

U. S. Food and Drug Administration
 FDA Fact Sheet
 April 27, 1998

FDA's Response to the Report of the Commission on Dietary <Supplement> Labels

In today's notice in the Federal Register, FDA responds to the recommendations and guidance by the Commission on <Dietary> <Supplement> Labels on regulatory and other issues raised by the <Dietary> <Supplement> Health and Education Act (DSHEA) of 1994.

The Commission's final report, included guidance for claims about the effect of <dietary> <supplements> on the structure or function of the body. FDA's general concurrence with the Commission's views is reflected in the agency's proposal, also published today, for "Regulations on Statements made for <Dietary> <Supplements> Concerning the Effect of the Product on the Structure or Function of the Body." (See separate fact sheet.)

In today's notice, the agency discusses guidance and recommendations the Commission report addressed to FDA, industry, scientific and other groups dealing with <dietary> <supplements>. The Commission's suggestions and FDA's responses are summarized below:

- FDA should work with others to improve postmarket surveillance of <dietary> <supplements>. FDA collects reports on serious adverse events associated with <dietary> <supplements> through two monitoring systems, but agrees that greater cooperation would be helpful. The agency presented this issue to its Food Advisory Committee (FAC) of outside experts. FAC has appointed a working group whose findings will be discussed at a later meeting.
- Manufacturers should include appropriate warning statements in their product information. FDA intends to work with the Food and Advisory Committee and industry to develop guidance on the use of warning statements in <dietary> <supplement> labeling.
- FDA should use its enforcement authority under DSHEA to swiftly resolve potential safety issues. FDA is committed to quickly removing unsafe products from the market, or to take other timely actions to protect consumers.
- FDA should ensure that there is broad input to ascertain the degree of scientific agreement for a health claim. FDA has considered and will continue considering the opinion of outside scientific experts in determining whether there is significant scientific agreement supporting the validity of health claims for foods and <dietary> <supplements>. This standard of significant scientific agreement is not affected by the FDA Modernization Act of 1997, which has provisions affecting health claims. The agency is open to suggestions from interested parties on how to improve its current approval process.
- Manufacturers should include in their notification letters for statements of nutritional support such additional information as a copy of the product label or the label mockup, and affirm that they can substantiate, i.e., the truthfulness, scientific validity, and nonmisleading nature of their labeling claims. FDA agrees, and will consider new rulemaking on this subject if experience warrants.
- Manufacturers' substantiation for statements of nutritional support should include such information as identification of the product's ingredients, evidence of safety, assurances that good manufacturing practices were followed, and the qualification of the person(s) who reviewed the data on safety and efficacy. The agency agrees with this guidance.
- FDA should monitor the use of publications used in connection with the sale of <dietary>

<supplements>. The agency intends to monitor the use of "third-party" publications to promote the sale of <dietary> <supplements> and, if necessary, will develop appropriate regulatory guidance to ensure that the information is balanced and truthful.

- A study is needed on the establishment of an alternative system for regulating botanicals with medical uses, and FDA should "promptly establish a review panel" for over-the-counter (OTC) claims made for such products. When there is sufficient support, FDA should consider the feasibility of approving botanicals for OTC uses. FDA has examined the regulatory status of botanicals with possible OTC uses for years, and has participated in conferences and symposia dealing with characterization of, and the safety and effectiveness of, botanical products for the past five years. The agency agrees that a much more comprehensive evaluation of a possible alternative system would be helpful. FDA personnel are available to cooperate with outside researchers on such matters, but FDA lacks the resources to initiate the comprehensive evaluation suggested by the Commission. FDA is in the process of proposing criteria for eligibility in the OTC drug review system that may allow the consideration of certain botanicals. The convening of a review panel, as suggested by the Commission would be premature until such criteria have been finalized.
- A study should be conducted to determine whether consumers want and can use the available <dietary> <supplement> information to select helpful products. FDA agrees, and has asked FAC to consider how to best gather data on how consumers use <dietary> <supplement> label information. FAC has appointed an internal working group to develop recommendations for the full advisory panel.
- FDA should encourage research about <dietary> <supplements>. FDA agrees that additional research should be undertaken to assess the relationships between <dietary> <supplements> and the maintenance of health and/or prevention of disease, and it will continue to provide assistance and guidance for such research by industry and other federal agencies. FDA will also continue working closely with the Office of <Dietary> <Supplements> of the National Institutes of Health.

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FDA's Dietary Supplement Proposal

FDA's proposal, "Regulations on Statements made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body," to be published in the Federal Register, clarifies for manufacturers what types of claims they may -- and may not -- use on labels of dietary supplements under the Dietary Supplement Health and Education Act (DSHEA) of 1994.

Clarification is provided by defining the term "disease" for the purpose of a dietary supplement label claim, and by describing what constitutes a disease claim, which DSHEA prohibits, as opposed to a structure/function claim, which it allows.

Relying on standard medical and legal usage, FDA's proposal defines "disease" as "any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms, including laboratory or clinical measurements, that are characteristic of a disease."

The proposal, which is generally consistent with guidance provided by the Commission on Dietary Supplement Labels (see separate fact sheet), describes allowable claims as truthful and nonmisleading statements of effect on a body system, organ, or function, provided that the context in which the claim appears does not suggest that the product treats, prevents, or mitigates a disease.

Under DSHEA, structure/function claims that meet these criteria may be used by the manufacturer without prior authorization by FDA.

The law, however, prohibits express or implicit claims that a dietary supplement has an effect on an identifiable disease, or a class of diseases.

The agency recognizes that because most disease treatments can be described in terms of their effects on a structure or function of the body, it is sometimes difficult to distinguish between allowable structure/function claims and prohibited disease claims.

The proposal therefore describes and provides numerous examples of the various types of prohibited disease claims, and when appropriate, contrasts them with examples of structure/function statements that are allowable. Under the proposal, prohibited disease claims are statements that imply or state that:

- the product has an effect on a specific disease or class of diseases. Examples of prohibited statements: "protects against the development of cancer," "reduces the pain and stiffness associated with arthritis." Examples of allowable structure/function claims (no reference to a disease): "helps promote urinary tract health," "helps maintain cardiovascular function," "promotes relaxation."
- the product is in a drug class that is intended to be used to diagnose, mitigate, treat, cure, or prevent a disease. Examples of prohibited claims include description of the product as an "antibiotic," "antiseptic," "antidepressant," or a "laxative," "vaccine," or "diuretic." Examples of allowable product descriptions (no reference to disease treatment or prevention): an "energizer," a "rejuvenative."
- the product has an effect on one or more recognizable signs or symptoms that are recognizable to health professionals or consumers as being characteristic of a specific disease or diseases. Examples of prohibited claims: "lowers cholesterol," or "reduces joint pain." Examples of allowable claims (symptoms do not identify a disease): "reduces stress and frustration," "improves

absentmindedness."

- the product is a substitute for, or augmentation of, a drug or other medical therapy. Examples of prohibited claims: product names such as "Herbal Prozac," or a suggestion that the product should be used "as part of your diet when taking insulin to help maintain a healthy blood sugar level."
- the product has a role in the body's response to a disease or carrier of disease. Examples of prohibited claims: "supports the body's antiviral capabilities," "supports the body's ability to resist infection." Example of an allowable claim (effect on a normal body function): "supports the immune system."
- the product has an effect on a consequence of a natural state that presents characteristic signs or symptoms recognizable as constituting an abnormality of the body. Examples of prohibited claims: "treats toxemia of pregnancy," or affects such abnormalities associated with aging as "decreased sexual function," "hot flashes," and "Alzheimer's disease."
- the product treats, prevents or mitigates adverse events associated with a medical therapy or procedure. Examples of prohibited claims: "helps avoid diarrhea associated with antibiotic use," "reduces nausea associated with chemotherapy." Example of an allowable claim (no mention of a therapy or procedure): "helps maintain healthy intestinal flora."
- the product has an effect on a disease, made in one or more of the following ways:
 - * The name of the product. Examples of prohibited product name: "Carpaltum" (implies effect on carpal tunnel syndrome), "Raynaudin" (Raynaud's phenomenon) or "Hepatacure" (liver problems). Examples of allowable product names: "Cardiohealth," "Heart Tabs."
 - * Statements about the formulation of the product, including the claim that the product contains an ingredient that is a *well-known regulated drug, such as aspirin, laetrile or digoxin.
 - * Citation of a publication in which the title refers to a disease use. Example of a prohibited claim for vitamin E: reference to an article entitled "Serial Coronary Angiographic Evidence That Antioxidant Vitamin Intake Reduces Progression of Coronary Artery Atherosclerosis."
 - * Use of the term "disease" or "diseased."
 - * Suggestions of an effect on disease through pictures, vignettes, symbols and other means.

Since the passage of DSHEA, FDA has received approximately 2,300 notifications from manufacturers about structure/function claims for their products. The agency has informed the manufacturers that about 150 of these claims are problematic, and it estimates that another 60 claims would not be permitted under the proposed criteria.

If the proposed rule becomes final, unacceptable structure/function claims will have to be removed from labeling, or the product will have to be approved as a drug under the Federal Food, Drug and Cosmetic Act.

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U. S. Food and Drug Administration
FDA Consumer
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An FDA Guide to Dietary <Supplements>

by Paula Kurtzweil

Set between a Chinese restaurant and a pizza and sub sandwich eatery, a Rockville health food store offers yet another brand of edible items: Bottled herbs like cat's claw, dandelion root, and blessed thistle. Vitamins and minerals in varying doses. Herbal and nutrient concoctions whose labels carry claims about relieving pain, "energizing" and "detoxifying" the body, or providing "guaranteed results."

This store sells <dietary> <supplements>, some of the hottest selling items on the market today. Surveys show that more than half of the U.S. adult population uses these products. In 1996 alone, consumers spent more than \$6.5 billion on <dietary> <supplements>, according to Packaged Facts Inc., a market research firm in New York City.

But even with all the business they generate, consumers still ask questions about <dietary> <supplements>: Can their claims be trusted? Are they safe? Does the Food and Drug Administration approve them?

