees: $500, initial certification; $100, annual maintenance. (Member suppliers will be assessed a fee to offset the cost of certification, including review of the application, the issuance of the certification and seal, and maintenance of the database) c. Appeal fee: $500, possibility of additional charges to cover any additional time or expenses incurred to resolve dispute.

National Nutritional Foods Association
BSE GUIDANCE MANUAL

Background

First diagnosed in 1986 in Great Britain, bovine spongiform encephalopathy (BSE), widely known as "mad cow disease," is a neurological disease affecting the central nervous system of cattle. BSE is classified as a transmissible spongiform encephalopathy (TSE). Other TSE's include scrapie in sheep and goats, chronic wasting disease of deer and elk, and Creutzfeldt-Jacob disease (CJD) in humans. Prions are aberrant proteins believed to cause the TSE's. Prions are not viruses, bacteria, fungi or other known pathogen and are resistant to enzymatic breakdown within the body. In humans, for categorization purposes, it is important to distinguish between classical CJD and new variant CJD (nvCJD). Classical CJD occurs in about one person per million per year and was around long before the emergence of BSE in cattle, occurring spontaneously via inheritance or accidentally as a result of medical procedures.[1,2,3] New variant CJD is directly linked to the consumption of meat/bone meal from BSE-infected cattle.

BSE is not known to exist in the United States. Though about 95 percent of all BSE cases have occurred in the United Kingdom, the disease also has been confirmed in native-born cattle in other European countries such as Belgium, France, Germany, Spain, and Switzerland. New cases of BSE in the U.K. peaked at 36,680 in 1992 and with active feed security measures, fewer than 1,500 cases were confirmed in 2000. Among humans, the total worldwide number of known nvCJD cases is 92, including 88 in the UK, three in France and one in Ireland.[2,4] NNFA has no knowledge of evidence linking these cases to dietary supplements.

There have been NO cases of the new variant CJD (nvCJD) in humans, nor of BSE among cattle, found in the United States.[2,4] The US has had BSE-surveillance programs for over a decade to prevent BSE in cattle or nvCJD in humans from occurring in this country. Working together, agencies within the federal government have taken numerous steps to prevent BSE in this country. The USDA's Animal and Plant Health Inspection Service (APHIS) enforces explicit regulations preventing importation of animal protein products, regardless of species, from BSE countries. The Centers for Disease Control and Prevention (CDC) conducts surveillance for CJD through examination of death certificate data for U.S. residents. This information is shared with the Food and Drug Administration (FDA), Food Safety and Inspection Service (FSIS), the National Institutes of Health (NIH), and stakeholders.[2,4] In addition, the American Association of Neuropathologists has established a National Prion Disease Pathology Surveillance Center at Case Western Reserve University and has actively been looking for nvCJD since 1994. No cases of nvCJD have been found.

FDA has stated that the BSE issue is a food issue, not specific to dietary supplements. However, manufacturers of dietary supplements that include bovine-derived materials must ensure they follow appropriate quality-control measures. Currently, there are no tests to identify prions in foods, raw materials or finished products, thus prevention is the necessary approach to minimizing risk.[3] FDA has identified three priorities in its approach to surveillance; 1) ensuring the sources of bovine-derived raw materials/products are from BSE-free countries, 2) ensuring manufacturers and importers are maintaining adequate documentation/paper trail that bovine-derived materials/products did not originate from a BSE-infected country or herd, and 3) prevention of contamination/adulteration and co-mingling of raw materials.

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[1] Prusiner, SB. The prion diseases. Scientific American 1995; 272: 48-57

[2] BSE: Background, Current Concerns, and U.S. Response *from* FDA available at their Web site: http://www.fda.gov/opacom/backgrounders/bse.html

[3] Trying to Keep "Mad Cow Disease" Out of U.S. Herds, FDA Consumer magazine (March-April 2001) available at their Web site at http://www.fda.gov/fdac/features/2001/201_cow.html

[4] HHS Fact Sheet *from* U.S. Department of Health and Human Service (February 5, 2001) available at their Web site: http://www.hhs.gov/news/press/2001pres/01fsbse.html

To assist manufacturers and importers of bovine-derived materials in developing their quality control plans, FDA has provided the following guidance in its Import Alert IA1704[5]:

a. *To ensure that bovine-derived materials (listed in IA1704 appendix A) used in the product(s) are from non-BSE-countries, identify all countries where the animals used were born, raised or slaughtered. The supplier of the bovine-derived materials should provide the necessary records.*
b. *Maintain traceable records for each lot of bovine-derived material and records of products containing the materials.*
c. *Maintain records for those products manufactured at foreign sites or by foreign manufacturers which contain bovine-derived materials.*

Manufacturing

Because there is no developed detection method of the causative agent of spongiform encephalopathy, it becomes of paramount importance for manufacturers to choose raw materials in a manner that will minimize the risk of transmission. These guidelines are provided to assist manufacturers in developing and documenting systems for minimizing that risk.

Where manufacturers have a choice to use ruminant or non-ruminant material, the use of non-ruminant material is preferred. Therefore, manufacturers must collect as much information as possible about the source material. The manufacturer should audit the supplier of these materials to ensure that they are sourced and handled in conformity with this guidance and appropriate quality control systems.

In gathering information, manufacturers should be cognizant of the parameters that are useful in determining the risk of contamination of source materials. The risk of transmission of infectious agents can be greatly reduced, then, by controlling a number of these parameters. These parameters include,

- Source of animals
- Nature of animal tissue used in manufacture
- Production process (es)

No single approach will necessarily establish the safety of a product and therefore the three approaches cited above may need to be complementary to each other for minimizing the risk of contamination.

The European Union has been a leader in developing resource materials that can aid a manufacturer in assessing the relevant parameters used to control contamination of source material.[6] A number of these publications and their availability are listed in the footnote.

Another guide to developing the appropriate investigation scheme comes from Health Canada in a request to Canadian Establishment License Holders in which questions were asked regarding actions taken to minimize risks of transmission of spongiform encephalopathy including an assessment of how the material is used by the manufacturer. The following is a list of those questions:

- Type of animal-derived materials used in production;
- Origin of the material (e.g., bovine, ovine, cervine);
- Country of original source of material (country from where the animals originated);
- Source of the material (primary manufacturer of the material);
- Supplier of the material (if different from the manufacturer);

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[5] Import Alert IA1704 *from* FDA available at their Web site at http://www.fda.gov/ora/fiars/ora_import_ia1704.html

[6] Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents Via Medicinal Products *from* the Committee on Proprietary Medicinal Products (EMEA/410/01 – FINAL) available at their website: http://www.eudra.org/humandocs Also, the Office International Des Epizooties (OIE) most recent version of the OIE International Animal Health Code, Chapter 2.3.13 on *Bovine Spongiform Encephalopathy* contains information on assessing BSE-free herds.

- Brief description of how the material is used in the manufacturing process or added to the final formulation (e.g. fermentation reagent, stabilizer);
- The level at which the material is present in the final product.

To assist in evaluating animal-derived source materials, the organs used by the manufacturers of source materials have been classified as to the level of infection that might be expected in each, were the animal diseased. (e.g., FDA Category i, high infectivity: brain, spinal cord.[7]) Both the European Union and the US FDA have developed classification schemes.[8]

In addition to the publications and above listed points to consider, the FDA recommends that information regarding animal origin, source material manufacturing, and use in dietary supplements be documented and that manufacturers retain those documents for possible review by the agency.

For those manufacturers who may also rely on processing to inactivate the agents responsible for the spongiform encephalopathy infection those processes should be appropriately and adequately validated. There are several publications generated by the European Union that can provide guidance on adequate process validations.[9] Again, all of the validation studies should be carried out under a well-defined protocol and all results documented.

In summary, this guidance offers only an introduction to development of individual procedures manufacturers will use for minimizing risks of spongiform encephalopathy transmission. Because there are many more details associated with a thorough evaluation of source materials, NNFA encourages its members at a minimum to very carefully consider and completely review all materials cited in this guidance before writing the standard procedure. After the procedure is established, then very carefully begin the assessment and documentation of each point.

Ingredient Sourcing

In order to comply with the FDA's recommendation to control the use of bovine-derived ingredients, including excipients and processing aids, that are sourced from animals born, raised, or slaughtered in specific BSE countries, manufacturers must develop quality controls throughout the company to eliminate such ingredients from being used in dietary supplements.

The Purchasing Department plays an essential role in assuring that the requirements established by the Quality Department are strictly followed. Standard Operating Procedures (SOP), supplier surveys, supplier audits, and a supplier certification program should be used to minimize the potential risk of BSE exposure in humans.

When developing purchasing procedures, supplier surveys and supplier audit checklists, the following should be considered and/or included:

- The name, the complete address and telephone number of the supplier.
- The name, title and phone number of the supplier contact person.
- The materials, including part numbers, considered for purchase.
- Bovine materials are to be obtained from countries which have a surveillance system for bovine spongiform encephalopathy (BSE) in place and which report zero cases of BSE.
- A certificate stating bovine materials are from as BSE-free country must accompany the material.
- No neurological bovine materials should be purchased or accepted.
- Reference to the specifications and other pertinent documents applicable to the materials considered for purchase.

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[7] Import Alert IA1704 *from* FDA available at their Web site at http://www.fda.gov/ora/fiars/ora_import_ia1704.html

[8] The European Union classification scheme is found in the EMEA/410/01 Note For Guidance, and the US FDA classification scheme comes from WHO Consultation on Public Health Issues Related to Animal and Human Spongiform Encephalopathies, World Health Organization, Office of International Epizootics, Geneva, Switzerland, November 12-14, 1991.

[9] The EMEA/410/of Note For Guidance

- A request for a statement from the supplier regarding his ability to comply with applicable regulatory requirements, such as GMP or ISO-9000 requirements.
- A request for a statement from the supplier regarding his manufacturing and quality control capabilities pertinent to the materials to be purchased.
- The signature and date that a responsible supplier company officer certifies that all statements made on the Supplier Survey form are accurate and complete.
- Purchasing is responsible for assuring, by means of complete documentation, that every supplier is currently certified to provide all materials, being purchased from that supplier.

Prior to qualifying vendors, companies should establish internal control parameters for setting raw material specifications. The following should be considered when developing specifications for any new raw materials:

- Does the product originate from animal sources or is any materials from animal origin used in the manufacture of the product?
- If "Yes," companies should list the relevant substances, detailing which animal species and which organ/tissues are involved for each substance.
- If "Yes," is the raw material bovine derived?
- If "Yes," companies should consider the internal quality control measures and documentation, such as those addressed in this QA guidance, required to minimize the risk of exposure to BSE diseases through contaminated materials.

NOTICE

By furnishing this guidance, NNFA does not provide any opinion as to:

- The safety of any product containing any ingredient;
- The efficacy of any product containing any ingredient;
- The use of any specific brand of product; or
- The level of substantiation for either the safety or efficacy of any such product.

Neither this guidance, nor any portion of this guidance, may be used in advertising or promotional materials. In addition, this guidance does not constitute, and is not to be used as, "third party literature" as that term is used in connection with section 5 of the Dietary Supplement Health and Education Act (DSHEA).

As with any health-related product, consumers should discuss the use of any products with a health care practitioner.

Sample Standard Operating Procedure

Title: Documentation for Ruminant Derived Products Effective Date:	Supersedes:	Page ___of ___

1. **PURPOSE:** To insure the safety of all ruminant sourced ingredients* through lot specific documentation. Transmittable Spongiform encephalopathy (TSE) found in bovine, cervine and ovine species is closely related to a new variant Creutzfeld-Jakob disease found in humans. This procedure establishes a paper trail to insure that ingredients of this type are from approved FDA/USDA countries and have been documented to be disease free.
   * Cosmetics are exempt.

2. **SCOPE**: All raw materials and finished bulk products derived solely or in part from ruminant derived sources.

3. **RESPONSIBILITY**: Quality Control

4. **DEFINITIONS**:
   A. Bovine: Cow
   B. Ovine: Sheep
   C. Cervine: Deer
   D. Creutzfeldt-Jakob disease: A brain wasting disease in humans similar to encphalopathies found in sheep, cows and deer.
   E. BSE (Bovine Spongiform Encephalopathy): A brain disease found in cows.
   F. encephalopathy: A disease of the brain

5. **FREQUENCY**: All incoming materials

6. **PROCEDURE**:
   A. Quality Control will maintain a current list of all non-exempt ruminant sourced materials used by (Company Name) and countries known to be affected by BSE and other related diseases
   B. Upon receipt of incoming goods, Quality Control will identify those raw materials and bulk finished products either solely or in part derived from non-exempt animal sources.
   C. During the inspection process, Quality Control will verify that the origin of these materials are from approved countries and substantiate they are from disease free sources through the certificate of analysis and/or other related documentation.
   D. Any material that falls into this category and whose origin is unknown or lacks the appropriate substantiation will be quarantined until such verification can be established.
   E. Materials failing to meet these criteria will be rejected.

7. **SAFETY**:

8. **ATTACHMENTS**:

9. **REFERENCES**:

10. **APPROVALS**

Prepared By:	Dept/Title:	Date:
Approved By:	Dept/Title:	Date:
Approved By:	Dept/Title:	Date:

Dietary Supplements and Mad Cow Disease

Q. Are there strict import regulations that are designed to prevent the import of ingredients contaminated with BSE that may be used in pharmaceuticals, foods and dietary supplements?

A. Yes. Dietary supplements are a subcategory of foods, and the import alerts and guidance documents on BSE apply equally to bovine ingredients used in conventional foods or in dietary supplements, as well as to bovine ingredients used in pharmaceuticals. For example, gelatin, is usually made from beef bones and is commonly used as an ingredient in conventional foods, dietary supplements, cosmetics and pharmaceuticals.

Q. What about gelatin?

A. The Food and Drug Administration issued a guidance document in 1997 describing appropriate source materials for gelatin products and gelatin manufacturers are required to comply with those guidelines. Gelatin is obtained from the bones and hides of beef and/or pork. The source materials are extracted under severe acid conditions for a period of days or under strong alkaline conditions for a period of weeks, and are then flash-sterilized with high heat.

Q. What are supplement manufacturers doing to be certain they are not receiving raw or finished materials that could be contaminated with BSE?

A. Currently, the only way that BSE can be diagnosed is through the brain autopsy of cattle; testing of glandular or other bovine-derived products is not yet possible. This is why it is critical for manufacturers to know and verify the sources of product ingredients derived from cows. In surveying our members, here's what we've found: Suppliers are getting their glandular products from only one source who is well-known to them; they are using only domestic cattle as sources; they require certificates indicating that the product is BSE-free.

Q. Should there be concern about glucosamine or chondroitin being contaminated with BSE?

A. Chondroitin does not come from neurological or glandular tissue, but is obtained from cartilage – specifically the trachea, which does not appear on the FDA's list of bovine tissues that may present a risk. There are domestic (U.S.) suppliers of chondroitin. There are also importers of this ingredient, who are required by the import alert to obtain their ingredients only from non-BSE countries, with appropriate documentation of the health of the animals as well as the country of origin. The processing of cartilage to extract chondroitin involves rigorous heat and chemical treatments. Chondroitin is frequently combined with Glucosamine, which is obtained entirely from shellfish and not from a bovine source.

Q. What countries do these ingredients come from?

A. In surveys of our membership, we are finding that most manufacturers are using only domestic (U.S.) sources. Those that do import bovine derived ingredients, do so from countries not identified as at-risk for BSE.

Q. What procedures are in place by FDA?

A. The FDA has kept the dietary supplement industry informed about BSE and advised through letters and guidance documents of appropriate precautionary measures to ensure dietary supplements are

BSE-free. Since 1992, manufacturers of FDA-regulated products have not been allowed to use materials that originate in BSE-countries. Since then, the FDA has issued three additional advisories, including the latest as recent as November of last year.

Q. One expert was quoted as saying that more than 50 percent of dietary supplements contain ingredients that could be contaminated with BSE. Is that true?

A. Contrary to some reports that suggest a large number of dietary supplements contain ingredients derived from animal glands or organs, such products – sometimes called "glandulars" – actually account for less than 0.4 percent of the market. More than 99 percent of sales are of vitamins, minerals, herbs or botanicals, sports nutrition products, meal supplements and specialty products that do not contain glandular ingredients.

Q. Is it true that you can find raw, ground-up brains and other organs in dietary supplement products?

A. First of all, organ products used in dietary supplements are not "raw," but are extensively processed. These ingredients are typically ground, heated, dried, defatted and powdered to remove water content, kill microorganisms and permit tableting of the material.

Organ meats, such as liver, are commonly consumed as conventional foods, and liver may also be used as a dietary supplement ingredient. Other organs, such as the pancreas provide the source of pharmaceutical enzymes such as pancreatin and may also be used as dietary supplement ingredients. Animal tissue such as brain, thymus (sweetbreads) and testicles (Rocky Mountain oysters) are consumed as foods and sometimes in glandular dietary supplements. USDA has issued no guidance against the use of such tissues, provided they are derived from health animals from non-BSE countries.

Mr. BURTON. Thank you, Mr. Seckman.

Mr. Blumenthal.

Mr. BLUMENTHAL. Good afternoon, Mr. Chairman, members of the committee.

Thank you for the opportunity to offer my testimony in the area of regulation of herbs, phytomedicines and related botanically derived products. I'm the founder and executive director of the American Botanical Council [ABC], an independent, non-profit research organization located in Austin, TX. We were founded in 1988 by a group of medicinal plant scientific experts.

At present, ABC's trustees and advisory board members represent 48 scientists, clinicians and other experts with extensive experience in the areas of the various sciences related to medicinal plants. Our members and readers represent thousands of consumers, industry members and scientists in the United States and abroad.

Throughout its history, ABC has been a leader in advocating sound, sensible, rational regulation of herbal products, plus truth and honesty in labeling, appropriate GMPs, as well as scientific research and public education on the various benefits and potential risks of these products. As part of our educational efforts, we have published HerbalGram, an acclaimed medicinal plant journal, plus books for health care professionals.

We are gratified by the positive reception our first book received from the medical community. This book, "The Complete German Commission E Monographs—Therapeutic Guide to Herbal Medicines," was ranked second of all medical books published in 1998. We believe this to be a strong indicator of the need by health care professionals for accurate, reliable and responsible information on herbs and related preparations. I have provided extensive materials from this book for the committee.

ABC believes that more information about the responsible use of dietary supplements for consumers and health care professionals is desirable so long as it is truthful and based on reasonable levels of scientific evidence. To that end, we have also been leaders in the area of providing third party literature on herbal supplements as provided for in section 5 of DSHEA, with almost 5 million copies of one of our herbal education brochures in print. I've also provided one of those for the committee.

ABC also believes that as much information should be available to consumers on the labels of herbal products, including information that deals with the therapeutic action, that is, the prevention or treatment of disease, of these ingredients when there is appropriate evidence to support such a claim. Regarding the Commission E Monographs from Germany, ABC translated, edited and published them for two primary reasons. One, to provide accurate, reliable information to health care professionals and the general public about the risks and benefits of herbs, and second, to serve as a model for regulatory reform in the area of recognizing the therapeutic aspects of herbal products.

Now, we are often asked, why Germany? Germany has been the world leader in the development of high quality herbal and phytomedicinal products, and has been a leader in the publication of clinical studies documenting the benefits of herbal preparations.

The development of this situation is not accidental, and is due in part to the rational system of regulation in Germany. Herbal materials used in non-prescription medicines must meet strict quality requirements as established by the German Pharmacopoeia.

Second, herbs are evaluated by the Commission E, a panel of experts appointed by the German counterpart of the FDA. These experts review all the available evidence to assess the safety and efficacy of these herbs. The Commission's findings are published as monographs in German, in the German equivalent to the Federal Register, and are printed as package inserts for herbal drug products over there herbal dietary products over here. This includes dosage, indications, but most importantly, the government approved uses.

The Commission used a "doctrine of reasonable certainty" in establishing its conclusions about efficacy and was more conservative in assessing safety. We believe it is imperative to recognize that much of the concern about safety of herbal products in the United States, while sometimes warranted, is often exaggerated, because occasional reports of adverse reactions are not countervailed with an officially recognized benefit. We believe that herbs should be reviewed for their benefits and potential risks, that this evaluation should be rational and appropriate to these products and their uses, as has been conducted in Germany.

We also believe that the current system for the evaluation of OTC drugs is not workable for most herbal products, thus requiring the addition of a Commission E type system to be established. Further, ABC still supports maintaining the dietary supplement status of herbs and related products, with the ability to make structure/function claims under DSHEA.

Reliable information is the key to responsible use of these products. It is important that consumers and health care professionals understand that there is a growing body of impressive scientific evidence based on clinical studies that supports the rational uses of herbs and phytomedicines. ABC is working to help professionals answer the growing number of questions that consumers ask their doctors and pharmacists.

To this end, ABC is currently completing a new set of monographs on the therapeutics of 30 leading herbs in the marketplace to be published as continuing medical education for health care professionals. This project is being accredited by the Texas Medical Association, the Texas Nurses Association, the College of Pharmacy at the University of Texas of Austin, and the American Dietetic Association.

ABC seeks and invites full collaborations with Government bodies, such as the Office of Dietary Supplements and organizations in the areas of professional and public education on herbs. We support the role and mission of ODS as an advisor to the Federal Government on health benefits of herbs and other dietary supplements.

ABC also supports the mission of the FDA in regulating the quality, safety and benefits of dietary supplements. We also support the need for FDA to enforce existing regulations regarding the manufacture and labeling of supplement products and the appropriateness of their structure/function claims. We believe the time is right to consider ways to expand the possibilities for labeling of

therapeutic information on herbal products and we look forward to working with all interested parties to help increase public and professional information in this area.

I thank you for this opportunity to present our views.

[The prepared statement of Mr. Blumenthal follows:]

Evaluating the Safety and Efficacy of Herbs and Phytomedicines

Mark Blumenthal
Founder, Executive Director
American Botanical Council
Austin, Texas
Editor, *HerbalGram*

testimony before the
House Government Reform Committee
March 20, 2001

Mr. Chairman and Members of the Committee:

Thank you for the opportunity to offer my testimony in the area of the regulation of herbs, phytomedicines, and related botanically-derived products.

To introduce myself, I am the founder and executive director of the American Botanical Council (ABC), an independent nonprofit research organization in Austin, Texas. We were founded in 1988 by a group of leading medicinal plant scientific experts. At present, ABC's Trustees and Scientific Advisory Board represents 48 scientists, clinicians and other experts with extensive experience in the areas of the various sciences related to medicinal plants.

Throughout its 12-year history ABC has been a leader in advocating sound, sensible, rational regulations of herbal products, plus truth and honesty in labeling, appropriate good manufacturing practices, as well as scientific research and public education on the various benefits and potential risks of these products.

As part of our educational efforts we have published *HerbalGram*, an acclaimed medicinal plant journal, plus books for healthcare professionals. We are gratified of the positive reception our first book received in the medical community. This book, *The Complete German Commission E Monographs –Therapeutic Guide to Herbal Medicines*,

was ranked second of all medical books published in 1998. This is a strong indicator of the need by health professionals for accurate, reliable, responsible information on herbs and related preparations. We also published a sequel (*Herbal Medicine: Expanded Commission E Monographs*) with updated information on recent research.

ABC believes that more information about the responsible use of dietary supplements for consumers and health care professionals is desirable so long as it is truthful and based on reasonable levels of scientific evidence. To that end, we also have been leaders in the area of providing so-called "third party literature" on herbal supplements as provided for in Section 5 of DSHEA, with almost five million copies of one of our herbal education brochures in having been printed.

ABC also believes that as much information should be available to consumers on the labels of herbal products, including information that deals with the therapeutic actions (i.e., the prevention or treatment of a disease or condition) of the ingredient(s), when there is appropriate evidence to support such a claim.

Regarding the Commission E monographs, ABC translated, edited and published them for two primary reasons:

1. To provide accurate, reliable information for healthcare professionals and the general public about the risks and benefits of herbs, and
2. To serve as a model for regulatory reform in the area of recognizing the therapeutic aspects of herbal products.

We are often asked, why Germany?

Germany has been the world leader in the development of high quality herb and phytomedicinal products and has been the leader in the publication of clinical studies documenting the benefits of herbal preparations. German physicians routinely study the use of herbs in medical school and prescribe herb preparations as part of standard clinical practice. Herb products constitute roughly one-third of all nonprescription medicines sold in German pharmacies. One half of these herbs are self-selected by consumers; half are prescribed by physicians.

The development of this situation is not accidental and is due in part to the rational system of regulation in Germany. Herbal materials used in nonprescription medicines must meet strict quality requirements as established by the German Pharmacopeia. Second, herbs are evaluated by the Commission E, the panel of experts appointed by the German counterpart of our FDA. These experts review all the available bibliographic evidence to assess the safety and efficacy of these herbs. The Commission's findings are published as monographs in the German equivalent to the *Federal Register* and are printed as package inserts for herbal products. These include government-approved use(s), proper dosage, contraindications, side effects, drug interactions, duration of use and any other data to help ensure responsible use.

The Commission E evaluated approximately 300 herbs, positively approving 254 herbs and herb combinations while 126 herbs and their combinations were not approved because adequate information to document their use was lacking or because the herb was considered too toxic for general use. The Commission used a *doctrine of reasonable certainty* in establishing its conclusions about efficacy and was more conservative in assessing safety.

Much of the concern about safety of herbal products in the U.S., while sometimes warranted, is often exaggerated because occasional reports of adverse reactions are not countervailed with an officially recognized benefit. We believe that herbs should be reviewed for their benefits and potential risks, but that this evaluation should be rational and appropriate to these products and their uses, as has been conducted in Germany.

We also believe that the current system for the evaluation of over-the-counter drugs is not workable for most herbal products, thus requiring the addition of a Commission E-type system. Further, ABC still supports maintaining the dietary supplement status of herbs and related products with the ability to make structure/function claims under DSHEA.

DSHEA was a solution for a regulatory problem. Now one of the main challenges is to fill in the framework for education of health professionals and consumers. Reliable information is the key to the responsible use of these products. It is important that health professionals understand that there is a growing body of impressive scientific evidence based on clinical studies (of various sizes, duration and design) that supports the rational use of herbs and phytomedicines. ABC is working to help professionals to answer the growing number of questions by consumers to their doctors and pharmacists.

To this end, ABC is currently completing a new set of monographs on the therapeutics of 30 leading herbs for continuing medical education for health professionals. This project is accredited by the Texas Medical Association, Texas Nurses Association, College of Pharmacy at the University of Texas at Austin, and the American Dietetic Association.

ABC seeks and invites useful collaborations with government bodies such as the Office of Dietary Supplements and, professional organizations in the areas of professional and public education on herbs. We support the role and mission of ODS as an advisor to the federal government on the health benefits of herbs and other dietary supplements.

ABC also supports the mission of the FDA in regulating the quality, safety, and benefits of dietary supplements. We also support the need for FDA to enforce existing regulations regarding the manufacture and labeling of supplement products and the appropriateness of their structure/function claims.

We believe that the time is right to consider ways to expand the possibilities for labeling of therapeutic information on herbal products and we look forward to working with all interested parties to help increase public and professional information in this area.

I thank you for this opportunity to present our views.

Mr. BURTON. Thank you, Mr. Blumenthal.

Mr. Riedel.

Mr. RIEDEL. Thank you, Mr. Chairman, Mr. Tierney and members of the committee. I appreciate this opportunity to represent not only my company, Nature's Life, which is a 30 year old family owned company in southern California, we sell to all 50 States plus about a dozen foreign countries, as well as the National Nutritional Foods Association, for which I have done different international regulatory efforts, including CODEX Alimentarius work for the last several years.

CODEX Alimentarius, and I want to thank you, Mr. Chairman, for so eloquently recapping what they do, stands for food law. They do involve 165 different countries currently participating in CODEX. It has two simple mandates: No. 1, to improve food safety by developing standards; and No. 2, to enhance international food trade by global acceptance of those standards. It is the world's premier international standard setting body for foods, and also for vitamin and mineral supplements, and is codified in several international trade agreements to which the United States is a signatory.

When CODEX standards are published, the United States has committed to evaluate these new standards against current U.S. laws and regulations and through normal rulemaking, make revisions as appropriate. The primary goal of this process, commonly called harmonization, is to enhance the international trade by making the regulations of different trading countries more similar, thus reducing technical barriers to trade.

CODEX has been discussing guidelines for the definition, safety and labeling of vitamin and mineral supplements since 1993 in detail. The 48 page presentation I have provides background, history, procedures and the current issues relating to CODEX, which is for your reference. Also some more detailed recommendations for you.

In terms of the current issues, the United States, along with a very few other countries, enjoys relatively unrestricted availability to a wide range of dietary supplements. This important health freedom was successfully championed by Congress as the DSHEA in 1994. Most countries around the world, however, regulate any dietary supplement as a drug if it contains ingredients other than essential nutrients or nutrient amounts in excess of the nominal RDA levels.

The current CODEX drafts for dietary supplement standards are much more restrictive than current U.S. law because of the restrictive mind set of many of the CODEX participants from other countries. Some U.S. consumers mistakenly believe that, if this draft becomes an approved CODEX standard that it will automatically become a U.S. regulation, thus restricting the availability of supplements here in the United States. This concern is unfounded and virtually impossible under current U.S. law, both because of the CODEX acceptance procedure and because of the protections that Congress added through the FDA Modernization Act.

Another concern, if the restrictive CODEX standards are approved, however, is the U.S. dietary supplement suppliers will be severely hampered in their ability to export and sell supplements in other countries. This means that not only incomes and jobs here

in the United States will be eliminated or reduced but also that health consumers in other countries will not have the same health freedom of choice that we enjoy here. This concern is not only real, but likely.

The solutions that I recommend to Congress, No. 1, continue the active participation in CODEX by U.S. delegates in all the committees, but with two caveats. No. 1, much more aggressive advocacy of DSHEA by U.S. delegates in all the CODEX committees, specifically the nutrition committee and food labeling committee, to ensure that the CODEX standards adequately provide for consumer health freedoms, and No. 2, much more monitoring and intervention, specifically attending meetings by Department of Commerce and U.S. Trade Representatives to ensure that the CODEX standards liberalize and do not restrict international trade and dietary supplements.

Finally, the U.S. CODEX office, although they are doing a very good job, I believe, the comprehensive annual report to Congress on all U.S. CODEX activity should be expanded to include all the new standards that have been approved by CODEX, including all new work authorized, the form of acceptance of all of these CODEX standards, and the potential implications of each new and developing standard, so that you are better informed and able to make decisions and supervise the work of the U.S. CODEX office. Also to upgrade their Web site to include all that current information on CODEX.

CODEX is an 800 pound gorilla. We can't ignore it, we don't always like what it does, we can't always control it, but we do need to continue working with it.

Thank you very much, Mr. Chairman.

[The prepared statement of Mr. Riedel follows:]

House Government Reform Committee
Dietary Supplement Hearing 03/20/01
Codex Alimentarius Executive Summary
Testimony of Karl Riedel – Nature's Life

The Topic:

Codex Alimentarius (Food Law) is a Joint Food Safety Program of the United Nation's Food & Agriculture and World Health Organizations, active since 1961 with 165 countries currently participating. Its mandates are to improve food safety by developing standards, and to enhance international food trade by global acceptance of those standards. It is the world's primary international standards setting body for foods (and vitamin/mineral supplements), and is codified in several international trade agreements to which the US is a signatory.

When Codex standards are published, the US has committed to evaluate new Codex standards against current US laws and regulations, and through normal rule-making, make revisions as appropriate. The primary goal of this process, commonly called harmonization, is to enhance international trade by making the regulations of different trading countries MORE similar – thus reducing technical barriers to trade. Codex has been discussing guidelines for the definition, safety and labeling of vitamin and mineral supplements since 1993.

The Issues:

US consumers, along with those from a very few other countries, enjoy relatively unrestricted availability to a wide range of dietary supplements. This important health freedom was successfully championed by Congress in the Dietary Supplements Health & Education Act of 1994 (DSHEA). Most countries around the world, however, regulate any dietary supplement as a drug if it contains ingredients other than essential nutrients, or nutrient amounts in excess of nominal RDA levels.

Current Codex drafts for dietary supplement standards are much more restrictive than current US law, because of the restrictive mind-set of many Codex participants. Some US consumers mistakenly believe that, if these draft become approved Codex standards, that they will automatically become US standards, thus restricting their current availability here in the US. This concern is unfounded and virtually impossible under current US law.

Another concern, if restrictive Codex standards are approved, is that US dietary supplements suppliers will be severely hampered in their ability to export and sell supplements in other countries. This means not only incomes and jobs in the US will be eliminated or reduced, but also that health conscious consumers in other countries will lose their health freedom of choice. This concern is not only real, but also likely.