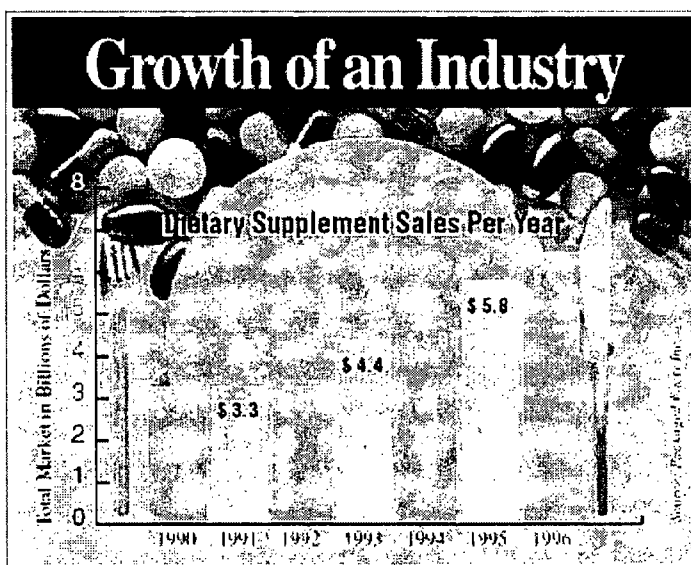
Many of these questions come in the wake of the 1994 <Dietary> <Supplement> Health and Education Act, or DSHEA, which set up a new framework for FDA regulation of <dietary> <supplements>. It also created an office in the National Institutes of Health to coordinate research on <dietary> <supplements>, and it called on President Clinton to set up an independent <dietary> <supplement> commission to report on the use of claims in <dietary> <supplement> labeling.

In passing DSHEA, Congress recognized first, that many people believe <dietary> <supplements> offer health benefits and second, that consumers want a greater opportunity to determine whether supplements may help them. The law essentially gives <dietary> <supplement> manufacturers freedom to market more products as <dietary> <supplements> and provide information about their products' benefits--for example, in product labeling.

The Council for Responsible Nutrition, an organization of manufacturers of <dietary> <supplements> and their suppliers, welcomes the change. "Our philosophy has been ... to maintain consumer access to products and access to information [so that consumers can] make informed choices," says John Cordaro, the group's president and chief executive officer.

But in choosing whether to use <dietary> <supplements>, FDA answers consumers' questions by noting that under DSHEA, FDA's requirement for premarket review of <dietary> <supplements> is less than that over other products it regulates, such as drugs and many additives used in conventional foods.

This means that consumers and manufacturers have responsibility for checking the safety of <dietary> <supplements> and determining the truthfulness of label claims.



Anatomy of the New Requirements for <Dietary> <Supplement> Labels

Information that will be required on the labels of <dietary> <supplements> includes:

- Statement of identity (e.g., "ginseng")
- Net quantity of contents (e.g., "60 capsules")
- Structure-function claim and 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."
- Directions for use (e.g., "Take one capsule daily.")
- Supplement Facts panel (lists serving size, amount, and active ingredient)
- Other ingredients in descending order of predominance and by common name or proprietary blend.
- Name and place of business of manufacturer, packer or distributor. This is the address to write for more product information.

View the dietary supplement labels in PDF format<> (252K).

What Is a <Dietary> <Supplement>?

Traditionally, <dietary> <supplements> referred to products made of one or more of the essential nutrients, such as vitamins, minerals, and protein. But DSHEA broadens the definition to include, with some exceptions, any product intended for ingestion as a supplement to the diet. This includes vitamins; minerals; herbs, botanicals, and other plant-derived substances; and amino acids (the individual building blocks of protein) and concentrates, metabolites, constituents and extracts of these substances.

It's easy to spot a supplement because DSHEA requires manufacturers to include the words "<dietary> <supplement>" on product labels. Also, starting in March 1999, a "Supplement Facts" panel will be required on the labels of most <dietary> <supplements>.

<Dietary> <supplements> come in many forms, including tablets, capsules, powders, softgels, gelscaps, and liquids. Though commonly associated with health food stores, <dietary> <supplements> also are sold in grocery, drug and national discount chain stores, as well as through mail-order catalogs, TV programs, the Internet, and direct sales.

FDA oversees safety, manufacturing and product information, such as claims, in a product's labeling, package inserts, and accompanying literature. The Federal Trade Commission regulates the advertising of <dietary> <supplements>.

One thing <dietary> <supplements> are not is drugs. A drug, which sometimes can be derived from plants used as traditional medicines, is an article that, among other things, is intended to diagnose, cure, mitigate, treat, or prevent diseases. Before marketing, drugs must undergo clinical studies to determine their effectiveness, safety, possible interactions with other substances, and appropriate dosages, and FDA must review these data and authorize the drugs' use before they are marketed. FDA does not authorize or test <dietary> <supplements>.

A product sold as a <dietary> <supplement> and touted in its labeling as a new treatment or cure for a specific disease or condition would be considered an unauthorized--and thus illegal--drug. Labeling changes consistent with the provisions in DSHEA would be required to maintain the product's status as a <dietary> <supplement>.

Another thing <dietary> <supplements> are not are replacements for conventional diets, nutritionists say. Supplements do not provide all the known--and perhaps unknown--nutritional benefits of conventional food.

Monitoring for Safety

As with food, federal law requires manufacturers of <dietary> <supplements> to ensure that the products they put on the market are safe. But supplement manufacturers do not have to provide information to FDA to get a product on the market, unlike the food additive process often required of new food ingredients. FDA review and approval of supplement ingredients and products is not required before marketing.

Food additives not generally recognized as safe must undergo FDA's premarket approval process for new food ingredients. This requires manufacturers to conduct safety studies and submit the results to FDA for review before the ingredient can be used in marketed products. Based on its review, FDA either authorizes or rejects the food additive.

In contrast, <dietary> <supplement> manufacturers that wish to market a new ingredient (that is, an ingredient not marketed in the United States before 1994) have two options. The first involves submitting to FDA, at least 75 days before the product is expected to go on the market, information that supports their conclusion that a new ingredient can reasonably be expected to be safe. Safe means that the new ingredient does not present a significant or unreasonable risk of illness or injury under conditions of use recommended in the product's labeling.

The information the manufacturer submits becomes publicly available 90 days after FDA receives it.

Another option for manufacturers is to petition FDA, asking the agency to establish the conditions under which the new dietary ingredient would reasonably be expected to be safe. To date, FDA's Center for Food Safety and Applied Nutrition has received no such petitions.

Under DSHEA, once a <dietary> <supplement> is marketed, FDA has the responsibility for showing that a <dietary> <supplement> is unsafe before it can take action to restrict the product's use. This was the case when, in June 1997, FDA proposed, among other things, to limit the amount of ephedrine alkaloids in <dietary> <supplements> (marketed as ephedra, Ma huang, Chinese ephedra, and epitonin, for example) and provide warnings to consumers about hazards associated with use of <dietary> <supplements> containing the ingredients. The hazards ranged from nervousness, dizziness, and changes in blood pressure and heart rate to chest pain, heart attack, hepatitis, stroke, seizures, psychosis, and death. The proposal stemmed from FDA's review of adverse event reports it had received, scientific literature, and public comments. FDA has received many comments on the 1997 proposal and was reviewing them at press time.

Also in 1997, FDA identified contamination of the herbal ingredient plantain with the harmful herb *Digitalis lanata* after receiving a report of a complete heart block in a young woman. FDA traced all use of the contaminated ingredient and asked manufacturers and retailers to withdraw these products from the market. (For information about other potentially dangerous <dietary> <supplements>, see "Supplements Associated with Illnesses and Injuries.")

DSHEA also gives FDA authority to establish good manufacturing practices, or GMPs, for <dietary> <supplements>. In a February 1997 advance notice of proposed rulemaking, the agency said it would establish <dietary> <supplement> GMPs if, after public comment, it determined that GMPs for conventional food are not adequate to cover <dietary> <supplements>, as well. GMPs, the agency said, would ensure that <dietary> <supplements> are made under conditions that would result in safe and properly labeled products. At press time, FDA was reviewing comments on the 1997 notice.

Some supplement makers may already voluntarily follow GMPs devised, for example, by trade groups.

Besides FDA, individual states can take steps to restrict or stop the sale of potentially harmful <dietary> <supplements> within their jurisdictions. For example, Florida has already banned all ephedra-containing products, and other states have said they are considering similar action.

Also, the industry strives to regulate itself, the Council for Responsible Nutrition's Cordaro says. He cites the GMPs that his trade group and others developed for their member companies. FDA is reviewing these GMPs as it considers whether to pursue mandatory industry-wide GMPs. Another example of self-regulation, Cordaro says, is the voluntary use of a warning about ephedra products that

his organization drafted. He says that about 90 percent of U.S. manufacturers of products containing ephedra alkaloids now use this warning label.

Understanding Claims

Claims that tout a supplement's healthful benefits have always been a controversial feature of <dietary> <supplements>. Manufacturers often rely on them to sell their products. But consumers often wonder whether they can trust them.

Under DSHEA and previous food labeling laws, supplement manufacturers are allowed to use, when appropriate, three types of claims: nutrient-content claims, disease claims, and nutrition support claims, which include "structure-function claims."

Nutrient-content claims describe the level of a nutrient in a food or <dietary> <supplement>. For example, a supplement containing at least 200 milligrams of calcium per serving could carry the claim "high in calcium." A supplement with at least 12 mg per serving of vitamin C could state on its label, "Excellent source of vitamin C."

Disease claims show a link between a food or substance and a disease or health-related condition. FDA authorizes these claims based on a review of the scientific evidence. Or, after the agency is notified, the claims may be based on an authoritative statement from certain scientific bodies, such as the National Academy of Sciences, that shows or describes a well-established diet-to-health link. As of this writing, certain <dietary> <supplements> may be eligible to carry disease claims, such as claims that show a link between:

- the vitamin folic acid and a decreased risk of neural tube defect-affected pregnancy, if the supplement contains sufficient amounts of folic acid
- calcium and a lower risk of osteoporosis, if the supplement contains sufficient amounts of calcium
- psyllium seed husk (as part of a diet low in cholesterol and saturated fat) and coronary heart disease, if the supplement contains sufficient amounts of psyllium seed husk.

Nutrition support claims can describe a link between a nutrient and the deficiency disease that can result if the nutrient is lacking in the diet. For example, the label of a vitamin C supplement could state that vitamin C prevents scurvy. When these types of claims are used, the label must mention the prevalence of the nutrient-deficiency disease in the United States.

These claims also can refer to the supplement's effect on the body's structure or function, including its overall effect on a person's well-being. These are known as structure-function claims.

Examples of structure-function claims are:

- Calcium builds strong bones.
- Antioxidants maintain cell integrity.
- Fiber maintains bowel regularity.

Manufacturers can use structure-function claims without FDA authorization. They base their claims on their review and interpretation of the scientific literature. Like all label claims, structure-function claims must be true and not misleading.

Structure-function claims can be easy to spot because, on the label, they must be accompanied with the disclaimer "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."

Manufacturers who plan to use a structure-function claim on a particular product must inform FDA of the use of the claim no later than 30 days after the product is first marketed. While the manufacturer must be able to substantiate its claim, it does not have to share the substantiation with FDA or make it publicly available.

If the submitted claims promote the products as drugs instead of supplements, FDA can advise the manufacturer to change or delete the claim.

Because there often is a fine line between disease claims and structure-function claims, FDA in April proposed regulations that would establish criteria under which a label claim would or would not qualify as a disease claim. Among label factors FDA proposed for consideration are:

- the naming of a specific disease or class of diseases
- the use of scientific or lay terminology to describe the product's effect on one or more signs or symptoms recognized by health-care professionals and consumers as characteristic of a specific disease or a number of different specific diseases
- product name
- statements about product formulation
- citations or references that refer to disease
- use of the words "disease" or "diseased"
- art, such as symbols and pictures
- statements that the product can substitute for an approved therapy (for example, a drug).

FDA's proposal is consistent with the guidance on the distinction between structure-function and disease claims provided in the 1997 report by the President's Commission on <Dietary> <Supplement> Labels.

If shoppers find <dietary> <supplements> whose labels state or imply that the product can help diagnose, treat, cure, or prevent a disease (for example, "cures cancer" or "treats arthritis"), they should realize that the product is being marketed illegally as a drug and as such has not been evaluated for safety or effectiveness.

FTC regulates claims made in the advertising of <dietary> <supplements>, and in recent years, that agency has taken a number of enforcement actions against companies whose advertisements contained false and misleading information. The actions targeted, for example, erroneous claims that chromium picolinate was a treatment for weight loss and high blood cholesterol. An action in 1997 targeted ads for an ephedrine alkaloid supplement because they understated the degree of the product's risk and featured a man falsely described as a doctor.

Fraudulent Products

Consumers need to be on the lookout for fraudulent products. These are products that don't do what they say they can or don't contain what they say they contain. At the very least, they waste consumers' money, and they may cause physical harm.

Fraudulent products often can be identified by the types of claims made in their labeling, advertising and promotional literature. Some possible indicators of fraud, says Stephen Barrett, M.D., a board member of the National Council Against Health Fraud, are:

- Claims that the product is a secret cure and use of such terms as "breakthrough," "magical," "miracle cure," and "new discovery." If the product were a cure for a serious disease, it would be widely reported in the media and used by health-care professionals, he says.
- "Pseudomedical" jargon, such as "detoxify," "purify" and "energize" to describe a product's effects. These claims are vague and hard to measure, Barrett says. So, they make it easier for success to be claimed "even though nothing has actually been accomplished," he says.
- Claims that the product can cure a wide range of unrelated diseases. No product can do that, he says.
- Claims that a product is backed by scientific studies, but with no list of references or references that are inadequate. For instance, if a list of references is provided, the citations cannot be traced, or if they are traceable, the studies are out-of-date, irrelevant, or poorly designed.
- Claims that the supplement has only benefits--and no side effects. A product "potent enough to help people will be potent enough to cause side effects," Barrett says.
- Accusations that the medical profession, drug companies and the government are suppressing information about a particular treatment. It would be illogical, Barrett says, for large numbers of

people to withhold information about potential medical therapies when they or their families and friends might one day benefit from them.

Though often more difficult to do, consumers also can protect themselves from economic fraud, a practice in which the manufacturer substitutes part or all of a product with an inferior, cheaper ingredient and then passes off the fake product as the real thing but at a lower cost. Varro Tyler, Ph.D., Sc.D., a distinguished professor emeritus of pharmacognosy (the study of medicinal products in their crude, or unprepared, form) at Purdue University in West LaFayette, Ind., advises consumers to avoid products sold for considerably less money than competing brands. "If it's too cheap, the product is probably not what it's supposed to be," he says.

Quality Products

Poor manufacturing practices are not unique to <dietary> <supplements>, but the growing market for supplements in a less restrictive regulatory environment creates the potential for supplements to be prone to quality-control problems. For example, FDA has identified several problems where some manufacturers were buying herbs, plants and other ingredients without first adequately testing them to determine whether the product they ordered was actually what they received or whether the ingredients were free from contaminants.

To help protect themselves, consumers should:

- Look for ingredients in products with the U.S.P. notation, which indicates the manufacturer followed standards established by the U.S. Pharmacopoeia.
- Realize that the label term "natural" doesn't guarantee that a product is safe. "Think of poisonous mushrooms," says Elizabeth Yetley, Ph.D., director of FDA's Office of Special Nutritionals. "They're natural."
- Consider the name of the manufacturer or distributor. Supplements made by a nationally known food and drug manufacturer, for example, have likely been made under tight controls because these companies already have in place manufacturing standards for their other products.
- Write to the supplement manufacturer for more information. Ask the company about the conditions under which its products were made.

Reading and Reporting

Consumers who use <dietary> <supplements> should always read product labels, follow directions, and heed all warnings.

Supplement users who suffer a serious harmful effect or illness that they think is related to supplement use should call a doctor or other health-care provider. He or she in turn can report it to FDA MedWatch by calling 1-800-FDA-1088 or going to www.fda.gov/medwatch/report/hcp.htm on the MedWatch Website. Patients' names are kept confidential.

Consumers also may call the toll-free MedWatch number or go to www.fda.gov/medwatch/report/consumer/consumer.htm on the MedWatch Website to report an adverse reaction. To file a report, consumers will be asked to provide:

- name, address and telephone number of the person who became ill
- name and address of the doctor or hospital providing medical treatment
- description of the problem
- name of the product and store where it was bought.

Consumers also should report the problem to the manufacturer or distributor listed on the product's label and to the store where the product was bought.

Today's <Dietary> <Supplements>

The report of the President's Commission on <Dietary> <Supplement> Labels, released in November

1997, provides a look at the future of <dietary> <supplements>. It encourages researchers to find out whether consumers want and can use the information allowed in <dietary> <supplement> labeling under DSHEA. It encourages studies to identify more clearly the relationships between <dietary> <supplements> and health maintenance and disease prevention. It urges FDA to take enforcement action when questions about a product's safety arise. And it suggests that FDA and the industry work together to develop guidelines on the use of warning statements on <dietary> <supplement> labels.

FDA generally concurred with the commission's recommendations in the agency's 1998 proposed rule on <dietary> <supplement> claims.

While much remains unknown about many <dietary> <supplements>--their health benefits and potential risks, for example--there's one thing consumers can count on: the availability of a wide range of such products. But consumers who decide to take advantage of the expanding market should do so with care, making sure they have the necessary information and consulting with their doctors and other health professionals as needed.

"The majority of supplement manufacturers are responsible and careful," FDA's Yetley says. "But, as with all products on the market, consumers need to be discriminating. FDA and industry have important roles to play, but consumers must take responsibility, too."

Paula Kurtzweil is a member of FDA's public affairs staff.

Supplement Your Knowledge

Some sources for additional information on <dietary> <supplements> are:

Federal Agencies

Food and Drug Administration:

Office of Consumer Affairs
HFE-88
Rockville, MD 20857

Food Information Line
1-800-FDA-4010
(202) 205-4314 in the Washington, D.C., area

FDA Website: www.cfsan.fda.gov/~dms/supplmnt.html

Federal Trade Commission
Public Reference Branch
Room 130
Washington, DC 20580
www.ftc.gov

National Institute on Aging
NIA Information Center
P.O. Box 8057
Gaithersburg, MD 20898-8057
1-800-222-2225
TTY: 1-800-222-4225
<http://128.231.160.11/nia/health/pubpub/hormrev.htm>

Health Professional Organizations

American Dietetic Association
216 W. Jackson Blvd.
Chicago, IL 60606-6995
1-800-366-1655 (recorded messages)
1-900-225-5267 (to talk to a registered dietitian)
www.eatright.org

Expert Advice

Before starting a <dietary> <supplement>, it's always wise to check with a medical doctor. It is especially important for people who are:

- pregnant or breastfeeding
- chronically ill
- elderly
- under 18
- taking prescription or over-the-counter medicines. Certain supplements can boost blood levels of certain drugs to dangerous levels.

Varro Tyler, Ph.D., Sc.D., distinguished professor emeritus of pharmacognosy at Purdue University, cites as examples garlic and the supplement ginkgo biloba. Both can thin the blood, which can be hazardous, he says, for people taking prescription medicines that also thin the blood.

In addition to medical doctors, other health-care professionals, such as registered pharmacists, registered dietitians and nutritionists, also can be sources of information about <dietary> <supplements>.

--P.K.

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Americans Gamble on Herbs as Medicine

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By JANE E. BRODY

Herbal medicine, the mainstay of therapeutics for centuries before modern purified drugs relegated it to the status of near-quackery, has in the last five years emerged from the fringes of health care with an astonishing flourish and now shows clear signs of joining the medical mainstream.

Despite many cautionary tales about adulterated and even dangerous products, herbs formulated as capsules, tinctures, extracts and teas -- and increasingly as additions to common foods like potato chips and fruit drinks -- are now routinely used by a third of American adults seeking to enhance their health or alleviate their illnesses. Each day the herbal realm wins new converts, particularly among those who have become disillusioned with the cost and consequences of traditional drugs, distrustful of conventional physicians and convinced that "natural" equals "good."

Yet, because herbal products are classified as dietary supplements, not drugs, and face none of the premarket hurdles drugs must clear, consumers have no assurance of safety or effectiveness. Indeed, scores of products sold in the United States are listed by European and American authorities as ineffective, unsafe or both, and manufacturing standards to assure high quality have been proposed but are not yet in force.

Thus, countless consumers are wasting their money on useless products or jeopardizing their health on hazardous ones. Among the serious side effects that have been linked to herbal remedies are high blood pressure, life-threatening allergic reactions, heart rhythm abnormalities, mania, kidney failure and liver damage. A few widely available products, including sassafras and comfrey, contain known carcinogens.