The Solutions:

#1. Support continued active participation in Codex by US**, but** with:

- more aggressive advocacy of the D.S.H.E.A. model by US delegates to ensure Codex standards provide for adequate consumer health freedoms
- more monitoring and intervention by DOC & USTR to ensure Codex standards liberalize, and not restrict international trade in dietary supplements

#2. Support a more pro-active and public role for the US Codex Office by ensuring that they:

- present a comprehensive annual report to congress on all US Codex activity, including all new standards approved, all new work authorized, the Form of Acceptance by the US of all new standards, and the potential implications of each new and developing standard
- upgrading the US Codex Office website to include all current Codex standards, and the Forms of Acceptance of all approved Codex standards

U.S. House of Representatives
Government Reform Committee
Dietary Supplements Hearing
March 20, 2001
Testimony of Karl Riedel, Representing

NATURE'S LIFE

NNA
National Nutritional Foods Association

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Congressional Considerations

- #1 - Continue supporting Codex participation– government + industry and consumers NGOs
- #2 – Continue protecting US industry & consumers against restrictive Codex standards

#3 – Ensure US Delegates strongly advocate D.S.H.E.A. health freedoms in Codex

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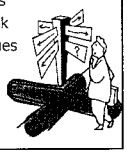

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United Nations
Joint FAO/WHO
Food Safety Program
2001 Update

FAO/WHO Food Standards - Normes Alimentaires FAO/OMS - Normas Alimentarias FAO/OMS

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CODEX ALIMENTARIUS COMMISSION DEFINITION

Authoritative inter-governmental organization mandated to develop international guidelines

- To protect consumer health and safety
- To ensure fair practices in food trade

Dietary Supplements <u>are</u> food

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CODEX ALIMENTARIUS COMMISSION FUNCTION

- <u>Inclusionary</u>
  - 165 governments
- <u>Voluntary</u>
  - attendance & participation
- <u>Periodic</u>
  - CAC Bi-Annually, Committees Annually
- <u>Worldwide</u>
  - CAC in Rome & Geneva, committees Global
- <u>Modus Operandi</u>
  - Consensual, Democratic and multi-lingual

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CODEX ALIMENTARIUS COMMISSION PARTICIPANTS

- Government Delegates
  (Health & Agricultural Officials)
- Non-Governmental Organizations
  (Industry & Consumer)
- FAO-WHO Staff

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U.S. CODEX ALIMENTARIUS COORDINATING COMMITTEE

Department of Agriculture:	16
Health & Human Services:	8
Department of Commerce:	3
U.S. Trade Representative:	2
Department of State:	2
Environmental Protection:	1
U.S. Codex Office Staff:	2

(See Appendix 1 for complete membership list)

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CODEX ALIMENTARIUS COMMISSION HISTORY

- 1945 - United Nations Founded
- 1948 - FAO & WHO Founded
- 1949 > 1954 - Argentina & Austria each propose regional Codex Alimentarii
- 1950 > 1960 - Various Joint FAO/WHO Food & Nutrition conferences held
- 1961 > 1962 - Codex Alimentarius Statutes adopted by FAO/WHO

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CODEX ALIMENTARIUS COMMISSION
International Agreements

- General Agreement on Trade & Tariffs (GATT)
- Agreement on the Application of Sanitary & PhytoSanitary Measures (SPS)
- Agreement on Technical Barriers to Trade (TBT)
- 1994 Uruguay Round Agreements establishing the World Trade Organization (WTO)
- Regional Agreements: MERCOSOUR, NAFTA, ANZFA, APEC
- All embody Codex as Standards Setter

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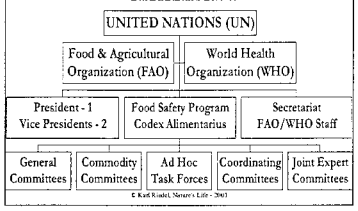
CODEX ALIMENTARIUS COMMISSION
HEIRARCHY



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CODEX ALIMENTARIUS COMMISSION
COORDINATING COMMITTEES

Africa (CCAFRICA) - Uganda
Asia (CCASIS) - Thailand
Europe (CCEURO) - Spain
Latin America & Caribbean (CCLAC) – Dominican Rep.
Middle East (CCME) - Saudi Arabia
North America & SW Pacific (CCNAP) – Australia

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CODEX ALIMENTARIUS COMMISSION GENERAL COMMITTEES

General Principles (CCGP) - France
Nutrition & Foods For Special Dietary Use (CCNFSDU) - Germany
Food Labelling (CCFL) - Canada
Food Additives & Contaminants (CCFAC) - Netherlands
Methods of Analysis & Sampling (CCMAS) - Hungary
Pesticide Residues (CCPR) - Netherlands
Food Hygiene (CCFH) - United States
Veterinary Drugs in Foods (CCRVDF) – United States.
Import/Export Systems (CCFIECIS) - Australia

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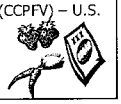
CODEX ALIMENTARIUS COMMISSION COMMODITY COMMITTEES

Fats & Oils (CCCFO) - United Kingdom
Fish & Fishery Products (CCFFP) - Norway
Milk & Milk Products (CCMMP) - New Zealand
Sugars (CCS) - United Kingdom
Processed Fruits & Vegetables (CCPFV) – U.S.



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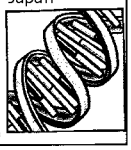
CODEX ALIMENTARIUS COMMISSION AD HOC TASK FORCES

- Biotechnology (CTFB) - Japan



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CODEX ALIMENTARIUS COMMISSION JOINT EXPERTS

Risk Assessment
Risk Management
Risk Communications
Assessing HACCP
Pesticide Residues
Chemical Exposure
Biotechnology
Food Additives (*)

(*Pertinent Contaminant)

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CODEX ALIMENTARIUS COMMISSION DEVELOPMENT PROCEDURES

- **For Codex Guidelines**
- New proposed work approved by CAC
- Proposed Drafts circulated within committees
- proposals/comments/discussion/consensus
- CAC approves drafts at each Step
- Final approval by CAC at Step 8 as approved guidelines

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CODEX ALIMENTARIUS COMMISSION PUBLISHED STANDARDS

- General Principles
- Definitions
- Code of Ethics
- Food Labelling
- Food Additives
- Contaminants in Food
- Irradiated Food
- Import Systems
- Export Systems

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PROCESSES & PROTECTIONS
IMPLEMENTATION PROCEDURES

- Guidelines adopted by CAC are published by the Secretariat as Codex Alimentarius standards and issued to all member countries
- Member countries should respond with their *Form of Acceptance* to the Secretariat
- Codex Secretariat then reports to the CAC any deviations of acceptance

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PROCESSES & PROTECTIONS
FORMS OF ACCEPTANCE

Full Acceptance:
Agreement to ensure that all products defined by the standard comply with the standard

Acceptance With Specified Deviations:
Agreement to ensure compliance with the standard except for specified exceptions

Free Distribution:
Agreement to allow unrestricted distribution of products conforming to the standard

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PROCESSES & PROTECTIONS
FORMS OF ACCEPTANCE

Full Acceptance:
Agreement to ensure that a product to which the standard applies will comply with all relevant requirements of the standard.

This means that a product compliant with the standard will NOT be subject to any other import requirements.

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PROCESSES & PROTECTIONS
FORMS OF ACCEPTANCE

Acceptance With Specified Deviations:

Agreement to give acceptance to the standard with the exception of such deviations as are specified in the declaration of acceptance.

This means that a product compliant with the standard may still be subject to specified import requirements.

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PROCESSES & PROTECTIONS
FORMS OF ACCEPTANCE

Free Distribution:

Agreement to allow a product conforming to a standard to be distributed freely. This is NOT acceptance of the standard.

This means that a product compliant with the standard will NOT be subject to any other import requirements.

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PROCESSES & PROTECTIONS
Harmonization Commitments

- US is signatory to several international treaties, including the General Agreement on Tariff & Trade, that bind the US to accept Codex standards for evaluating products for import.
- US may not use as a technical trade barrier any standard that disagrees with Codex standards.

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PROCESSES & PROTECTIONS
Harmonization Protections #1

The US Codex Office, after required consultation with affected US Agencies, may advise the Codex Secretariat that the US will:

A) accept a standard with specified deviations

B) not accept a standard but allow free distribution

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PROCESSES & PROTECTIONS
Harmonization Protections #2

- Harmonization does NOT mean the US must accept Codex standards for domestic trade.
- A US Agency (USDA/DHHS), to adopt a Codex standard, must use the formal rule-making process, including soliciting public comment.

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PROCESSES & PROTECTIONS
Harmonization Protections #3

International agreements do not dictate domestic laws, regulations or policy, they apply specifically and exclusively only to products sold through international trade.

> Uruguay Round Agreements

> SPS & TBT Agreements

> GATT

> NAFTA

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PROCESSES & PROTECTIONS
Harmonization Protections #4

FDAMA- The Food and Drug Administration Modernization Act of 1997 provides specific exemptions to international agreements for dietary supplements (Public Law 105-115 Section 410 / 21 USC 383) (See Appendix 2)

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2000 Codex Actions
Food Labelling (CCFL)

- **Organically Produced Foods**
  Co-authored by the organic industry – Proposed draft for livestock husbandry – at intermediate Step 5 for comments
- **Biotechnology**
  Label foods from biotechnology if a potential allergen is expressed - approved for submission to CAC at Step 8 in 2001

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2000 Codex Actions
Food Labelling (CCFL)

- **Nutrition Labeling**
  Labeling of 4 macronutrients (sugar, fiber, saturated fatty acids & sodium) *IF* a label declaration or claim is made about any of them. Still retained at proposed draft stage at Step 3 for comments.
- **Benefit Statements**
  Basic nutrient-content claims, plus "deficiency prevention", "enhanced function" and "disease risk-reduction" claims now included - retained at proposed draft stage at Step 3 for comments

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2000 Codex Actions
Food Additives (CCFAC)

- **Food Additives**
  Draft proposed list of excipients for consideration to be added specifically for use in the manufacture of vitamin/mineral supplements - initial Step 3 for comments
- **Food Irradiation**
  Revised General Standard for Irradiated Foods – Draft proposal at initial Step 3 for comments.

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2000 Codex Actions
Ad Hoc Biotechnology Task Force

- Proposed draft guidelines will be developed on the basis of scientific evidence, risk analysis, and, where appropriate, other legitimate factors relevant to consumer health and fair trade.
- Definitions of terminology and agreement on scope of work, were proposed at initial Step 3 for comments and review by the CAC in July 2001; final Step 8 recommendations to the CAC no later than 2003

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2001 CODEX Issues - CCNFSDU
Nutrition & Foods for Special Dietary Use

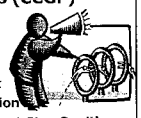
- **Nutrient Content Claims – For Foods**
  Guidelines for inclusion of US's "serving size" as appropriate method for NRV/RDA% AND the minimum NRV/RDA% for using a "high" or "source" nutrient claim – approved for submission to CAC at final Step 8 in 2001

2001 CODEX Issues - CCNFSDU
Nutrition & Foods for Special Dietary Use

- **F.S.D.U. Guidelines**
- Agreed to develop criteria & principles for draft guidelines for Vitamin & Mineral in Foods for Special Dietary Use. These are NOT supplements, but fortified foods. Committee agreed NOT to solicit specific ingredients or specific levels. Pre-Step 3
- **Health Claims**
  Deferred consideration of the scientific criteria for health claims until the CCFL defines them - initial discussion at Pre-Step 3

2001 CODEX Issues
General Principles (CCGP)

- RISK ANALYSIS:
  - #1 - Risk Evaluation
  - #2 - Risk Assessment
  - #3 - Risk Management
  - #4 - Risk Communication
  - continues in discussion at Step 3 with the dangerously malleable term "Precautionary Principle" still bracketed, and approval of non-scientific "other factors" still undefined.



2001 CODEX Issues
Food Labelling (CCFL)

Ingredients Labeling

- A) Ingredient Declarations:
  Carbohydrates as sugars/fiber/dietary fiber
  Fats: saturated/unsaturated/monounsaturated
  Unsaturated fats as trans/cis
  - returned for Final comments at Step 8
- B) Quantitative Ingredient Declaration (QUID) IF a content claim is made
  - Draft guidelines at Step 3 for comment

2001 CODEX Issues
Food Labelling (CCFL)

- **Biotechnology**
  Scientific risk analysis says no labelling required, Consumers say they want informed consent - draft in discussion at Step 3
- **Health Claims (Benefit Statements)**
  "Enhanced Function" and "Disease-Risk-Reduction" - proposed draft guidelines at Step 3 for LIVELY discussion

2001 CODEX Issues
Food Additives & Contaminants (CCFAC)

- **Supplement Food Additives**
  Additions to the priority list of food additives (additives and permissible amounts) for use in vitamin/mineral supplements - draft in discussion at Step 3
- **Risk Analysis Application**
  Application of Risk Analysis principles for approval of food additives and amounts, and to enhance the Risk Management role of the CCFAC - still in discussion at Step 5

2001 CODEX Issues - CCNFSDU
Nutrition & Foods for Special Dietary Use

Vitamin/Mineral Supplements Guidelines

Proposed draft guidelines to be discussed – primary controversies are:

A) upper safe limits for nutrients: policy-based NRV/RDA multiples versus nutrient appropriate scientific risk assessment.

B) consumer benefits statements: "health claims" - including "structure/function" and"disease risk-reduction".

Proposed draft in discussion at initial Step 3

Industry Codex Concerns - 2001
Vitamin & Mineral Supplement Guidelines

- **Some countries want to stop development of the guidelines, because they would be foods, not drugs.**
- **Some countries want to develop guidelines based on RDA potency, and disallow ANY benefit statements, and require registration and sale as ONLY as drugs, not foods.**
- **Some consumers want to stop development of the guidelines, in the mistaken belief that such guidelines will threaten their access to dietary supplements here in the USA.**

Congressional Codex Strategy

- #1 - Continue supporting Codex participation– government + industry and consumers NGOs
- #2 – Continue protecting US industry & consumers against restrictive Codex standards

#3 – Ensure US Delegates strongly advocate D.S.H.E.A. health freedoms within Codex

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Congressional Codex Tactics

- **Increase Codex participation by USTR & DOC to advocate trade-liberalizing standards**
- **Obtain frequent input from US Codex Office on draft guidelines that may be barriers to trade**
- **Ensure US Codex Office provides annual update of new Codex standards & US Acceptance Form, and maintains current website with full text of all guidelines, standards and acceptances.**
  (19 USC 2578 Section 491)
- **Encourage US Codex Delegates to advocate for DSHEA health freedoms within Codex!**

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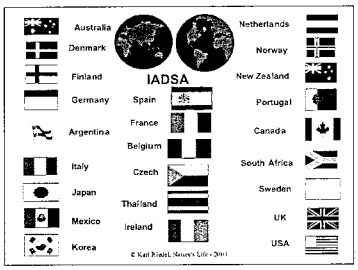
International Alliance of Dietary Supplement Associations (IADSA)

- ***"To facilitate a legislative and political framework to build a growing international market in dietary supplements based on consumer confidence and sound scientific principles"***

Since 1995 – I.N.G.O. Certified by Codex



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TEL: (202)205-7760 / FAX: (202)720-3157 / E-mail: uscodex@usda.gov / Website: www.fsis.usda.gov/oa/codex

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Email: info@nnfa.org / Website: www.nnfa.org

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Mr. BURTON. Thank you, Mr. Riedel.

Dr. Benjamin.

Dr. BENJAMIN. I kept practicing what I was going to say to you all the way down on the plane from New York. And I think I'm going to change just a little bit of what I've written down in testimony. Because I'm not the person who's been involved in CODEX legislation, other than to read about what's going on.

But I'll tell you what I am. I'm a principal in a company, a very small company that makes multivitamins and minerals. But primarily, I'm a practicing pediatrician, I'm a professor of pediatrics and complementary and alternative medicine in a medical school in New York. I've been a physician for about 25 years, I've worked in the south Bronx of New York, the hovels of urban and rural Mexico and in more affluent Phoenix, AZ. During that time, the one thing that I have found to hold true is that people, regardless of their background and their education, have the ability to make intelligent decisions for themselves, and if they are empowered to do so, they'll always make the right decisions, if they're provided appropriate information.

I think that the FDA always needs to be sure, and I recognize the incredible burden that they have with regard to protecting public safety, must nevertheless recognize what their goal is, and that's to facilitate good outcome in health care in this country, and to facilitate individuals to exercise their personal freedom to make appropriate choices in health care.

Having said that, and recognizing the importance of the cost of care which is accelerating here in the United States with the some $2.6 trillion budget for health care projected by the Federal Government by 2010, there are numerous strategies and issues that I know all of you in Congress need to grapple with. But one of them has got to be to encourage the use of good nutritional habits and good use and appropriate use of nutritional supplements, including minerals, vitamins and herbal products, not just to maintain a state of health as is set forth by the RDA, but to promote optimal health and to focus on prevention.

Medical schools are struggling to train students in a discipline that is rapidly changing. I can tell you from personal experience that nutrition, health promotion and disease prevention most often take a back seat to much more glamorous, high tech modalities. Yet I receive calls daily from physicians and patients, and physicians admitting that patients know more about what's going on, that they want information about it, and that their patients are using dietary supplements. I get lots of incredible calls from patients, and patients that I see, with regard to results as a result of using nutritional and dietary supplements.

I'd like to give you a few examples. One that I did not write down but that Mr. Waxman mentioned that apparently was of some concern to the FDA, and where I disagree, St. John's Wort. There is a patient of mine in Long Island whose husband is self employed, they have an average income, I think, annually of about $38,000 a year. Regrettably, there is no insurance available for them, they are working uninsured people.

This lady is a wonderful person who works at nights in a diner. She's very depressed, for appropriate reasons. It is very expensive

to get mental health assistance. And her husband, and incidentally, both she and her husband think that the use of any kind of prescription product with regard to mental health would be a sign of craziness, they don't acknowledge the need for potentially seeing a health care professional with regard to mental health issues.

However, she purchased St. John's Wort because she read about it on the Internet. And it made a significant difference in her life. While I don't think that it alone is the best treatment, it gave her access to something that she didn't have at a cost that was reasonable. It allowed her to do something.

I recognize that the FDA has appropriate concerns about St. John's Wort. But they also need to see the woods from the trees. There are millions of people who don't have access to more expensive prescription products, and this offers a rational and reasonable alternative. Nothing is perfect. But you need to look at that from a global perspective.

Here are some other patient stories. A patient that I've seen with moderate hypertension who was on an antihypertensive drug but still required additional intervention and who was able to lower his blood pressure further to an acceptable level by adding 500 milligrams of vitamin C once a day. Or the patient with angina whose favorable response to nitrates, nitroglycerin, was attenuated over time, such that he would require additional and more expensive prescribed medications, but was able to stay on nitrates longer, because he learned how his own vitamin E could help. Indeed, by adding vitamin E, he learned that he could decrease that attenuation effect.

The 11 year old who has exercise induced asthma, who found that instead of steroids and inhalants, he was able to substantially decrease his medications by using vitamin C and lycopene supplements. The 55 year old male with non-insulin dependent diabetes who took vitamin E, vanadium, chromium and bitter melon, and as a result was able to wean himself off much more expensive medications.

I could probably go on and on, and that's not appropriate, because I'm already over time. I would only point out that in addition to this, preventive issues are extremely important. Vitamin E has been shown to decrease the incidence of prostatic cancer and the mortality associated with it. Selenium has been associated with a reduction in total cancer mortality, total cancer incidence and the incidence of lung, colorectal and prostate cancers.

I would only add this one last thing. I believe that there is a great need to control quality of products. But I think everyone has talked about that already. I think we need to be sure about the purity of the products that are produced, and that what is on the label indeed is in the product. And I recognize the importance of that. I encourage the FDA to consider better enforcement of DSHEA as has already mentioned.

I thank you very much.

[The prepared statement of Dr. Benjamin follows:]

Samuel D. Benjamin, M.D., M.D. (H)
Associate Professor of Pediatrics
Director of the Center for Complementary and Alternative Medicine
State University of New York at Stony Brook School of Medicine
Chairman- InVite Health

Mr. Chairman I thank you for the privilege of addressing this committee today.
I am a principle in a company that manufacturers vitamins. However, first and foremost I am a physician and a pediatrician, having worked in the South Bronx of New York, the hovels of urban and rural Mexico and in a more affluent Phoenix, Arizona. One thing that I have always found to hold true is that people- regardless of their background and their education have the ability to make intelligent decisions for themselves if they are empowered to do so with good information. We are facing health care spending of some 2.6 trillion dollars by 2010 by one account. Prescription drugs account for nearly 10% of our present health budget and their costs are projected to rise by 12.6% annually according to federal economists.
While the Federal government determines how to control those costs one of the strategies, must include how to encourage the use of both good nutrition and nutritional supplements (including minerals, vitamins and herbal products) to not just maintain a minimum state of health (as the RDA's set forth), but to optimize health, focus on prevention and address those issues that relate to the quality of our lives. Our medical teaching institutions are struggling to train students in a discipline that is rapidly changing. Nutrition, health promotion and disease prevention most often take a back seat to more "glamorous" high tech modalities. Yet, I receive calls daily from physicians whose patients come to their offices each day knowing more about nutrition and supplements than they do.
There is a substantial public groundswell for preventive, less costly approaches to healthcare, for example:

1. The patient with moderate hypertension who was on an antihypertensive drug but still required additional intervention and who was able to lower his blood pressure further and to an acceptable level by adding 500mg. of Vitamin C once a day.
2. The patient with angina whose favorable response to nitrates (nitroglycerin) was attenuated over time such that he would require additional and more expensive prescribed medications but who was able to stay on nitrates longer because he learned on his own that Vit E could help.
3. The 11 year old whose exercise induced asthma required inhalers and steroids and with Vitamin C and supplemental lycopene (a carotenoid) was able to decrease his dependence on more expensive and potentially dangerous prescription medications
4. The 55 year old male with non insulin dependent diabetes mellitus who was able to ween himself off medications when he combined an appropriate diet and exercise with Vitamin E, Vanadium, Chromium and Bitter Melon. or
5. The 20 year old with obsessive compulsive disorder that used inositol (a B vitamin) to treat his emotional problem instead of a very expensive prescription drug with a number of often serious deleterious effects.

In addition vitamins and minerals as the public knows can alter the course or prevent disease.
1. Vitamin E has been shown to decrease the incidence of prostatic cancer and the mortality

associated with it.It can decrease the risk of vascular and mixed dementias associated with aging.
2. Selenium has been associated with a reduction in total cancer mortality, total cancer incidence and the incidence of lung, colorectal and prostate cancers while
3. Lycopene has been associated with slowing or preventing the progression of atherosclerotic disease.

All of these are available without prescription. To limit the availability of these products by placing controls on the amount or kind of content would not be in the interests of our nation's health.
Of the examples I gave, if these individuals were not allowed to complement their own therapies themselves or if they were dependent on their physicians they would all still be using more expensive prescription alternatives that I believe would be potentially more dangerous as well.None of these patients chose to leave their care outside of the medical system These self initiated therapies encouraged other changes as well. Life style changes such as relaxation techniques, better compliance with prescription medications , exercise and better diet became much more important to them.They got more involved with the kind preventive changes we encourage in medicine but seem to fall short of eliciting effectively in a "top down" medical approach.

However, we do need to be sure that the consumer is not mislead with regard to vitamins and minerals and I support those efforts that encourage the production of these products to the same standards that prescription drugs are held to. The retailer has one primary focus- cost! In order to sell product, production corners can be cut to decrease wholesale costs and meet retailers' demands. However, if all of the industry were held to one high standard then it would be an even playing field that would benefit the consumer and encourage competition based not just on cost but value, quality and research.

I support stricter labeling, pharmaceutical grade purity, child resistant closures , some vehicle for registration of these products before use and a vehicle for documenting clinical experiences once marketed. The consumer must be assured that what is on the label is indeed in the container and that it is free of impurities that could be potentially harmful. In addition, I support the efforts of the USP and other governmental and nongovernmental agencies that are seeking to establish standards for evaluating the quality of nutritional supplements.

The American medical system has focused on acute disease detection and therapy and has been very successful although at a great cost. To make these kinds of sophisticated and costly technologies available to all of us over the next decade we must support strategies that address prevention, chronic disease and quality of life issues efficiently. Instead of limiting a national movement that is successfully encouraging Americans to take control of their health with the use of diet and dietary supplements I suggest that you continue support for the law that already can assure the safety through better quality products but still will encourage consumers to continue this process of self empowerment.

Mr. BURTON. Thank you, Dr. Benjamin. Your practice on the way down was well done. I thought you made a nice statement.

Dr. Wolfe.

Dr. WOLFE. A former college roommate, now an investment banker, told me 2 years ago that herbal/dietary supplement companies were a hot investment item, because they do not have to spend money for research to show that products are safe and effective, in contrast to the 100 million, some companies would say more, it takes to get a pharmaceutical through the FDA drug review process. Several people in the industry have estimated to me that it takes a mere, lots of money, but a mere $3 million to $5 million to get a supplement to the market.

The legal cover for this profitable investment strategy comes from DSHEA. I thank you for the opportunity to review the increasing evidence that this 1994 law is dangerous for people in this country.

The American Association of Poison Control Centers currently and correctly categorizes herbals and dietary supplements as pharmaceutical products in their categorization of toxicity that they collect from poison controls, since they do have pharmacologic activity. For drugs, the FDA has two opportunities to collect data on safety: one, legally mandated pre-market safety studies; and second, post-market adverse reports. For dietary supplements, neither of these is required.

FDA has estimated that about 1 out of 10 adverse reactions to prescription drugs are reported to the agency, most from the pharmaceutical companies, 90 percent because they're required by law to do so. For dietary supplements, it's likely that this is less than 1 percent of reactions are reported to FDA, one reason being that there's no legal obligation on the part of the manufacturers to do so.

Every year, the American Association of Poison Control Centers publishes an annual report in the American Journal of Emergency Medicine, tabulating the number of adverse reactions reported by its toxic exposure surveillance system. The figure that I've compiled on page 2 from their data shows that from 1994 through 1999, the number of such reports each year for dietary supplements was 35,400. Contrast this to only roughly 3,000 reports, same interval of time, sent to the FDA, 10 times higher for the reports sent to the American Association of Poison Control Centers.

This doesn't even include a large number of reports for botanicals, which they have not yet categorized into commercial versus non-commercial botanicals. Nor does it include adverse reactions that don't result in emergency room conditions or emergency room hospitalizations.

I also have shown a chart here where you can see there's practically an identity, other than one CH3 methyl group being substituted for an H group, ephedrine is really otherwise the same as phenylpropanolamine, now off the market. Well documented concerns with cardiac arrhythmias from ephedrine also occur with other family drugs, such as amphetamine phenylpropanolamine.

The son of one of my colleagues, Dr. Randy Sasich, who is a 3d year resident in internal medicine at Barnes-Jewish, the main teaching hospital of Washington University, within a 7-month pe-

riod had two patients admitted to the coronary care unit after serious acute adverse reactions to Herbalife. One woman in her late 50's presented in the emergency room with ventricular tachycardia. She had been using Metabolife. She was admitted to the coronary care unit for observation.

Second, a woman in her late 30's suffered a heart attack and cardiac arrest while using a dietary supplement. She suffered brain damage. A third person, not admitted to the coronary care unit, a nurse, had rapid heart rate shortly after using dietary supplements. She was observed with an electrocardiogram.

FDA commissioned two reviews to be done of the 140 adverse reactions that had been reported to it, not from the American Association of Poison Control Centers, but just through the Medwatch system. In both the reviews, they found 10 deaths in the first 17 cases of hypertension, 13 people with palpitations or fast heartbeat, 10 strokes. The other review, looking more at the arrhythmias, found 10 cases of sudden death, also 9 arrhythmias and 23 more possible arrhythmias.

The FDA ban on PPA was based on a much smaller number of serious adverse reaction reports in their files than now exists, even with the extraordinary underreporting for ephedra.

I don't have time to talk about some other problems that are in the testimony, a number of studies have shown that a number of different herbs can interfere significantly with the anti-blood clotting properties of Coumadin, increase them, so that people who should be taking blood thinners such as Coumadin may have their blood too thin and may risk bleeding. There are some case reports of serious bleeds in people who took, in addition to their blood thinner, an herbal supplement that had unknown quantities of unknown contents that have anticoagulant effects.

The President of the American Society of Anesthesiology has recently said, "It is very troubling to see our patients use products that they believe will provide health benefit, but in fact may jeopardize their lives during surgery if they don't tell us what they're taking." Right now, legislation could be introduced, combined with the right signals during the FDA appropriation process, and a number of people have previously mentioned the issues, does FDA have enough funding, and a strong version of the belated, I think I share with all of you, the fact that this thing is taking too long to come out, the belated GMP regulations to rapidly lessen the damage being done by this dietary supplement industry wish list masquerading as, and having the force, of Federal law.

Improvements include mandatory adverse event reporting, requirements for all dietary supplement manufacturers, mandatory warning labels for risks, requirements for company and product registration and identification of the raw ingredients and the source by country for each of the ingredients in each product. This latter requirement is necessary to ensure that BSE-contaminated recycled cow organs do not appear on the shelves in this country as dietary supplements. That's bovine spongiform encephalopathy.

In addition, mandated funds are necessary to implement and enforce the GMP regulation that will hopefully be finalized soon. In addition, FDA should be appropriated the funds to purchase the entire dietary supplement data base of the American Association of

Poison Control Centers. At present, only the ephedra part has been purchased.

When the first member of this committee, or of Congress, or their families has a stroke, a fatal cardiac arrythmia or some other life threatening adverse reaction to dietary supplements, perhaps there will be a belated reconsideration of the damage done by DSHEA. I say this not in a casual way, because every single law that's been passed in the history of the Food and Drug Administration concerning safety of products only occurred after various kinds of disasters.

The law will then either be significantly modified or repealed so that pre-market safety and efficacy testing becomes the preferable alternative to post-marketing human experimentation. Until then, trust the snake oil companies. Not all the companies are snake oil companies, but as many have stated previously, there are some snake oil companies there. Their only concern is your health.

I have attached 26 articles we've published in our monthly newsletter called Worst Pills, Best Pills News, which is the monthly supplement to our book, Worst Pills, on various problems that have occurred, usually resulting in recalls or warnings on various kinds of herbal supplements over the years.

Thank you.

[The prepared statement of Dr. Wolfe follows:]

Testimony of Sidney M. Wolfe, M.D.
Director, Public Citizen Health Research Group
House of Representatives Committee on Government Reform
Hearing on Dietary Supplements
March 20, 2001

A former college roommate, now an investment advisor, told me two years ago that herbal/dietary supplement companies were a hot investment item because they do not have to spend money for the research to show that the products are safe and effective. In contrast to the $100 million (some companies claim more) it takes to get a pharmaceutical through the FDA drug review process, several people in the industry have estimated to me that it takes a mere $3 to 5 million to get a supplement to the market. The legal cover for this profitable investment strategy comes from the Dietary Supplement Health and Education Act (DSHEA). I thank you for the opportunity to review the increasing evidence that this 1994 law is dangerous for people in this country.

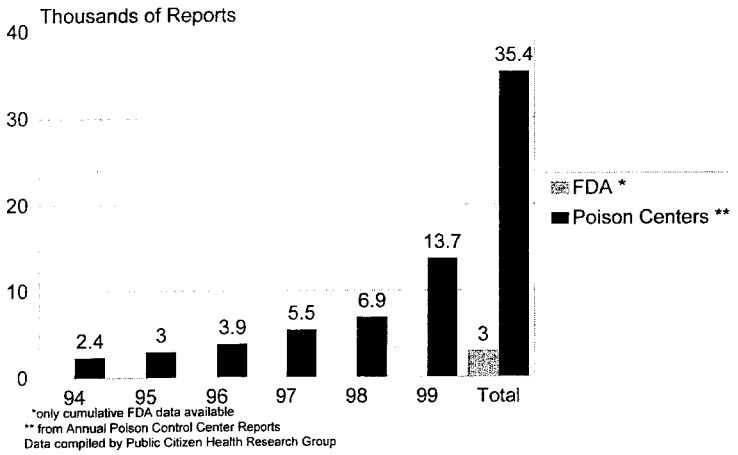
The American Association of Poison Control Centers (AAPCC) correctly categorizes herbals/dietary supplements as pharmaceutical products since they do have pharmacologic activity. For drugs, the FDA has two opportunities to collect data on safety: legally mandated pre-market safety studies and post-marketing adverse reports. For dietary supplements, neither of these is required of the industry.

Scope of the Problem:

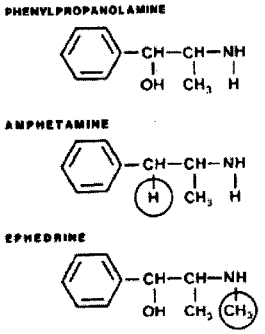
FDA has estimated that about 10% of adverse reactions to prescription drugs are reported to the agency, most of which come from the pharmaceutical companies who are required, by law, to report such reactions. For dietary supplements, it is likely that less than 1% of such reactions are reported to the FDA, one reason being that the manufacturers have no legal obligation to report. Based on data collected by the national network of Poison Control Centers, mostly located in hospitals throughout the country, the AAPCC publishes an annual report, in the American Journal of Emergency Medicine, which tabulates the number of adverse reactions reported by its toxic exposure surveillance system.

The figure on the next page shows, for 1994 through 1999, the number of such reports each year for dietary supplements. The total of such reports for AAPCC is 35,400 for that period, more than ten times higher than the 3000 reported to the FDA. The number of AAPCC reports would be even higher if it included those commercial herbal supplements currently categorized as botanicals/plants. Nor does it capture the non-emergent hospitalizations due to adverse reactions that are more chronic than acute.

Adverse Reaction Reports for Dietary Supplements
FDA and National Poison Control Centers



Ephedra
The following chart shows the close chemical structures of PPA, ephedrine and amphetamine:



The well-documented concerns about the cardiac (arrhythmias) toxicity and brain toxicity of ephedrine (also associated with a large number of strokes due to bleeding in the brain), the known brain toxicity of amphetamine and the

use of amphetamine as an appetite suppressant confirm that there are pharmacological as well as chemical similarities between all of these compounds.

Randy Sasich, M.D., the son of my colleague Larry Sasich, Pharm D., MPH, is in his third year of internal medicine residency at Barnes-Jewish, the main teaching hospital of Washington University in St. Louis. Within just a 7-month period during his residency, he took care of two patients admitted to the coronary care unit because of ephedra (Metabolife) -induced life-threatening cardiac arrhythmias. He is aware of a third patient, also discussed below, who used Metabolife and experienced an arrhythmia but was not hospitalized:

Case 1 –April 1999. This patient, a female in her late fifties, presented at the emergency room in with a dangerously rapid rate of contractions of one of the large chambers of the heart, or ventricles (ventricular tachycardia or V-tach), after using a dietary supplement for weight control containing ephedra. She was admitted to the coronary care unit for observation. She was subsequently discharged.

Case 2 –April 1999. This patient, a female in her late thirties, suffered a heart attack (acute anterior MI) and cardiac arrest while using a dietary supplement containing ephedra for weight control. She was a smoker but had no evidence of previous atherosclerotic disease of any significance. She suffered brain damage due to a lack of oxygen.

Case 3 –October 1999. A female nurse, age unknown, experienced a rapid heart rate while using a dietary supplement containing ephedra. The rapid rate was documented by her colleagues using an electrocardiogram (ECG or EKG). She was observed until her rapid rate resolved.

Two reviews of 140 adverse reaction cases reported to the FDA involving the use of ephedra alkaloids confirmed the cardiac toxicity of ephedra. The first study found that 47% of cases involved the cardiovascular system (17 cases of hypertension, 13 with palpitations or fast heartbeat, 10 strokes). There were also 7 reports of seizures.[1] The second study found that of the 104 reports in which causation by ephedra was very likely, there were 10 cases of sudden death, nine cardiac arrhythmias, another 23 possible arrhythmic events, three heart attacks, ten cases of chest pain and 15 severe strokes.[2]

The FDA ban on PPA was based on a much smaller number of serious adverse reaction reports in their files than now exists, even with the extraordinary underreporting discussed above, for ephedra.