At the same time, according to a report last year in the journal *Psychosomatics*, unsuspecting consumers "have used herbal remedies with good results only to discover that the benefit was actually derived from the presence of undisclosed

medicines," including steroids, anti-inflammatory agents, sedatives and hormones.

"The lack of quality standards is the No. 1 problem in the whole industry," said Dr. Varro Tyler, emeritus professor of pharmacognosy (the study of active ingredients in plants) at Purdue University. Tyler, who has no financial connection to herbal products and is arguably the nation's leading independent expert on herbal medicine, said: "I feel sorry for the typical consumer. How is he or she to know what is best, what products are reliable and safe? Even when a label says the product has been standardized, the consumer has no way to know if it actually meets that standard." And even if an herbal product has been reliably made in some standard dose, it does not mean that scientific studies have shown it to be effective.

The industry itself is promoting a "good manufacturing practices" doctrine. Annette Dickinson, director of scientific and regulatory affairs for the Council for Responsible Nutrition, a trade organization for producers of dietary supplements, said a consortium of associations submitted a document of manufacturing standards to the Food and Drug Administration two years ago. Although such a standard would say nothing about an herb's safety or effectiveness, it would result in reliable methods that the industry would have to use to assure the identity and quality of its products. The agency has issued a notice of proposed rules but no final ruling as yet.

Nonetheless, botanicals -- as herbal products are more accurately known -- are enjoying an annual retail market approaching \$4 billion, up from \$839 million in 1991 and growing about 18 percent a year. Hundreds of products formulated with virtually no government oversight are crowding shelves of health food stores, food markets and pharmacies nationwide. Supplements are also widely sold by marketers like Amway, through catalogs and on the Internet.

Now, even major pharmaceutical companies like Warner Lambert, American Home Products, Bayer and SmithKline Beecham are introducing herbal products, adding respectability to this marginalized market.

Some herbs -- like echinacea, goldenseal, American ginseng and wild yam -- have become so popular that their continued supply from natural sources is in danger. As the plants become scarcer and more expensive, products containing them are increasingly likely to be adulterated and may even contain none of the herb listed on the label. Peggy Brevoort, president of East Earth Herb Inc., a company in Eugene, Ore., that produces botanicals, said the demand for St. John's wort, used for mild depression, and kava, a calmativie said to reduce anxiety, now exceeds their supply, introducing the "danger of adulteration" by "unscrupulous dealers."

At the same time, two major new publications -- a 1,244-page Physicians' Desk Reference for Herbal Medicines, produced by the same company that publishes the Physicians' Desk Reference, and an English-language edition of Germany's therapeutic guide to herbal medicines, The Complete German Commission E Monographs -- have been issued to help educate physicians, pharmacists and interested consumers about the known uses, proper dosages and safety concerns of more than 600 botanicals now sold in this country. The evaluations in both books are based on studies, most done in Germany and reviewed by teams of experts.

Last month, the National Institutes of Health began listing on the Internet international bibliographic information on dietary supplements, including herbal products. The address is www.nal.usda.gov/fnic/IBIDS/.

In addition, a few medical and pharmacology schools have recently introduced courses in phytomedicine, the study of botanicals. And next month the American Pharmaceutical Association will conduct a two-day program on herbal medicine as part of its annual meeting. Still, most doctors remain wary of botanicals, especially when patients choose self-medication with plant extracts over established medical remedies.

The very act of Congress that has fostered this growth -- the 1994 Dietary Supplement Health and Education Act -- has also permitted chaos to reign in the botanical marketplace, with no mechanism to assure that products are safe or effective. Pushed heavily by Republican Sen. Orrin Hatch of Utah, the home base of many supplement makers, and passed over the objections of the FDA, the law created a new product class, the dietary supplement, that was not subject to regulations applied to drugs. Now any substance that can be found in foods, regardless of amount or action and including substances that act as hormones or toxins, can be produced and sold without any premarket testing or agency approval.

Marketed as neither a food nor a drug, herbal products are not obliged to meet any established standards of effectiveness or safety for medicinal products, which require extensive laboratory and clinical trials before approval. As with other substances classified as dietary supplements, the FDA can restrict the sale of an herbal product only if it receives well-documented reports of health problems associated with it. The agency took four years, and more than 100 reports of life-threatening symptoms and 38 deaths, to act against ephedra, often sold as the Chinese herb ma huang, a stimulant that can prove disastrous to people with heart problems.

With FDA authority limited by the 1994 law, the Federal Trade Commission, which monitors advertising, has taken a more active role in monitoring supplement makers.

The FTC last year took legal action against seven manufacturers that had broken rules requiring advertising be truthful and verifiable. The companies were selling remedies or purported cure-alls for ailments like impotence, cancer and obesity.

The commission also sent e-mail warnings to 1,200 Internet sites that it said had made "incredible claims" for drugs, devices and supplements, including herbal remedies that would supposedly ward off AIDS. Also, the commission late last year issued its first set of advertising guidelines aimed specifically at the supplement industry.

Still, the current regulations have created a quagmire of consumer confusion and set up potential health crises that even industry officials say could ultimately hurt producers as well as users of herbal products. Under the 1994 law, consumers have no assurance that an herbal product contains what the label says it does or that it is free from harmful contaminants. Independent analyses of some products, particularly those containing costly or scarce herbs, revealed that some have little or none of the purported active ingredient listed on the label.

Adding to the confusion is that botanical makers are allowed to describe products only in terms of their effects on the structure or function of the body, not their potential health benefits. Thus, a product label might say "promotes cardiac function" but it cannot say "lowers cholesterol."

Likewise, although the law does allow health warnings on the label, most manufacturers have yet to include them.

Consumers are warned, however, that federal drug safety officials are not watching the store. All botanicals must display a disclaimer on the label following the description of the product's structural or functional role: "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." To which Tyler commented, "If that is true, why on earth would anyone use it?"

The seeds of the modern herbal market were sown in the '60s when "green, organic and natural became buzzwords," Tyler said. But they did not mature until the '90s with the growing consumer interest in "self-care and controlling one's destiny," he said. Many turned to herbs as a gentler way to treat health problems and a potential tool for preserving mental and physical health.

The interest has spawned scores of Internet sites and hundreds of books on various herbs. But much of the literature is replete with poorly documented health claims and, with few exceptions (among them, Tyler's books), advocacy prevails over objectivity.

Because plants contain a mixture of relatively diluted chemicals, they naturally tend to have milder actions, both in their therapeutic benefits and side effects, than the concentrated, single chemicals in most drugs. Thus, botanicals generally take longer to act than regular pharmaceuticals and few have the potency of a prescription, the one possible exception being saw palmetto, which a well-designed study indicated may be as helpful for an enlarged prostate as the more expensive and riskier drug, Proscar.

The combination of chemicals in botanicals is potentially both a plus and a minus. When two or more chemicals enhance one another's activity, the therapeutic benefit could theoretically exceed that of an isolated substance formulated as a drug. Mark Blumenthal, who heads the American Botanical Council, noted that the herb St. John's wort, widely used in Germany and increasingly in the United States to counter mild depression, is standardized for a substance called hypericin. But, he explained, "hypericin is not directly linked to its antidepressant activity." Rather, other substances in the herb seem to have diverse actions on brain chemicals, all of which work together to counter depression.

Equally possible, though, when using an herb with two or more active chemicals, is that one will cancel the benefits of another or introduce a hazard. Without careful chemical tests and large, well-controlled clinical trials such actions are often hard to detect.

Consumer confidence in herbal medicine is bolstered by the common but erroneous assumption that "natural" equals "safe" and the public's failure to realize that many plants contain chemicals that are potent drugs or outright poisons. Natural laxatives like the herb Cascara sagrada are just as habit-forming and harmful to the colon as laxatives sold as drugs.

Indeed, one quarter of prescription drugs and hundreds of over-the-counter products were originally isolated from plants. Ephedra, for example, contains a natural stimulant that is approved for use as a decongestant and bronchial dilator in some pharmaceutical products. However, when used in uncontrolled dosages or by people with certain underlying health problems, it can cause a dangerous rise in blood pressure and, in its herbal form, has been responsible for serious adverse reactions and dozens of deaths, mainly among people who

inappropriately used it as a stimulant or diet aid.

Complicating the safety issue is the fact, shown in several recent surveys, that most patients fail to tell their physicians they use herbal supplements and thus sometimes risk dangerous drug interactions or endure costly tests or treatments when an herb causes an unrecognized side effect. Experts say many patients withhold information about herbal drug use because they fear being ridiculed by their doctors.

Although all German physicians must take courses on herbal remedies, only a handful of American medical and pharmacology schools offer courses in this field.

A year ago, the President's Commission on Dietary Supplement Labels recommended that the FDA appoint a committee to evaluate the safety and effectiveness of herbal products. "This could be the most important step in the United States toward legitimizing herbal medicine," Tyler said.

However, the agency responded that it lacked the budget to support such an effort. American physicians have completed and published only a few well-designed studies of some popular botanicals. Among them were studies showing that saw palmetto can shrink an enlarged prostate and ginkgo biloba can improve memory in patients with early Alzheimer's disease.

The Office of Dietary Supplements at the National Institutes of Health is helping to finance a three-year multicenter study of St. John's wort as a treatment for clinical depression and a study of plant-based estrogens as a preventive for postmenopausal health problems.

However, thousands of studies of botanicals have been completed abroad -- mainly in Germany -- that strongly suggest a health-promoting role for more than 200 plant products. Germany's Commission E evaluated 380 botanicals, approving 254 as safe and reasonably effective and disapproving 126 as ineffective, unsafe or both.

The Germans use a different criterion to assess an herb's benefits -- a doctrine of "reasonable certainty" that the herb has the desired effect and is safe, Blumenthal said. Whereas standard testing of a drug for approval by the FDA can cost as much as \$500 million per product -- a prohibitive amount for companies to spend on botanicals that cannot be patented -- tests to establish "reasonable certainty" would cost only \$1 million to \$2 million, Tyler estimated.

In June 1996, Dr. Robert Temple, director of medical policy for the FDA's Center for Drug Evaluation, suggested that, rather than subjecting botanicals to the extensive tests required for drugs, the agency might consider applying less stringent criteria to assess an herb's effects, at least when a product is to be used only for a short time. He said, "A long history of safe use might provide sufficient safety information for products that are intended for short-term use."

More than four dozen botanicals or botanical formulations have been submitted to the agency as investigational new drugs. If any meet the agency's criteria for safety and effectiveness and are eventually approved as drugs, they would be allowed to carry direct health claims -- instead of just structure and function statements -- on labels and in advertising.

Meanwhile, Dr. Joerg Gruenwald, medical director of a German phytomedicine company and primary editor of the new Physicians' Desk Reference for Herbal

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November 18, 1998

F.T.C. Guidelines Restrict Ad Claims for Supplements

By DENISE GRADY

For the first time, the Federal Trade Commission is issuing advertising guidelines aimed specifically at the nation's booming dietary supplement industry.

The guidelines are the commission's second action within a week on claims by the industry, which earned nearly \$12 billion in 1997 and is growing at about 20 percent a year. Last week the commission e-mailed warnings to 1,200 Internet sites that it said had made "incredible claims" for drugs, devices and dietary supplements, including herbal remedies that purported to ward off AIDS or cure cancer.

In addition, the commission has taken legal action this year against seven supplement manufacturers over advertising claims for various products, including an impotence remedy called Vaegra and a shark cartilage product that supposedly cured cancer, rheumatism, arthritis, diabetes, fibroid tumors, bursitis, circulatory problems and cysts. Several weight-loss potions were also targeted by the commission.

The guidelines, which are being posted Wednesday on the commission's Web site and sent to trade associations for the supplement industry, do not amount to any change in policy, said Michelle Rusk, a lawyer for the commission. Basically the FTC requires that advertising be truthful, that it not be misleading and that advertisers be able to back up their claims. The new guidelines explain how those requirements apply to the supplement industry and spell out the kinds of claims that supplement manufacturers can and cannot make.

Jodie Bernstein, director of the FTC's Bureau of Consumer Protection, said that in recent years the commission had issued similar guidelines to define "low fat" for the food industry and terms like "recycled" and "recyclable" for other producers.

The new supplement guidelines were prompted by the tremendous growth of the industry, Ms. Bernstein said, and by confusion among manufacturers about what was allowed in advertising.

"There are a lot of new players," she said.

In addition, the Dietary Supplement Health and Education Act of 1994 limited the authority of the Food and Drug Administration to regulate supplements, and that change left many manufacturers wondering what the rules were.

Ms. Bernstein said the commission had worked with industry and consumer groups for a year to develop the guidelines.

Response from the industry has been favorable. Alan Raul, a lawyer at Sidley & Austin, a Washington law firm that represents the National Nutritional Foods Association, said: "The FTC has really reached out to the dietary supplement industry to provide assistance and guidance in the sort of advertising claims on dietary supplements that are appropriate. It looks like a thorough, helpful piece of guidance that will be useful to the public and to the industry."

Dr. Annette Dickinson, director of scientific and regulatory affairs for another trade association, said, "We think it's a very good idea, and a useful guide."

The guide, a 26-page document, explains that the Food and Drug Administration is responsible for claims on labeling, and the FTC for advertising claims, including those on the Internet. It provides 36 hypothetical examples of advertising claims, and explains how the law would apply to them.

Advertisers are responsible for implied claims as well as expressly stated ones, the guide says, so that if an advertisement cites "university studies" in support of a product, the studies must not only exist but also deliver on the implied message, which is that they are reliable studies.

Similarly, if an advertisement says that 90 percent of cardiologists take a certain product, the manufacturer must be able to demonstrate not only that fact but also the implied claim that the product is good for the heart.

Unlike FDA labeling rules, which forbid claims that supplements can treat or prevent disease, the FTC guidelines allow such claims in advertisements, provided that the manufacturer can substantiate them. What qualifies as substantiation is also explained in the guidelines: "competent and reliable scientific evidence," including tests, analyses, research and studies conducted and evaluated by qualified professionals.

But advertisers cannot, by picking and choosing among studies, present only those that back their claims. The guidelines say the advertisements must reflect "the totality of the evidence."

The commission also requires that advertisers disclose, clearly and prominently, "qualifying information" like side effects or the fact that a weight-loss product works only if the consumer also diets and exercises.

Companies must also disclose whether a person who endorses a particular product is being paid for the endorsement and whether the person is qualified to make such an endorsement. If, for example, a person identified as "Dr. Jones" speaks on behalf of vitamins but is a doctor of Romance languages rather than of medicine, the advertising is not acceptable.

Advertisers are also barred from implying that any food supplement has been approved by the FDA, which has no authority to regulate supplements unless they violate its labeling rules or become implicated in consumer illness.

Other Places of Interest on The Web

- Federal Trade Commission
- Federal Trade Commission, Diet, Health & Fitness.

Dietary Supplements: An Advertising Guide for Industry

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I. INTRODUCTION

The dietary supplement industry is a dynamic one. Scientific research on the associations between supplements and health is accumulating rapidly. The number of products — and the variety of uses for which they are promoted — have increased significantly in the last few years. The role of the Federal Trade Commission, which enforces laws outlawing "unfair or deceptive acts or practices," is to ensure that consumers get accurate information about dietary supplements so that they can make informed decisions about these products.¹

The Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) work together under a long-standing liaison agreement governing the division of responsibilities between the two agencies. As applied to dietary supplements, the FDA has primary responsibility for claims on product labeling, including packaging, inserts, and other promotional materials distributed at the point of sale. The FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials. Marketing on the Internet is subject to regulation in the same fashion as promotions through any other media. Because of their shared jurisdiction, the two agencies work closely to ensure that their enforcement efforts are consistent to the fullest extent feasible.

In 1994, the Dietary Supplements Health and Education Act (DSHEA) significantly changed

the FDA's role in regulating supplement labeling.² Although DSHEA does not directly apply to advertising, it has generated many questions about the FTC's approach to dietary supplement advertising. The answer to these questions is that advertising for any product — including dietary supplements — must be truthful, not misleading, and substantiated. Given the dramatic increase in the volume and variety of dietary supplement advertising in recent years, FTC staff is issuing this guide to clarify how long-standing FTC policies and enforcement practices relate to dietary supplement advertising.

The FTC's approach to supplement advertising is best illustrated by its Enforcement Policy Statement on Food Advertising (Food Policy Statement).³ Although the Food Policy Statement does not specifically refer to supplements, the principles underlying the FTC's regulation of health claims in food advertising are relevant to the agency's approach to health claims in supplement advertising. In general, the FTC gives great deference to an FDA determination of whether there is adequate support for a health claim. Furthermore, the FTC and the FDA will generally arrive at the same conclusion when evaluating unqualified health claims. As the Food Policy Statement notes, however, there may be certain limited instances when a carefully qualified health claim in advertising may be permissible under FTC law, in circumstances where it has not been authorized for labeling. However, supplement marketers are cautioned that the FTC will require both strong scientific support and careful presentation for such claims.⁴

Supplement marketers should ensure that anyone involved in promoting products is familiar with basic FTC advertising principles. The FTC has taken action not just against supplement manufacturers, but also, in appropriate circumstances, against ad agencies, distributors, retailers, catalog companies, infomercial producers and others involved in deceptive promotions. *Therefore, all parties who participate directly or indirectly in the marketing of dietary supplements have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support behind those claims.*

II. APPLICATION OF FTC LAW TO DIETARY SUPPLEMENT ADVERTISING

The FTC's truth-in-advertising law can be boiled down to two common-sense propositions: 1) advertising must be truthful and not misleading; and 2) before disseminating an ad, advertisers must have adequate substantiation for all objective product claims.⁵ A deceptive ad is one that contains a misrepresentation or omission that is likely to mislead consumers acting reasonably under the circumstances to their detriment. The FTC's substantiation standard is a flexible one that depends on many factors. When evaluating claims about the efficacy and safety of foods, dietary supplements and drugs, the FTC has typically applied a substantiation standard of competent and reliable scientific evidence.

To determine whether an ad complies with FTC law, it is first necessary to identify all express and implied claims that the ad conveys to consumers. Once the claims are identified, the scientific evidence is assessed to determine whether there is adequate support for those claims. The following sections describe this two-step process with examples illustrating how principles of ad interpretation and substantiation apply in the context of dietary supplement advertising. The examples have been simplified to illustrate one or two specific points. Therefore, advertisers should use these examples as general guidance only.⁶

A. Identifying Claims and Interpreting Ad Meaning

1. Identifying Express and Implied Claims

The first step in evaluating the truthfulness and accuracy of advertising is to identify all express and implied claims an ad conveys to consumers. Advertisers must make sure that whatever they say expressly in an ad is accurate. Often, however, an ad conveys other claims beyond those expressly stated. Under FTC law, an advertiser is equally responsible for the accuracy of claims suggested or implied by the ad. Advertisers cannot suggest claims that

they could not make directly.

When identifying claims, advertisers should not focus just on individual phrases or statements, but rather should consider the ad as a whole, assessing the "net impression" conveyed by all elements of the ad, including the text, product name, and depictions. When an ad lends itself to more than one reasonable interpretation, the advertiser is responsible for substantiating each interpretation. Copy tests, or other evidence of how consumers actually interpret an ad, can be valuable. In many cases, however, the implications of the ad are clear enough to determine the existence of the claim by examining the ad alone, without extrinsic evidence.

Example 1: An advertisement claims that "university studies prove" that a mineral supplement can improve athletic performance. The advertiser has expressly stated the level of support for the claimed benefit and is therefore responsible for having "university studies" that document the advertised benefit. Furthermore, the implied reference to scientific evidence likely conveys to consumers the implied claim that the studies are methodologically sound.

Example 2: An advertisement for a vitamin supplement claims that 90% of cardiologists regularly take the product. In addition to the literal claim about the percentage of cardiologists who use the product, the ad likely conveys an implied claim that the product offers some benefit for the heart. Therefore, the advertiser must have adequate support for both representations.

Depending on how it is phrased, or the context in which it is presented, a statement about a product's effect on a normal "structure or function" of the body may also convey to consumers an implied claim that the product is beneficial for the treatment of a disease. If elements of the ad imply that the product also provides a disease benefit, the advertiser must be able to substantiate the implied disease claim even if the ad contains no express reference to disease.