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[1] Haller CA, Benowitz NL. Adverse cardiovascular and central nervous system events associated with dietary supplements containing ephedra alkaloids. New Engl J Med 2000;343:1833-8.
[2] Letter from Ray Woosley, M.D., Ph.D, Georgetown University School of Medicine, August 18, 1999 to the FDA.

Bleeding, Blood-clotting Risks of Herbals

A recent review on the potential effects of herbal medicines on blood clotting in patients being given anticoagulants such as coumadin discussed two sets of potential problems:

Supplements which, by virtue of providing additional sources of vitamin K beyond those in food, could decrease the anti-clotting effects of coumadin, thereby increasing the risks of blood clots in those patients who are already at risk for blood clots. These include Passion Flower, Juniper and Verbena.

Supplements which can increase the anti-coagulant effects of coumadin thereby increasing the risk of bleeding in such patients. These include Japonicum, ginseng, ginkgo biloba, Papaw, Red Clover and Horse Chestnut and therefore should not be used in patients on either anticoagulant or antiplatelet therapy. [3] In addition, the standard text on drug interactions, *Evaluation of Drug Interactions*, lists several supplements, including ginkgo, ginseng, dong quai, vitamin C, and green tea as having interactions with coumadin. [4]

Herbal Risks During Surgery

A recent news article in the *Journal of the American Medical Association*, entitled Herbs and Anesthesia, quoted the President of the American Society of Anesthesiology, Dr. John B Neeld, Jr., who said that because of changes in heart rate or blood pressure in people using herbals such as St. John's Wort, ginkgo biloba and ginseng, patients should stop taking herbal medicines at least 2 to 3 weeks before surgery. He pointed out that "It is very troubling to see our patients use products that they believe will provide a health benefit but, in fact, may jeopardize their lives during surgery if they don't tell us what they are taking." [5]

Short-term and Long-Term Remedies

Right now, legislation could be introduced—combined with the right signals during the FDA appropriation process and a strong version of the GMP regulations---to rapidly lessen the damage being done by this dietary supplement industry wish list masquerading as, and having the force of, a Federal Law,

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[3] Argento A, et al. Oral anticoagulants and medicinal plants. An emerging interaction. Ann Ital Med Int 2000; 15(2):139-43.
[4] Evaluation of Drug Interactions, October, 2000. First Databank, Inc.
[5] R Voelker. Herbs and anesthesia. JAMA 1999;281: 1882.

DSHEA. These improvements include a mandatory adverse event reporting requirement for all dietary supplement manufacturers, mandatory warnings for risks, requirements for company and product registration, and identification of the raw ingredients and the source (by country) for each of the ingredients in each product. This latter requirement is necessary to ensure that BSE-contaminated recycled cow organs do not appear on the shelves in this country as dietary supplements. In addition, mandated funds are necessary to implement and enforce the Good Manufacturing Practices regulation that will hopefully be finalized soon. In addition, FDA should be appropriated the funds to purchase the entire dietary supplement database of the AAPCC. At present, only the ephedra alkaloid cases have been contracted for by the FDA.

When the first member of this committee or of Congress or their families, has a stroke, a fatal cardiac arrhythmia, or some other life-threatening adverse reaction to dietary supplements, perhaps there will be a belated reconsideration of the damage done by DSHEA. The law will then either be significantly modified or repealed so that pre-marketing safety and efficacy testing become the preferable alternative to post-marketing human experimentation. Until then, trust the snake oil companies. Their only concern is your health.

The following appendix contains very brief summaries from 26 articles concerning dietary supplements published in the last six years in our monthly newsletter, *Worst Pills, Best Pills News*.

Appendix

WORST PILLS, BEST PILLS NEWS*
(This monthly supplement to our book *Worst Pills, Best Pills*, has a circulation of approximately 140,000.)

HERBAL AND DIETARY SUPPLEMENT ARTICLES

April 1995, Vol. 1 #2

Herbal Product and Liver Side Effects

Cases of liver toxicity reported in the November 15, 1994 issue of the *Annals of Internal Medicine* were reviewed. These cases involved a Chinese herbal remedy called Jin Bu Huan. The report describes seven patients, six female and one male, aged 24 to 66, with no history of liver disease, obesity, diabetes, allergy, or excessive alcohol intake or use of drugs known to cause liver toxicity. The Food and Drug Administration (FDA)

issued an import alert in an attempt to stop the importation of Jin Bu Huan into the United States.

February 1996, Vol. 2 #2

Adverse Reactions from Herbal Medicines

The World Health Organization's (WHO) Collaborating Centre for International Drug Monitoring has received more than 5,000 reports of suspected adverse reactions from herbal medicines. Serious adverse reactions with unregulated supplements such as royal jelly, chaparral or creosote bush, and Chinese herbal remedies were discussed.

December 1996, Vol. 2 #12

DHEA (Dehydroepiandrosterone) Safety and Effectiveness Have Not Been Proven

The editors of *The Medical Letter on Drugs and Therapeutics* said regarding the dietary supplement dehydroepiandrosterone (DHEA) "Patients would be well advised not to take it." Various masculinizing effects of DHEA in women, including acne, hair loss, abnormal hairiness and deepening of voice had been reported. Substances such as DHEA can stimulate the growth of prostate cancer in men.

July 1997, Vol. 3 #7

Warning: Potentially Deadly Chomper Herbal Laxative Recalled

This laxative was recalled because specific lots were found to be contaminated with a digitalis-like substance. Drugs derived from digitalis, such as digoxin (Lanoxin), are used to treat heart conditions, but if too much is taken, these substances can cause serious heart rhythm disturbances and death.

August 1997, Vol.3 #8

Warning: Recall of More Dangerous Dietary Supplements

The Food and Drug Administration (FDA) advised consumers that the raw material labeled plantain used by various dietary supplement manufacturers may contain digitalis. Digitalis can cause life-threatening heart rhythm disturbances.

February 1998, Vol. 4 #2

What Do We Know About St. John's Wort?

The editors of *The Medical Letter on Drugs and Therapeutics* evaluated the scientific research regarding St. John's Wort, an herb heavily promoted as an anti-depressant. The editors concluded "Better, longer studies are needed to establish the effectiveness and safety of St. John's Wort for treatment of depression. The active ingredient, the potency and purity of the preparations sold in the USA are all unknown."

June 1998, Vol. 4 #6

Melatonin and Increased Seizures in Disabled Children

Researchers from the Children's Memorial Hospital and Northwestern University Medical School published a study in the journal *The Lancet* of melatonin used as a sleep aid for six children aged 9 months to 18 years with nervous system damage who also had chronic, severe sleep complaints. The study was terminated before its completion because of increased seizures in four of the six children.

August 1998, Vol. 4 #8

What We Know About Garlic For Cholesterol-Lowering

German researchers, writing in the June 17, 1998 issue of the *Journal of the American Medical Association*, used the scientific "gold standard" to test garlic's effect on cholesterol: a randomized, placebo-controlled, double-blind study. The researchers found that garlic had no effect compared to a placebo in lowering cholesterol in men who had moderately elevated blood levels of cholesterol.

October 1998, Vol. 4 #10

FDA Confirms Impurities in the Dietary Supplement 5-Hydroxy-L-tryptophan

Mayo Clinic researchers reported in the September 1, 1998 issue of *Nature Medicine* that they had found chemical impurities in the nutritional supplement 5-hydroxy-L-tryptophan (5HTP) from six different undisclosed manufacturers. 5HPT is being hyped as an aid for insomnia, depression, obesity, and in children with attention deficit disorder. These impurities are similar to those found in L-tryptophan and were associated with a 1989 epidemic of eosinophilia-myalgia syndrome (EMS).

November 1998, Vol. 4 #11

Untested "Alternative Medicine" Remedies

The September 17, 1998 issue of *The New England Journal of Medicine* was devoted to the dangers of alternative medicine. The Journal published two studies, three letters-to-the-editor and a strongly worded editorial about this issue.

March 1999, Vol. 5 #3

FDA Warns About Products Containing Gamma Butyrolactone (GBL)

The Food and Drug Administration (FDA) alerted the public in January 2000 not to purchase or consume products, sometimes sold as dietary supplements, that contain gamma butyrolactone (GBL for short). The agency had received reports of serious health problems – some potentially life-threatening – associated with the use of GBL.

April 1999, Vol. 5 #4

The Poor Quality of Some Melatonin Products

Researchers from the University of Maryland School of Pharmacy reported in the *Journal of the American Pharmaceutical Association* their results of a study of the quality of melatonin products. Melatonin is a nutritional supplement that has been hyped as a cure for practically everything from aging to jet lag. The researchers concluded that poor design and manufacture of melatonin tablets and capsules is another example of a widespread problem with dietary supplements. These poor quality products can exist in the marketplace because, like other dietary supplements, they are not regulated by the FDA.

August 1999, Vol. 5#8

Warning! Deaths Reported With the Unregulated Dietary Supplement 1,4 Butanediol (BD)

The Food and Drug Administration (FDA) warned the public of a new group of dietary supplement products being marketed as sleep aids that have been associated with at least three deaths and several adverse non-fatal reactions. These products are chemically related to gamma butyrolactone (GBL) and gamma hydroxybutyric acid (GHB), substances that have been determined to pose a significant public health hazard.

October 1999, Vol. 5#10

More Serious Reactions and Deaths Associated with Dietary Supplements Containing GBL, GHB, or BD

The Food and Drug Administration (FDA) announced on August 25, 1999 that the count had risen to at least 122 serious illnesses, including three deaths, associated with the use of gamma butyrolactone (GBL), gamma butyric acid (GHB), or 1,4 butanediol (BD).

Fish Oil Protects Against Second Heart Attack but Vitamin E Does Not, Italian Study Reveals

Italian researchers reported in the August 7, 1999 issue of *The Lancet* that daily supplements of polyunsaturated fatty acids (PUFA) derived from fish demonstrate a beneficial effect on morbidity and mortality in patients with a recent heart attack, while daily use of 300 milligrams of synthetic vitamin E has no such beneficial effect.

January 2000, Vol.6#1

Ineffective and Dangerous Dietary Supplements: S-adenosyl-methionine (SAMe) For Depression and the Diet Pill Tiratricol (Triax)

The editors of *The Medical Letter on Drugs and Therapeutics* reviewed the dietary supplement s-adenosyl-methionine or SAMe for the treatment of depression. The Medical Letter editors concluded "There is no convincing evidence that SAME, a dietary supplement is effective or safe for treatment of depression."

In the same article we wrote that the Food and Drug Administration (FDA) was warning consumers not to purchase or use Triax Metabolic Accelerator, a dietary supplement containing tiratricol, a breakdown product of natural thyroid hormone. Triax was being sold in health food stores and over the Internet as a diet pill. Excess thyroid hormone may cause serious health consequences including heart attacks and strokes.

February 2000, Vol.6#2

Hypericum Extract (from St. John's Wort) in the Treatment of Moderate Depression

A well-designed clinical trial published in the December 11, 1999 *British Medical Journal* compared the effect of St. John's Wort to the tricyclic antidepressant imipramine (Tofranil) or an inactive placebo. The study found that the St. John's Wort was more effective than placebo and at least as effective a imipramine for the treatment of moderate depression. These findings may be irrelevant for the unregulated products sold in the United States, many of which have much less St. John's Wort than used in the study.

April 2000, Vol.6#4

Save Your Money: Do Not Use Vitamin E for Preventing Heart Attack and Stroke

Researchers from the Canadian Cardiovascular Collaboration Project reported in the January 20, 2000 issue of *The New England Journal of Medicine* that daily supplementation with natural vitamin E had no effect in preventing cardiovascular events such as heart attack and stroke in high-risk patients.

California Health Director Warns Consumers About Prescription Drugs in Herbal Products

California health authorities warned consumers to immediately stop using five specific herbal products because they were adulterated with two prescription diabetes drugs. An investigation was begun after a diabetic patient in Northern California suffered from several episodes of low blood sugar (hypoglycemia) after consuming one of the products.

May 2000, Vol.6#5

New Warnings! Clinically Important Drug Interactions With St. John's Wort

The British equivalent of our Food and Drug Administration (FDA), the committee on Safety of Medicines, warned doctors, pharmacists and the public about of a number of significant drug interactions between the herb St. John's Wort (*Hypericum perforatum*) and prescription drugs.

The Health Research Group wrote FDA Commissioner Jane Henney on March 2, 2000 urging the agency to warn American physicians and patients about all (more than 25) drugs listed in the British warning, rather than only the AIDS drugs.

June 2000, Vol.6#6

'Gold Standard' Study Shows No Detectable Benefit Derived From Coenzyme Q10 For Congestive Heart Failure Patients

Researchers from the University of Maryland School of Medicine and the Veterans Affairs Medical Center in Baltimore publishing in the April 18, 2000 issue of the *Annals of Internal Medicine,* concluded that adding the dietary supplement coenzyme Q10 to standard treatment was of no benefit to patients with congestive heart failure.

Shoddy Manufacturing and Labeling Practices Found in Dietary Supplements Containing Ephedra

Reinforcing the need for tighter control of dietary supplements, researchers at the University of Arkansas College of Pharmacy found serious problems with some products containing the Chinese herbal supplement ephedra. The research, reported in the May 15, 2000 issue of the *American Journal of Health-System Pharmacy*, compared the amounts of ephedra listed on the labels of 20 products to the actual content of the substance in the tablets and capsules of these dietary supplements.

Not surprisingly, the amounts listed on the labels often differed sharply from the scientifically determined contents, both over-and understating by substantial percentages ranging from 0 to 154 percent.

July 2000, Vol.6#7

More Reports of Serious Drug Interactions Between St. John's Wort and the Anti-organ Rejection Drug Cyclosporine (NEORAL, SANDIMMUNE)

Additional reports of this dangerous drug interaction were published in May 27, 2000 issue of *The Lancet*, from doctors at an organ transplant service in Hannover, Germany. These doctors identified a group of patients whose cyclosporin blood levels had decreased by an average of 49 percent after starting to use St. John's Wort.

Warning! Do Not Use! Chinese Herbal Supplements Containing Aristolochic Acid

The Food and Drug Administration (FDA) asked lobbying groups representing the herbal supplement industry to ask their members to test and not sell herbal supplements containing aristolochic acid. This herb has been used in Chinese medicine in products sold for weight loss and skin problems. In Belgium, in 1993, at least 70 cases of kidney failure were reported in association with the use of products containing aristolochic acid.

February 2001, V7#2

Kidney-toxic and Cancer Causing Chinese Herbal Supplements are Recalled

A recall was issued on November 21, 2000 of Chinese herbal supplements produced by a Eugene OR firm containing aristolochic acid. Aristolochic acid is known to cause kidney failure and urinary tract cancer.

Ginkgo Biloba is Found Ineffective for Dementia and Age-Associated Memory Impairment in the Elderly

Researchers from The Netherlands reported in the October 2000 issue of the *Journal of the American Geriatrics Society* that a standardized extract of the widely

hyped herb ginkgo biloba was found ineffective for older adults with dementia and age-associated memory impairment. The results of this study contrast sharply with those of previous ginkgo biloba trials.

Mr. BURTON. Thank you, Dr. Wolfe.

Mr. Silverglade.

Mr. SILVERGLADE. Good afternoon. I'd like to thank the committee for the opportunity to testify.

Since the enactment of DSHEA, there has been both good news and bad news to report. First, the good news is that more and more Americans are getting the message that dietary supplements can play an important role in maintaining good health and can provide a valuable adjunct to conventional medical treatment. The bad news is that benefits have not been established for many supplements now on the market. Some of these products may be unsafe. And some consumers may not be able to make the best choices to promote their own health.

As Americans increasingly rely on supplements, it's critical that Congress ensure that such products are safe before they're sold, and that label claims are valid. Unfortunately, DSHEA has made it difficult to achieve these dual objectives. Under the law, dietary supplements are presumed safe until the FDA can prove that they pose a significant or unreasonable risk. While assigning the FDA this new enforcement burden, Congress failed to provide the agency with additional resources for this purpose.

Thus, as a practical matter, the FDA has not been able to effectively utilize its enforcement authority. Instead, the agency has relied on inadequate remedies, such as issuing public warnings that may be heard by some people and not by others, or by requesting voluntary recalls that may or may not be heeded. The wisdom of this approach must be seriously questioned, given Americans' reliance on dietary supplements to protect their health.

While good manufacturing practice regulations will help ensure potency and reduce the chances that products are contaminated, they will not ensure that the underlying ingredient is safe for its intended use.

Moving to the area of labeling, DSHEA permits producers to make so-called structure function claims concerning health benefits without obtaining FDA authorization. Many of these claims are poorly substantiated, because they have not been submitted for review prior to marketing, nor are they based on established scientific monographs.

Furthermore, as the General Accounting Office noted in a report last summer, consumers incorrectly view structure function claims as a claim to reduce the risk of or treat a disease. GAO thus concluded that consumers may attempt to treat a disease with a product that is not capable of producing the benefit.

For example, one of the most popular herbs, garlic, has been widely promoted for maintaining heart health and/or healthy cholesterol levels. Typical claims include statements such as, regular consumption of garlic may help promote healthy heart function and regulate cholesterol levels. I have several samples here today. The GAO has found that such claims imply disease prevention.

However, a scientific literature review released last October by the Agency for Health Care Research and Quality conclude that garlic "does not attempt to offer long term protect against cardiovascular disease." Yet we are still able to purchase garlic supplements in a local drug store just yesterday, and all of them, not just

this company, but almost half a dozen, continue to make such claims.

Let me talk just for a moment about possible solutions. DSHEA is having a negative impact, not just on consumers, but on the industry as well. Problems related to dietary supplement safety have been reported in the media. There was reference to a cover story in U.S. News and World Report, for example. Such reports, coupled with increasing skepticism about unfounded claims, may explain why some sales data indicate that supplement sales seem to have reached a plateau.

It is therefore in the interest of both industry and consumers to support a systematic, comprehensive review of dietary supplement safety and efficacy. The results of such a study would provide greater legitimacy for supplements that are truly beneficial and could lead to the removal from the marketplace of any dangerous or ineffective products that tarnish the reputation of the entire industry.

Now, this result may be a bitter pill for some companies. But like a supplement that may taste bitter, the long term benefits will be rewarding for the industry as a whole.

The U.S. National Academy of Sciences is beginning an FDA funded project to develop seven prototype monographs on leading dietary supplement ingredients. Congress should provide additional funds for this project so that it can be expanded to cover all of the most popular dietary supplements now on the market.

This would normally conclude my testimony, but today we are in a global economy, and we need to review activities of international regulatory bodies that may impact on policies set by Congress and the FDA. We are specifically concerned about the adverse impact that standards developed by a U.N. body called the CODEX Alimentarius Commission may have on regulatory requirements established by Congress and the executive branch. We're pleased that the committee is investigating this matter.

Prior to 1995, CODEX standards had no legal effect in the United States. But since the formation of the World Trade Organization, CODEX standards can potentially have an impact on domestic regulatory policies, because the U.S. Government can be sued at the WTO for maintaining regulatory requirements that exceed them.

While it is true that nothing in the WTO agreement requires that governments accept CODEX standards, the threat of a WTO challenge certainly puts pressure on the United States. Let's say for example that the FDA finalizes good manufacturing practice regulations. Another country, let's say for example, India, which has been quite active in CODEX Alimentarius, that companies in India produce herbal supplements who don't like the FDA's good manufacturing practice regulations. They could ask the government of India to challenge the FDA rules at the World Trade Organization as a trade barrier, because current CODEX requirements do not include such regulations.

If that happens, and the United States loses the suit, which it has done before at the WTO, the entire FDA regulatory scheme for GMPs could be thrown in disarray, after all the work that the agency and the Congress and the Office of Management and Budg-

et has done on the issue. Unfortunately, the United States has not fared very well at semi-annual meetings of the CODEX Alimentarius Commission. The United States cannot say that it controls the standards development process at that organization very effectively.

Therefore, the operation of the WTO agreement should be re-evaluated, and these problems should be taken into account in any new trade agreements.

I wish to thank the committee again for the opportunity to testify.

[The prepared statement of Mr. Silverglade follows:]

Committee on Government Reform
U.S. House of Representatives

Oversight Hearings

Six Years After the Enactment of the Dietary Supplement Health and Education Act: The Status of National and International Dietary Supplement Regulation and Research

Testimony of

Bruce Silverglade
Director of Legal Affairs
Center for Science in the Public Interest

* * *

March 20, 2001

Good afternoon. I am Bruce Silverglade, Director of Legal Affairs, of the Center for Science in the Public Interest (CSPI). We are pleased to have this opportunity to testify on the status of national and international dietary supplement regulation and research. CSPI is a nonprofit consumer advocacy organization based here in Washington, D.C. We were founded in 1971 and are now supported by more than 800,000 subscribers to our *Nutrition Action Healthletter*, membership donations, and foundation grants. We accept no money from industry or government.

Most of our current work focuses on improving the safety and nutritional quality of our food supply and reducing the damage caused by alcoholic beverages. We have also worked to ensure that dietary supplements are safe and honestly labeled. In recent years, we have expanded our activities in these areas to the international arena. In order to more effectively participate in international regulatory activities, we co-founded the International Association of Consumer Food Organizations and I also serve as President of that organization.

I. Introduction

It has been almost seven years since the enactment of the Dietary Supplement Health and Education Act of 1994 (DSHEA) and it is certainly appropriate to review the impact of this legislation on consumers. In this regard, there is both "good news" and "bad news" to report. First, the "good news" is that since 1994, Americans have become increasingly cognizant of the benefits that many dietary supplements can provide. A generation ago, only "health nuts" regularly consumed vitamins and minerals and herbal medicines were virtually unheard of. Today, half of all American adults take vitamin or mineral supplements, and one in three has tried herbs.

One of the reasons for this trend is that many Americans are disenchanted with a medical establishment that increasingly funnels patients through doctors' offices as if they were on an assembly line. In addition, consumers hear more and more about promising research that some dietary supplement ingredients may hold the key to preventing cancer and other dreaded diseases. Our publication, *Nutrition Action Healthletter*, regularly reports on these developments. In light of such factors, many Americans want to take control of their own health and engage in self-medication.

Many supplements are undoubtedly beneficial. For example, millions of Americans need to consume more calcium to help prevent osteoporosis. Women of childbearing age who consume sufficient amounts of folic acid can reduce the risk of neural tube defects in their unborn children. A growing number of studies suggest that saw palmetto can help men with benign enlarged prostates and that St. John's wort can be useful in treating cases of mild depression. In brief the "good news" is that more and more Americans are getting the message that dietary supplements can play an important role in maintaining good health and can sometimes provide a valuable adjunct to conventional medical treatment.

The "bad news" is that benefits have not been established for all supplements and many

consumers cannot determine on their own which products are worth consuming and which are nothing more than 21st century snake oil. As Americans increasingly use supplements to promote their health, it is critical that Congress ensure that such products are safe and that label claims are accurate and scientifically valid.

II. Safety Problems

Unfortunately, the Dietary Supplement Health and Education Act (DSHEA) has made it difficult to achieve those objectives. In enacting that law, Congress changed the prevailing approach to product safety under the Federal Food Drug and Cosmetic Act. The manufacturers of food additives, drugs and medical devices must prove that their products are safe before they can be sold. Under DSHEA, dietary supplements are presumed safe until FDA can prove that they may pose a significant or unreasonable risk.

While assigning the FDA this new enforcement burden, Congress failed to provide the agency with specific additional resources for this purpose. Thus, as a practical matter, the FDA has not been able to effectively utilize its authority to ensure that dietary supplements are safe, and regulated appropriately. Instead, the agency has been forced to rely on inadequate remedies such as issuing public warnings and requesting voluntary recalls. The wisdom of this approach must be seriously questioned.

For example, St. John's wort may interfere with a protease inhibitor used to treat HIV infection. It may also interact with oral contraceptives and drugs used to treat heart disease or to prevent conditions such as transplant rejection. The FDA has issued an alert about such problems, but how many consumers are actually aware of that information? There is also the basic question as to whether consumers can accurately diagnose themselves for cases of mild depression. What may seem like mild depression to one person may be nothing more than a case of the "blues" requiring no treatment or a case of clinical depression requiring medical intervention. Clearly, more needs to be done to ensure that St. John's wort is used by consumers in a proper manner.

The safety problem is compounded by manufacturers that sell traditional herbal medicines for non-traditional purposes. A herb that may have produced minimal side effects when used for a traditional purpose may cause severe adverse reactions when used for a different purpose. For example, some traditional Chinese herbs are sold in the U.S. for non-traditional purposes such as dieting or body building. Consumers may assume that the herb is safe because it has been used in China for hundreds of years. What people do not realize is that while a botanical may be safe for some uses, it may not be safe for other uses.

Also, many consumers do not understand that if a supplement such as a herbal medicine has health benefits, it probably also has health risks simply because it is pharmacologically active. Many prescription drugs come from plants, and the dangers of prescription drugs are well known. But supplement consumers often mistakenly believe that "if it is natural it must be safe."

Unfortunately, nothing could be further from the truth. All of these considerations call for a reexamination of the regulatory framework set out in DSHEA to ensure supplement safety.

III. Good Manufacturing Practice Regulations

DSHEA authorized the FDA to issue Good Manufacturing Practice Regulations (GMPs).[1] GMPs help ensure that the product contains the precise amounts of ingredients specified on the label and specify production processes that reduce the chances that products are contaminated with undesirable substances. For example, some dietary supplements containing calcium made from bone meal and consumed by pregnant women had high levels of lead that potentially could harm the fetus. Other dietary supplements sold to improve brain function contain concentrated raw brain tissue from cows. That practice is considered inappropriate given the prevalence of mad-cow disease in Europe and the potential that it can lead to a new variety of Creutzfeldt-Jakob disease (CJD) in humans.[2]

The FDA issued an Advance Notice of Proposed Rulemaking on GMPs in 1997 and sent a proposed rule to the Office of Management and Budget on November 8, 2000.[3] However, on February 1, 2001, after the Bush Administration took office, the FDA withdrew the proposed rule, thus delaying publication of the proposal.[4] That delay is unfortunate given the importance of GMPs.

While the development of GMPs is important, they do not ensure that supplement ingredients themselves are safe and effective for their intended use. For example, even if all St. John's wort tablets manufactured in the U.S. met rigorous GMPs, consumers could still suffer adverse health consequences if they consumed this herbal supplement while also taking various prescription medications.

IV. Misleading Labeling Claims

DSHEA permits supplement producers to make certain claims regarding their products' health benefits without first demonstrating that such products are truly effective. These claims are often referred to as "structure/function claims." While the law still requires companies to get

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[1] FDCA § 402(g)(2), 21 U.S.C. § 342(g)(2).

[2] Geoffrey Cowley, *Cannibals to Cows: The Path of a Deadly Disease,* Newsweek, Mar. 12, 2001 at 53, 61.

[3] Office of Management and Budget, Office of Information and Regulatory Affairs *Regulations Pending and Reviews Completed Last 30 Days* <http:///www.whitehouse.gov/library/omb> (visited Feb. 9, 2001).

[4] *Id.*

FDA pre-market authorization to make express disease prevention claims, often referred to as "health claims," firms are free to make a myriad of other *health-related* structure/function claims by simply notifying the agency within 30 days *after* marketing a product.

The distinctions between the types of claims requiring FDA pre-market authorization and those that do not are often meaningless to consumers. For example, under FDA rules that attempt to implement this portion of DSHEA, companies can claim that a supplement maintains healthy lung function but cannot say, without first obtaining FDA approval, that a supplement maintains healthy lungs in smokers.[5] However, in both cases, consumers are likely to assume that the products will decrease their risk of lung disease.

As the General Accounting Office (GAO) noted in a report last summer, "FDA conducted nine focus groups on dietary supplement labeling in three cities around the country. Among other things, this research found, 'there was no indication that participants differentiated at all between structure/function claims and health claims.' . . . .As such, consumers incorrectly view claims to maintain health (structure/function claims) as claims to reduce the risk of, or treat a disease. Consequently, we believe that consumers may attempt to treat a disease with a product not capable of producing this benefit."[6]

This loophole in the law is particularly disturbing considering that the presumed benefits of some supplements are based on anecdotal evidence or studies that were not conducted in accordance with modern scientific techniques. Moreover, many, if not most, companies making health-related structure/function claims have reportedly failed to even comply with the weak FDA notification requirement contained in DSHEA.[7] Not surprisingly, many outlandish claims on supplements have appeared on store shelves since DSHEA was enacted.

For example, one of the most popular herbs, garlic, has been widely promoted for maintaining heart health and/or healthy cholesterol levels. Typical claims include statements such as "regular consumption of garlic may help promote healthy heart function and regulate cholesterol levels." However, a recent review commissioned by the Agency for Healthcare Research and Quality (AHRQ) concluded that garlic does not appear to have benefits that endure beyond six months and "does not appear to offer long-term protection against cardiovascular

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[5] Food and Drug Administration Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Final Rule, 65 Fed. Reg. 999, 1018 (Jan. 6, 2000).

[6] General Accounting Office, *Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and 'Functional Foods,"* at 23 (GAO/RCED--00-156 July 2000)

[7] Chris Adams, *Splitting Hairs on Supplement Claims, Under the FDA's Guidelines, Improving Health is OK; Curing a Disease Isn't,* Wall St. J., Feb. 22, 2000, at B1.

disease."[8] The inability of garlic supplements to reduce cholesterol levels beyond six months is crucial because it is the *prolonged* elevation of blood cholesterol levels that raises the risk of cardiovascular disease. Thus, a product that does not work beyond six months is virtually useless.

V. International Regulation

As I mentioned at the beginning of my testimony, CSPI helped found the International Association of Consumer Food Organizations (IACFO). One purpose of IACFO is to ensure that consumer interests are represented at international standard setting organizations such as the Codex Alimentarius Commission (Codex). We are concerned about the adverse impact that Codex standards may have on regulatory requirements issued by the FDA and other U.S. regulatory agencies and we are pleased that the Committee is investigating this matter.

Codex was established in 1962 by the United Nations (UN) World Health Organization and Food and Agricultural Organization. Matters pertaining to dietary supplements are handled by the Codex Committee on Nutrition and Foods for Special Dietary Uses. That Committee is currently considering establishing standards for vitamins and minerals and has previously considered matters pertaining to botanicals.

Prior to 1995, Codex standards had no legal effect in the U.S. However, since the formation of the World Trade Organization (WTO), Codex standards can potentially have an impact on domestic regulatory policies established by Congress and the executive branch. The WTO Agreement on Sanitary and Phytosanitary Measures (SPS), enacted by Congress as part of the Uruguay Round Agreements Act, specifically refers to standards set by Codex and with the codification of the SPS Agreement, Codex's role has changed greatly.

Article 3.2 of the SPS Agreement provides that a country employing a Codex "standard, guideline or recommendation" is presumed to be in compliance with its WTO obligations. Article 3.3 of the SPS Agreement provides that a country with a regulatory requirement that results in a higher level of safety than a Codex "standard, guideline, or recommendation" is presumed to have erected a barrier to international trade unless the country can show that its standard has a "scientific justification." A country that the WTO determines has erected such a barrier must either change its regulatory requirement[9] or pay an international penalty. This penalty can take the form of either compensating the foreign government whose exports to the country have been limited or permitting that country to impose trade restrictions on imports from the country that

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[8] AHRQ, *Garlic Effects on Cardiovascular Risks and Diseases, Protective Effects Against Cancer, and Clinical Adverse Effects* (Oct. 2000).

[9] In several cases (not involving the SPS Agreement) the United States has elected to change its regulations after losing a WTO decision. For example, the Environmental Protection Agency changed its Clean Air Act regulations for oil refineries after Venezuela successfully challenged them.

maintained the different standard.

While it is true that nothing in the SPS agreement requires the U.S. government to abide by Codex standards, the operation of the agreement certainly puts pressure on the U.S. in at least two ways. First, the existence of a Codex standard can pressure the FDA to lower its requirements to the level of an international standard because of the potential of being sued at the WTO for exceeding the international norm. While this problem may not occur in the area of dietary supplements if the U.S. maintains regulatory requirements that are lower, not higher, than the Codex standard, it could occur in other areas of FDA regulation where the opposite is true.

Second, the mere existence of a Codex standard often influences manufacturers to produce products that comply with Codex rules so as to facilitate the export of those products to various countries. Many companies that do business on an international scale wish to produce a single product that can be sold on a global basis and avoid reformulating products for specific national markets. Thus, even if no nation challenges a U.S. regulatory requirement as a trade barrier because it is higher than a Codex standard, companies may gradually drift toward producing products that meet Codex requirements. Such developments could reduce the variety of products available to American consumers.

Thus, Codex standards have attained a new importance. Unfortunately, the U.S. has not fared well at the semiannual meetings of the Codex Alimentarius Commission; recent actions by Codex illustrate that the U.S. cannot control the standard development process to protect its national interests. For example, at the 1997 Codex meeting the United States lost two key votes. Codex adopted over U.S. objections (by a vote of 33 to 31 with 10 abstentions) an international safety standard for natural mineral waters that permits higher levels of lead and other contaminants than the FDA now allows; and adopted (by a vote of 46 to 16 with seven abstentions) an international standard for food safety inspection systems that permits self-evaluation by the companies or non governmental third-parties even though in the United States such food safety inspections are the responsibility of the United States Department of Agriculture (USDA), the FDA, and State governments.

At the 1999 meeting of the Codex Alimentarius Commission, the U.S. avoided losing recorded votes by acquiescing to several Codex standards that vary from U.S. regulatory requirements. For example, Codex approved a residue tolerance for methyl parathion (and other pesticides) even though several weeks later the Environmental Protection Agency (EPA) -- as mandated under United States law -- banned methyl parathion for fruits and vegetables because of its potential adverse effects on children. Codex also approved an international standard that does not require pasteurization of dairy products even though pasteurization of dairy products is generally required by the FDA. The United States presumably acquiesced to the approval of these Codex standards because it believed that it would not prevail if it insisted on a recorded vote.

These actions indicate that the operation of the WTO SPS agreement should be reevaluated. We urge the Committee to make appropriate recommendations to ensure that U.S.

sovereignty is maintained.

VI. Conclusion

Problems related to the safety of dietary supplements have been widely reported in the media and many consumers are becoming concerned. Such problems, coupled with increasing skepticism about exaggerated claims, may be having an impact on the industry; recent sales figures indicate that supplement sales seem to have reached a plateau. By continuing to oppose greater regulation, the dietary supplement industry may be harming its own long term interests. Some consumers are already failing to consume certain vitamin and mineral supplements that are critically important to health. As more and more adverse reactions to supplements are reported in the media,[10] and false and misleading claims become more commonplace, consumers may increasingly turn away from supplements and sales will decline.

It is, therefore, in the interest of both industry and consumers, to support a systematic, comprehensive review of dietary supplement safety and efficacy. (Vitamin and minerals known to be Generally Recognized as Safe (GRAS), and whose role in maintaining health is not the subject of controversy within the scientific community, could be exempted from the review). The results of such a study would provide greater legitimacy for dietary supplements that are truly beneficial and could lead to the removal from the marketplace of any dangerous products that could tarnish the reputation of the entire industry.

The U.S. National Academy of Sciences (NAS) is beginning a FDA-funded project to develop seven prototype monographs on leading dietary supplement ingredients. That is a start. Congress should provide additional funds for this project so that it can be expanded to cover all of the most popular dietary supplements now on the market. Ultimately, regulatory agencies must be empowered to act swiftly on any recommendations of the NAS, so as to protect consumers and maintain the credibility of the industry as a whole.

Dietary-supplement consumers deserve no less. As Americans come to depend on supplements to address serious health concerns, it is all the more important that government ensure that products are safe and that claims on labels are backed by solid scientific evidence.

We wish to thank the Committee for the opportunity to testify.

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[10] Amanda Spake, *Natural Hazards Tonic or Toxic? Americans are Gobbling Up Nature's Remedies for Everything from Obesity to Depression*, U.S. News & World Report, Feb. 12, 2001 at 43.

Mr. BURTON. Thank you, Mr. Silverglade.

We will now proceed to questions of the panel. I'd like to start with Mr. Israelsen. The dietary supplement industry is a big industry in Utah. And if CODEX restricted international trade, how would that affect the economy of Utah?

Mr. ISRAELSEN. A number of our companies are significant exporters. If they're limited in their ability to sell in a number of foreign markets that do follow CODEX guidance, that would clearly have an economic impact on our State.

At the moment, it would be difficult for me to judge what the numbers would be. But significant would be the right word.

Mr. BURTON. Do you have any idea how many people are employed in this industry in Utah?

Mr. ISRAELSEN. We believe it's something in the range, directly and indirectly, of about 10,000 people.

Mr. BURTON. About 10,000 people. What do you think the FDA should do about ephedra?

Mr. ISRAELSEN. I was afraid you were going to ask me that question.

Mr. BURTON. I may ask all of you that question.

Mr. ISRAELSEN. Ephedra remains one of our most difficult issues. It would be my proposal that the draft guidance document which has been prepared by industry, after a great deal of deliberation, be reconsidered by the agency. I think the single most important issue is the dosage amounts of ephedra permitted per dose and per day. I believe the rest of the guidance is largely in the range of general agreement.

I don't want to speak for the agency. You'll probably ask them the same question. I think we're down to numbers at this point.

Mr. BURTON. Are you familiar with the study that was done, that has not yet been published, by Columbia University and Harvard University, it was a 6-month study on the efficacy and safety of herbal ephedrine and caffeine in the area of weight loss?

Mr. ISRAELSEN. I'm aware of the study. I have not read it.

Mr. BURTON. I have read a synopsis of it, my staff has as well. It's shown if properly taken, according to the directions, ephedra is not harmful. I hope that it will be widely disseminated as soon as it comes out, so everybody in the industry and everybody who opposes ephedra can see what this study did. Because it wasn't some fly by night organization or organizations that did this study. It was Harvard and Columbia, two highly regarded institutions.

What are your views about the *Pearson* v. *Shalala* case and the FDA's actions since that case? Are you familiar with that?

Mr. ISRAELSEN. I am. My first observation is that it appears to have been a significant resource drain within the agency. I'm concerned about that, because it's distracted time and resource from many of the other issues that we discussed today in terms of moving GMPs and other important regulatory guidance policy forward.

I think everyone here, myself included, are ardent supporters of free speech and the rights provided by the first amendment. I have some personal concerns as to consumer understanding of the messages created by *Pearson* v. *Shalala.* That's a personal perspective, is that as we go forward, I think consumers are looking for and do expect and deserve messages that they have confidence in. Quali-

fied health claims are by definition that, qualified. To the extent consumers have difficulty judging how qualified is qualified, I'm afraid that it may actually undermine confidence consumers have in supplement claims.

Mr. BURTON. Mr. Seckman, do you think the industry overall is responsible and has sanitary and quality products?

Mr. SECKMAN. We completely agree with that. As indicated in my testimony, the initiation of the industry's own self-regulatory efforts of our GMP programs I think is a clear indication of that.

Mr. BURTON. How will NNFA's Good Manufacturing Practices Program be affected by the FDA's establishment of standards?

Mr. SECKMAN. When the proposed regulation comes out, we're going to compare our standards to what the FDA is proposing. I think we're going to see something that's very similar to the NNFA's program, with some adjustments. And the industry, when the advance notice of proposed rulemaking came out in 1997, the comments were made, I think the agency learned a lot when it was coming up with their proposed regs. I think what NNFA did in the meantime was come up with our standards. We'll actually have manufacturers who will be better prepared when the final GMP regulations are issued by the FDA to be able to meet those standards.

Mr. BURTON. Have you sent your standards to the FDA for review to see if they would incorporate those into theirs?

Mr. SECKMAN. We have had previous meetings with them and shared our standards with them, and the FDA has been very open about receiving those and taking them into consideration as they built their own proposed regulations.

Mr. BURTON. Is the BSE or mad cow disease issue going to be a concern to this country with dietary supplements?

Mr. SECKMAN. It's not going to be, in relationship to dietary supplements. I think there's a lot of misinformation that's out there currently about that. There's never been a case of BSE in this country. There's never been a link to any dietary supplement in this country or globally with BSE and dietary supplements.

So I think it's just an issue of trying to get the information out there. The FDA and the industry has worked long and hard since the early 1990's. The FDA has issued several guidance. The industry has followed those guidance. We worked together to make sure that this is not an issue or a concern, a safety issue to the public. In fact, our association just recently issued a BSE guidance in our standards and operating procedures just to make sure they're all following the same procedures.

Mr. BURTON. Mr. Tierney, do you have questions?

Mr. TIERNEY. Yes, I do. Thank you, Mr. Chairman.

Dr. Wolfe and Mr. Silverglade, let me just ask you, I shouldn't think that the concepts of safety and consumer confidence or industry success would be mutually exclusive concepts to consider. Can you tell me what your knowledge is in terms of what testing has been done to determine the risks of these products? Has there been a great field of studies on this that would meet the satisfactory level for consumers to have confidence?

Dr. WOLFE. About a year and a couple months ago, Dr. Godfrey Oakley, who was head of the birth defect section at the Centers for

Disease Control and I wrote a letter to the FDA to try and stop them from their dangerous proposal to allow women with nausea and vomiting in the first trimester of pregnancy or with edema pregnancy to be promoted herbals or dietary supplements for those two purpose. We argued that these are conditions for which, because of pregnancy, you shouldn't be giving people drugs, chemicals, pharmaceuticals, which have not been tested.

During a hearing which the FDA convened after that, they actually responded to our request and stopped those kinds of foolish and dangerous plans, during a hearing, someone from the Herbal Drugs Association was asked, what fraction of the several hundred drugs that are listed in their monographs as being safe have actually been tested adequately for pregnancy. And he sort of paused and said, very, very few. So just on that one note for starters, products that are often promoted, explicitly or otherwise, for pregnant women, have not been tested to see whether they cause birth defects.

There have been some articles published recently about the leading 10 selling, by sales, herbal products. If you look carefully at all the randomized controlled trials on the effectiveness of those drugs, those products, two or at the most three of them actually have good evidence of effectiveness. They all have dangers, as all chemicals do. And if the effectiveness were significant and proven, the benefits might outweigh the risk. But if there isn't any acceptable evidence of effectiveness, then whatever dangers there are are risks without concomitant benefits.

I think generally we have learned much more from adverse reaction reports when particularly they occur in a large number of people than we have from any kind of rigorous safety testing that's occurred. If you go back 100 years ago, the source of many of what we now call very acceptable pharmaceuticals were botanicals or herbals.

And that's fine, and I don't see any problem with sourcing for human therapeutic benefit products out of these. The difference is that they need to be subjected to tests to make sure that they are safe, using randomized controlled trials, if appropriate, which is usually appropriate, and effective. I think most of the products on the market have not been.

It will be very interesting to see, and I support all the efforts to do, at Government expense, as it turns out, proper studies to evaluate existing literature and to do new studies. I think that some of these products will turn out to be beneficial. I have little doubt about that. I think that most of them will not. And to the extent that it not only defrauds people but also subjects them to risks without concomitant benefit, I don't think that's a good idea.

Mr. SILVERGLADE. I would concur with what Dr. Wolfe said, and just add two points. One is that for the individual consumer, it's not possible for them to know which products have been tested adequately for safety and which have not. They're all on the market with claims that they're safe. Contrary to what Dr. Benjamin says, I don't believe that the average consumer can go to the store shelf and judge which ones are appropriate to take and which ones aren't, which ones are based on adequate safety studies and which ones are not.

I'd also just note, when it comes to Chinese herbals, many practitioners of Chinese herbal medicine are very upset about what American companies are doing by selling Chinese herbs for nontraditional purposes. While a particular herb may have been effective in China for thousands of years to treat a particular condition, that says nothing about whether it's safe and effective to be used in the United States for jet lag or dieting or things that it was never used for in China.

Mr. TIERNEY. With respect to the study that the chairman mentioned earlier, do you happen to know whether or not that study was sponsored by industry or by an independent source?

Dr. WOLFE. You're talking about the Harvard-Columbia study on ephedra?

Mr. TIERNEY. Exactly.

Dr. WOLFE. I do not know that. But it would be very surprising, regardless of who does it. I mean, wonderful institutions can do good studies and some of them can do studies that aren't very well designed. Earlier studies on phenylpropanolamine indicated that it was OK. When a more rigorous study was done, it turned out that it was really quite dangerous in terms of strokes. And I pointed out the chemical similarity between the two.

I would be shocked, given what we know, from well documented case reports of people who have had cardiac arrhythmias and strokes and other problems right after using ephedra, I'd be shocked to find out that it turned out to be safe. It may be effective for a short term. None of the dietary drugs, whether they're over the counter, former PPA drugs, prescription or ephedra, have ever been shown on a long term basis to have weight reduction.

So I think that on both the safety and effectiveness side, for a public health purpose, namely long term effectiveness and safety, I would be very surprised, despite Harvard and Columbia's names being on it, that study is designed in such a way to really definitively answer the question and overwhelm all the other evidence that's been accumulating for decades on these drugs.

Mr. TIERNEY. Thank you.

Mr. HORN. I thank the gentleman. I'm just going to go up and down on a couple of questions. Let's start with Mr. Silverglade. What do you recommend about ephedra?

Mr. SILVERGLADE. The Center for Science in the Public Interest has no specific recommendations on ephedra. As a lawyer, I'm not going to restrain myself from giving anything that could resemble medical advice.

I would just note that while ephedra was used in various forms in China for asthma and respiratory congestion, it's sold in the United States for weight loss, body building, fatigue and other purposes for which it wasn't traditionally used for in China. While it may be safe in China, the dosage and frequency of administration is different in the United States. That's where some of these safety problems derive from.

Mr. HORN. Thank you. Dr. Wolfe, what do you recommend about ephedra?

Dr. WOLFE. We recommend the same thing about ephedra that we recommended in a petition about phenylpropanolamine, it should come off the market. There's really very little difference.

The fact that ephedra is regulated or not able to be as well regulated because it falls under DSHEA as PPA did falling under the Food, Drug and Cosmetic Act should not be a barrier in the face of all the evidence to taking it off the market.

Mr. HORN. Dr. Benjamin, how do you feel about it?

Dr. BENJAMIN. I cannot support the use of ephedra. I think that it is a very effective tool for some things. Ma Huang, when used in China, is used for acute bronchitis or asthma. But I think that there's unfortunately, as with any product, always room for a considerable amount of abuse. With regard to weight loss, while I'm sure that there is weight loss, it's a thermogenic product, nevertheless, I have great concerns about its potential for complications, and how similar it is to phenylpropanolamine.

Last but not least, I have a problem in general with any product that attempts to induce weight loss over the short run. We've seen very often that most people, after they've taken any kind of product for a short run, short term weight loss in the end either gain all of the weight back they had to begin with at a much more rapid clip, which is incidentally more dangerous, or for that matter, end up most usually at a higher weight after therapy than they did when they started.

So regrettably, while I do believe that people can make intelligent decisions, I think there are some products that offer considerable danger. I cannot support its use.

Mr. HORN. Mr. Riedel, how do you feel, and what do you recommend about ephedra?

Mr. RIEDEL. Ephedra, I would almost like to echo Mr. Silverglade and Dr. Benjamin regarding its historical use in China and its use here in the United States, which is largely inappropriate. I think perhaps a recommendation, and my company does not sell it, I regard it as a stimulant.

Mr. ISRAELSEN. If the FDA defined energy and restricted its use, I think that it would perhaps resolve a significant part of the problem.

Mr. HORN. Thank you.

Mr. Blumenthal.

Mr. BLUMENTHAL. Well, I think that ephedra needs to be dealt with, because here we are having a conversation about herbs in general, and ephedra seems to be dominating the conversation.

We believe in scientific research. We support the petition that was filed last fall by some of the trade associations for FDA to promote more research with the dietary supplements, and for the National Center for Complimentary and Alternative Medicine and FDA and the industry to resolve this issue from a scientific perspective.

We acknowledge, for example, in Germany—the Commission E Monograms, for example, since that's part of my testimony—that over there, ephedra is approved at dosages up to 300 milligrams per day, which is fairly significant, for bronchiodilation and cases of asthma and hay fever, that kind of thing. That's the only limited indication for the herbal preparation in Germany.

We believe that scientific research should be carried out, it should be evaluated impartially, and then the results should drive the regulatory situation.

Mr. HORN. Mr. Seckman, how do you feel?

Mr. SECKMAN. We agree with Mark that further research should be done on this and we have supported that in the past. Additionally, we have also indicated our belief that we should have a dosage limit, as Loren had mentioned before, that almost all the associations have agreed on, not to exceed 100 milligrams per day, and it should be limited for usage to persons age 18 or older.

Mr. HORN. How about you, Mr. Israelsen?

Mr. ISRAELSEN. Same opinion as last time, actually. I think the committee may be benefited by reviewing the guidance document which was generated by industry, which is very detailed with respect to labeling, caution warnings, dosage levels. A lot of thought and care went into trying to design something that would try to accommodate all views and perspectives on this. I think that's the current state-of-the-art with regard to proper dosing and labeling, and I think if the agency and industry will sit down and look at that document, there may be a basis to find a resolution.

Mr. HORN. Well, I thank you. Let's go to the next question. We'll start with you, Mr. Israelsen.

What do consumers need to keep in mind as they look to choose between vitamins and botanicals?

Mr. ISRAELSEN. Between vitamins and botanicals?

Mr. HORN. Yes, to choose one or the other. What do you feel about that? At least, for the consumer—we're trying to educate the consumer.

Mr. ISRAELSEN. I would encourage them to use both, Mr. Horn. People use vitamins and herbals differently, in my judgment. Vitamins have a long tradition and history of use as nutritional supplements. Botanicals have a longer tradition as therapy, for prevention and for other purposes. My hope is that consumers are clear in their expectation of what the product can do. Typically, vitamins are taken for long-term care. Botanicals, on the other hand, often have shorter-term benefits.

Consumer education is fundamental. I'm not sure I'm answering your question, but in terms of making a choice between the two, it's very much a question of what their hope and expectation is for the outcome.

Mr. HORN. Do you agree with that, Mr. Seckman?

Mr. SECKMAN. I do. I think it should be a choice of the individuals to take either/or, or both.

Mr. HORN. Mr. Blumenthal.

Mr. BLUMENTHAL. I think it's a question of "both/and."

Mr. HORN. I couldn't hear the last part.

Mr. BLUMENTHAL. I think it's a "both/and" issue. For example, I take vitamins and minerals and herbal products, both. I take vitamins just to enhance my nutritional wellness. I take herbs for specific purposes; for example, I am over 50; I am taking saw palmetto. I have been diagnosed with BPH, benign prosthetic hyperplasia. I know there have been over 18 clinical studies that have been meta-analyzed and published in the Journal of the American Medical Association about the safety and benefits of saw palmetto.

Under DSHEA, by the way, you can only make a claim that it helps maintain prostate health, or some such claim like that, when

the truth of the matter is, as confirmed and documented by numerous clinical studies, that it is safe and effective in helping to reduce the symptoms associated with BPH, but as a claim that it is a drug, or a therapeutic claim, it cannot be made. That speaks to my previous testimony, that I believe it's time to open up the range of available claims for these products because, as a consumer, I would like to be able to read on the label exactly what these products really can do, if they can be documented by reasonable scientific evidence.

I think it's a "both/and" question.

Mr. HORN. Is it true that Germany requires a prescription if you're going to buy vitamins?

Mr. BLUMENTHAL. I'm not sure about vitamins, no. With herbs, they are sold over the counter—what we would call "over the counter," but in Germany it's called "nonprescription" because they limit nonprescription drugs to pharmacy only. Herbal products for general tonics and teas are sold in supermarkets, health food stores, etc., but the ones with the medicinal indications on them that have been approved by the Commission are sold in pharmacy only. They represent one-third of all nonprescription drug sales, and half of that one-third is selected by consumers. They can go in and buy those products without a prescription, and they can also go in after visiting their physician and buy with a prescription and then get reimbursement under the health care plan.

German physicians routinely prescribe herbal products, and they represent half of the herbals sold in German pharmacies, by prescription.

Mr. HORN. Well, Mr. Riedel, what do consumers need to keep in mind as they look to choose vitamins, between botanicals or the "same as botanicals"?

Mr. RIEDEL. Yes. The primary purpose that consumers take any dietary supplement for, the primary is to maintain good health; second, to prevent ill health; and third, to treat illness. The primary purpose, in other words, to maintain good health, is the primary venue for nutrients, vitamins and minerals.

The second venue is to prevent ill health, which is both herbs and vitamins and minerals—slightly higher dosage vitamins and minerals, in some cases—and the third case is to treat illnesses, self-treat, self-medicate, self-prescribe, both herbs as well as vitamins, minerals, and other dietary ingredients.

Mr. HORN. Dr. Benjamin.

Dr. BENJAMIN. Well, I'll tell you what I do. I have, for a number of years—and I'm happy now that the American Heart Association is supporting the use of soy—I take at least 25 to 40 milligrams of soy a day, whenever I possibly can. I travel a lot. When I can, I try to make certain that I have a certain amount of fish, deep-water fish; but if I can't, because for weeks on end I travel, I will supplement my diet with fish oils.

I am saddened that we haven't made some recommendations in that regard, and I think there are a number of cardiologists and academic institutions around the United States that would be concerned equally. I would want to be sure that those fish oils are not contaminated with mercury and other potential impurities that can

occur when you're fish that oftentimes are—deep-water fish that might be caught off the shores of industrialized countries.

I also have a family history of diabetes, and although I am not a diabetic, I like to take a multi-vitamin. There is some evidence—and I don't take gigantic doses of vitamins, but I take more than what I believe I can get out of a good balanced diet, which includes chromium, because there has been a reasonable amount of data suggesting at this point that it increases insulin sensitivity, which is key in non-insulin-dependent diabetes melitis, which has been seen in my family.

So I think that—I also like to take vitamin A. In fact, I think there was a study done recently—although there have been numerous studies done about the benefits, and there have been arguments in academia about its benefits, I think there is reasonable data to suggest that vitamin E, when taken along with vitamin C in moderate doses as supplements, can significantly slow down or decrease the incidence of mixed vascular dementias associated with aging, and at age 53 I now have to think about those things. I have two little kids, and I'd like to know that I can enjoy them over the next decade or so.

So having said that, I think that using some things in moderation and being sure that you have appropriate information about them so that you know how to rationally utilize them, I think is laudable and appropriate and I would hope to see this not only as something that is a freedom for patients, but I would hope that increasingly medical teaching institutions would be able to disseminate appropriate information to young health care professionals so that they can give this information to the patients and the families that they treat.

Mr. HORN. Let me ask you, how deep does the fish have to be that you want to eat for dinner? [Laughter.]

And is the mercury zone?

Dr. BENJAMIN. I look very carefully at the bottles that I purchase, and the concern that I have, which I mentioned in my written testimony and never got to, is that my concern is to be certain that indeed what is on that label is in fact what is in that product. I think all of us want to be assured of that kind of safety.

So I knowingly take a risk. May I tell you that when I see my patients and I recommend things—and I do recommend fish oils—I give them written information about the potential dangers. I give them informed consent. I do that, by the way, even about giving somebody acetaminophen, because there is increasing data now that giving—I am a pediatrician, don't forget. Well, my kids get sick, and they get to 102.5 or 103 fever, and I get very nervous, so I give them Tylenol sometimes—I shouldn't mention brand names—to treat myself. Nothing wrong with the product, but there was a study at the University of Maryland over the last year or so that suggested that the indiscriminate use of acetaminophen—which I am guilty of, as a pediatrician and a dad—can prolong the process of certain viral symptoms, like the flu. I think that it is incumbent upon health care professionals to provide informed consent that gives information not only about natural products, but we need to do that as well when we—I don't know if "informed con-

sent" is a fair word; "provide rational balanced information," so that people can make intelligent choices for themselves.

That's why Mr. Silverglade made a comment, which I understand what he's addressing. I, too, think that consumers can make intelligent decisions. I have confidence in them, and I believe that we have an obligation, it is incumbent upon us to be sure that we give them good information. I read what Dr. Wolfe writes about, and others, and I am very impressed with it. The Pharmacist's Letter has a thing called "the Natural Data base" which is absolutely outstanding, and I think it is incumbent upon health care professionals to do this. There is lots of Internet information available.

So my answer is, if you provide balanced information and you're honest about it, people can make choices. My patients opt for things, understanding that there are some potential downsides in prescription products, just as well as in natural products.

Mr. HORN. Salmon and trout could be in the farms of salmon and trout——

Dr. BENJAMIN. Yes.

Mr. HORN [continuing]. And presumably that would be fresh water. Is that what you ought to look for if you're ordering fish?

Dr. BENJAMIN. It depends on the content analysis of Omega–3 fatty acids, which I think would be the big issue.

Mr. HORN. Dr. Wolfe, what is your feeling on this? What do people first need to keep in mind as they look to choose between vitamins and botanicals?

Dr. WOLFE. Well, I agree with several things that Dr. Benjamin has said. First, I think people need to be able to make decisions, intelligent decisions, but in order to do that they have to have information. And to the extent that anything we're talking about—some of the things we're talking about don't have adequate information on safety and efficacy or effectiveness, they can't make intelligent decisions.

It was of interest to hear that fish is consumed by my colleague, Dr. Benjamin. [Laughter.]

In one of the things that we attached to the testimony today it said that in the August 7, 1999 issue of The Lancet, it "was found that daily supplements of polysaturated fatty acids derived from fish oil demonstrate a beneficial effect on morbidity and mortality in patients with a recent heart attack, while daily use of 300 milligrams of synthetic vitamin E has no such beneficial effect."

I think that one of the things that is becoming clear is that it isn't just the vitamin A or the vitamin E, whatever, it's the food. So I think that one of the best answers to the question is that neither botanicals nor vitamins, but foods, eating healthy foods. And we know what they are; we know more than we did before about what the content is.

My mother, who will shortly—hopefully—be 93, uses calcium, a mineral supplement, and she takes one multiple vitamin a day. She sometimes thinks she doesn't need it because when she can get her hands on enough fruits and vegetables, it's OK.

So I think a dietary approach to maintaining good health, preventing ill health, to the extent that it can be done, is a good one. We don't have the overly and artificially concentrated amounts of

some of the ingredients that occur in some of the herbals and some of the food supplements.

So I think that whether one is talking about prescription drugs, over-the-counter drugs, botanicals, or vitamins, the choice should be based on adequate information on safety and effectiveness, and we just happen to have much more information about over-the-counter drugs and prescription drugs.

It is interesting that in the last few years, in a friendlier atmosphere, the FDA has been processing a much larger number of botanical products through the drug approval process. And to the extent that I'm sure that some of those will get through, they will be able to make the claims that they "treat this and treat this" because there will be evidence for it, as opposed to the limitations that are made on the claims for dietary supplements because there is a lack of evidence.

Mr. HORN. Well, while Chairman Burton comes back to preside, Mr. Silverglade, what's your answer to the question of what consumers need to keep in mind, should they look to the vitamins and the botanicals?

Mr. SILVERGLADE. Well, when I speak to individual consumers I try to explain it this way. Vitamins and minerals are one category, and herbals are in another category. Vitamins and minerals provide nutritional value; herbals do not. They may be pharmacologically active.

And regarding all these safety controversies that have existed in the dietary supplement area, whether one agrees with those reports of adverse reactions or disagrees with them, I would note for the record that they almost all—none of them involved vitamins and minerals. They almost all involved herbal products or other types of dietary supplements beyond vitamins and minerals.

Mr. BURTON [resuming Chair]. Let me just ask one question, and then I will yield to my colleague from Washington.

The fish that you were talking about that have mercury in them, to ingest those is not good, it creates a danger for people, doesn't it?

Dr. BENJAMIN. Chronic mercury intoxication has a direct effect on the central nervous system.

Let me mention just one of a number of other adverse effects——

Mr. BURTON. Let me ask you this. So mercury given to anybody, children or adults, to take internally, is——

Dr. BENJAMIN. Absolutely unpardonable.

Mr. BURTON [continuing]. Absolutely unpardonable. I hope everybody heard that, because do you know that the vaccinations that we give children contain thimerosal, which contains mercury? And there is a growing body of evidence that it may contribute to autism in kids, and it may be a contributing factor in Alzheimer's. And yet we have products on the market that are given on a regular basis, in injection form, vaccinations in injection form, that are putting mercury into our kids. My grandson got 47 times the amount of mercury that is supposedly tolerable in an adult, in 1 day, and he's autistic.

Dr. WOLFE. But the FDA is in the process of phasing that out. You're absolutely right. There was really no excuse for it being put

in there in the first place. There are other non-mercury preservatives——

Mr. BURTON. Sure, but the FDA has been saying they're going to phase it out for years and years and years, and they have enough vaccinations today.

Dr. WOLFE. Congressman, you just haven't done enough oversight over them. [Laughter.]

Mr. BURTON. You may rest assured, I was not really one of those people who was aware of how autism affects families across this country until it happened to my own. But we are aware now, and you may rest assured we're going to—but the point is that you, as leaders in the health food industry and as doctors, need to stress very strongly that these toxic substances should not be given to adults or children in this country in any form.

Yes, sir?

Mr. RIEDEL. If I may, on fish oils, OK, which are the fish body oils that we're talking about here, most of the mercury resides in the flesh of the fish, which is not a dietary supplement. That's the food.

Mr. BURTON. Yes, sir.

Mr. RIEDEL. OK. The fish body oil—every CFA for fish body oil indicates, in microgram dosages, the levels of mercury, and you can reject that CFA if it exceeds your specifications. Quite frankly, there are no Government specifications, which is another thing they can go after.

Mr. BURTON. Yes, sir?

Dr. BENJAMIN. You know, I am involved in this industry, but I am also, as I mentioned, a physician.

I really think we need help with standards, and I really look to the FDA to help us in this regard. I don't always trust those CFAs. We don't make herbal products; we make minerals and vitamins, and even though as you mentioned, Mr. Silverglade, there are no reports of toxic reactions, I take this responsibility very seriously, and I can tell you that just yesterday, a product that we were about to finish did not have an adequate amount of iodine, and we had to—fortunately we were able to catch it and re-do it, simply because the CFA was not appropriate. I think that we need appropriate guidelines.

There is one other thing that I would like to tell you about that. If you go to three or four—we use independent laboratories to test our product. I could send it to three or four labs, and I'm going to get three or four different responses on the same product, and indeed we have. There need to be standards of validating testing methodologies. I would think that would be true in herbal products; it is certainly true in vitamins and minerals. It is a great concern. I don't see that as a control; I see that as an asset. I know the USP has been involved in trying to set some of these standards in minerals and vitamins, and I could tell you that I, for one, would welcome it because it would help us separate the wheat from the chaff. It is very hard to determine, with the best of intentions, if what you're making is meeting the standards that you want to have.

Mr. BURTON. The gentlelady from Washington?

Mrs. NORTON. Mr. Chairman, I appreciate this hearing. I think it is an immensely important hearing.

I am impressed with the huge market and, if I might say so, lucrative market, that has developed in dietary supplements. I should also say, "count me in," because I am impressed with the scientific evidence that is beginning to be developed on the effectiveness of at least some of these supplements—beginning to be developed because, of course, there isn't a lot of incentive to use traditional scientific methodology here at all. When you consider that the market is expansive beyond all measure—we are bordering on irresponsibility to allow it to grow the way it did when it was insignificant in our society. I think there are important new substances, I am convinced, new supplements, that have an important effect one way or the other upon health. But this industry is in danger of giving dietary supplements a bad name. When people read that untested supplements have had adverse effects, what are they to think? They ought to think that they are unprotected.

I am concerned at two levels: at the level of danger—I thought I lived in a society that at least protected us from danger, and ephedra may bring out some of those concerns, and second I am concerned at the level of unwanted scientific claims. Surely, we are raising children—we are a well-educated society—to believe in the scientific method. You know, you show me A's causality to B. And yet these same well-educated people go into the market and buy what looks like it works. Well, nobody would think of taking pharmaceuticals that "look like they work." I want a doctor to tell me they work. I want somebody to indicate that there have been some kinds of trials to indicate that they do work.

When we took dietary supplements effectively out of the FDA regulatory scheme, it seems to me we had an obligation to put something in its place. I can understand the concern with regulation when you consider the proliferation of the substances we're talking about, but have we considered, for example, how many of the elderly must surely be encouraged to take these supplements at this time, not to mention very young people. Or when we hear about interactions with known substances, "ask your pharmacist" because you need to know whether or not something you are taking will interact with something that seems perfectly benign, and yet these substances proliferate. I wonder, when I think about what's happened to all kinds of things in the stock market, I'll bet these haven't been affected in the stock market. These things have a life of their own; people just go out and get them. They are elixirs. They are magic. Whatever happened to the way we have been trained to understand whether or not you should take something in your body, or you should take whatever is written on a label—and you can write anything on a label in these things.

I am concerned because I think some of these dietary supplements hold great promise. If traditional regulation is not the answer, then there must be an answer better than recklessness, and that's where we're getting to as we encourage old people looking for longer life, children who read these labels and think "this is harmless; I can take it and get what it says I will get," young people still in the formation of their brains and in the formation of their bodies—this is not the way we do business in a society that prides itself on taking an intelligent approach to human health.

I think a hearing like this ought to encourage us to think deeply about tailoring to these dietary supplements, what it would take to make them safe and to make them truthful. I think it is shameful to be an advanced society which allows to proliferate substances which are even making obviously false claims, or claims that have not been proved, or may even go so far as to be dangerous. I would expect that in traditional societies where you have witch doctors or others who claim things that they cannot prove. That is not supposed to be the country in which I live, and I think we need to do more than talk about these claims. We need to do something that is very difficult, to think of a way to get at this without obliterating the very good work that these substances clearly have shown they could do for human health.

Thank you, Mr. Chairman.

Mr. BURTON. I thank the gentlelady.

I have two more questions for this panel and then we will conclude and go to the people from the FDA.

Dr. Benjamin, do you think we need to re-do the recommended daily allowance guidelines?

Dr. BENJAMIN. No. I am not against the RDA because I think they are minimum standards, but I don't think that they necessarily encourage optimal health. I think they are two separate issues.

Mr. BURTON. OK.

Anybody else have any comment on that?

[No response.]

Mr. BURTON. If not, Mr. Israelsen, please explain what happened to Shaman Botanics last year.

Mr. ISRAELSEN. Shaman Pharmaceuticals?

Mr. BURTON. Yes.

Mr. ISRAELSEN. What would you like to know? [Laughter.]

Mr. BURTON. Just 1 second.

Can you explain the process that they went through with the Food and Drug Administration last year?

Mr. ISRAELSEN. Oh, yes.

Mr. BURTON. OK.

Mr. ISRAELSEN. It's actually a longer story than that. I will try to be brief.

This is a company that was in existence about 15 years, and the concept was to do ethnobotanical prospecting, principally in the equatorial belts around the world, to identify new substances that could be developed into new drug products. It was a very high-tech, high-expense process.

They had developed two or three very promising products, one for diabetes, one for severe diarrhea, and several others. They had an NDA before FDA, and they were at phase 3 and were quite sure that they were going to be approved. Apparently they were put on clinical hold, and it essentially bankrupted the company. They simply couldn't advance the project beyond that.

They determined that because they had a number of botanical products in their portfolio—they had collected for a number of years hundreds and hundreds of very interesting plants, a number of which were dietary ingredients—that they selectively chose a couple of products that could be marketed as dietary supplements,

trying to salvage a very large investment. I think the unfortunate news is that they simply couldn't hang on, so as of today they are in the process of selling off the assets of the company, and it will fairly soon be out of business.

Mr. BURTON. Well, I want to thank you all very much. We really appreciate your being here and your patience, and we're going to continue to ride herd on this issue. If you have anything further that you would like to give to the committee, if you could submit that to me in writing, we would sure appreciate it. Thank you very much.

The next panel is Mr. Joseph Levitt, Director of the Center for Food Safety and Applied Nutrition, and Elizabeth Yetley, Ph.D., U.S. Delegate to the CODEX Alimentarius Commission on Nutrition and Foods for Special Dietary Uses.

Would you both please rise?

[Witnesses sworn.]

Mr. BURTON. Thank you. Be seated.

OK, Mr. Levitt, did you have an opening statement, or Dr. Yetley?

STATEMENTS OF JOSEPH LEVITT, DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION; AND ELIZABETH YETLEY, U.S. DELEGATE TO THE CODEX ALIMENTARIUS COMMISSION ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Mr. LEVITT. Thank you very much, Mr. Chairman. It is a pleasure for me to be here today. As you noted in your opening statement, this is a return visit to give you an update on how we are progressing on dietary supplements.

As you will recall, when we testified here nearly 2 years ago, there was a recognition that while FDA had taken a number of steps, the progress review was too slow; and even more importantly, that we did not have, if you will, an overall plan or strategy, or blueprints, for how we should implement this law.

We took those concerns to heart. We sat down and we developed that, the FDA Dietary Supplements Strategic Plan. It has four program objectives.