Example 3: An ad for an herbal supplement makes the claim that the product boosts the immune system to help maintain a healthy nose and throat during the winter season. The ad features the product name "Cold Away" and includes images of people sneezing and coughing. The various elements of the ad — the product name, the depictions of cold sufferers, and the reference to nose and throat health during the winter season — likely convey to consumers that the product helps prevent colds. Therefore, the advertiser must be able to substantiate that claim. Even without the product name and images, the reference to nose and throat health during the winter season may still convey a cold prevention claim.

Example 4: An ad for a dietary supplement called "Arthricure" claims that the product maintains joint health and mobility into old age. The "before" picture shows an elderly woman using a walker. The "after" picture shows her dancing with her husband. The images and product name likely convey implied claims that the product is effective in the treatment of the symptoms of arthritis, and may also imply that the product can cure or mitigate the disease. The advertiser must be able to substantiate these implied claims.

2. When to Disclose Qualifying Information

An advertisement can also be deceptive because of what it fails to say. Section 15 of the FTC Act requires advertisers to disclose information if it is material in light of representations made or suggested by the ad, or material considering how consumers would customarily use the product. Thus, if an ad would be misleading without certain qualifying information, that information must be disclosed. For example, advertisers should disclose information relevant to the limited applicability of an advertised benefit. Similarly,

advertising that makes either an express or implied safety representation should include information about any significant safety risks. Even in the absence of affirmative safety representations, advertisers may need to inform consumers of significant safety concerns relating to the use of their product.

Example 5: An advertisement for a multi-vitamin/mineral supplement claims that the product can eliminate a specific mineral deficiency that results in feelings of fatigue. In fact, less than 2% of the general population to which the ad is targeted suffers from this deficiency. The advertiser should disclose this fact so that consumers will understand that only the small percentage of people who suffer from the actual mineral deficiency are likely to experience any reduction in fatigue from using the product.

Example 6: An advertiser for a weight loss supplement cites a placebo-controlled, double-blind clinical study as demonstrating that the product resulted in an average weight loss of fifteen pounds over an eight-week period. The weight loss for the test group is, in fact, significantly greater than for the control subjects. However, both the control and test subjects engaged in regular exercise and followed a restricted-calorie diet as part of the study regimen. The advertisement should make clear that users of the supplement must follow the same diet and exercise regimen to achieve the claimed weight loss results.

Example 7: An advertiser claims that its herbal product is a natural pain reliever "without the side effects of over-the-counter pain relievers." However, there is substantial evidence that the product can cause nausea in some consumers when taken regularly. Because of the reference to the side effects of other pain relievers, consumers would likely understand this ad to mean that the herbal product posed no significant adverse effects. Therefore, the advertiser should disclose information about the adverse effects of the herbal product.

Example 8: An herbal weight loss product contains an ingredient which, when consumed daily over an extended period, can result in a significant increase in blood pressure. Even in the absence of any representation about the product's safety, the advertiser should disclose this potentially serious risk.

3. Clear and Prominent Disclosure

When the disclosure of qualifying information is necessary to prevent an ad from being deceptive, that information should be presented clearly and prominently so that it is actually noticed and understood by consumers. A fine-print disclosure at the bottom of a print ad, a disclaimer buried in a body of text, a brief video superscript in a television ad, or a disclaimer that is easily missed on an Internet web site, are not likely to be adequate. To ensure that disclosures are effective, marketers should use clear language, avoid small type, place any qualifying information close to the claim being qualified, and avoid making inconsistent statements or distracting elements that could undercut or contradict the disclosure. Because consumers are likely to be confused by ads that include inconsistent or contradictory information, disclosures need to be both direct and unambiguous to be effective.

Example 9: A marketer promotes a supplement as a weight loss aid. There is adequate substantiation to indicate that the product can contribute to weight loss when used in conjunction with a diet and exercise regimen. The banner headline claims "LOSE 5 POUNDS IN 10 DAYS," the ad copy discusses how easy it is to lose weight by simply taking the product 3 times a day, and the ad includes dramatic before-and-after pictures. A fine print disclosure at the bottom of the ad, "Restricted calorie diet and regular exercise required," would not be sufficiently prominent to qualify the banner headline and the overall impression

that the product alone will cause weight loss. The ad should be revised to remove any implication that the weight loss can be achieved by use of the product alone. This revision, combined with a prominent indication of the need for diet and exercise, may be sufficient to qualify the claim. However, if the research does not show that the product contributes anything to the weight loss effect caused by diet and exercise, it would be deceptive, even with a disclosure, to promote the product for weight loss.

Qualifying information should be sufficiently simple and clear that consumers not only notice it, but also understand its significance. This can be a particular challenge when explaining complicated scientific concepts to a general audience, for example, if an advertiser wants to promote the effect of a supplement where there is an emerging body of science supporting that effect, but the evidence is insufficient to substantiate an unqualified claim. The advertiser should make sure consumers understand both the extent of scientific support and the existence of any significant contrary evidence. Vague qualifying terms — for example, that the product "may" have the claimed benefit or "helps" achieve the claimed benefit — are unlikely to be adequate. Furthermore, advertisers should not make qualified claims where the studies they rely on are contrary to a stronger body of evidence. In such instance, even a qualified claim could mislead consumers.

Example 10: A company has results from two studies suggesting that the main ingredient in its supplement helps to maintain healthy cholesterol levels. There are, however, significant limitations to each of the studies and a better controlled study is necessary to confirm whether the effect is genuine. The company makes a claim in advertising that "scientific studies show that our product may be effective in reducing cholesterol." The use of the word "may" is not likely to be a sufficient disclaimer to convey the limitations of the science. A disclosure that clearly describes the limitations of the research, in language consumers can easily understand, and states directly and unambiguously that additional research is necessary to confirm the preliminary results is more likely to be effective. As discussed in the following section on substantiating claims, the extent to which studies support an unqualified claim will depend largely on what experts in the relevant field would consider to be adequate support.

B. Substantiating Claims

In addition to conveying product claims clearly and accurately, marketers need to verify that there is adequate support for their claims. Under FTC law, before disseminating an ad, advertisers must have a reasonable basis for all express and implied product claims. What constitutes a reasonable basis depends greatly on what claims are being made, how they are presented in the context of the entire ad, and how they are qualified. The FTC's standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science. At the same time, it is sufficiently rigorous to ensure that consumers can have confidence in the accuracy of information presented in advertising. A number of factors determine the appropriate amount and type of substantiation, including:

- **The Type of Product.** Generally, products related to consumer health or safety require a relatively high level of substantiation.
- **The Type of Claim.** Claims that are difficult for consumers to assess on their own are held to a more exacting standard. Examples include health claims that may be subject to a placebo effect or technical claims that consumers cannot readily verify for themselves.
- **The Benefits of a Truthful Claim, and**
- **The Cost/Feasibility of Developing Substantiation for the Claim.** These factors are

often weighed together to ensure that valuable product information is not withheld from consumers because the cost of developing substantiation is prohibitive. This does not mean, however, that an advertiser can make any claim it wishes without substantiation, simply because the cost of research is too high.

- **The Consequences of a False Claim.** This includes physical injury, for example, if a consumer relies on an unsubstantiated claim about the therapeutic benefit of a product and foregoes a proven treatment. Economic injury is also considered.
- **The Amount of Substantiation that Experts in the Field Believe is Reasonable.** In making this determination, the FTC gives great weight to accepted norms in the relevant fields of research and consults with experts from a wide variety of disciplines, including those with experience in botanicals and traditional medicines. Where there is an existing standard for substantiation developed by a government agency or other authoritative body, the FTC accords great deference to that standard.

The FTC typically requires claims about the efficacy or safety of dietary supplements to be supported with "competent and reliable scientific evidence," defined in FTC cases as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." This is the same standard the FTC applies to any industry making health-related claims. There is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration. There are, however, a number of considerations to guide an advertiser in assessing the adequacy of the scientific support for a specific advertising claim.

1. Ads that Refer to a Specific Level of Support

If an advertiser asserts that it has a certain level of support for an advertised claim, it must be able to demonstrate that the assertion is accurate. Therefore, as a starting point, advertisers must have the level of support that they claim, expressly or by implication, to have.

Example 11: An ad for a supplement includes the statement "Scientists Now Agree!" in discussing the product's benefit. This statement likely conveys to consumers that the state of science supporting the benefit has reached the level of scientific consensus. Unless the advertiser possesses this level of evidence, the claim is not substantiated.

Example 12: An advertiser claims that its product has been "studied for years abroad" and is now the "subject of U.S. government-sponsored research." In addition to the explicit claim that the product has been studied, such phrases likely convey to consumers an implied claim that there exists a substantial body of competently-conducted scientific research supporting the efficacy of the product. The advertiser would be responsible for substantiating both claims.

2. The Amount and Type of Evidence

When no specific claim about the level of support is made, the evidence needed depends on the nature of the claim. A guiding principle for determining the amount and type of evidence that will be sufficient is what experts in the relevant area of study would generally consider to be adequate. The FTC will consider all forms of competent and reliable scientific research when evaluating substantiation. As a general rule, well-controlled human clinical studies are the most reliable form of evidence. Results obtained in animal and *in vitro* studies will also be examined, particularly where they are widely considered to be acceptable substitutes for human research or where human research is infeasible. Although there is no requirement that a dietary supplement claim be supported by any specific number of studies, the replication of research results in an independently-conducted study adds to the weight of the

evidence. In most situations, the quality of studies will be more important than quantity. When a clinical trial is not possible (e.g., in the case of a relationship between a nutrient and a condition that may take decades to develop), epidemiologic evidence may be an acceptable substitute for clinical data, especially when supported by other evidence, such as research explaining the biological mechanism underlying the claimed effect.

Anecdotal evidence about the individual experience of consumers is not sufficient to substantiate claims about the effects of a supplement. Even if those experiences are genuine, they may be attributable to a placebo effect or other factors unrelated to the supplement. Individual experiences are not a substitute for scientific research.⁷

Example 13: An advertiser relies on animal and in vitro studies to support a claim that its vitamin supplement is more easily absorbed into the bloodstream than other forms of the vitamin. However, the animal research uses a species of animal that, unlike humans, is able to synthesize the vitamin, and the in vitro study uses a different formulation with a higher concentration of the compound than the product being marketed. In addition, human research is feasible and relatively inexpensive to conduct in light of the potential sales of the product and is the type of research generally accepted in this particular field of study. The substantiation is likely to be inadequate in this case, both because there are significant methodological problems and because, in this particular instance, human research is both feasible and the accepted approach in the field.