No. 1, we should fully implement DSHEA. In doing that, we would seek to provide a high level of consumer confidence in the safety, composition, and labeling of these products. We would do that through a science-based regulatory approach, the same kind of approach that has made our other programs successful; and four, regretfully, it would take some time. It would take time to do this. We recognized that it was a long-term project, not a quick fix.

In developing the plan we had substantial public input. I chaired public meetings, both here in Washington and in California, and through that we developed six overall elements for our strategic plan.

No. 1 is safety. Everyone we talked to correctly said "safety first." That covers our adverse event reporting, which you are familiar with; our GNPs, and product-by-product actions as they be needed.

Second is labeling. As you know, there are a lot of interesting claims—structure function claims, health claims, substantiation of claims, and so forth.

Third are the boundary issues. What is the coverage of DSHEA? What intrudes into the drug rules, the convention of food rules, or even the cosmetic rules? So we need to set the boundaries and make sure they are clear.

Fourth is enforcement. As you have heard today, there are calls from all quarters that there need to be stronger FDA enforcement, both to be sure that the law is being enforced, and that there is a level playing field so that those who do try to follow the rules are not unduly hampered by those who do not.

Fifth, and what I feel is the most important part of the strategic plan, is the need for a strong underpinning of a strong scientific base. Again, as we heard today, public confidence and credibility will come primarily from the knowledge that there are scientific studies and scientific knowledge undergirding these products, their safety, their uses, and so forth, and that is very, very important.

And finally, as we added to our plan following the public meetings, there needs to be a commitment to an ongoing dialog with the entire dietary supplement community, the industry, consumers, health professionals, and that needs to be a two-way dialog so that we continue having that. We have started, through our Advisory Committee process, a standing Advisory Committee so that we have a forum that we can regularly bring these issues to, and we should have our first meeting of that later this year.

In terms of a progress report, recognizing that this was a long-term plan, each year we have developed, at the beginning of the year, what I call our "yellow book" or our goals for that year. What can we do within our established resource levels? At the beginning of the year we say, "This is what we can do." At the end of the year, through our blue book or our report card, we report up what we did accomplish, and we have been very successful in accomplishing the incremental progress that we felt we could do year by year.

Finally, Congress recognized, as we are gratified that nearly every speaker here today recognized, that there are significant funding issues. Our Appropriations Committee asked us this past fall, "OK, you've got your strategic plan, now tell us what it would take to implement that plan." That report is due to Congress this spring, and we are actively working on it and hope to be submitting that. When we do submit that, you will see fairly quickly why it is so important. The current funding levels on this chart show that the current funding for dietary supplements is about $6 million for a Food and Drug Administration that has a budget over $1 billion. That is compared to even a small program, like the Food Additive Pre-Market Review, which has more than four times that amount, at $28 million. And you see on the right the very large programs, the New Drug Review Program and the Food Safety Initiative Program. While nobody would say that the dietary supplement needs are of the order of magnitude that you have on the right, nevertheless you see by comparison that this is virtually our smallest program, something that we clearly do need to get more into the middle set of funding needs.

We have thought about, if we got funding, how we would implement that, and as we've done with other programs, we need to implement things in phases. We have felt that the three primary

areas are, No. 1, dealing with the safety and the regulatory framework, primarily first, followed by the field needs, and finally, buttressing the science needs. So if we got funding in three stages, you see that in the first year, on the left, we will put more than half of it in the first year to the safety and the regulatory needs, with some starting in the field and some starting on the science base.

In the second year, anticipating that the good manufacturing practice regulations would be out and it is time to start inspecting against those regulations, so in the middle year the primary addition would be in the field area.

And finally, when we get to full fruition, we would be adding to the science base, which is the bottom part there, and would allow us both intramurally, but also extramurally—one thing we were able to do, starting this year, is we did get $1 million as a starting point to work with the University of Mississippi, which is a very capable botanical center, and we are looking forward to that as a starting point, but also as a point for future growth.

So we feel that we do now have a plan. We feel that through the development of this plan, we do have a way to fully implement DSHEA, to provide what I think everybody wants, and that is a high level of confidence in the safety, composition, labeling of the products. We know that the progress to date has been, I'll say generously, incremental. But when you look at the comparative funding chart, that is what we are dealing with. Nearly all of our funding now, more and more, is becoming clearly earmarked. Food safety money goes to food safety. Food additive money goes to food additive. No money is earmarked for the I3 supplements, except for the $1 million that I mentioned.

We are hoping that in the coming sessions the Congress will be able to deal with that, and that we will be able to provide the kind of information that the Congress needs.

Finally, Mr. Chairman, while not specific to dietary supplements, as our program looks broadly into the future, we have committed ourselves within the Center for Food Safety and Applied Nutrition to establishing what we consider to be a truly world-class organization. That starts with, No. 1, having a science-based decision-making capacity for public health-based decisions; No. 2, they have the capacity to implement those decisions in a timely way, which will be something that everybody supports; and No. 3, is to have a culture that is based both on accountability, like reporting up, which we've done, but also a culture involving cooperation and respect for our stakeholders and the public that we serve. We feel that taking these together will provide a very strengthened organization and will create what we call "a new day in the Center."

With that introduction, we are pleased to answer questions. I will introduced Dr. Yetley; she is the lead scientist for food nutrition in our Center. She is also, as you mentioned, the U.S. Delegate to the CODEX committee that is of interest to this committee.

I will apologize to the chairman that my written testimony did not address the CODEX issue. I apologize for that. We felt that

having Dr. Yetley here, between her and I we would be happy to answer any questions that you have. It clearly is an issue of interest, and we will be happy to submit any additional information for the record that may be needed to fill out that issue.

[The prepared statement of Mr. Levitt follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Statement

By

Joseph A. Levitt, Esq.

Director, Center for Food Safety and Applied Nutrition

Food and Drug Administration

Department of Health and Human Services

Before The

Committee on Government Reform

Chairman Dan Burton

U.S. House of Representatives

March 20, 2001

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Introduction

Mr. Chairman and Members of the Committee, my name is Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration (FDA or Agency). I am joined by Dr. Elizabeth A. Yetley, Lead Scientist for Nutrition, at CFSAN. I am pleased to be here today to update you on FDA's progress in the area of dietary supplements since I testified before this committee on May 27, 1999.

We would like to share with you today what we have accomplished in this program over the last two years, the Agency's priorities for the next year, and the program challenges as we see them.

Background

The dietary supplement industry has grown exponentially since the enactment of the Dietary Supplement Health and Education Act of 1994 (DSHEA). Today's multi-billion dollar dietary supplement industry is now one of the world's fastest growing industries. Moreover, in the past,

dietary supplements were mainly sold to adults in health food stores. These products are now purchased in supermarkets, retail stores, and even through the Internet, making them available to a much wider range of consumers of all ages.

There are an estimated 1566 establishments[1] that claim to manufacture dietary supplements. Many large pharmaceutical companies have entered the dietary supplement business. Dietary supplement sales are reported to have reached $17.1 billion in 2000.[2] Between 1994 and 2000, consumer spending on dietary supplements nearly doubled, and sales continue to grow at better than 10 percent a year.[3]

Surveys show that over 158 million consumers use dietary supplements.[4] An estimated 115.3 million Americans buy

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[1] Survey of Manufacturing Practices in the Dietary Supplement Industry: Final Report, RTI Task Order No. 6, May 17, 2000

[2] "U.S. Dietary Supplements Market Size Expressed as Dollar Sales by Top Six Product Categories for 1994 to 1998 and Forecast for 1999 and 2000", National Business Journal, 2000, Dialog file No. 93, San Francisco: The Dialog Corporation, 2000

[3] Nutrition Business Journal, San Diego, 1998

[4] PREVENTION Magazine's Survey of Consumer Use of Dietary Supplement, 2000, p. 4

vitamins and mineral for themselves, and 55.8 million purchase them for family members, including children.[5] According to a Prevention Magazine survey published in 2000, consumers use dietary supplements to help them achieve their self-care goals and as a means of ensuring good health. They also use them for "medicinal" purposes such as treating and preventing various illnesses, colds, flu, increasing mental sharpness, and alleviating depression.[6]

The consumer's desire for self-care and the widespread use of dietary supplements raises a number of issues. This includes the possibility of harmful interactions between dietary supplements and prescription or over-the-counter (OTC) pharmaceutical products. Indeed, an estimated 19.6 million consumers use them with a prescription product.[7] Herbals and botanicals constituted 32 percent of the estimated $17.1 billion dietary supplement market in 2000 compared to vitamins that account for 38 percent of the

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[5] PREVENTION Magazine, p.5

[6] PREVENTION Magazine, P. 4-5

[7] PREVENTION Magazine p. 5

market.[8] Finally, as the overall use of these products increases, so does the potential for adverse effects.

A different type of FDA program

When Congress passed DSHEA, it created a unique regulatory framework for dietary supplements. Its purpose was to strike the right balance between providing consumers access to dietary supplements and truthful information about them, while preserving regulatory authority for FDA to take action against supplements that present safety problems or false or misleading labeling.

As you know, the regulation of dietary supplements is, for the most part, a postmarketing program. Since Congress considered dietary ingredients marketed prior to the passage of DSHEA to be safe, dietary supplements containing these ingredients are permitted to be freely marketed, just like regular foods (e.g., fresh fruits and vegetables, processed foods and beverages, and seafood). Should safety problems arise after marketing, the adulteration provisions

[8] National Business Journal, 2000, Dialog File No. 93, San Francisco: the Dialog Corporation, 2000.

of the statute come into play. Under DSHEA, a dietary supplement is adulterated if it or one of its ingredients presents "a significant or unreasonable risk of illness or injury" when used as directed on the label, or under normal conditions of use (if there are no directions). The burden of proof is on FDA to show that a product or ingredient presents such a risk. In addition, the Secretary of Health and Human Services may also declare that a dietary supplement or dietary ingredient poses an imminent hazard to public health or safety.

With such a "post-marketing" emphasis, DSHEA's statutory framework requires FDA to utilize such tools as good manufacturing practices (GMPs), labeling rules and adverse event reporting to identify and address potential health risks to consumers associated with the use of dietary supplements. As a preventive measure, DSHEA grants FDA explicit authority to establish GMP regulations for dietary supplements. Such regulations would provide a mechanism to help assure quality, purity and consistency in dietary supplement products. Recognizing the utility of GMPs in helping to ensure the safety of dietary supplement products, FDA has made the publication of a GMP proposed

rule and stakeholder outreach a high priority in Fiscal Year (FY) 2001.

The only "premarket" provision of DSHEA requires dietary supplement manufacturers that wish to market certain new dietary ingredients (specifically, new dietary ingredients that were not marketed in the United States (U.S.) before 1994 and that have not been in the food supply as articles used for food without chemical alteration) to submit to FDA, at least 75 days before the product is expected to go on to the market, information that supports the conclusion that a supplement containing the ingredient will reasonably be expected to be safe. There is no requirement that the manufacturer receive FDA approval or clearance before marketing the product after the 75-day period has expired. This makes it essential for public health protection that FDA have the resources to review the notifications in a timely manner. So far we have been able to keep up. But the further we get from 1994, the more the industry will likely seek to market to new dietary ingredients.

Dietary Supplement Strategic Plan

In January 2000, CFSAN published its overall dietary supplement strategy. It represents the work of an expert team from across the Agency that worked collaboratively to establish a road map to fully implement DSHEA. Built on law and science, the strategy sets out clear program goals to be accomplished by the year 2010. It is a science-based regulatory program, which will fully implement DSHEA to provide consumers with a high level of confidence in the safety, composition, and labeling of dietary supplements.

There are five major points from this strategy that I would like to highlight:

1. FDA held public meetings on June 8, 1999, in Washington, D.C. and on July 20, 1999, in Oakland, Californiaa, which I chaired personally, to solicit comments on the development of its overall dietary supplement strategy. Also, throughout 1999, FDA held several other public meetings on other dietary supplement issues that were incorporated into the strategy. These included meetings on current GMPs and structure/function claims.

2. After the June 8, 1999 meeting, FDA developed five internal dietary supplement strategy teams to consider the addition of stakeholder input, and to discuss dietary supplement activities. Teams were established to examine safety, labeling, boundary issues, enforcement and research issues.

3. This strategy is built on the "twin pillars" of law and science. Clear, science-based program goals have been established that will fully implement DSHEA by the year 2010.

4. As with other new legislative mandates, there needs to be a long-term implementation process to accomplish all of the dietary supplement activities the Agency and/or its stakeholders identified. FDA will develop, on an annual basis, specific items that are to be accomplished that year by the Agency.

5. FDA recognizes that the success of the strategy will depend on new and continued partnerships with other government agencies, academia, health professionals, industry and consumers. FDA will continue its outreach to stakeholders. FDA is committed to establishing

stronger working relationships with our stakeholders as well as leveraging resources, and communicating accurate dietary supplement information.

The Plan is divided into six sections, consistent with the stakeholder input that we received: Safety, Labeling, Boundaries, Enforcement, Science-Base, and Outreach.

Safety

Virtually every stakeholder has urged us to address "safety first." FDA's Adverse Event Report Monitoring System for dietary supplements provides an essential tool for signaling potential safety problems that may be associated with the use of a particular product or type of products already in the marketplace that need to be investigated and critically evaluated. As noted earlier, DSHEA grants FDA the authority to establish GMP regulations governing the preparation, packaging, and holding of dietary supplements under conditions that help ensure their safety, and CFSAN has listed publishing the dietary supplement GMP proposed rule and conducting outreach as a high Agency priority for FY 2001. There is broad public support, including from industry, that dietary supplements GMPs are needed to

ensure that the public has confidence in using these products. Instituting a credible GMP system will require resources to hire new FDA investigators to inspect manufacturers to ensure that they are manufacturing products in accordance with the GMPs.

Product Labels

DSHEA allows the use of certain claims (often called structure/function claims) of general well-being from consumption of a dietary ingredient, and claims of benefits related to classical nutrient deficiency diseases. These claims require notification to FDA within 30 days of marketing. Manufacturers must have substantiation that the claims are truthful and not misleading, and the product label must bear the statement "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." FDA published a final "structure/function" regulation in January 2000.

FDA reviews proposed health claims for dietary supplements under the provisions of the Nutrition Labeling and Education Act of 1990 (NLEA), implementing regulations and

relevant case law. A number of dietary supplement health claims are authorized by regulation, including claims for calcium and reduced risk of osteoporosis and for psyllium and reduced risk of heart disease. Claims that a dietary supplement treats or mitigates a disease may not be made unless the supplement is approved for that use under the new drug provisions of the Federal Food, Drug and Cosmetic Act.

Boundaries

The Boundaries section highlights one of the profound challenges of DSHEA - determining the regulatory category of a product. It is important to draw boundaries between dietary supplements, drugs, and conventional foods and to give manufacturers notice of the regulatory regime that applies to their products. FDA's "structure/function" rule, referenced above, began to address the drug/supplement boundary issues.

Enforcement

The plan also outlines FDA's enforcement priorities, with safety issues at the top. This section also includes

activities devoted to improving FDA's internal capacity in the enforcement area.

Under DSHEA, FDA will take appropriate action against unsafe products, inaccurate and misleading labeling and consumer fraud. FDA will also conduct marketplace surveillance and monitoring activities. Consumer groups and many in the industry have called for stronger FDA enforcement in order to create a "level playing field" and ensure that all companies adhere to the same rules. FDA will establish partnerships with Federal, State, and local agencies to enhance enforcement efforts by sharing data, heightening communication, and utilizing resources.

Science-Base

The Science-Base section is the most important component of the plan because, like all FDA-regulated products, public credibility comes with knowing there is an adequate scientific foundation to the products and their claims. However, it is also the least well-developed section of the plan. For example, unlike conventional foods, FDA has limited experience and expertise with dietary supplement ingredients. Leveraging and partnerships will be needed to

forge a strong scientific underpinning for dietary supplements. For example, we are working closely with the Office of Dietary Supplements and the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health. FDA has already begun leveraging with outside organizations as well.

Outreach

Finally, the Outreach section of the plan reflects FDA's continued commitment to a two-way dialogue with the dietary supplement community. Communication with the general public, FDA field offices, health care professionals, and industry in an appropriate and timely manner, is critical, including information about potential adverse effects associated with dietary supplements. FDA will continue its commitment to establish a stronger working relationship with organizations interested in promoting two-way communication and cooperation. As a result of input from FDA's stakeholders and the increasing scope of the scientific questions concerning dietary supplements, a standing Dietary Supplement Subcommittee was officially added to FDA's restructured Food Advisory Committee on June 26, 2000.

CFSAN Dietary Supplement Accomplishments

Mr. Chairman, let me assure you that fully implementing DSHEA is a priority at CFSAN. Within our current resource allocation, however, we can only expect to make incremental progress. At the ends of FY 1999 and 2000, CFSAN published documents titled: CFSAN Program Priorities 1999 Report Card and CFSAN Program Priorities 2000 Report Card. (Appendix) The publication lists the Agency's accomplishments for FY 2000, including those in the area of dietary supplements. Let me highlight several areas.

Institute of Medicine (IOM)/National Academy of Sciences (NAS) Study

Last year FDA entered into a contract with the IOM at the NAS entitled, "Framework for Evaluating the Role of Dietary Supplements in Health." The IOM will develop a protocol for the Agency to use in reviewing the safety of dietary supplements. The contract is for two years and covers the time period September 30, 2000 through September 29, 2002.

Because this project is critical to the responsible and timely implementation of the DSHEA, the Agency believes it

should be an open process driven by well-grounded scientific rationale. The contract requires that the IOM constitute a committee that will:

1. Develop a proposed framework for categorizing and prioritizing dietary supplement ingredients based on safety issues;

2. Describe a process for developing a review system with specifications for evaluating the safety and role in health of dietary supplement ingredients; and

3. Develop at least six prototypes as examples of using the proposed framework.

The framework will include a methodology to examine the available peer-reviewed literature with regard to the role of dietary supplement ingredients in health. Methods that other expert bodies have used to categorize and review issues related to safety and the possible roles of dietary supplements and their ingredients in health will also be taken into consideration.

The IOM process includes opportunities for public input. The Agency expects that a proposed framework will be

developed during the first year (FY 2001) of the project and released for comment and review prior to being finalized by the end of the second year (FY 2002).

***Pearson v. Shalala* policy**

The U.S. Court of Appeals for the District of Columbia, in the matter of *Pearson v. Shalala*, ordered FDA to clarify its significant scientific agreement (SSA) standard, reevaluate four claims the Agency had previously denied, and permit health claims that do not meet the SSA standard if a disclaimer can ensure that the claim will not mislead consumers.

The Agency is committed to fully implementing the Federal court order. FDA published a revised strategy for implementation of the *Pearson* court decision in an October 6, 2000, Federal Register (FR) Notice (65 FR 59855 - 59857). FDA noted that it had completed three steps of its original implementation strategy (published December 1, 1999, 64 FR 67289-67291). These steps were:

- a literature review and public request for scientific data to retrieve relevant scientific information that

had become available on the four claims in dispute since FDA's initial 1991 and 1993 review;

- publication of a guidance clarifying the SSA standard; and

- convening of a public meeting (on April 4, 2000) to solicit input on changes to the general health claims regulations for dietary supplements, in light of the *Pearson* decision.

Under its revised strategy, FDA announced that we intend to respond in one of three ways to the four health claims at issue in *Pearson* and, pending rulemaking to amend its regulations in response to *Pearson*, to new health claim petitions that are filed for comprehensive review. As are outlined in the revised strategy, the three possible responses include:

1. If the SSA standard is met, the Agency will propose to authorize the health claim, and will consider using its interim final rule authority which would allow use of the health claim immediately upon publication of the proposal.

2. If the SSA standard is not met but the scientific evidence in support of the health claim outweighs the evidence against the claim, and if certain other general criteria enumerated in the October 6 Notice are met, FDA will consider exercising enforcement discretion for dietary supplements that bear an appropriately qualified health claim. The petitioner will be notified by letter about the basis for FDA's decision and the criteria for the Agency's exercise of its enforcement discretion.

3. If the evidence against the claim outweighs the evidence for the claim, the substance that is the subject of the claim poses a threat health, or if other conditions of the implementation plan are not met, the claim will be denied and the petitioner will be notified by letter.

FDA has announced decisions, under its implementation plan, on three of the claims at issue in *Pearson* (two on October 11, 2000, and another on October 31, 2000). In addition, FDA has reconsidered two additional petitions, submitted in 1999, that were initially denied. Decisions under the implementation plan on those petitions were

issued on November 28, 2000, and February 9, 2001. Of these five claims, qualified claims were allow for two instances (omega-3 fatty acids and heart disease, B vitamins and heart disease), two were denied in two instances on the basis that the evidence against the claims outweighed the evidence for the claims (fiber and cancer, vitamin E and heart disease), and one claim was denied *per se* but alternative qualified language was offered (relating intake levels and sources to effectiveness of folic acid in reducing risk for neural tube defects in infants). The Agency is in the final stages of review for the last *Pearson* health claim, the relationship between antioxidant vitamins and reduction of risk of some cancers.

Priorities for Dietary Supplements

In addition to CFSAN's Dietary Supplement Strategic Plan, in January 2001 CFSAN published its FY 2001 overall program priorities. These priorities are broken down into A and B lists, with A items being given top priority and B items being completed when Agency resources allow. The CFSAN "A" list goals for dietary supplements for the next year include:

Regulations/Guidance

In the area of regulations, FDA is committed to seeing that the dietary supplement GMP proposed rule is published. This will include conducting an outreach program after the publication of the proposed rule. FDA is working to complete health claim evaluations for antioxidants and cancer begun in FY 2000. CFSAN will continue to review premarket (75-day) notifications for new dietary ingredients within the statutory timeframe.

Enforcement/Outreach

The Center will continue to identify high priority safety issues and initiate appropriate enforcement actions against unsafe, adulterated, or misbranded dietary supplement products and ingredients. CFSAN is looking into ways for making adverse event reports (AERs) promptly available to manufacturers that complies with Freedom of Information regulations and patient privacy issues. We are continuing to study the scientific evidence related to dietary supplements that contain ephedrine alkaloids, based on the March 2000 release of AERs and related material and the

August 2000 public meeting/public comments. Finally, we also plan to create and publish a Dietary Supplement Labeling Guide.

Research/Science-Base

As previously mentioned, CFSAN is working with NAS and IOM, to establish a framework to review dietary supplement safety. The Center will develop mechanisms to expedite dietary supplement adverse event investigations and enhance timely clinical assessment of dietary supplement AERs. The Center plans to review analytical methods for isoflavones in soy.

Finally, we will also complete and disseminate the dietary supplement research plan.

Reports to Congress

The Agency plans to submit three reports to Congress including:

(1) A report summarizing the total funding spent in

FY 2000 to assess the safety of dietary supplements, including related costs required to meet the statutory burden of proving adulteration under DSHEA.

(2) A report on the cost for implementing our Dietary Supplement Strategic Plan.

(3) A report on implementation of the U.S. Court of Appeals for the District of Columbia Circuit decision in *Pearson v. Shalala* regarding dietary supplement health claims.

Challenges

Recognizing that no new funds were authorized or appropriated in DSHEA, the Strategic Plan announced that a long-term implementation process to achieve all the goals that were identified to ensure the safety of dietary supplements. We have outlined a flexible ten-year implementation plan, that could be accelerated or decelerated, depending on resources available and safety concerns.

Resources: What FDA needs to fully implement DSHEA

As noted earlier, the 2001 Agriculture, Rural Development, the Food and Drug Administration, and Related Agencies Appropriations Bill directed FDA to issue a report on the dollar cost to implement the Dietary Supplement Strategic Plan.

The Dietary Supplement Strategic Plan is designed to be implemented in stages, becoming fully functional after several years. To be successful, the program must continue at these levels over a sustained period of time. As a starting point, the Agency's current base for dietary supplements in FY 2001 is approximately $6 million and 46 Full-Time Employees.

The Report to Congress will set forth the resources needed for headquarters safety and regulatory activities (e.g., AER reporting and regulations development), for field activities, and science-based activities, both intramural and extramural.

Leveraging: University of Mississippi Research

In FY 2001, Congress appropriated $1 million in FDA's budget for collaborative research between FDA and the National Center for Natural Products Research (NCNPR) at the University of Mississippi. NCNPR is nationally and internationally recognized for its expertise and research experience in botanicals used for health purposes. The NCNPR mandate is to bring government, academia, industry, consumers, health professionals and industry together to solve scientific problems in this area. We are enthusiastic about this new partnership and hope to be able to expand it in future years.

Bovine spongiform encephalopathy (BSE) in dietary supplements

As you may know, much has been written about the BSE crisis in Europe. With concerns over the disease in Europe, Americans are asking perfectly reasonable questions about whether there are gaps in the U.S. systems that could allow BSE to enter this country. The FDA, U.S. Department of Agriculture (USDA) and other government agencies have been

vigilant in making sure that BSE is kept out of this country. There has been much media attention to the fact that there are dietary supplements being sold in health food stores that contain animal tissues, including tissues and organs from cattle. Some of these dietary supplements contain central nervous system tissues such as brain or spinal cord tissue. However, these types of products do not constitute a large part of the market. In fact, information provided to us by one trade association, the National Nutritional Foods Association, indicates that such products likely make up less than 1.0 percent of the marketplace. Nonetheless, even though the market share for these products is small, FDA has taken seriously the threat that they might pose to public health if they were to be contaminated with the infectious agent that causes BSE. Both FDA and USDA have taken steps to minimize the possibility that cow tissues from a BSE country might find its way into a dietary supplement.

In 1991, the USDA banned the importation of cattle tissues and organs from countries infected with mad cow disease. Amid concerns that USDA's restrictions might not capture all FDA-regulated products, we imposed an import bulletin in 1992 (later upgraded to an import alert in 1995) to halt

imports of high-risk bulk dietary ingredients, as well as to provide guidance to FDA inspectors to examine other bulk and finished dietary supplements to ensure that they did not originate from BSE countries. Additionally, in 1992 FDA issued a letter to the dietary supplement industry laying out our concerns about the use of cow derived ingredients in dietary supplements and advising them that they should take immediate steps to ensure that no cow derived ingredients originated from animals in a BSE country. FDA has periodically re-issued the letter over the years to keep the industry focused on this issue, the last letter being issued in November 2000. We remain concerned about this issue and are actively reviewing our current regulatory controls to ensure that they are as effective as they can be to ensure the safety of consumers who choose to use products that contain cow derived ingredients. But, at this time, the information we have from the industry and from our own import and domestic inspectional programs, while limited, provides no evidence that cow derived ingredients from BSE countries are being used in dietary supplements.

We are addressing these issues within the Agency's overall strategy of BSE containment.

Conclusion

Mr. Chairman, we are committed to making safe products available to consumers who choose to use dietary supplements to improve their health. DSHEA was enacted to ensure access to these products and the Agency is committed to fully implementing DSHEA over the next ten years. As I stated in my testimony, we will accelerate or decelerate our program priorities depending on resources and safety issues. It is our goal to make sure these products are safe and accessible to all American consumers.

I would be happy to respond to any questions the Committee may have.

Dietary Supplement Strategic Plan: Program Objectives

- **Fully Implement DSHEA**
- **Consumer Confidence in Dietary Supplements**
- **Science-Based, Regulatory Approach**
- **Long-Term Effort**

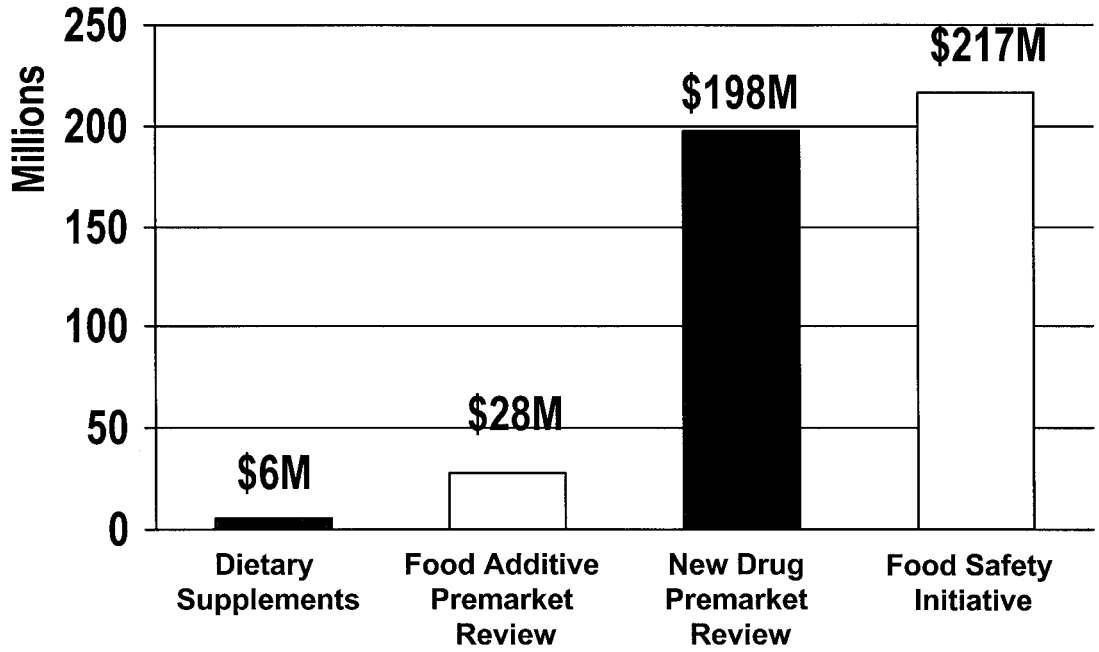
Dietary Supplement Strategic Plan: Overall Elements

- **Safety**
- **Labeling**
- **Boundaries**
- **Enforcement**
- **Science-Base**
- **Outreach**

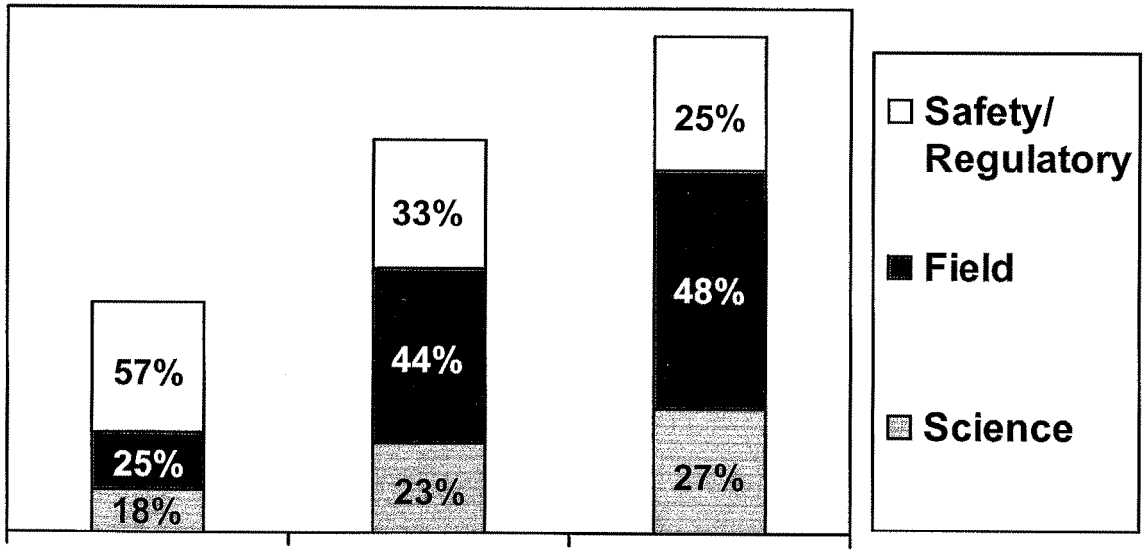
Dietary Supplement Progress Report

- **Annual Priorities Established (Yellow Book)**
- **Annual Report Card Published (Blue Book)**
- **Report to Congress on Program Costs – Due this Spring**

Estimated Funding for Dietary Supplements Compared to Other Programs in FY2001 Dollars



DIETARY SUPPLEMENT STRATEGIC PLAN: NEEDS PHASED IN OVER 3 INCREMENTS



Appendix

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
February 3, 2000

Program Accomplishments

February 1, 1999 - January 31, 2000

Letter from Center Director
Highlights
Part I: Food Safety Initiative
Part II: Major Program Areas
Part III: Cross-Cutting Areas
Appendix 1: Goals Carried Over
Appendix 2: Other Significant Accomplisments

Dear Colleague, FDA Foods Community

As promised, I am pleased to provide you with an end-of-the-year "Report Card" on our 1999 program priority accomplishments for FDA's foods program. These are the "boulders" we pledged to move up and over the mountain top. As you will see, we completed nearly 90% of our "A" list goals (73 out of 83 activities). I am very proud of this success rate. This represents a clear management strategy to focus our resources on where we provide the most benefit to American consumers.

Implementation of the President's Food Safety Initiative, the Center's top priority, constitutes the Centerpiece of our 1999 accomplishments. Of particular note is the Presidential radio address on December 11 which announced the Egg Safety and Imported Food Action Plans. After food safety, our 1999 accomplishments include important advances in such areas as food additives, dietary supplements, food labeling, cosmetics and international activities. Twenty areas of particular note have been highlighted for you.

Last fall, I wrote to you about our declaring a "New Day" at CFSAN, and about our broader vision of building a "World Class Organization." The dedication of the many FDA staff who embraced the concept of the 1999 workplan and who worked diligently to complete nearly 90% of our goals demonstrates that we are, indeed, on our way to reaching that goal. I am also pleased to tell you that our 2000 Program Priorities document will be available in the coming weeks. The format of the 2000 workplan will be similar to the 1999 workplan, except it will be a nine-month plan (through September 30, 2000) so as to align our program priorities with the federal budget cycle.

In closing, I very much appreciate the support I have received from many stakeholders on this management approach. I look forward to continuing this tradition of building predictability, productivity and accountability into our Foods program. The American public deserves no less.

Sincerely,

Joseph A. Levitt

Director
Center for Food Safety and Applied

Enclosure

1999 Program Priorities Accomplishments

February 1, 1999 -- January 31, 2000

Highlights

Imports: Improved the safety of imported food products by enhancing border surveillance and greatly expanding FDA's overseas presence. At the border, FDA initiated a 1,000 sample survey of high volume fresh produce imports. Overseas, FDA doubled the number of foreign food establishment inspections, conducted fiveassessments of foreign food safety systems, and provided extensive education and technical assistance on use of the Good Agricultural Practices/Good Manufacturing Practices guidance for produce.

Imported Foods Action Plan: As announced by President Clinton in his December 11, 1999 radio address, FDA and the U.S. Customs Service developed an Imported Foods Action Plan to further enhance border surveillance. The Plan will be implemented in 2000.

Seafood HACCP Inspections: FDA conducted the second year of seafood HACCP inspections, with priority to processors with implementation problems. FDA found clear progress by most seafood processors, but also issued warning letters to those firms with significant, unaddressed deficiencies.

Sprouts: CFSAN issued two guidance documents to enhance the safety of sprouts, including guidance for microbiological testing.

Prevention Measures for Eggs: CFSAN published a proposed rule that would require refrigeration of shell eggs at retail and safe handling statements on labels of shell eggs.

Egg Safety Action Plan: In collaboration with USDA, EPA and the Department of Commerce, FDA completed an Egg Safety Action Plan that identifies the systems and practices that need to be implemented to sharply reduce eggs as a source of human *Salmonella enteritidis* illnesses. The Plan was announced by President Clinton in his December 11, 1999 radio address, and implementation will begin in 2000.

Risk Assessments: Completed, with public input, draft risk assessments for *Listeria* and *Vibrio parahaemolytics*. Final risk assessments will be completed in 2000.

Food Code: CFSAN completed revisions to the Food Code to enhance the safety of food prepared outside the home, including restaurants, nursing homes, hospitals, and day care centers. The Food Code was adopted by agencies in 15 states.

Expedited Review: CFSAN developed and implemented new procedures to expedite the review of food additives that are intended to decrease the incidence of foodborne illnesses through their antimicrobial actions against human pathogens that may be present in food. CFSAN approved four antimicrobial agents which had been designated for expedited review -- three sodium chlorite solutions and one

peroxyacetic acid solution.

Trans Fatty Acids: CFSAN published a proposed rule to require that the amount of trans fatty acids in food be included in the Nutrition Facts panel.

Infant Formula: CFSAN reviewed all 35 notifications for infant formulas within statutory timeframes.

New Dietary Ingredients: CFSAN reviewed all 24 notifications for new dietary ingredients within statutory timeframes.

Health Claim/Nutrient Content Claim Petitions and Notifications: CFSAN responded to these submissions within statutory timeframes and use of two health claims were authorized: (1) The relationship between whole grain foods and heart disease and certain cancers; and (2) The role of soy protein in reducing the risk of coronary heart disease.

Dietary Supplement Overall Strategy: CFSAN developed an overall strategy to fully implement the Dietary Supplement Health and Education Act of 1994. Once implemented, this science-based plan is intended to provide a high level of consumer confidence in the safety, composition and labeling of dietary supplement products.

Strategy for *Pearson* Court Decision: CFSAN informed the public of its strategy to implement the court decision in *Pearson v. Shalala*. As part of this strategy, CFSAN developed guidance for the industry clarifying the meaning of the "significant scientific agreement" standard as it applies to the review of scientific data for health claims.

Biotechnology Public Meetings: Three meetings were held to give the public an opportunity to provide comments on CFSAN's process for assuring the safety of food produced through biotechnology. In 2000, CFSAN will develop and implement strategies based on these public meetings.

National Food Safety System: In collaboration with CDC, USDA, and state and local governments, continued progress was made towards development of a plan for a national food safety system. Long-term planning ideas will be integrated into the strategic planning process being conducted by the President's Council on Food Safety.

International Affirmative Agenda: CFSAN published its Affirmative Agenda for International Activities for 2000 – 2002. The Agenda addresses broad priorities in five major international activities: Regulatory; Harmonization; Development, Maintenance and Dissemination of CFSAN's Science Base; Equivalence Evaluations, Food Safety Needs Assessments, and Food Safety Technical Cooperation and Assistance; and Trade-Related Activities.

Cosmetics Voluntary Registration Program: Reinstated the Cosmetics Voluntary Registration Program, utilizing restoration funds provided in the FY 99 Appropriations.

"New Day": CFSAN implemented a "New Day" initiative to improve the quality of worklife for all employees. This initiative provides the foundation for CFSAN building itself into a World Class Organization.

Part I. Food Safety Initiative

*Items marked with ** were accomplished in the 4th quarter.*

Imports

1. **Enhance follow-up and containment of foodborne disease outbreaks associated with imported food:** CFSAN and Office of Regulatory Affairs (ORA) have developed and implemented the publication; "Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations." In conjunction with the publication of this document, three satellite training courses for FDA and State/Local investigators e.g., Food Microbiology (3-day), Foodborne Disease Epidemiology (3-days), Tracebacks (2-days) have been conducted. These training courses were attended by over 10,000 participants. An extensive "Farm Investigation Questionnaire" for use on farms implicated in produce tracebacks has also been developed.

2. **Increase surveillance of imported food products at the border:** CFSAN and ORA initiated a 1000 sample survey of high volume imported fresh produce. These commodities were analyzed for *Salmonella, Shigella,* and *E. coli* O157:H7. Of the first 500 samples, approximately 5% tested positive for bacteria. CFSAN and ORA conducted 19 traceback investigations and visited 10 farms as the result of outbreak tracebacks or positive samples in the Imported Produce Sampling Program.

3. ** **Imported Foods Action Plan:** As announced by President Clinton in his December 11, 1999 radio address, FDA and the U.S. Customs Service developed an Imported Foods Action Plan to further protect consumers from unsafe imported food. The Plan includes actions that FDA and Customs will take to: (1) prevent distribution of imported unsafe food by means such as requiring food to be held until reviewed by FDA; (2) destroy imported food that poses a serious public health threat; (3) prohibit the re-importation of food that has been previously refused admission, and require the marking of shipping containers of imported food that is refused admission for safety reasons; (4) set standards for private laboratories for the collection and analysis of samples of imported food for the purpose of gaining entry in the U.S.; (5) increase the amount of the bond posted for imported foods when necessary to deter premature and illegal entry into the U.S.; and (6) enhance enforcement against violations of U.S. laws related to the importation of foods, including through the imposition of civil monetary penalties.

4. **Initiate education/outreach and technical assistance to foreign countries on the use of Good Agricultural Practices (GAP)/Good Manufacturing Practices (GMP) guidance for produce**: A new tool to help explain the Produce Safety Initiative was completed: "Assuring Safer Produce: A Global Issue," a six-minute video that provides an overview of the good agricultural and good manufacturing practices, is available in English, Spanish, French and Portuguese.

   CFSAN/JIFSAN held an international conference, "Enhancing the Safety of Fresh Produce at the Source: Training Modalities and Methods, Needs and Opportunities". This landmark workshop was attended by 175 participants from 24 countries. The workshop began the process for determining how to develop an education and outreach program for growers and producers that will benefit public health and the market place.

   FDA held two international meetings for government officials and food producers with food safety responsibilities. The first, targeted to countries of North and Central America, was held in Mexico City; and the second, targeted to countries of South America, was held in Santiago, Chile.

5. **Evaluate food regulatory systems in foreign countries:** CFSAN, ORA, and other FDA staff

conducted an assessment of the food safety systems in Nicaragua, Costa Rica, El Salvador, Guatemala and Honduras.

6. **Conduct 75-100 foreign inspections of food establishments:** CFSAN and ORA completed 82 foreign inspections in FY 1999 of food plants (78) and farms (4) that produce food products at high risk of microbial contamination. Of the first 26 Establishment Inspection Reports (EIRs) reviewed: eight establishments were placed on DWPE (Detention Without Physical Examination) because of unsanitary conditions; four establishments were issued warning letters; and fourteen establishments were in compliance with FDA regulations. Review of the remaining EIR's is ongoing.

Hazard Analysis and Critical Control Points (HACCP)

7. ** **Seafood HACCP Inspections:** FDA conducted the second year of rigorous seafood HACCP inspections, with priority to processors with implementation problems. FDA inspectors evaluated the adequacy of HACCP plans for 11 types of hazards, ranging from pathogens and histimines to use of unlawful pesticides and food additives. Based on data available at the end of calendar year 1999, FDA found clear progress being made by most seafood processors. FDA will issue a second year "progress report" once more detailed information is available.

8. ** **Seafood HACCP Enforcement Strategy**: CFSAN and ORA developed and implemented an enforcement strategy for the second year of HACCP inspections. The enforcement strategy was embodied in the Compliance Program for the FDA foods program. Based on data available at the end of calendar year 1999, FDA issued warning letters to approximately 5% of seafood firms.

9. ** **Seafood HACCP Training:** In collaboration with the Seafood HACCP Alliance, CFSAN developed a follow-on training program for seafood processors. Unlike the original course for processors in basic HACCP, which stressed fundamental concepts and HACCP theory, this course focused on practical problem solving and was based on problems that processors were found to be having in implementing their HACCP systems. Over 20 courses were taught around the country, attended by over 300 seafood industry representatives.

10. ** **Seafood HACCP Government Performance and Results Act (GPRA) Goal:** The GPRA goal for FY 99 was to have 50% of the seafood industry operating adequately under appropriate HACCP systems. Data available through the end of calendar year 1999 indicates that the GPRA goal was exceeded by approximately 5 percent.

11. ** **Seafood HACCP "Transition" Policy:** CFSAN published a draft "transition" policy for public comment on March 26, 1999 (64 FR 14736). The draft policy describes when scientific issues need to be resolved before FDA will take regulatory action against a processor that has deficiencies in their HACCP system. The final policy is expected to be published in the first quarter of 2000.

Produce Initiative

12. **Good Agricultural Practices:** In conjunction with USDA, CFSAN disseminated and promoted the use of the Good Agricultural Practices/Good Manufacturing Practices guidance document to both domestic and foreign agriculture communities. This guide has been translated into three languages: Portuguese, French, and Spanish.

13. ** **Sprouts:** On October 25, 1999, CFSAN issued two guidance documents to enhance the safety of sprouts. The guidance advises sprout producers and seed suppliers of steps they should take to reduce microbial hazards common to sprout production. A companion guide provides producers with the latest information about testing spent irrigation water, an important step to ensure the safety of sprouts.

Additional Prevention Efforts

14. ** **Citrus Juices:** In conjunction with the Florida Department of Citrus, the State of California and the National Center for Food Safety and Technology, CFSAN developed guidance to help the industry develop practical means for achieving the FDA-required reduction in pathogens (100,000 fold or 5-log) in lieu of the labeling requirement. This included conducting pilot HACCP programs, developing new microbiological methods, evaluating new technologies under commercial conditions and developing tools that industry could use to evaluate the effectiveness of their programs. CFSAN conducted a series of workshops to ensure that the information was adequately disseminated to the citrus industry.

15. **Preventive Measures for Eggs:** On July 6, 1999, CFSAN published a proposed rule that would require refrigeration of shell eggs at retail and safe handling statements on labels of shell eggs (64 FR 36491).

16. **Status Report on Eggs:** In conjunction with USDA, and in accordance with the Appropriations Conference Report, a status report on actions taken to enhance the safety of shell eggs and egg products was submitted to Congress on March 16, 1999.

17. **Food Code:** Revisions to the Food Code were completed and a notice of its availability was published in the Federal Register on February 22, 1999 (64 FR 8576). Agencies in 15 states have adopted the Food Code. This exceeds the FY 99 Government Performance and Results Act (GPRA) goal to achieve adoption of the Food Code by 25 percent of States.

18. **MOU with FSIS:** A Memorandum of Understanding (MOU) with the Food Safety and Inspection Service (FSIS) regarding food establishments under the jurisdiction of both FDA and FSIS was finalized on March 1, 1999.

19. ***Vibrio vulnificus*:** In the Federal Register of January 21, 1999 (64 FR 3300), CFSAN published a notice soliciting comments on citizen petition 98P-0504 requesting that FDA establish a performance standard for *Vibrio vulnificus*.

Surveillance and Outbreak Response

20. **Outbreak Response:** A document describing the decision-making criteria for handling outbreaks has been developed. This document will help CFSAN, in conjunction with the field, follow-up and contain foodborne disease outbreaks associated with domestic food.

21. **Foodborne Outbreak Response Coordinating Group (FORC G):** Under FORCG, HHS and USDA are in the process of refining, with States, the uniform procedures developed for all agencies to follow in coordinating outbreak investigations. In regards to this effort, CFSAN, in conjunction with the field, USDA, AFDO and others, developed a document entitled: "Foodborne Outbreak Response and Coordination." This document is intended to guide Federal agencies, State or local health officials, and state food regulatory officials involved in food or waterborne

outbreaks on procedures for coordinating responses to a multi-state outbreak of food or waterborne illness.

22. ***Listeria*:** A questionnaire has been developed to conduct, through CDC and the FoodNet sites, a case-control study of *Listeria* infections to guide control efforts.

23. ** ***Salmonella enteritidis (SE)*:** In collaboration with USDA, EPA and the Department of Commerce, FDA completed an Egg Safety Action Plan that was announced by President Clinton in his December 11, 1999 radio address. The Action Plan identifies the systems and practices that need to be implemented to sharply reduce eggs as a source of human SE illnesses.

Research

24. **Food Safety Initiative Research and Risk Assessment:** CFSAN conducted food safety research as outlined in the Center's "Three-Year Plan for Research in Support of the National Food Safety Initiative and the Produce and Imported Food Safety Initiative." In addition, a review of the research projects and a plan update is complete.

25. **Extramural Research:** Second year funding for the multi-year grants awarded in fiscal year 1998 is complete. Project officers for each of the grants completed the extramural project reviews to obtain a status and update for the project.

26. ** **Consultation with USDA:** CFSAN worked closely with USDA to develop Requests for Proposals (RFPs) for USDA's Special Research Grants Program and the Epidemiological Approaches for Food Safety Program, pursuant to the $5 million identified in the FY 99 Agriculture Appropriations Bill. CFSAN's research needs were presented in the RFPs, and a broader listing of needs was communicated in a letter to USDA.

27. ** **Joint Institute for Food Safety Research (JIFSR):** In conjunction with USDA, a final report articulating the concept of JIFSR, a proposed structure, operating principles, goals and outcomes, and an implementation schedule was developed and transmitted to the President on July 2, 1999.

Risk Assessment

28. ** ***Listeria*:** To aid in conducting a risk assessment of *listeria* in ready-to-eat foods, a notice was published requesting the submission of scientific data and information (May 26, 1999, 64 FR 28351). In addition, in conjunction with the Risk Assessment Working Group of the National Advisory Committee on Microbiological Criteria for Foods, public meetings were held on May 26 and September 23, 1999 to provide an opportunity for open discussion of the risk assessment of *Listeria*. Subsequently, CFSAN completed a draft risk assessment which was sent to the Risk Assessment Consortium for review. The final risk assessment will be completed in 2000.

29. ** ***Vibrio Parahaemolyticus*:** To aid in conducting a risk assessment of *Vibrio parahaemolyticus* in shellfish, a notice was published requesting the submission of scientific data and information (May 7, 1999, 64 FR 24664). In addition, in conjunction with the Risk Assessment Working Group of the National Advisory Committee on Microbiological Criteria for Foods, public meetings were held on May 26 and September 24, 1999 to provide an opportunity for open discussion of the risk assessment of *Vibrio parahaemolyticus*. Subsequently, CFSAN completed a draft risk assessment which was sent to the Risk Assessment Consortium for review. The final risk assessment will be completed in 2000.

30. ** **Methylmercury:** CFSAN completed a draft risk assessment of methylmercury based on a subset of data from two key studies. CFSAN will finalize this risk assessment in 2000, as well as develop an overall risk assessment of methylmercury in seafood incorporating new data expected to be available in the Spring of 2000.

Education

31. **Shell Eggs Education Campaign:** A specialized "egg safety" campaign was developed in an effort to reduce the incidence of foodborne illnesses caused by *Salmonella enteritidis*. Two easily reproduced fact sheets were developed: "Playing it Safe with Eggs" for consumers and "Assuring the Safety of Eggs" for food service personnel. A news article was written in English and Spanish and distributed to small dailies, weeklies and local advertisement-type publications.

32. **"Fight BAC!":** In conjunction with the Public-Private Partnership for Food Safety Education, food safety education efforts targeted to school children and high risk population -- i.e., the very young, the elderly, and those with impaired immune systems -- have been initiated.

33. **Food Safety Education Month:** The President's Council on Food Safety issued a proclamation declaring September 1999, National Food Safety Education Month. This was an opportunity to promote food safety to consumers and the food industry. This year's theme was "Cook It Safely." FDA, in conjunction with USDA, developed and mailed consumer education planning guides to public health departments, FDA public affairs specialists and USDA extension agents throughout the country. The guide contained reproducible activities and publicity ideas for food safety education during September. In addition, special mailings were sent to over 100,000 food service directors for at-risk audiences, school food service directors, day care directors and nursing home food service directors with special information about food safety.

Strategic Planning

34. ** **President's Council on Food Safety:** CFSAN participated in the President's Council for Food Safety Strategic Planning Task Force activities to develop a comprehensive Food Safety Strategic Plan. A public meeting was held on July 15, 1999 to solicit comments from consumers, industry and academia, as well as state and local officials. Using input received from the public meeting, the Task Force prepared a Draft Preliminary Strategic Plan and published a summary in the Federal Register (December 15, 1999, 64 FR 70167), leading up to a second public meeting on January 19, 2000. CFSAN will continue to participate in the Council's activities to finalize the comprehensive Strategic Plan by July 2000.

Part II. Major Program Areas

Premarket Review of Food Ingredients

35. **Expedited Review:** New procedures have been implemented to expedite the review of food additives that are intended to decrease the incidence of foodborne illnesses through their antimicrobial actions against human pathogens that may be present in food. Guidance on implementation of the expedited review process was published in the Federal Register on January 5, 1999 (64 FR 517). In 1999, CFSAN approved food additive petitions for four antimicrobial agents which had been designated for expedited review -- three sodium chlorite solutions and one

peroxyacetic acid solution.

36. ** **Food and Color Additives:** CFSAN exceeded the GPRA performance goal to complete 30% of food and color additive petitions within 360 days. Specifically, for petitions received in FY 98, 54% were completed within 360 days. This cohort of food and color additive petitions was larger than any received in the past decade. Because of the large number of new petitions, less progress was made in reducing the number of overdue petitions than initially projected. Specifically, at the end of the fiscal year, 42% of the petitions under review were overdue (goal was 30 percent).

37. ** **Indirect Additives (Food Contact Substances):** On November 22, 1999, CFSAN issued two guidance documents for the industry on the submission of premarket notifications for food contact substances, incorporating feedback from a public meeting held in March 1999. Full implementation of this program will be initiated in 2000 as a result of new resources made available in the FY2000 Congressional appropriations.

38. **Irradiation Labeling:** An advanced notice of proposed rulemaking to solicit comments on whether revisions on the current irradiation labeling requirements are needed published in the Federal Register on February 17, 1999 (64 FR 7834).

39. **Food Quality Protection Act:** On July 27, 1999, CFSAN announced the availability of a guidance document entitled "Antimicrobial Food Additives – Guidance" (64 FR 40612). This document is intended to clarify FDA's jurisdiction over antimicrobials that are used in or on food, including those used in or on edible food, in water that contacts edible food, and those used in the manufacture of, or in or on, food-contact articles, subsequent to the enactment of the Food Quality Protection Act of 1996 (FQPA), and the Antimicrobial Regulation Technical Corrections Act of 1998 (ARTCA).

Nutrition, Health Claims and Labeling

40. ** **Trans Fatty Acids**: In the Federal Register of November 17, 1999 (64 FR 62745) a proposal was published to amend regulations on nutrition labeling to require that the amount of trans fatty acids in a food be included in the Nutrition Facts panel.

41. ** **Infant Formula Premarket Notifications:** CFSAN received 35 new infant formula notifications, and all were reviewed within the 90-day statutory timeframe.

42. ** **Nutrient Content/Health Claim Notifications Based on an Authoritative Statement:** CFSAN received one health claim notification based on an authoritative statement. The petition was reviewed within the 120-day statutory timeframe, and use of a health claim was authorized about the relationship between whole grain foods and heart disease and certain cancers.

43. ** **Nutrient Content/Health Claim Petitions:** CFSAN received five nutrient content/health claim petitions and all five were responded to within statutory timeframes. One of these petitions was approved in a final rule published in the Federal Register on October 26, 1999 (64 FR 57700) that authorized the use of a health claim about the role of soy protein in reducing the risk of coronary heart disease.

44. **Citizen Petition:** As directed in the Appropriations Conference Report, FDA responded to citizen petition 98P-0968 regarding the labeling of Surimi through publication of a proposed rule to amend the ingredient labeling regulations on April 9, 1999 (64 FR 17295).

45. **Surimi Final Rule:** In the Federal Register of September 17, 1999 (64 FR 50445), CFSAN published a final rule to amend its ingredient labeling regulation to permit the use of "and/or" labeling for the various fish species used in the production of processed seafood products, i.e., surimi and surimi-containing foods. This rule will permit manufacturers of surimi and surimi-containing products to maintain a single label inventory identifying all of the fish species that may be used in the manufacture of the surimi product. This action responds to petition 98P-0968 submitted by the National Fisheries Institute (NFI) requesting more flexible ingredient labeling for the fish ingredients used in the production of surimi products.

46. **Food Regulatory Report:** As directed in the Senate Appropriations Report, a report to Congress regarding the Agency's performance on various applications, notifications, submissions, petitions, and requests for advisory opinions was submitted to Congress on April 21, 1999.

Dietary Supplements

47. ** **New Dietary Ingredients:** CFSAN received 24 notifications for new dietary ingredients and all were reviewed within the 75-day statutory timeframe.

48. **Nutrient Content/Health Claims Proposal:** A proposed rule on the applicability to dietary supplements of the FDAMA provisions on nutrient content/health claim notifications based on an authoritative statement was published in the Federal Register on January 21, 1999 (64 FR 3250).

49. ** **Overall Strategy:** CFSAN developed an overall strategy for achieving effective regulation of dietary supplements under the Dietary Supplement Health and Education Act of 1994. The strategy addresses six broad areas: safety, labeling, boundaries, enforcement activities, science-base, and outreach. A copy of this ten-year plan is available on CFSAN's home page (www.cfsan.fda.gov).

50. ** **Stakeholder Outreach**: CFSAN held five stakeholder meetings in 1999 to provide an opportunity for public input into various dietary supplement issues. Two meetings focused on development of the overall strategy; one meeting addressed structure/function claims; and three meetings focused on good manufacturing practices regulations. In addition, CFSAN revised and expanded its web site for dietary supplements and established a database of stakeholders to facilitate outreach. Lastly, FDA visited seven dietary supplement manufacturers to learn about their quality control and good manufacturing practices.

51. ** **Strategy for Pearson Court Decision**: In the Federal Register of December 1, 1999 (64 FR 67289), CFSAN informed the public of its strategy to implement the court decision in *Pearson v. Shalala*. In the notice, CFSAN also announced its intent to hold a public meeting in the first quarter of 2000.

52. ** **Guidance on Significant Scientific Agreement:** As part of the *Pearson* strategy, CFSAN developed guidance for the industry clarifying the meaning of the "significant scientific agreement" standard as it applies to the review of scientific data for health claims. A notice of availability of this guidance document was published in the Federal Register on December 22, 1999 (64 FR 71794.)

53. **Citizen Petition:** A response to citizen petition 98P-0509 regarding FDA's jurisdiction over publications associated with dietary supplements was issued on April 9, 1999.

Chemical and Other Contaminants

54. **Pesticide Monitoring Improvements Act (PMIA):** FDA's pesticide monitoring data and summary information was made available on the internet, as required by PMIA, on March 31, 1999.

55. **Total Diet Study Workshop:** An international workshop was convened in Kansas City, Missouri from July 25 through August 6, 1999, under the auspices of FDA (CFSAN & ORA) and the World Health Organization (WHO). The focus of the workshop was to discuss all aspects of total diet studies (TDS) with those countries which have TDS and to assist those countries which don't have TDS, particularly with developing countries in their efforts to establish dietary monitoring systems for contaminants, pesticides, and nutritional elements in their food supplies.

56. ** **Fumonisin:** In conjunction with National Center for Toxicological Research, the Department of Agriculture, the National Institute of Environmental Health Sciences, and the International Life Sciences Institute North America, CFSAN convened an international conference on fumonisin. The goal of the conference, which was held on June 28 – 30, 1999, was to review the available data on the chemistry, toxicities, and mechanisms of action of the fumonisin mycotoxins.

Cosmetics

57. **Alpha Hydroxy Acids:** An FDA sponsored clinical study of the affects of AHAs on the sensitivity of human skin to ultraviolet light was completed. This study, along with others, will help support agency decisions concerning possible public health risks. FDA also worked collaboratively with the NCTR and NTP in the development of a state-of-the-art phototoxicity testing facility and the development of photocarcinogenicity testing protocol for measuring the long-term effects of AHAs as used in topically applied cosmetic products.

58. ** **Diethanolamine (DEA):** CFSAN's Cancer Assessment Committee completed an evaluation of the NTP dermal carcinogenicity study of DEA and three DEA-derived cosmetic ingredients. The risk posed by dermal exposure to DEA was then assessed by CFSAN's Quantitative Risk Assessment Committee and a draft risk assessment memorandum completed. In 2000, CFSAN will finalize the DEA risk assessment and formulate appropriate risk management approaches.

59. **Cosmetics Voluntary Registration Program:** The Cosmetic Voluntary Registration Program was reinstated effective January 1, 1999. In addition, CFSAN initiated steps to build a web-based program in response to suggestions by the cosmetics industry that participation requirements should be streamlined.

60. **Program Restoration:** FDA developed and implemented a plan to restore $2.5 million to the cosmetics program, as provided in the FY 99 Appropriations. A public meeting to solicit input from Stakeholders on development of the plan was held on January 22, 1999. Plan elements included reallocating staff back to cosmetics activities, recruitment of new personnel and allocation of funds to critical program needs.

Part III. Cross Cutting Areas

Science Base

61. **Joint Institute for Food Safety and Applied Nutrition (JIFSAN):** On July 26, 1999, CFSAN published a Federal Register notice indicating FDA's intent to supplement the original cooperative agreement award. The intent of the notice was two fold; 1) to incorporate the cosmetics program and to include dietary supplements and food labeling under the broad program area of applied nutrition; and 2) to permit supplementation of the cooperative agreement beyond the Agency limitation of 25 percent. Supplemental funding was awarded on 9/30/99. On September 27, 1999, CFSAN completed its descriptions of the JIFSAN program management structure and coordination activities within FDA.

62. **National Center for Food Safety and Technology (Moffett Center):** A cooperative agreement with the National Center for Food Safety and Technology has been renewed for five additional years. In addition, their capabilities were expanded to rapidly develop, evaluate, and transfer technologies that control emerging food safety problems, such as sprouts and unpasteurized juices.

63. **** Consolidated Management System for Research:** An internal task group was formed to develop a research program management system that ensures that priority, mission-relevant public health needs are addressed in a cost- effective, timely, accountable, and transparent fashion. Following finalization of the group's report in 2000, the Research Management Task Group will develop a plan for implementing its recommendations.

64. **Peer Review:** The subcommittee of the FDA Science Board reviewed the Center's non-FSI research program. The subcommittee's peer review report is expected to be presented to the FDA Science Board at its first meeting in 2000.

65. **Regulatory Scientists:** A report titled "Preliminary Training Plan" has been prepared to identify and address training needs of regulatory scientists to strengthen and thereby, enhance the Center's total science base. This preliminary plan is intended to apply to the needs of all Center scientists, including those involved with regulatory programs, laboratory or other research, administration and management. In addition to training activities planned by components within CFSAN, the report includes activities that are developed by and conducted through the Center's consortia, the Joint Institute for Food Safety and Applied technology and the National Center for Food Safety and Technology.

66. **** Biotechnology Public Meetings**: Three meetings were held to give the public an opportunity to provide comments on CFSAN's policy for assuring the safety of food produced through biotechnology. The first meeting was on November 19, 1999 in Chicago, Illinois; the second meeting was on November 30 in Washington, D.C.; and the third was on December 13 in Oakland, California. In 2000, CFSAN will develop and implement strategies based on these public meetings.

Federal - State - Local

67. **National Food Safety System:** In collaboration with CDC, USDA, and state and local governments, continued progress was made towards development of a plan for a nationally integrated food safety system. All three 1999 milestones were completed: Creation of a Coordinating body to focus on a vision and next steps; establishment of work groups to draft proposed plans and projects; and solicitation of input from stakeholders. A public workshop was held in conjunction with a meeting of the Association of Food and Drug Officials on June 6 in San Antonio, Texas. Long-term planning ideas will be integrated into the strategic planning process

being conducted by the President's Council on Food Safety.

International

68. ** **Develop Affirmative Agenda:** In the Federal Register of December 20, 1999 (64 FR 71145), CFSAN published a notice of availability of its Affirmative Agenda for International Activities for 2000 – 2002. The Agenda addresses broad priorities in five major international activities: Regulatory; Harmonization; Development, Maintenance and Dissemination of CFSAN's Science Base; Equivalence Evaluations, Food Safety Needs Assessments, and Food Safety Technical Cooperation and Assistance; and Trade-Related Activities.

Human Resources

69. **Communications:** Goals to increase communication among all levels of employees within CFSAN have been accomplished. A variety of mechanisms were implemented to increase communication, including all-hands e-mail messages from the Center Director; the Center Director's monthly meetings with CFSAN staff; continuation of "Break Time" seminars; re-instatement of a bi-monthly newsletter; and issuance of the CFSAN Employee Survey.

70. **Training:** CFSAN accomplished its goal to increase its internal capacity to train employees. CFSAN pilot-tested an electronic training nomination form to facilitate quicker, more efficient processing of forms and enrollment into classes. The Intranet site was expanded to provide information to employees about training opportunities and resources, and to respond to frequently asked questions about these opportunities and resources. Thirdly, catalogues, workshops, software and other materials were publicized electronically.

71. **Quality Environment:** Several initiatives were accomplished to improve the quality of worklife for all employees. CFSAN implemented the Healthy Lifestyles Program; provided quarterly fitness classes; established an Employee Worklife Network to compile, triage and address issues raised by employees; provided health seminars and nutrition workshops; implemented a "New Day" initiative and companion "Tool Kit" on workplace policies and procedures; established partnerships with union representatives; and assured that the goals of the equal employment opportunity program were promoted and adhered to.

72. **Future Skill Needs**: CFSAN developed a recruitment policy guide for identifying future skill needs by inventorying the skills currently available in the Center and identifying where gaps exist in scientific expertise and other human resource needs.

73. ** **Enterprise Administrative System Environment (EASE) Implementation:** EASE is an electronic data system that replaces the manual process of time and attendance recordkeeping with automated verification, submission, and approval of timecards. In 1999, EASE software was installed and training for timekeepers, administrative staff and supervisors was initiated.

Appendix 1: Goals Carried-Over as 2000 Program Priorities

Ten goals in the Program Priorities document were not fully completed in 1999; however, considerable progress was made on each. For example, with respect to publication of a final rule on juice HACCP, CFSAN presented data to the National Advisory Committee for Microbiological Criteria in Food on

production practices and safety issues associated with fresh citrus juice. With regards to development of an action level for patulin, CFSAN presented an assessment of the risk and a proposed action level to the Foods Advisory Committee. Accordingly, the following ten initiatives will be carried over to 2000 and new goals be established:

1. **Juice HACCP -- Final Rule**
2. **HACCP at Retail -- Pilot Program**
3. **GRAS Determinations -- Final Rule**
4. **Infant Formula -- Final Rules on GMP's and Quality Factors**
5. **Ephedra**
6. **Patulin -- Action Level and Compliance Policy Guide**
7. **Bottled Water Feasibility Study**
8. **Food Code -- Incorporation into Interstate Transportation and Sanitation Regulations**
9. **Equivalence Criteria -- Final Guidance**
10. **Equivalence Determinations**

Appendix 2: Illustrative List of Other Significant Accomplishments

CFSAN addressed a number of unanticipated issues during 1999 that were not included in the Program Priorities document. For example, during the summer it was reported that food-producing animals in Belgium may have consumed feed that was contaminated with dioxin, a potential carcinogen. In response, in collaboration with ORA, CFSAN implemented an import detention program and sampling plan for potentially contaminated food products, such as eggs. Consumer warnings and advisories about potentially contaminated food are another example of unanticipated issues not included in the Program Priorities that necessitated a commitment of CFSAN resources during 1999.

In addition to the above-mentioned unanticipated issues, CSFAN fully completed a number of its "B" list goals. These are listed below with an asterisk.

Consumer Alerts

- Alerted consumers not to purchase or consume products, some of which are labeled as dietary supplements, that contain gamma butyrolactone (abbreviated as GBL).
- Warned consumers not to eat El Sembrador brand frozen mamey from Guatemala or drinks made from El Sembrador brand frozen mamey due to reports of typhoid fever in South Florida.
- Advised all persons to be aware of the risks associated with eating raw sprouts (e.g., alfalfa, clover, radish).

- Warned parents in Southern California who feed their babies Mead Johnson's Nutramigen Powder infant formula to be aware of a potential counterfeit labeling fraud.

Consumer Information

- Established an Outreach and Information Center to facilitate access by consumers to the most up-to-date, reliable food safety information. The information hotline can be reached by calling 1-888-SAFEFOO[D].

- * In conjunction with USDA, developed and implemented an Information Network to enhance availability of food safety-related information and publications. The Information Network can be accessed at www.FoodSafety.gov.

- Increased the information consumers will see on labels of dietary supplement products, including an information panel titled "Supplement Facts," a clear identity statement, and a complete list of ingredients.

Seafood

- * Updated guidance on frequently asked seafood HACCP questions.

- * Developed a HACCP "template" code of practice for fish products through the Codex international workgroup.

- Worked with the ISSC to develop a control plan for *Vibrio parahaemolyticus* in shellfish.

Research and Risk Assessment

- * Finalized the charter for the Risk Assessment Consortium.

- * Held a public meeting to develop a framework for the Risk Assessment Clearinghouse.

- Expanded PulseNet capability to six FDA district laboratories.

- Developed an improved polymerase chain reaction (PCR) method for the detection of *Cyclospora*.

- Demonstrated that surface heating of apples is an effective method to inactivate 2-3 logs of microorganisms, including *E. coli* O157:H7, in apple processing facilities.

Imports and Domestic Samples Analysis

- Worked with the Guatemalan berry industry to help improve the safety of berries and other fresh produce exported from Guatemala to the U.S.