Example 14: A company wants to advertise its supplement as helpful in maintaining good vision into old age. There have been two long-term, large-scale epidemiologic studies showing a strong association between life-long high consumption of the principal ingredient in the supplement and better vision in those over 70. Experts have also discovered a plausible biological mechanism that might explain the effect. A clinical intervention trial would be very difficult and costly to conduct. Assuming that experts in the field generally consider epidemiological evidence to be adequate to support the potential for a protective effect, and assuming the absence of any stronger body of contrary evidence, a claim that is qualified to accurately convey the nature and extent of the evidence would be permitted.

Example 15: An advertisement for a supplement claims that the product will cause dramatic improvements in memory and describes the experiences of 10 people who obtained these results. The descriptions of these anecdotal experiences are truthful, but the advertiser has no scientific substantiation for the effect of its product on memory and cannot explain why the product might produce such results. The individual experiences are not adequate to substantiate the claim without confirming scientific research.

3. The Quality of the Evidence

In addition to the amount and type of evidence, the FTC will also examine the internal validity of each piece of evidence. Where the claim is one that would require scientific support, the research should be conducted in a competent and reliable manner to yield meaningful results. The design, implementation, and results of each piece of research are important to assessing the adequacy of the substantiation.

There is no set protocol for how to conduct research that will be acceptable under the FTC substantiation doctrine. There are, however, some principles generally accepted in the scientific community to enhance the validity of test results. For example, a study that is carefully controlled, with blinding of subjects and researchers, is likely to yield more reliable results. A study of longer duration can provide better evidence that the claimed effect will persist and resolve potential safety questions. Other aspects of the research results — such as evidence of a dose-response relationship (*i.e.*, the larger the dose, the greater the

effect) or a recognized biological or chemical mechanism to explain the effect — are examples of factors that add weight to the findings. Statistical significance of findings is also important. A study that fails to show a statistically significant difference between test and control group may indicate that the measured effects are merely the result of placebo effect or chance. The results should also translate into a meaningful benefit for consumers. Some results that are statistically significant may still be so small that they would mean only a trivial effect on consumer health.

The nature and quality of the written report of the research are also important. Research cannot be evaluated accurately on the basis of an abstract or an informal summary. In contrast, although the FTC does not require that studies be published and will consider unpublished, proprietary research, the publication of a peer-reviewed study in a reputable journal indicates that the research has received some measure of scrutiny. At the same time, advertisers should not rely simply on the fact that research is published as proof of the efficacy of a supplement. Research may yield results that are of sufficient interest to the scientific community to warrant publication, but publication does not necessarily mean that such research is conclusive evidence of a substance's effect. The FTC considers studies conducted in foreign countries as long as the design and implementation of the study are scientifically sound.⁸

Example 16: An advertiser conducts a literature search and finds several abstracts summarizing research about the association between a nutrient and the ability to perform better on memory tests. The advertiser relies on these summaries to support a claim that its supplement, which contains the same nutrient, aids memory. However, without looking carefully at the specifics of the study design, implementation, and results, there is no way for an advertiser to ascertain whether the research substantiates the product claims. (For example, did the research use a comparable formulation of the ingredient? Was the study adequately controlled? Did the study yield results that are statistically significant?) The advertiser should carefully review the underlying science, with the assistance of an expert if necessary, before drafting advertising claims.

Example 17: An advertiser makes an unqualified claim about the anti-clotting effect of a supplement that contains a compound extracted from fruit. There are three studies supporting the effect and no contrary evidence. One study consists of subjects tested over a one-week period, with no control group. The second study is well-controlled, of longer duration, but shows only a slight effect that is not statistically significant. The third study administers the compound through injection and shows a significant anti-clotting effect, but there is some question whether the compound would be absorbed into the bloodstream if administered orally. Because the studies all have significant limitations, it would be difficult to draft even a carefully qualified claim that would adequately convey to consumers the limited nature of the evidence. The advertiser should not base a claim on these studies.

Example 18: The marketer of an herbal supplement claims that its product promotes healthy vision and is approved in Germany for this purpose. The product has been used extensively in Europe for years and has obtained approval by the German governmental authorities, through their monograph process, for use to improve vision in healthy people. The company has two abstracts of German trials that were the basis of the German monograph, showing that the ingredient significantly improved the vision of healthy individuals in the test group over the placebo group. Animal trials done by the company suggest a plausible mechanism to explain the effect. Although approval of the supplement under the German monograph suggests that the supplement is effective, advertisers should still examine the underlying research to confirm that it is relevant to the advertiser's product (for example, that the dosage and formulation are comparable) and to evaluate whether the studies are

scientifically sound. Advertisers should also examine any other research that exists, either supporting or contradicting the monograph, especially if it is not possible to identify and review the research on which the monograph is based.

4. The Totality of the Evidence

Studies cannot be evaluated in isolation. The surrounding context of the scientific evidence is just as important as the internal validity of individual studies. Advertisers should consider all relevant research relating to the claimed benefit of their supplement and should not focus only on research that supports the effect, while discounting research that does not. Ideally, the studies relied on by an advertiser would be largely consistent with the surrounding body of evidence. Wide variation in outcomes of studies and inconsistent or conflicting results will raise serious questions about the adequacy of an advertiser's substantiation. Where there are inconsistencies in the evidence, it is important to examine whether there is a plausible explanation for those inconsistencies. In some instances, for example, the differences in results are attributable to differences in dosage, the form of administration (e.g., oral or intravenous), the population tested, or other aspects of study methodology. Advertisers should assess how relevant each piece of research is to the specific claim they wish to make, and also consider the relative strengths and weaknesses of each. If a number of studies of different quality have been conducted on a specific topic, advertisers should look first to the results of the studies with more reliable methodologies.

The surrounding body of evidence will have a significant impact both on what type, amount and quality of evidence is required to substantiate a claim and on how that claim is presented — that is, how carefully the claim is qualified to reflect accurately the strength of the evidence. If a stronger body of surrounding evidence runs contrary to a claimed effect, even a qualified claim is likely to be deceptive.

Example 19: An advertiser wishes to make the claim that a supplement product will substantially reduce body fat. The advertiser has two controlled, double-blind studies showing a modest but statistically significant loss of fat at the end of a six-week period. However, there is an equally well-controlled, blinded 12-week study showing no statistically significant difference between test and control groups. Assuming other aspects of methodology are similar, the studies taken together suggest that, if the product has any effect on body fat, it would be very small. Given the totality of the evidence on the subject, the claim is likely to be unsubstantiated.

Example 20: Advertisements for a fiber supplement make the claim that the product is "proven" to aid weight loss. Although the company has two published, peer-reviewed studies showing a relationship between fiber and weight loss, neither of these studies used the same proportions of soluble and insoluble fiber or the same total amount of fiber as the supplement product. There are numerous controlled, published human clinical studies, however, using the amount and type of fiber in the supplement product, that provide evidence that the product would not result in measurable weight loss. The totality of the evidence does not support the "proven" claim and, given the stronger body of contrary evidence, even a qualified claim is likely to be deceptive.

Example 21: An advertiser runs an ad in a magazine for retired people, claiming that its supplement product has been found effective in improving joint flexibility. The company sponsored a 6-week study of its supplement, involving 50 subjects over the age of 65, to test the product's effect on improving flexibility. The study was double-blinded and placebo-controlled and has been accepted for publication in a leading medical journal. The study showed dramatic, statistically significant increases in joint flexibility compared to placebo, based on objective measurements. In addition, several large trials

have been conducted by European researchers using a similar formulation and dose of the active ingredient in the supplement. These trials also found statistically significant results. The advertiser reviewed the underlying European research and confirmed that it meets accepted research standards. The evidence as a whole likely substantiates the claim.

5. The Relevance of the Evidence to the Specific Claim

A common problem in substantiation of advertising claims is that an advertiser has valid studies, but the studies do not support the claim made in the ad. Advertisers should make sure that the research on which they rely is not just internally valid, but also relevant to the specific product being promoted and to the specific benefit being advertised. Therefore, advertisers should ask questions such as: How does the dosage and formulation of the advertised product compare to what was used in the study? Does the advertised product contain additional ingredients that might alter the effect of the ingredient in the study? Is the advertised product administered in the same manner as the ingredient used in the study? Does the study population reflect the characteristics and lifestyle of the population targeted by the ad? If there are significant discrepancies between the research conditions and the real life use being promoted, advertisers need to evaluate whether it is appropriate to extrapolate from the research to the claimed effect.

In drafting ad copy, the advertiser should take care to make sure that the claims match the underlying support. Claims that do not match the science, no matter how sound that science is, are likely to be unsubstantiated. Advertising should not exaggerate the extent, nature, or permanence of the effects achieved in a study, and should not suggest greater scientific certainty than actually exists. Although emerging science can sometimes be the basis for a carefully qualified claim, advertisers must make consumers aware of any significant limitations or inconsistencies in the scientific literature.

Example 22: An ad for a supplement claims that a particular nutrient helps maintain healthy cholesterol levels. There is a substantial body of epidemiologic evidence suggesting that foods high in that nutrient are associated with lower cholesterol levels. There is no science, however, demonstrating a relationship between the specific nutrient and cholesterol, although it would be feasible to conduct such a study. If there is a basis for believing that the health effect may be attributable to other components of the food, or to a combination of various components, a claim about the cholesterol maintenance benefits of the supplement product is likely not substantiated by this evidence.

Example 23: A number of well-controlled clinical studies have been conducted to suggest that a mineral supplement can improve mental alertness and memory in subjects with significantly impaired blood circulation to the brain. A claim suggesting that the supplement will improve memory or mental alertness in healthy adults may not be adequately substantiated by this evidence. Advertisers should not rely on research based on a specific test population for claims targeted at the general population without first considering whether it is scientifically sound to make such extrapolations.