- Implemented an import detention and domestic sampling plan for certain European products in response to concerns about potential dioxin contamination.

FDA Modernization Act (FDAMA)

- Held a public meeting on the FDAMA provisions on health claims based on authoritative

statements.

- Issued guidance document entitled "Mercury Compounds in Drugs and Food," as required by section 413 of FDAMA.

Chemicals and Other Contaminants

- * Issued a Compliance Policy Guide on Adulteration Involving Sharp Foreign Objects in Food.

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
December 5, 2000

CFSAN 2000 Program Priorities Report Card

- Letter from Center Director
- Summary List of Accomplishments & Final Grade
- Report Card
  - Highlights
  - I. Food Safety Initiative
  - II. Major Program Areas
  - III. Cross Cutting Areas
  - IV. Appendices

Dear Colleague, FDA Foods Community:

As promised, I am pleased to provide you with the end-of-the-year "Report Card" on our 2000 program priority accomplishments for FDA's foods program. I am even more pleased to tell you that we exceeded our productivity goal. As you may recall, in order to align our program priorities with the federal budget cycle, we condensed implementation of the 2000 workplan into three-fourths of the year (nine months). Accordingly, our goal was to fully complete at least three-quarters of the "A" list activities. As you will see, we exceeded this goal by completing 78% of our "A" list goals (84 out of 108 activities). I am very proud of this success rate.

This represents a clear management strategy to focus our resources on where we provide the most benefit to American consumers. This record also demonstrates that we have increased productivity over what we accomplished last year – i.e., we completed more items this year in just nine months as we completed in 12 months last year. (73 out of 83 "A" list activities were completed in calendar year 1999.) Moreover, while there were too few "B" list accomplishments to highlight in last year's "Report Card," I am pleased to report that this year, we completed 21 "B" list activities as well (Appendix A). So, the system is working!

Four major program areas dominated in 2000: (1) food safety; (2) food additives; (3) dietary supplements; and (4) food biotechnology. We have highlighted for you our most significant accomplishments in these areas, followed by an item-by-item description of each of the 84 "A" List and 21 "B" List activities. These follow the same order as they appear in the original Program Priorities Plan for 2000 ("Yellow Book").

I also want to acknowledge that twenty-four goals in the Program Priorities document were not fully completed before the end of fiscal year 2000; however, substantial progress was made on each of these goals. These goals will be carried over to our 2001 workplan and their completion will be a high priority for FY 2001. They are listed in Appendix B.

In closing, I very much appreciate the support I have received from many stakeholders on this management approach. I look forward to continuing this tradition of building predictability, transparency, and accountability into our Foods program. The American public deserves no less.

Sincerely,

Joseph A. Levitt
Director
Center for Food Safety and Applied

Enclosure

2000 CFSAN Program Priority Report Card
Final Grade: Exceeded Goal*

Reporting Period January 1 - September 30, 2000

Accomplished

1. Import inspection protocol
2. Foreign Inspections
3. 1,000-sample survey of imported produce
4. Imports Report to Congress**
5. Timely Testing of Produce Imports
6. High-risk Domestic Food Inspections
7. Evaluation of State Programs
8. Food Recalls Report to Congress
9. Seafood HACCP
10. Dairy HACCP
11. Produce - Evaluate Adoption of Sprout Guidance
12. Produce Sampling Assignment
13. Fruit/ Vegetable Agricultural Survey
14. Food Code - Resolve issues with the 1999 Food Code
15. Food Code - Increase adoption of the Food Code
16. Outbreak Response traceback investigations
17. Outbreak Response - *Salmonella enteriditis*
18. Guidelines for Coordinating Outbreaks
19. Seafood Parasites Survey
20. Harmonize Standards for *E.coli* O157:H7
21. GAPs - Producer Education & Outreach Program
22. Sprout Video
23. FSI Foreign Outreach and Education
24. Food Safety Report to Congress**
25. Fresh - Stakeholders Meeting
26. Application Review (Expedited Review)
27. Application Review (F/C Petitions - routine review)

28. Application Review (F/C Petitions - reduce backlog)
29. Application Review (biotechnology consultations)
30. Application Review (GRAS Notifications)
31. Application Review (PNM's)
32. Food Contact Substances - Guidance
33. Food Contact Substances - Proposed Rule
34. Food Contact Substances - NEPA Requirements
35. Food and Color Additives - Public Outreach
36. Simultaneous Review of Meat and Poultry - MOU
37. Simultaneous Review of Meat and Poultry - Final Rule
38. Infant Formula Premarket Notifications
39. Nutrient Content/Health Claim Submissions
40. Enforcement Procedures - Food Label
41. Dietary Supplement Safety Issues - Aristolochic Acid
42. Dietary Supplement Safety Issues - NAS Study
43. Ephedra - Public Availability of AERS
44. Public Availability of Dietary Supplement AERs - Reduce Backlog
45. Dietary Supplement Premarket Notifications - 75-day
46. Dietary Supplement Routine Compliance
47. Structure/Function Claims
48. Pearson v. Shalala
49. Health Claims - Folic Acid and Neural Tube Defects
50. Health Claims - Fiber and Cancer
51. Health Claims - Omega-3 Fatty Acids and CHD
52. Claims for Mitigation of Disease
53. Health Claim Petitions
54. Dietary Supplement Strategic Plan
55. Advisory Committee on Dietary Supplements
56. Implementation of the Food Quality Protection Act
57. Patulin
58. Pesticide Monitoring Improvements Act (PMIA)
59. Fumonisin Workshop
60. Fumonisin Guidance
61. Bottled Water Feasibility Study - Draft
62. Bottled Water Feasibility Study - Final
63. AHAs - Support NTP Testing
64. Beta Hydroxy Acids - Support NTP Safety Study
65. Streamline Voluntary Cosmetics Registration Program
66. Participation Incentives for Cosmetics
67. External Peer Review of Science Program
68. Report of the Research Management Task Force
69. MOD 1 - Report and Implementation Plan
70. Professional Development
71. Restructure CFSAN Food Advisory Committee
72. Codex Committees and Working Groups
73. WHO - Cooperation on Food Safety
74. Biotechnology Strategy
75. Conduct Meetings on Food Allergens
76. CFSAN Relations with the Office of Regulatory Affairs (ORA)
77. Regulations Process
78. Communications

79. "New Day"
80. Implement the National Treasury Employees Union Contract
81. Recruitment and Hiring

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82. New Employee Training
83. Integrated Financial Management System
84. College Park - Information Sharing and Action Plans

Total: 84 Goals Accomplished

Substantial Progress
High Priority for FY2001

1. Administration's Food Safety Strategic Plan
2. Egg Safety Labeling and Refrigeration - Final Rule
3. Egg Safety Standards - Proposed Rule
4. Imported Foods Action Plan Initiatives
5. Juice HACCP - Final Rule
6. Seafood HACCP Program Evaluation
7. *Listeria monocytogenes* - Risk Assessment
8. Listeria Action Plan
9. *Vibrio parahaemolyticus* - Risk Assessment
10. *Vibrio vulnificus* - Respond to Citizen Petition
11. Trans Fatty Acids - Final Rule
12. "Healthy" - Respond to Citizen Petition
13. Good Manufacturing Practices for Dietary Supplements - Proposed Rule
14. Ephedra - Overall Strategy
15. Health Claim: Antioxidant Vitamins and Cancer
16. Alpha Hydroxy Acids - Labeling Guidance
17. Diethanolamine (DEA) - Final Risk Assessment
18. Declaration of Carmine and Cochineal Extract - Proposed Rule
19. Strategy for Issuance of 740.10 Warning Letters
20. Strategy for Issuance of Untitled Letters
21. Equivalence Criteria
22. Integrated Adverse Events Reporting System
23. CFSAN Bioterrorism Plan
24. Common/Usual Names for Several Species of Crab - Final Rule

Total: 24 Carryover Priorities

* Because this plan covered a 9-month period, or 3/4 of the year, CFSAN's goal was to complete 75% of objective

** Goal completed but awaiting Administration clearance

CFSAN 2000 Program Priorities Report Card

Highlights
I. FOOD SAFETY INITIATIVE
- Imports
- Domestic Inspections
- HACCP
- Produce
- Food Code
- Outbreak Response
- Risk Assessment/Risk Identification
- Risk Communication, Education and Training

II. MAJOR PROGRAM AREAS
- Premarket Review of Food and Color Additives and Food Ingredients
- Nutrition, Health Claims and Labeling
- Dietary Supplements
- Chemicals and Other Contaminants
- Cosmetics

III. CROSS CUTTING AREAS
- Science Base
- International
- Emerging Areas
- Regulatory Processes
- Management Initiatives

IV. APPENDICES
Appendix A -- "B" list Accomplishments
Appendix B -- Goals Where Substantial Progress Was Made, But Completion To Be Carried-Over In 2001 Program Priorities

Highlights: 2000 Program Priority Accomplishments

General:

- Exceeded overall goal by completing 78% of "A" List activities (84 out of 108 activities). Goal was 75%.
- Completed more activities (84) in 9 months in 2000 (January to September) than in previous 12 months (1999) (73 activities).
- Completed an additional 22 "B" List activities.

Food Safety:

- Significantly increased the number of "high risk" domestic food inspections as well as foreign on-site food inspections.
- Completed the collection and laboratory analysis of 1000 samples of high volume imported produce, and initiated an assignment to collect 1000 samples of domestic produce.
- Conducted third year of domestic seafood HACCP inspections, and completed first enforcement action (consent decree of permanent injunction).
- Sponsored international food safety conferences/workshops in the Central American, South American, and South Pacific regions.
- Achieved adoption of the Food Code in 20 state agencies having jurisdiction over retail-level establishments (exceeding our goal of 35 percent of states).

Food Ingredients:

- Successfully launched new Food Contact Substances program, including publications of a proposed rule and companion guidance for premarket notifications.
- Exceeded goals for timeliness in reviews of food and color additive petitions, both for those qualifying for "expedited review" and for "routine" petitions.
- Announced plans for further enhancements/streamlining of direct food and color additive petitions.
- Streamlined, with USDA, process for reviewing food additives for meat and poultry products.

Dietary Supplements:

- Disseminated Dietary Supplement Strategies Plan and engaged stakeholders at multiple forums throughout the year.
- Published a final rule that defines the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body.
- Published strategy for implementing *Pearson* v. *Shalala*. Issued final determination on three of four *Pearson* claims.
- Reduced backlog of Freedom of Information (FOI) requests for adverse event reports related to dietary supplements.

Biotechnology:

- Announced strategy to strengthen FDA's regulation of foods developed through biotechnology, including a proposed rule for premarket notifications, guidance for voluntary labeling, and enhanced advisory committee expertise.

Additional Accomplishments:

- Met statutory timeframes for review of infant formula premarket notifications, dietary supplement new ingredient notifications, and petitions for health claims on conventional foods.
- Published draft guidance on three chemical contaminants: "Channels of Trade" policy for Methyl Parathion residues; adulteration level for patulin in apple juice products; and fumonisin levels in food and feeds.
- Completed programming for an interactive system for streamlining the Voluntary Cosmetics Registration Program.
- Actively participated in 18 international meetings of Codex committees and related working groups.
- Restructured the Food Advisory Committee to consist of a "parent" committee and four standing subcommittees.
- Worked with leadership of the National Treasury Employee Union to ensure a smooth implementation of new contract.

Part I. Food Safety Initiative

Imports

1. **Import Inspections Protocol:** In cooperation with the Office of Regulatory Affairs (ORA) finalized a standardized inspection protocol. Distribution of the final standardized inspection protocol to CFSAN management and Program Offices and appropriate ORA personnel began in mid-September, 2000.
2. **Foreign Inspections:** In FY 1999 FDA conducted 85 inspections of foreign food establishments. FDA nearly doubled the number of inspections by conducting 165 inspections of foreign food establishments in FY 2000.
3. **Imported Produce Sample Survey:** Completed the collection and laboratory analysis of 1000 samples of high volume imported produce.
4. **Imported Foods Report:** In accordance with House Report 106-157, prepared a report to Congress on activities undertaken to improve coordination and cooperation with the U.S. Customs and in the inspection and regulation of imported foods. The report is currently undergoing final Administration clearance.
5. **Timely Testing of Produce:** Reviewed and approved for use by field laboratories a number of rapid methods for detection of pathogens in imported produce.

Domestic Inspections

6. **High-Risk Food Inspections:** In FY 2000, the number of "high-risk" food inspections was approximately 5700 compared to approximately 3000 for FY 1999 (increase of 90% over 1999).

7. **Evaluation of State Programs:** Announced comprehensive strategy to enhance FDA evaluation of state inspection programs, to be implemented over 3 years. Developed a "State Contracts Audit Course" to train FDA field personnel to audit establishment inspections that were conducted through FDA's State contract program. The first state contract audit course was held in October (Maryland) with two additional offerings to be held in November (SW/US) and December (NW/US).

8. **Food Recalls Report:** In accordance with Senate Report 106-80, submitted a report to Congress on April 22, 2000 regarding food recall activities.

HACCP

9. **Seafood HACCP:** Conducted third year of seafood HACCP inspections. FDA sent 148 seafood HACCP Warning Letters. The agency pursued the first seafood HACCP injunction against a purveyor of hot and cold smoked fish because the firm was not controlling the hazard of *Clostridium botulinum.* The firm entered into a consent decree and agreed to stop processing until this hazard could be controlled.

10. **Dairy HACCP**: In collaboration with the National Conference of Interstate Milk Shippers, initiated a Dairy Grade A HACCP Pilot Program in six dairy processing plants. The six pilot plants have implemented the voluntary HACCP Pilot and were listed in the Interstate Milk Shippers List under the HACCP alternative to the traditional PMO-based program. The National Conference of Interstate Milk Shippers (NCIMS) HACCP Pilot Evaluation Team has completed information gathering activities at the six pilot plants and is preparing a report of findings and recommendations that will be presented to the NCIMS HACCP Committee.

Produce

11. **Sprout Guidance:** In April, 2000, issued a field assignment to visit 150 sprout growers in the US to determine the extent to which the industry is adopting the sprout guidance. Agency field staff finished the initial inspections of those firms and are compiling results of those inspections. Preliminary evaluation indicates mixed results. The positive side is that the added testing is identifying some contaminated sprouts before they reach consumers, and there were fewer outbreaks from sprouts in FY 2000 compared to prior years. However, nearly half the sprout growers had not adopted effective preventive controls, in particular, microbial testing of spent irrigation water. Warning letters were sent to firms not adopting effective preventive controls and/or operating under unsanitary conditions. On October 18, FDA had a meeting with the industry to discuss barriers to implementation of the guidance. A final report of the assignment will be issued in FY 2001.

12. **Produce Sampling Assignments:** On May 10, 2000, issued the Domestic Produce Sampling Assignment. The assignment requests collection of 1,000 samples of eight domestically produced fresh fruits and vegetables to determine the incidence of microbial contamination. As of October 3, 2000, 312 samples had been collected and 277 analyses completed.Seven samples were positive, indicating an apparent positive percentage of 2.5%. A copy of the assignment is available on CFSAN's web site (www.cfsan.fda.gov/~dms/prodsur2.html).

13. **Produce Survey**: To measure adoption of the GAP/GMP guidance, FDA worked with USDA's National Agricultural Statistical Service (NASS) to perform an extensive survey of production practices of fresh fruit and vegetable growers and packers in the U.S. This survey gathered data on

the types of practices (e.g., agricultural water source, manure use, employee hygiene and facility sanitation) covered in the guide. A report of the survey results is expected to be available early 2001. Repeating the survey in the future will allow FDA to measure changes in practices.

Food Code

14. **Conference of Food Protection:** In August 2000, CFSAN representatives met with the Conference for Food Protection (CFP) Executive Board to discuss and resolve controversial Food Code provisions. Final decisions on those controversial issues of the 1999 Food Code will be integrated into the 2001 Food Code.

15. **Food Code Adoption:** State agencies having jurisdiction over retail-level establishments in 20 states have adopted the Food Code. This exceeds our goal to achieve adoption of the Code by 35 percent of states (18 states).

Outbreak Response

16. **Outbreak Response [traceback investigations]:** In conjunction with ORA, two documents were developed: the "CFSAN Emergency Response Procedures" and the "White Paper: Food & Cosmetics Emergencies." Both documents are being distributed to the ORA field and headquarters components.

17. **Outbreak Response [*Salmonella enteritidis*]:** Evaluated *Salmonella enteritidis* protocol in light of general protocol, and concluded that the *Salmonella enteritidis* protocol needed to be revised. A draft "*Salmonella enteritidis*" Traceback Investigation Protocol" has been developed. The protocol is scheduled for completion in FY 2001.

18. **Outbreak Response Coordination:** A document titled: "Multi-State Foodborne Outbreak Investigation: Guidelines for Improving Coordination and Communication" has been developed. It was distributed to stakeholders on May 24, 2000. The National Food Safety System Outbreak Coordination Workgroup will continue to meet to address the comments of the stakeholders. The final document is scheduled for completion in FY 2001.

Risk Assessment and Risk Identification

19. **Seafood Parasites Survey:** FDA asked the American Gastroenterologist Association (AGA) to survey its members to determine the incidence of gastroenterological parasitic infections in the United States as a result of consumption of raw fish. A sample of 1000 members of the AGA have been selected. The sample allocation is designed to yield 500 completed surveys from member gastroenterologists practicing in states bordering the Atlantic and Pacific Oceans and the Gulf of Mexico. The survey data will be used to determine the actual frequency of occurrence of fish-borne helminth illnesses. This information will help the Agency better evaluate the need for control of helminth parasites in fish intended for raw consumption and to evaluate effective means for control where controls are found necessary. Results of the survey will be completed in FY2001.

20. **Harmonize Standards for *E. coli* O157: H7:** FDA, in conjunction with USDA, provided funding for a pilot project with eight federal, state and local laboratories to develop standards for sampling and testing methods for *E. coli* 0157:H7. This pilot is taking *E. coli* O157:H7 food sample testing already ongoing at eight labs and standardizing their methods, as well as working

toward accreditation of the procedures used. The pilot will be completed in FY 2001.

Risk Communication Education and Training

21. **Good Agricultural Practices:** In collaboration with USDA, funded a grant to Cornell University to develop a Producer Education and Outreach Program, a training program on Good Agricultural Practices for domestic growers. Training programs have been held throughout the U.S. A related program has been developed through JIFSAN for international growers. The preliminary program was tested in Chile in June 2000.

22. **Sprout Video:** In collaboration with the California Department of Health Services, the Sprout industry and ORA, developed a video to assist the industry in producing safer sprouts. The video was made available to the public in June 2000.

23. **FSI Foreign Outreach and Education**: The U.S. - Chile Seminar on Food Safety entitled "An Integrated Food Safety System; Processes and Partnerships" was held on June 2, 2000. JIFSAN in conjunction with the Government of Chile held a training program on produce safety, emphasizing good agricultural practices (GAPs) on June 5 - 9, 2000. FDA also conducted dairy farm sanitation and milk safety training, emphasizing on-farm practices, on August 7 -11, 2000 in San Salvador, El Salvador. Proceedings of the outreach meetings in Chile and Mexico were completed and placed on the Web. The posting was unique for CFSAN in that it included videos of the presentations. The availability of this posting was widely publicized through constituent updates, the Agricultural Research Library, and through food safety education publications. Foreign outreach and education was continued by co-sponsoring a regional food safety meeting in Auckland, New Zealand on August 15-16, 2000.

24. **Food Safety Report:** In accordance with Senate Report 106-80, in consultation with the U.S. Department of Agriculture, prepared a report to Congress on how to educate the public about the safety of our food supply. The report is currently undergoing final Administration clearance.

25. **Fresh:** Held a public meeting in Chicago, IL on July 21, 2000 to discuss the use of term "fresh" in the labeling of foods processed with alternative non-thermal technologies. The purpose of this meeting was to solicit views on whether the use of the term "fresh" is truthful and non-misleading on foods processed with these alternative technologies and on what type of criteria FDA should use when considering the use of the term with future technologies.

Part II. Major Program Areas

Premarket Review of Food and Color Additives and Food Ingredients

Application Review Goals:

26. **Expedited Review**: Completed the safety evaluation in less than 360 days for all five food and color additive petitions that qualified for expedited review. This exceeds our goal to complete 80-90% of these petitions within 360 days. A list of pending and completed petitions eligible for expedited review is available on our web site at the subheading, "Technical Documents for Industry," under the Food Additives and Premarket Approval program heading.

27. **Non-expedited Review Petitions:** Completed the safety evaluation in less than 360 days for 77% (59 of 77) of food and color additive petitions that did not qualify for expedited review. This exceeds our goal to complete 50 – 60% of these petitions within 360 days.

28. **Reduce Backlog:** Action was taken on 11 of 25 petitions (nearly 50%) that were more than 4 years overdue at the beginning of the fiscal year.

29. **Biotechnology Consultations:** Six biotechnology notifications were received in FY 2000. Three biotechnology notifications were completed in FY 2000 with the initial review taking 4-5 months.

30. **GRAS notifications:** Responded to 23 GRAS notices, 4 within 90 days; 12 within 180 days; and 7 notices in greater than 180 days.

31. **Food Contact Substances:** Action was taken on 82 of 83 (98.8%) food contact notifications in the FY 2000 cohort within 120 days.

32. **Food Contact Substances Guidance:** Guidance for the industry on preparation of premarket notification for food contact substances published in the Federal Register on July 13, 2000 (65 FR 43377).

33. **Food Contact Substances Proposed Rule:** A proposed rule to implement the premarket notification process for food contact substances published on July 13, 2000 (65 FR 43269).

34. **Food Contact Substances – NEPA Requirements:** The direct final rule and companion proposed rule covering treatment of these notifications under the National Environmental Policy Act (NEPA) published in the Federal Register on May 11, 2000 (65 FR 30352, and 30366, respectively.) The effective date of the direct final rule was August 24, 2000.

35. **Food and Color Additives:** On May 5, 2000, a notice was published in the Federal Register (65 FR 26215) requesting public comment on ways to improve the food and color additive petition review process based on new resources made available in the FY 2000 congressional appropriations. A "Dear Colleague" letter was issued on October 5, 2000 announcing specific steps being taken to improve the food and color additive petition review process. The letter also provides an interim progress report on the scope of changes that are anticipated in the premarket processes. A copy of the letter is available on our web page at www.cfsan.fda.gov/~dms/opa-stak.html.

36. **Simultaneous Review of Food Ingredients in Meat and Poultry:** Published a memorandum of understanding to establish the working relationship to be followed by FDA and USDA/FSIS in responding to requests for the sanctioning of the use of food ingredients and sources of radiation subject to regulation by FDA and intended for use in the production of meat and meat food products (65 FR 33330, May 23, 2000).

37. **Simultaneous Review of Food Ingredients in Meat and Poultry:** Published a final rule on the simultaneous review of food ingredients in meat and poultry (65 FR 51758, August 25, 2000).

Nutrition, Health Claims and Labeling

38. **Infant Formula Premarket Notifications:** CFSAN received ten new infant formula notifications, and all were reviewed within the 90-day statutory timeframe.

39. **Nutrient Content/Health Claim Submissions:** CFSAN continues to meet its statutory obligations for nutrient content and health claim submissions. CFSAN published a final rule authorizing a health claim for soy protein and heart disease (21 CFR 101.82) on October 26, 1999. CFSAN completed the evaluation of two additional health claim petitions within statutory timeframes. One petition was for sterol esters and heart disease. The other was for stanol esters and heart disease. The agency issued an interim final rule authorizing these health claims on September 8, 2000 (65 FR 54686)(21 CFR 101.83).

40. **Enforcement Procedures:** CFSAN established procedures to evaluate food label complaints and respond to significant or precedent setting discrepancies in food labeling.

Dietary Supplements

41. **Safety Issues - Aristolochic Acid:** Issued a letter to industry on May 16, 2000, and a separate letter to health care professionals on May 31, 2000, to communicate our concern about the use and marketing of dietary supplements or other botanical-containing products that may contain aristolochic acid. FDA issued an Import Alert on these products on July 6, 2000. Copies of all three documents are available on CFSAN's home page.

42. **Safety Issues - NAS Study:** Contracts were arranged with the National Academy of Science's Institute of Medicine to establish a scientific framework for assessing the safety of dietary supplements, and to apply that framework to several specific dietary supplement products.

43. **Ephedra:** Published three Federal Register notices announcing the availability of new adverse event reports and related information on dietary supplements containing ephedrine alkaloids, and announcing withdrawal of the provisions of the ephedrine alkaloids proposed rule relating to the dietary ingredient level and duration of use limit for these products (65 FR 17474 – 17510; April 3, 2000). On May 23, 2000, informed Congress that the report requested on the Agency's methodology to be used in Ephedra rulemaking was no longer necessary as certain portions of the proposed rule had been withdrawn by FDA. Participated in a public meeting on August 8 – 9, 2000, sponsored by the Public Health Service, to discuss the available information about the safety of dietary supplements containing ephedrine alkaloids.

44. **Public Availability of Adverse Event Reports:** At the beginning of this fiscal year, the Freedom of Information (FOI) backlog included requests for SN/SEMS information that date from 1998. This backlog consisted of 53 requests (790 adverse events), with each request averaging twenty separate adverse event records. Single records vary from one page to over a thousand pages. In August 2000, the backlog from 1998 - 1999 was essentially eliminated and remains up to date at present. Resources are currently being devoted to FOI requests received in the year 2000. The purchase and update of equipment and the provision of additional staff via contract and "detail" assignments accomplished this work. The information provided via these requests benefit consumers, health professionals and industry by providing timely information on potential adverse events associated with dietary supplement products.

45. **Notifications:** CFSAN received twenty-four notifications for new dietary ingredients. All were reviewed within the statutory timeframes. Of these 24 notifications, nine were filed without comment (i.e., FDA did not object at the time of the review to its marketing); 15 were objected to either because they had inadequate information to provide a basis that it will reasonably be expected to be safe (11) or because they failed to meet procedural requirements in 21 CFR 190.6 (2). The remaining 2 were not dietary supplements.

46. **Routine Compliance:** The Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Drug Evaluation and Research (CDER) have agreed that CFSAN should have lead responsibility in a streamlined case development process for cases where a dietary supplement carries a "disease claim" instead of a "structure/function" claim. That agreement is being memorialized in a memorandum of understanding (MOU) between the Centers.

47. **Structure/Function Claims:** Published a final rule that defines the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body (65 FR 9999; January 6, 2000). Participated in FDA public meeting addressing pregnancy-related claims under the structure/function rule. During the period January 2000 through October 2000, FDA received approximately 1,400 structure/function notifications. After reviewing the notifications, the agency sent 102 letters to firms notifying them that the claims for one or more of the products that were the subject of their notifications were not structure/function claims, but were disease claims not permitted for use in the labeling of dietary supplements pursuant to section 403(r)(6) of the FD&C Act.

48. ***Pearson v. Shalala*:** Published Federal Register notice on the strategy for responding to petitions for health claims for dietary supplements, including the health claims at issue in *Pearson* (65 FR 59855; October 6, 2000). Held a public meeting on April 4, 2000 to solicit comments on implementation of the *Pearson* decision.

49. **Health Claim Regarding Folic Acid and Neural Tube Defects:** On October 10, 2000, issued a final determination on one of the four Pearson claims. FDA determined that the proposed claim that stated 0.8 mg of folic acid in a dietary supplement was more effective in reducing the risk of neural tube defects than a lower amount in foods was not authorized. Although FDA determined that this claim could not be appropriately qualified without being misleading, the agency did provide examples of appropriate qualified claims. A copy of this letter is available on our home page at www.cfsan.fda.gov/~dms/ds-ltr7.html.

50. **Health Claim Regarding Fiber and Colorectal Cancer:** On October 10, 2000, issued a final determination on a second of the four *Pearson* claims. FDA determined that the proposed health claim about dietary fiber and reduced risk of colorectal cancer could not be authorized because the results of studies about dietary fiber consistently showed a lack of relationship between dietary fiber supplements and the risk of colorectal cancer. Neither could the claim be qualified because the suitable evidence against the claim outweighed the evidence for it. A copy of this letter is available on our home page at www.cfsan.fda.gov/~dms/ds-ltr8.html.

51. **Health Claim Regarding Omega-3 Fatty Acids and Coronary Heart Disease:** On October 31, 2000, issued a final determination on the third of four *Pearson* claims. FDA is using its enforcement discretion to allow a qualified claim about the use of omega-3 fatty acids in dietary supplements and the reduced risk of coronary heart disease. The qualified claim applies to daily intakes that do not exceed three grams per person per day from conventional food and dietary supplement sources.

52. **Claims for Mitigation of Disease:** Following a public meeting, on May 26, 2000, denied a petition requesting authorization of a health claim concerning the relationship between dietary supplements containing saw palmetto and benign prostatic hyperplasia (BPH). FDA's response noted that claims about effects on existing diseases do not fall within the scope of the health claim provisions of the Act and therefore may not be the subject of an authorized health claim.

53. **Health Claim Petitions:** CFSAN continues to meet its statutory obligations for health claims for dietary supplements. CFSAN denied, by operation of the statue (on December 1, 1999) and formally on May 26, 2000, a health claim for saw palmetto extracts and symptoms of BPH. CFSAN also denied on January 11, 2000, a petition for vitamin E and heart disease due to lack of significant scientific agreement to support the claim.

54. **Dietary Supplement Strategic Plan:** On January 3, 2000, the Dietary Supplement Strategic Plan was distributed to stakeholders and posted on the web page. The Plan establishes a clear program goal to have, by the year 2010, a science-based regulatory program that fully implements the Dietary Supplement Health and Education Act of 1994, and that provides consumers with a high level of confidence in the safety, composition, and labeling of dietary supplement products. This plan has been discussed at multiple public meetings during the year.

55. **Advisory Committee:** A standing Dietary Supplement Subcommittee was officially added to the restructured Food Advisory Committee on June 26, 2000. A request for membership nominees having the requisite scientific expertise to serve on the new subcommittee appeared in the Federal Register on July 28, 2000 (65 FR 46463).

Chemical and Other Contaminants

56. **Implementation of Food Quality Protection Act (FQPA):** Published draft guidance entitled, "Guidance for Industry – Channels of Trade Policy for Commodities with Methyl Parathion Residues," in the Federal Register on June 2, 2000 (65 FR 35376). The guidance presents FDA's policy for foods containing methyl parathion residues in accordance with the "channels of trade" provision of FQPA. [NOTE: Based on EPA's action on azinphos methyl, a "channels of trade" policy for commodities with azinphos methyl residues is not required.]

57. **Patulin:** Published a draft compliance policy guide (CPG) entitled, "Apple Juice, Apple Juice Concentrates, and Apple Juice Products – Adulteration with Patulin," in the Federal Register on June 6, 2000 (65 FR 37791). The purpose of the CPG is to advise FDA's field offices and the industry concerning enforcement actions that may be taken against apple juice products that contain patulin.

58. **Pesticide Monitoring Improvements Act (PMIA):** FDA's pesticide monitoring data and summary information was made available on the Internet, as required by PMIA, on May 18, 2000.

59. **Fumonisin Workshop:** On January 12, 2000, in collaboration with the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and the World Health Organization, convened an international workshop to consider all available risk assessment data on fumonisin.

60. **Fumonisin Guidance**: Published draft guidance entitled, "Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds," in the Federal Register on June 16, 2000 (65 FR 35945).

61. **Draft Bottled Water Feasibility Study:** Solicited comments on the draft feasibility study in the Federal Register of February 22, 2000 (65 FR 8718).

62. **Final Bottled Water Feasibility Study:** Published in the Federal Register of August 25, 2000 (65 FR 51833), a final report on the feasibility of appropriate methods of informing customers of the contents of bottled water, as required by the Safe Drinking Water Act (SDWA) Amendments.

Cosmetics

63. **Photocarcinogenicity Testing of Alpha Hydroxy Acids (AHA's):** CFSAN participated in a meeting of the Toxicology Study Section and Review Committee (TSSRC) convened to evaluate progress and report on the testing of AHA photocarcinogenicity sponsored by the National Toxicology Program (NTP).

64. **Beta Hydroxy Acids:** CFSAN participated in a meeting of the Toxicology Study Section and Review Committee (TSSRC) convened to evaluate NTP sponsored safety study of Beta Hydroxy Acids.

65. **Streamline Voluntary Cosmetics Registration Program (VCRP):** Programming for an online, interactive system for streamlining the VCRP is complete. The system is awaiting the installation of a "T3" high speed communication line before undergoing beta testing, any necessary modification, and final implementation. The installation and testing of the "T3" line have been slowed by a Washington, DC, moratorium on fiber optic installation due to the heavy amount of road damage necessary for the work.

66. **Participation Incentives:** Evaluated a variety of incentives to encourage participating in the registration program. Candidate incentives determined to be feasible within the current structure of the VCRP include providing a "Certificate of Participation" or letter of acknowledgement; establishment of a participant e-mail list for receiving information from the agency; and posting of company names and brand names on the web. These, and other incentives, will be considered as the VCRP is shifted to an internet-based program.

Part III. Cross Cutting Areas

Science Base

67. **External Peer Review:** On April 21, 2000, presented the External Peer Review Report to the FDA Science Board. The Science Board voted to accept the report. The report's recommendations are being implemented as outlined at that meeting.

68. **Research Management Task Group:** The Task Group has completed two extensive reports, which recommend options for identifying research needs, planning research resources, planning research activity, tracking research resources, tracking research progress, reporting research activity, reviewing research activity, and terminating research activity. Implementation will occur in FY 2001.

69. **MOD-1 Task Group Report:** The Task Group's report has been finalized, and a proposed office structure, staff allocation and functional statement has been developed and approved by the Agency. Effective August 14, 2000, Interim Director appointed to the new "MOD1 Office."

70. **Professional Development:** Three training courses on risk communication were presented to Senior-level and Mid-level Managers. Groundwork was laid for creation of the CFSAN Staff College in FY 2001.

71. **Leveraging Scientific Expertise:** To better respond to the increasing breadth of the scientific questions that must be addressed, FDA restructured the Food Advisory Committee to consist of a "parent" Committee and four standing Subcommittees: (1) Additives and Ingredients; (2) Contaminants and Natural Toxicants; (3) Dietary Supplements; and (4) Food Biotechnology. A request for membership nominees having the requisite scientific expertise to serve on the new subcommittees appeared in the *Federal Register* on July 28, 2000 (65 FR 46463).

International

72. **Codex Committees and Working Groups:** Participated in 18 Codex committees and related meetings to promote development of harmonized food safety and labeling standards. Participation in the Ad-Hoc Task Force on Foods Derived from Biotechnology in July 2000, included participation in the Task Force's Working and Drafting Groups that are developing draft international Guidelines for the Safety Assessment of Foods Derived from Biotechnology. In June 2000, provided a leadership role for the Codex Committee on Nutrition and Foods for Special Dietary Uses in developing international Guidelines for Vitamin and Mineral Supplements.

73. **World Health Organization (WHO) - Cooperation on Food Safety:** The World Health Assembly, under the auspices of the WHO, adopted a resolution on food safety by consensus of all countries. The resolution calls upon WHO to significantly strengthen its leadership role in food safety, particularly with regard to controlling foodborne diseases associated with microbial pathogens.

Emerging Areas

74. **Biotechnology:** On May 3, 2000, made a public announcement on plans to strengthen the regulatory approach for bioengineered foods. Three initiatives were announced: (1) Development of a proposed rule requiring that developers of bioengineered foods notify the agency before they market such products; (2) the addition of scientists to the Food Advisory Committee that have expertise in biotechnology; and (3) the development of labeling guidance to assist manufacturers who wish to voluntarily label their foods being made with or without the use of bioengineered ingredients.

75. **Food Allergens:** Held meetings at fourteen locations to raise consumer and industry awareness to the presence of allergens in foods and on labeling approaches to identify the presence of allergens.

Regulatory Processes

76. **CFSAN-Field Relations:** CFSAN and ORA initiated a number of activities to improve FDA's foods program. Following a meeting of CFSAN/ORA Senior Managers on December 14, 1999, a CFSAN/ORA Taskforce was formed to strengthen working relations in six program areas: (1) budget and workplan; (2) outbreaks and tracebacks; (3) inspections and field programs; (4) international programs; (5) enforcement; and (6) laboratories. In addition to the Task Force activities, CFSAN met with/hosted a number of joint CFSAN/ORA meetings aimed at improving efficiencies and effectiveness of the foods program. These include a meeting with the Field Food Committee on June 6 - 8; a meeting with representatives of field laboratories on June 28 - 29; a meeting with ORA headquarters and Field personnel on July 24 - 28; a foods program session at ORA's Senior Staff meeting on August 29; and a meeting with ORA's Field Directors of Investigations/Compliance and Laboratory Branch on September 18.

77. **Regulations Process:** Standard Operating Procedures were developed and distributed for responding to citizen petitions, including development of denial letters; advanced notices of proposed rulemaking; proposed rules; and final rules. In addition, preliminary recommendations on improving the regulations process at CFSAN were developed. The Center is advertising for a Senior Regulations Manager.

78. **Communications:** The Office of Field Programs (OFP) of the Center for Food Safety and Applied Nutrition developed an Intranet site in order to improve communication outreach efforts with the Field Offices, the states and other federal agencies. Additionally, two documenting systems to track both correspondence and case reports have been developed. In FY2001, CFSAN will move to centralize both tracking functions utilizing a single software.

Management Initiatives

79. **"New Day":** Conducted mandatory conduct and performance training for all employees and mandatory performance management training for all supervisors as a first step towards implementation of the "New Day" in CFSAN.

80. **Implement the National Treasury Employees Union (NTEU) Contract:** Worked with NTEU Leadership to ensure smooth implementation of the contract. The contract established a positive working relationship throughout CFSAN with regard to the following areas. (1) NTEU/Union Implementation - exchanged information, discussed issues and made recommendations e.g., awards, parking, alternative workplace program; (2) College Park - continuing to oversee the move to College Park and (3) Realignment - three reorganizations/realignments were completed in 2000.

81. **Recruitment and Hiring:** CFSAN has finalized a Strategic Recruitment Plan. This plan, which sets forth goals, objectives, and procedures for recruiting and retaining qualified scientific and professional personnel, will be implemented in FY2001. A Personnel Management Specialist was hired in April 2000.

82. **New Employee Training:** A new, WEB-based, CFSAN Employee Orientation Program has been developed and will be utilized for new employees, in FY2001.

83. **Integrated Financial Management System (FMS):** Established connectivity with the Agency through the center's new Hyperion Financial Management System. Downloads are being analyzed to insure financial integrity. Minor software problems continue to be corrected. Reports are being written to extract operating data and payroll in requested formats. Preliminary reports are in review and additional reports under development.

84. **College Park:** CFSAN is fully involved in the planning for the move to its new facilities at College Park, Maryland. Working in partnership with the employees union (NTEU), task groups have been formed to handle the details of laboratory and office moves, contract support for basic services, information technology transfer, and records management practices to transition the organization to the new facilities. An intensive information sharing effort has been mounted with bi-monthly updates with the most up-to-date information on the move.

Appendix A
CFSAN 2000 Program Priorities - "B"
List Accomplishments

Food Safety Initiative

1. Evaluated and updated the 3-year Research Plan to ensure that the research projects the Center is performing provide a strong scientific basis for our regulatory mission.

2. Updated "Bad Bug Book" on the Internet. The "Bad Bug Book" provides basic facts regarding foodborne pathogenic microorganisms and natural toxins.

3. Updated and posted the First Six Chapters of the BAM Manual on the Internet. The Bacteriological Analytical Manual (BAM) is published in collaboration with AOAC International and provides analytical methods for the detection of microorganisms and certain of their metabolic products.

4. Completed development of the survey instrument for the Food Safety Consumer Survey Cycle IV. The survey is used to monitor the impact of food safety initiatives and to identify consumer education needs.

Premarket Review of Food and Color Additives and Food Ingredients

5. We exceeded our goal and placed six new chapters of the "Redbook" (Toxicological Principles for the Safety of Food Ingredients) on the CFSAN Worldwide Website. The electronic version can be found on CFSAN's Web Site (http://vm.cfsan.fda.gov/~redbook/red-toca.html).

Nutrition, Health Claims and Labeling

6. Publish a notice of availability on citizen petition 99P-2630 requesting that FDA establish a daily reference vale for added sugars and that FDA list added sugars in the Nutrition Facts panel.

Dietary Supplements

7. Enhanced collaborations with FTC on labeling issues. CFSAN and the Federal Trade Commission have established a process for the mutual exchange of information on ongoing strategies and specific policy and enforcement actions. ONPLDS continues to meet on a routine basis with FTC and plans on additional and regular collaborations.

8. Incorporated compliance with new labeling regulations into inspection program.

9. Continued to review 30-day postmarket notifications for supplement claims in a timely manner.

10. Developed database for 30-day label claim notifications and courtesy letters. During this past year, ONPLDS and OMS have initiated a limited trial program to assess the 30-day document management and retrieval system. To date, over six hundred (600) 30-day reports have been scanned into the database.

11. Identify ways to leverage resources to address dietary supplement issues and research needs. Leveraging was accomplished for a number of dietary supplement topic areas. In the area of research, formal meetings with both NCTR and USP were instituted and work toward a CRADA with the Univ. of Mississippi was initiated. Contracts were arranged with the NAS's Institute of Medicine to address dietary supplement safety and the scientific framework for health claims on dietary supplements. Formal routine meetings with NIH's Office of Dietary Supplements as well as the Federal Trade Commission were instituted; increased interaction with NIH's Center for Complimentary and Alternative Medicines is planned. A contract was finalized to develop a guidebook for industry on commonly asked questions concerning regulation of dietary supplements.

12. Recruit pharmacognosy expertise in headquarters. An interdisciplinary scientist position description was created, approved and widely advertised. Interested individuals submitted applications for consideration between August 21 and October 4. The Center is seeking specific expertise in the areas of new dietary supplements and botanical products.

13. Disseminated information kits for FDA field staff and instituted regular updates with field staff.

14. Communicated dietary supplement enforcement policies and procedures to the general public, FDA field offices, health care professionals, and industry. ONPLDS has met with several organizations to share information concerning dietary supplement enforcement policies and procedures. For example: Food and Drug Law Institute - a panel discussion on dietary supplements; Virginia Department of Agriculture and Baltimore/Richmond Resident Post - an enforcement training program; Kentucky Health Department - a seminar on dietary supplements; AFDO Annual Meeting - presentations on dietary supplement enforcement and boundary issues; AFDO local chapter - enforcement; Nutrition 2000 Conference and EXPO East Annual Meeting - dietary supplement issues.

Cosmetics

15. Updated and enhanced cosmetics WEB page.

16. Continued to support EU-US bilateral program and the Cosmetics Harmonization and International Cooperation (CHIC) initiative. The continued support exists on several levels - Through formal meetings such as CHIC and the US-EU Bilateral meetings, direct contacts (mostly phone, e-mail and written contacts) and targeted meetings. For example, our EU counterpart was here in April for specific discussions on cosmetics and OTC drugs. There have also been exchanges of information at the technical and scientific level.

17. Complete review of ingredient dictionary and began developing proposed regulation for cosmetic ingredient nomenclature.

Science Base

18. Enhanced Visiting Scientist Program through the development of mechanisms to recruit and provide support for visiting scientists through JIFSAN/University of Maryland.

19. Implement recommendations for the Scientific Manuscript Clearance Task Group.

Management Initiatives

20. Continued to provide mechanisms for improved communication and quality of worklife by promoting Center programs, i.e. Employee Orientation, Leadership Assignment Program, Mentoring Programs, and widespread use of the Individual Development Plan to help employees be more productive and ensure that the mission of the Center is carried out.

21. Provided an adequate infrastructure for new and existing IT systems and networks. Provided support to the Center through an upgraded and fully staffed Help Desk.

Appendix B
Goals Where Substantial Progress Was Made, But Completion To Be Carried-Over In 2001 Program Priorities

1. Administration's Food Safety Strategic Plan
2. Egg Labeling and Refrigeration – Final Rule
3. Egg Safety Standards – Proposed Rule
4. Imported Food Action Plan Initiatives
5. Juice HACCP – Final Rule
6. Seafood HACCP Program Evaluation
7. *Listeria monocytogenes* – Risk Assessment
8. *Listeria monocytogenes* – Action Plan
9. *Vibrio parahaemolyticus* – Risk Assessment
10. *Vibrio vulnificus* – Respond to Citizen Petition
11. *Trans* Fatty Acids – Final Rule
12. "Healthy" – Respond to Citizen Petition
13. Good Manufacturing Practices for Dietary Supplements – Proposed Rule
14. Ephedra – Overall Strategy
15. Health Claim: Antioxidant Vitamins and Cancer
16. Alpha Hydroxy Acids – Labeling Guidance
17. Diethanolamine (DEA) – Risk Assessment
18. Declaration of Carmine and Cochineal Extract – Proposed Rule
19. Strategy for Issuance of 740.10 Warning Letters
20. Strategy for Issuance of Untitled Letters
21. Equivalence Criteria – Final Criteria
22. Integrated Adverse Event Reporting System – Plan
23. CFSAN Bioterrorism Plan
24. Common/Usual Names for Several Species of Crab – Final Rule

Mr. BURTON. Thank you.

How long will it take to implement this program?

Mr. LEVITT. We have set out when we began, which was just about a year ago, that we could get this fully implemented in 10 years. Now, last year was 1 year; this year is 2 years. Before we got funding it would probably be year 3 or year 4 to begin a 3-year funding, so that's why we think it would take up to 10 years to do it.

Mr. BURTON. Is that the outside or the insider?

Mr. LEVITT. It depends on whether the funding comes in the 3d or 4th year, or in the 7th or 8th year.

Mr. BURTON. So you're saying that we need to get busy and get you the money?

Mr. LEVITT. That is correct.

Mr. BURTON. Well, why is it that doesn't surprise me? [Laughter.]

Mr. LEVITT. We said when we distributed the plan that the thing could be accelerated or, unfortunately, even decelerated, depending on what funding and resources are available to address it. Like any other program, our successful programs are those, not surprisingly, that have got people dedicated to work on that project day in and day out.

Mr. BURTON. OK.

I have a few questions for you.

Dr. Yetley, is there any difference between reports you receive from manufacturers and medical professionals, and those received directly from consumers, such as the adverse events reports that the FDA says are associated with ephedra, such as the quantity, and more importantly the quality, of the information in the report?

Mr. LEVITT. Our adverse events system, as your question implies, does welcome reports from any source. We actually receive relatively few from manufacturers themselves. We receive most of our reports from health professionals or consumers.

Generally, where a health professional submits the report, it is more focused than if a consumer submits a report. Very often when a consumer submits a report, although it is very lengthy—"Here are all my medical records; all I really know is I got sick, it might have had to do with this product, here, see if you can figure it out." And so consumer reports, while we welcome them, often do require a lot of investigatory work, followup work, if you will, detective work from the FDA. If a health professional has screened it, if a company has screened it and tried to do some of that legwork to try to figure out what is going on here, some can easily be dropped out. The other focus is, "Get this information and we will know better whether this is something related to the product or not."

Mr. BURTON. The reason I asked that question is, you heard me refer earlier today to the study that was done at Harvard and Columbia Universities, which is not yet in the public domain but there has been a synopsis that came out—do you have a copy of that?

Mr. LEVITT. Yes, we do.

Mr. BURTON. It shows that if these products are taken and they are labeled properly, and they are taken in a proper manner, that

they are safe. I hope that you will take a look at the entire report, as well as the synopsis of it.

Mr. LEVITT. If I may, Mr. Chairman, we are very much looking forward to reviewing the full results of that study. As you know, we have been trying to solicit from the investigators the full report of that study for many months. And it is an important study; we agree with that. And if there is anything you can do to help us get access to that underlying report, we think it would be very important for everybody involved to have access to that.

Mr. BURTON. We are pushing to get that published. The reason is—and I think you alluded to this—in a random sample of the adverse events reports, in 92 out of 864 reports we found that 39 percent lacked information on the amount of the product consumed, and they could have taken three times as much as they should have, or shouldn't have; 41 percent lacked information on the frequency with which the product was consumed; 28 percent lacked information on the duration for which the product was consumed; and a total of 45 percent of the adverse events reports lacked information on either dose, frequency, or duration, and 24 percent lacked information on all three dimensions. Finally, 62 percent of the adverse events reports in our sample did not contain medical records, which are important in determining potential underlying conditions that might have caused the adverse event—you know, they may have had something wrong with them initially and they shouldn't have been taking it in the first place. Rather than assuming ingestion of dietary supplements containing ephedra, alkaloids caused the event.

The reason I focus on this so much is that just before the last administration left there was strong indication that there was going to be an ephedra regulation passed by the FDA before this report had been fully reviewed, and I am happy to say that they deferred action on that until they could read the report and do further study on that.

In 1999, in both a January letter and at a May hearing, I discussed with the FDA a number of areas in which the agency was what I consider to be "deficient" in relation to its duties under DSHEA. For example, we discussed the poor quality of the adverse events reporting data base, the deficiencies with the MedWatch program system, and other such items. Those problems included the fact that the adverse events reports contained information that was largely anecdotal, and the fact that the MedWatch system was overburdened.

Have you fixed the problems that were identified in 1999?

Mr. LEVITT. One of the problems that we have fixed, you will recall that one of the legitimate concerns was that it was taking companies a very long time to get access, through the Freedom of Information Act, to the reports that affected their own products. We did, with the funding that we had, fundamentally eliminate that, so that's one problem that was solved.

Second, we have started to design what really ought to be a modernized, 21st century state-of-the-art system. This is not gold-plated; this is standard stuff. Unfortunately, as I believe you are also familiar, for 2 consecutive years the President requested $2.5 million in the budget to fund that system, and that was not received

in either of those 2 years. So we are still, if you will, at the design phase. We very much want to modernize our system, and we have put together, as I said, design-phase steps, but we are still short of where we want to be on adverse event reporting, and we're hopeful that one of these years the funding that we have been requesting will come through.

Mr. BURTON. You know, I heard what you said a while ago, and it was not lost on me that you said that a lot of the money is earmarked for specific functions, and therefore it can't be used for something else.

Now, how much money does the FDA get, annually?

Mr. LEVITT. The FDA budget is over $1 billion, maybe $1.2 billion or $1.3 billion, in that area. The Congress then breaks it down by FDA function—foods, drugs, whatever. Within the food part, there is the headquarters and the field. So the food budget for my Center is about $125 million; for the field, together, it is close to $300 million. Most of that is earmarked for food safety. Most of the rest is tied up in salaries of people with particular knowledge and expertise that have jobs to do.

Mr. BURTON. The reason I ask these questions in more detail is that, you don't have any latitude with any of this money so that you could move in a different area that you felt needed more current attention or more rapid attention?

Mr. LEVITT. We have incredibly little latitude. In fact, in recent years the budget has become increasingly earmarked. As an example, even with food safety, we have six separate categories of food safety, whether it is for surveillance, whether it is for compliance and inspections, research, education, and so forth. So our moneys are increasingly restricted and not increasingly flexible, and there are very strict rules about the extent to which the agency is able to move money between programs in reasonably small amounts of money.

Mr. BURTON. So what you're saying is that Congress is putting fences around your money so that you can only use it for one purpose, and the only way we could get more money into these areas that we're talking about today is to appropriate more money?

Mr. LEVITT. That is correct.

Mr. BURTON. Would you prefer it if there was less earmarking so that you could be a little more flexible, or do you like the earmarking?

Mr. LEVITT. I think almost any administrator would prefer more flexibility; almost any appropriator would prefer earmarking.

Mr. BURTON. I understand that. I work with those guys. [Laughter.]

Mr. LEVITT. What we have to do—and I don't want to overemphasize it—but through the development of this strategic plan, not only the contents of it, but the manner, the spirit, the mode in which we have developed it, we have tried to really say very clearly, "We want to implement this law. We want to do it to the very best of our ability." We don't like coming up here, testifying how we can do one regulation every 2 years, and why things take so long and why we can't do this. We have an energetic group of people who, frankly, would like to move ahead.

Mr. BURTON. In May 1999, the FDA committed that there were problems with the adverse reporting system for dietary supplements. FDA agreed in that hearing to fix a number of serious problems. I guess you pretty much answered this; you moved in that direction, but not very rapidly because of the resources, and you're saying it's going to take what, 10 years?

Mr. LEVITT. I want to do two things, if I may. One is to speak to that 10 years.

Sometimes there is the belief, and I would like to rectify that, what it means is that nothing will happen for 10 years. That's not what we're saying. We will continue to make improvements every year. The pace at which, before we're at the level everybody would like to be at, will be in 10 years, but we think we're already better than we were 2 years ago, and we will keep getting better. That's point No. 1.

Point No. 2, on the adverse events reporting system, thinking back to the hearing a couple years ago, one of the points you raised was that when FDA reviews these reports, to what extent do we do it at—I'm going to call it a "triage"—is this likely to be related, is this unlikely to be related in this particular report? Because they're going to be different. And when we did review the reports related to ephedra, we did go through very carefully and try to do that triage, and many of the reports, we ourselves concluded, did not have enough information to reach a conclusion. There were some that we thought were likely to be related; some we thought were possibly related; some we thought were probably not related at all. But we believe that the process of going through that, I would say, is itself an improvement in the system, and we subject our review to peer review in several ways. We not only asked our own group to do it, we asked a separate group in our Drug Center to review those. We asked a number of independent experts to go out and review those. And while people did not judge every report exactly the same way, there is a considerable amount of consistency in those reports. So we feel that, if you will, the expertise and the consistency and the transparency of how we are looking at these kinds of reports is also being improved. And I think transparency is another element that I think is very important, so that the Congress, the public, the industry know how we are functioning and can have confidence in it.

Mr. BURTON. Has the FDA made any effort to meet with industry trade associations to discuss how to resolve the outstanding issues with respect to the ephedra products?

Mr. LEVITT. Ephedra again, I think, as almost every speaker said earlier, has probably been our single most difficult issue that we've had to deal with.

Mr. BURTON. Have you met with any industry officials?

Mr. LEVITT. What we have done is, we had a public meeting in which everybody was invited. It was actually chaired by the Department of Health and Human Services, Office of Women's Health, and I believe that virtually all of the industry groups that were interested in participating certainly had an opportunity to do so, and most did come and present data.

We have not tried to have separate meetings. We have felt that this is an important issue, that everything be done out in public

out in the open, so that nobody is viewed as "we're meeting with this group instead of that group." There are a lot of groups, as you know. That has been our way of trying to be evenhanded.

Mr. BURTON. Well, according to what we have here, other than a meeting with CRN concerning the Cantox report, we are aware of no such efforts since the issuance of FDA's June 1997 proposal. The CRN meeting was similar to two other meetings FDA had with industry trade associations in December 1997 and May 1999, where the FDA listened but refused to discuss the issues, claiming the existence of the proposed rule prevented any such discussion.

Are these listening sessions where you just listen, and then you don't have any dialog between——

Mr. LEVITT. Well, the reason that we met with the Council for Responsible Nutrition on the Cantox study was because that was an avenue where they said, "We are collecting a new scientific analysis," and they wanted to comment and say, "Do you agree with this kind of analysis?" We did give them some comments on it. And when they had that analysis nearly completed, they asked to come in and present to us what it said.

Also, now that I'm thinking back—I wasn't anticipating that particular question—I do recall a meeting that I held. I remember that Mr. Israelsen was there with a group of ephedra manufacturers and trade associations—by now, it was probably a couple of years ago; it was some time—that did result in them submitting that industry guidance document that was referred to a little bit. I think our concerns there were—what we tried to do, we tried to separate out first, what is the nature of the risk, before we jump to the remedy. And so the meetings I tried to have, tried to focus on, what are the data that you have? You can't believe how much we tried to meet with the investigators doing that important study, so that we can try to get a better sense of what the data are. And without people coming in with new data—I mean, everybody wants to meet, but in fairness, nobody wants to bring in new data.

Mr. BURTON. Well, let me just say here—and then I'm going to turn this over to my colleague, Representative LaTourette—it seems to me that there needs to be a dialog, because they are on one side on this issue and you apparently are on the other side.

Hopefully, the Harvard and Columbia studies will serve as a catalyst for that kind of discussion, because that should be new information. I mean, that was a 6-month safety and efficacy trial; that should help.

But, you know, I've always been a believer, and I think my colleagues on the Democrat side will attest to the fact that we usually get along a little bit better when we talk instead of just starting to throw bombs at each other, you know what I mean?

Mr. LEVITT. I absolutely agree.

Mr. BURTON. Well, but when you have these meetings, according to the information that we have, it was more of a listening session for you, without any dialog back and forth. If they say something about a claim they are making, it seems to me that you and other scientists at the FDA should say, "Well, give us the information. What is it that we're missing here that we don't see?" so that there can be a dialog. Sometimes the cold, hard facts that they give you on a piece of paper, or something that they say in a meeting, isn't

sufficient to answer all the questions that you may have unless you let them know that.

I don't think I'm telling you anything that you don't know.

Mr. LEVITT. Mr. Chairman, I take that as a fair suggestion. I appreciate that.

Mr. BURTON. All right.

I will turn this over to Mr. LaTourette because my back is bothering me. I have ice on it, and if I don't get up and walk around a little bit, I'm going to be frozen to this seat for the rest of my life. [Laughter.]

Mr. LaTourette.

Mr. LATOURETTE [assuming Chair]. Well, thank you, Mr. Chairman, and I want to apologize for being late. We had a little plane difficulty, getting in from Cleveland, but this is a hearing that I very much wanted to be in attendance at. I appreciate your willingness to be here, and we will let the chairman sort of recuperate and walk around and get some sustenance.

Mr. Levitt, I think the chairman might have been talking to you—if I repeat something because I wasn't in the room, I apologize——

Mr. LEVITT. That's quite all right.

Mr. LATOURETTE [continuing]. And I take guidance better than most on my side of the aisle.

As a result of the 1999 GAO audit, at least in the minds of some of us, established that the FDA had no scientific basis for the serving and duration limits contained in the 1997 proposed rule. It's my understanding that the FDA withdrew most of this proposal, leaving only other proposed actions in place.

My question is, does the FDA maintain that the remaining portions of that proposed rule prevent the agency from having an open dialog with the industry on ephedra?

Mr. LEVITT. No.

Mr. LATOURETTE. OK. Then why didn't the FDA withdraw the entire rule?

Mr. LEVITT. Well, let me go back.

As your question states, the FDA issued a proposed rule by now close to 4 years ago. It had a number of provisions. The cornerstone, if you will, of that regulation was a proposed limit on the dose, on how much ephedra could be in each tablet. The agency believed that it did have a credible basis for proposing that through the public comment period and through the review by GAO. That was called into question. And while the GAO certainly agreed with us that there is an underlying public health issue here, they did not believe that the data we presented to support that dosing level was sustainable.

As a result of that and other public comments, we withdrew the dosing portion of the final rule. We withdrew other related parts of the final rule in terms such as, how many days duration the product could be used, things that were intertwined with that requirement.

What that basically left was some general warnings that had been proposed, and a question on whether or not there ought to be a combination allowed with caffeine, or whether it ought to be sold only as a single ingredient and not in combination with caffeine.

We solicited public comment on those and other issues, and in part because we are waiting on results from that study, those are all still open questions.

Mr. LATOURETTE. The response to my longer question was a simple "no." I think this might have been when I walked in and you and the chairman were having a conversation. The end of the question is, is it your belief that it doesn't prevent that dialog from occurring?

Mr. LEVITT. It does not prevent that dialog, correct. Inevitably what happens is that when we have that dialog, we tend to ask, "What scientific studies do you have to support what you are proposing?" And they ask us what evidence we have to prevent what they are proposing, and we reach an impasse.

Mr. LATOURETTE. And is that an accurate description of what has in fact occurred? I mean, there have been dialogs, but you've reached this Mexican standoff?

Mr. LEVITT. Yes.

Mr. LATOURETTE. Because nobody is able to convince the other side with evidence that they would choose to have?

Mr. LEVITT. Again, that is why we went to the format of a public meeting, chaired by someone other than the FDA. And I think those who attended that meeting did feel that the spirit was genuine, that it was a clear desire to get at whatever information was available out there. There were relatively few well-controlled studies out there to report in, which is part of the level we're all in. We have a very large number of adverse event reports. People have different interpretations of what they mean; whatever they mean, they're a signal of something. And if one is to try to get at additional data that would help clarify what that signal is, or confirm it and so forth, is where we are trying to get.

We are also working with the National Institutes of Health, the Office of Dietary Supplements, the Center for Complimentary and Alternative Medicine on what research they might be able to fund that could help provide answers to these questions. I think everybody wants to know what the answers are because everybody wants to provide consumers with the best information available.

Mr. LATOURETTE. OK.

Are you familiar with the FOIA request filed 4 or 5 months ago by certain industry groups of the FDA concerning this issue?

Mr. LEVITT. We have a long series of requests from different members of the industry. As I mentioned before, the general issue of adverse event reports, that we were actually up to 2 years behind schedule, has been rectified. And as of the beginning of this fiscal year, we were up to date. I am told that since then—I think sometime during the winter, although your dates may be better than mine; if you have an actual date—there has been a relatively recent request for a very large volume of documents, and we are busy processing that now.

Mr. LATOURETTE. OK. Are you able to give us any thought or idea of when that might occur?

Mr. LEVITT. Well, I don't have a date. If you like, I could try to submit one for the record.

Mr. LATOURETTE. That would be good. I would appreciate it.

Some other information that we had was that since December 1999, adverse event reports had not been released. Are you saying that has been rectified?

Mr. LEVITT. Well, the FOIA requests that had been longstanding have all been filled, and those that were submitted last year have been filled, and we have a process now for responding to FOI requests for these kinds of reports.

There is a step further—and it may be your next question, and we have it listed in our goals for this year—to try and establish a process that is more, when reports come in, manufacturers can get real-time access to those. We are actively involved in reviewing how to do that. There are some legal restrictions that we are running into in terms of when people submit their medical records. There are Privacy Act issues that run into disclosability. So we are trying to sort through those conflicting obligations on us. One is to release, and one is to be sure you don't release. And when they are intertwined in the same document set, we want to be sure we do that right and don't do an injustice either way.

But our goal is to have a system that is responsive on more or less a real-time basis for manufacturers.

Mr. LATOURETTE. OK. Maybe I confused myself, but I was thinking of two separate issues. One is the Freedom of Information requests. The other information that I think the committee had was that there had been no release to the public at all of any AERs since December 1999.

Is that what you're in the process of coming up with a better system——

Mr. LEVITT. What we're coming up with is a better system of getting reports directly to the manufacturers where the manufacturers are identified, once they come in to us. In other words, not waiting for them to figure out there's a report and submit a FOI; we presume that companies have a standing FOI request for reports that are about their products.

Mr. LATOURETTE. Good. Is it, based upon your knowledge and accurate observation, though, that the agency has not made public any adverse event reports on ephedra since a year ago December?

Mr. LEVITT. Yes. That's probably accurate, yes.

Mr. LATOURETTE. And the reason for that is?

Mr. LEVITT. Same reason. What we have done is, we have responded to the—we have simply responded to the FOI requests and devoted our energy there. We released last year—and let's just be sure we have the dates correct, because I do lose track of time—it was actually March 2000, and now we're 2001. It was in March 2000 that we released all of the reports, and those were all of the reports more or less up to that time. I'm sure there was a cutoff time; I'm sure it wasn't the day before. So it might have been December 1999. That probably sounds about right.

Mr. LATOURETTE. OK.

Dr. Yetley, the committee——

Mr. LEVITT. Excuse me, if I may. Maybe I should quit while I'm ahead.

Mr. LATOURETTE. You're doing great, and the more information, the better.

Mr. LEVITT. I'm sorry, I lost my train of thought. If I think of it, I'll get back to it.

Mr. LATOURETTE. Well, Mr. Levitt, we'll get back to you.

Dr. Yetley, just a couple questions for you.

We have received some observations that perhaps the United States isn't being represented by you according to the DSHEA in the CODEX meetings. I would invite you to respond to that observation that the committee has received.

Ms. YETLEY. The representation that we have at the U.S. CODEX meetings includes a delegation that consists of approximately 25 people, with a very broad range of interests. We certainly work with that group throughout the meeting.

I think it is important to note—if you check our written comments that were submitted to the committee, to the CODEX committee, prior to the meeting, as well as their record of the comments made at the meeting, that the U.S. Delegate indicated very clearly that we support consumer choice and access to dietary supplements that are safe and that are labeled in a truthful and nonmisleading manner, wanting very much to underscore the philosophy and approach that we're using within the United States.

Mr. LATOURETTE. Can you explain to the committee—and I guess the committee is just me at the moment—can you explain to the committee the National Academy of Sciences document that you shared at the CODEX meeting, and its relevance?

Ms. YETLEY. I didn't hear the last part of the question.

Mr. LATOURETTE. And its relevance.

Ms. YETLEY. At the time we shared that document, which was in 1998, the committee was leaning very strongly toward setting maximum upper limits in these guidelines that were based on arbitrary standards of approximately 150 percent of the RDA. That clearly is not consistent with how we approach this issue in the United States, and it is also not consistent with a sound science-based approach to CODEX matters.

So we therefore countered that particular proposal by suggesting we might consider a sound science-based risk assessment approach that had been developed by our National Academy of Sciences, and we therefore submitted that document for their consideration.

Mr. LATOURETTE. And the document was a description——

Ms. YETLEY. The document was a description of the conceptual model system that our National Academy of Sciences is currently using to set upper limits that are based on a risk assessment approach for nutrients.

Mr. LATOURETTE. OK.

What is the current standing of the U.S. DSHEA position within CODEX today?

Ms. YETLEY. Well, the CODEX itself deals with international trade. The Dietary Supplement Health and Education Act and other relevant provisions of the Food, Drug and Cosmetic Act, as well as FDA regulations, still will govern and will continue to govern, regardless of what CODEX does, how dietary supplements are marketed within the United States.

What the CODEX standards do—and I think Mr. Riedel from the previous panel explained this—by not having CODEX standards for vitamin and mineral supplements, the U.S. industry is finding that

they are encountering trade barriers to exporting their products to other countries.

So the CODEX standard simply will affect the ability of our manufacturers to export products. It will not in any way affect how products are made available and distributed within the United States.

Mr. LATOURETTE. Does the agency have information as to how the other 164 countries in the CODEX regulate minerals, botanicals, and things of that nature?

Ms. YETLEY. We don't have specific information about the different countries. There clearly, based on the discussions we've had, is a wide range of methods by which these products are regulated. Again, as the previous panel noted, some are regulated as drugs in some countries, and in other countries they are regulated as foods. So it varies considerably from country to country.

Mr. LATOURETTE. Focusing specifically on Germany, are you aware as to how Germany regulates vitamins and botanicals?

Ms. YETLEY. I don't know the specifics on many of their products. I think you heard, again from the previous panel, Mr. Blumenthal gave some description of how they deal with botanicals when they are marketed as drugs.

Mr. LATOURETTE. And during the course of these meetings have you, as the representative, experienced any problems—not before the meetings, during the course of these meetings—what problems have you encountered and how have you dealt with them?

Ms. YETLEY. Well, as with all meetings, you have a great range of opinions, some of which are quite strongly held. We have worked closely with the other members of our delegation to consult before we go into sessions, to decide how the United States wants to deal with these issues.

We have worked with countries that we think will be allies on various positions. So I think, very much as you do here in the Congress, we try to find an optimum solution.

Mr. LATOURETTE. But when you say, sort of confabbing before the delegation goes in, by the time you get to the meeting is there unanimity of opinion, or at least on what the United States' position is?

Ms. YETLEY. Well, we present or submit a written position from the U.S. delegation prior to going to the meeting, and then obviously we have to adjust during the meeting. The written statement, the written position of the U.S. delegation, is put out for comment. We have two public meetings prior to finalizing it and sending it out. We very much take into account the comments that we get, to the best of our ability. We try to reach consensus, but it does go through a very public and transparent process prior to being submitted.

Mr. LATOURETTE. You mentioned the Congress. Here, we don't all agree on every issue, as you know, on a daily basis, but is that the type of document, since I haven't read one, is that the type of document that has minority views or dissenting views?

Ms. YETLEY. Well, there is a report of the committee meeting that lays out where the various countries—what their positions were on various issues. So there is a report for each of the committee sessions that is publicly available.

Mr. LATOURETTE. All right.

Well, I don't have any further questions.

Mr. Levitt, did you recall what it is that you wanted to say a few minutes ago?

Mr. LEVITT. No.

Mr. LATOURETTE. Well, if it comes to you in a dream or something later, maybe you can write it down and send it to us.

Seeing that there is nobody else here, I thank you very much for your attendance. I thank everyone who appeared today, and this meeting or this hearing will be adjourned.

[Whereupon, at 3:50 p.m., the committee was adjourned, to reconvene at the call of the Chair.]