Example 24: An advertiser wants to make claims that its combination herbal product helps increase alertness and energy safely and naturally. The product contains two herbs known to have a central nervous system stimulant effect. The advertiser compiles competent and reliable scientific research demonstrating that each of the herbs, individually, is safe and causes no significant side effects in the recommended dose. This evidence may be inadequate to substantiate an unqualified safety claim. Where there is reason to suspect that the combination of multiple ingredients might result in interactions that would alter the effect or safety of the individual ingredients, studies

showing the effect of the individual ingredients may be insufficient to substantiate the safety of the multiple ingredient product. In this example, the combination of two herbs with similar stimulant properties could produce a stronger cumulative stimulant effect that might present safety hazards. A better approach would be to investigate the safety of the specific combination of ingredients contained in the product.

Example 25: Several clinical trials have been done on a specific botanical extract showing consistently that the extract is effective for supporting the immune system. The studied extract is a complex combination of many constituents and the active constituents that may produce the benefit are still unknown. An advertiser wishes to cite this research in its advertising, as proof that its product will support the immune system. The advertiser's product is made using a different extraction method of the same botanical. An analysis of the extract reveals that it has a significantly different chemical profile from the studied extract. The advertiser should not rely on these clinical trials alone as substantiation because the difference in extracts may result in significant differences in the two products' efficacy.

C. Other Issues Relating to Dietary Supplement Advertising

In addition to the basic principles of ad meaning and substantiation discussed above, a number of other issues commonly arise in the context of dietary supplement advertising. The following sections provide guidance on some of these issues including: the use of consumer or expert endorsements in ads; advertising claims based on traditional uses of supplements; use of the DSHEA disclaimer in advertising; and the application to advertising of the DSHEA exemption for certain categories of publications, commonly referred to as "third party literature."

1. Claims Based on Consumer Experiences or Expert Endorsements

An overall principle is that advertisers should not make claims either through consumer or expert endorsements that would be deceptive or could not be substantiated if made directly.⁹ It is not enough that a testimonial represents the honest opinion of the endorser. Under FTC law, advertisers must also have appropriate scientific evidence to back up the underlying claim.

Consumer testimonials raise additional concerns about which advertisers need to be aware. Ads that include consumer testimonials about the efficacy or safety of a supplement product should be backed by adequate substantiation that the testimonial experience is representative of what consumers will generally achieve when using the product. As discussed earlier, anecdotal evidence of a product's effect, based solely on the experiences of individual consumers, is generally insufficient to substantiate a claim. Further, if the advertiser's substantiation does not demonstrate that the results are representative, then a clear and conspicuous disclaimer is necessary. The advertiser should either state what the generally expected results would be or indicate that the consumer should not expect to experience the attested results. Vague disclaimers like "results may vary" are likely to be insufficient.

Example 26: An advertisement for a weight loss supplement features a before-and-after photograph of a woman and quotes her as saying that she lost 20 pounds in 8 weeks while using the supplement. An asterisk next to the quotation references a disclaimer in fine print at the bottom of the ad that reads, "Results may vary." The experience of the woman is accurately represented, but the separate, competent research demonstrating the efficacy of the supplement showed an average weight loss of only 6 pounds in 8 weeks. Therefore, the disclosure does not adequately convey to consumers that they would likely see

much less dramatic results. The placement and size of the disclaimer is also insufficiently prominent to qualify the claim effectively. One approach to adequate qualification of this testimonial would be to include a disclaimer immediately adjacent to the quote, in equal print size that says, "These results are not typical. Average weight loss achieved in clinical study was 6 pounds."

When an advertiser uses an expert endorser, it should make sure that the endorser has appropriate qualifications to be represented as an expert and has conducted an examination or testing of the product that would be generally recognized in the field as sufficient to support the endorsement. In addition, whenever an expert or consumer endorser is used, the advertiser should disclose any material connection between the endorser and the advertiser of the product. A material connection is one that would affect the weight or credibility of the endorsement, or put another way, a personal, financial, or similar connection that consumers would not reasonably expect.

Example 27: An infomercial for a dietary supplement features an expert referred to as a "Doctor" and a "leading clinician in joint health" discussing the effect of a supplement product on the maintenance of healthy joints. The expert is not licensed to practice medicine, but has a graduate degree and is a trained physical therapist, running a sports clinic. The expert has not conducted any review of the scientific literature on the active component of the supplement. In return for appearing in the infomercial, she is given a paid position as an officer of the company. The ad is likely to be deceptive for several reasons. First, her qualifications as an expert have been overstated and she has not conducted sufficient examination of the product to support the endorsement. In addition, her connection to the company is one that consumers might not expect and may affect the weight and credibility of her endorsement. Even if she is adequately qualified and has conducted an adequate review of the product, her position as an officer of the company should be clearly disclosed.

Example 28: A best-selling book about the benefits of a supplement product includes a footnote mentioning the most effective brand of the supplement, by name. The manufacturer of the brand cited in the book has an exclusive promotional agreement with the author and has paid him to reference the product by name. The manufacturer's ad touts the fact that its product is the only brand recommended in this best-selling book. The ad is deceptive since it suggests a neutral endorsement when, in fact, the author has been paid by the manufacturer to promote the product.

2. Claims Based on Traditional Uses

Claims based on historical or traditional use should be substantiated by confirming scientific evidence, or should be presented in such a way that consumers understand that the sole basis for the claim is a history of use of the product for a particular purpose. A number of supplements, particularly botanical products, have a long history of use as traditional medicines in the United States or in other countries to treat certain conditions or symptoms. Several European countries have a separate regulatory approach to these traditional medicines, allowing manufacturers to make certain limited claims about their traditional use for treating certain health conditions. Some countries also require accompanying disclosures about the fact that the product has not been scientifically established to be effective, as well as disclosures about potential adverse effects. At this time there is no separate regulatory process for approval of claims for these traditional medicine products under DSHEA and FDA labeling rules.

In assessing claims based on traditional use, the FTC will look closely at consumer perceptions and specifically at whether consumers expect such claims to be backed by supporting scientific evidence. Advertising claims based solely on traditional use should be presented carefully to avoid the implication that the product has been scientifically evaluated

for efficacy. The degree of qualification necessary to communicate the absence of scientific substantiation for a traditional use claim will depend in large part on consumer understanding of this category of products. As consumer awareness of and experience with "traditional use" supplements evolve, the extent and type of qualification necessary is also likely to change.

There are some situations, however, where traditional use evidence alone will be inadequate to substantiate a claim, even if that claim is carefully qualified to convey the limited nature of the support. In determining the level of substantiation necessary to substantiate a claim, the FTC assesses, among other things, the consequences of a false claim. Claims that, if unfounded, could present a substantial risk of injury to consumer health or safety will be held to a higher level of scientific proof. For that reason, an advertiser should not suggest, either directly or indirectly, that a supplement product will provide a disease benefit unless there is competent and reliable scientific evidence to substantiate that benefit. The FTC will closely scrutinize the scientific support for such claims, particularly where the claim could lead consumers to forego other treatments that have been validated by scientific evidence, or to self-medicate for potentially serious conditions without medical supervision.

The advertiser should also make sure that it can document the extent and manner of historical use and be careful not to overstate such use. As part of this inquiry, the advertiser should make sure that the product it is marketing is consistent with the product as traditionally administered. If there are significant differences between the traditional use product and the marketed product, in the form of administration, the formulation of ingredients, or the dose, a "traditional use" claim may not be appropriate.

Example 29: The advertiser of an herbal supplement makes the claim, "Ancient folklore remedy used for centuries by Native Americans to aid digestion." The statement about traditional use is accurate and the supplement product is consistent with the formulation of the product as traditionally used. However, if, in the context of the ad, this statement suggests that there is scientific evidence demonstrating that the product is effective for aiding digestion, the advertiser would need to include a clear and prominent disclaimer about the absence of such evidence.

Example 30: A supplement manufacturer wants to market an herbal product that has been used in the same formulation in China as a tonic for improving mental functions. The manufacturer prepares the product in a manner consistent with Chinese preparation methods. The ad claims, "Traditional Chinese Medicine — Used for Thousands of Years to Bring Mental Clarity and Improve Memory." The ad also contains language that clearly conveys that the efficacy of the product has not been confirmed by research, and that traditional use does not establish that the product will achieve the claimed results. The ad is likely to adequately convey the limited nature of support for the claim.

Example 31: A supplement manufacturer markets a capsule containing a concentrated extract of a botanical product that has been used in its raw form in China to brew teas for increasing energy. The advertisement clearly conveys that the energy benefit is based on traditional use and has not been confirmed by scientific research. The ad may still be deceptive, however, because the concentrated extract is not consistent with the traditional use of the botanical in raw form to brew teas and may produce a significantly different effect.

Example 32: A supplement ad claims that a supplement liquid mineral solution has been a popular American folk remedy since early pioneer days for shrinking tumors. The ad is likely to convey to consumers that the product is an effective treatment for cancer. There is no scientific support for this disease benefit. Because of the potential risks to consumers of taking a product that may or may not be effective to treat such a serious health condition, possibly without

medical supervision, the advertiser should not make the claim.

3. Use of the DSHEA Disclaimer in Advertising

Under DSHEA, all statements of nutritional support for dietary supplements must be accompanied by a two-part disclaimer on the product label: that the statement has not been evaluated by FDA and that the product is not intended to "diagnose, treat, cure or prevent any disease." Although DSHEA does not apply to advertising, there are situations where such a disclosure is desirable in advertising as well as in labeling to prevent consumers from being misled about the nature of the product and the extent to which its efficacy and safety have been reviewed by regulatory authorities. For example, a disclosure may be necessary if the text or images in the ad lead consumers to believe that the product has undergone the kind of review for safety and efficacy that the FDA conducts on new drugs and has been found to be beneficial for the treatment of disease. Failure to correct those misperceptions may render the advertising deceptive.

At the same time, the inclusion of a DSHEA disclaimer or similar disclosure will not cure an otherwise deceptive ad, particularly where the deception concerns claims about the disease benefits of a product. In making references to DSHEA and FDA review, advertisers should also be careful not to mischaracterize the extent to which a product or claim has been reviewed or approved by the FDA. Compliance with the notification and disclaimer provisions of DSHEA does not constitute authorization of a claim by FDA and advertisers should not imply that FDA has specifically approved any claim on that basis.

Example 33: A company markets a supplement for "maintaining joint flexibility." The product packaging is similar in color and design to a nonprescription drug used to treat joint pain associated with arthritis and the product name is similar to the drug counterpart. The ad includes statements urging consumers to "ask their pharmacist" and "accept no generic substitute." The various elements of the ad may lead consumers to believe that the supplement is, in fact, an approved drug, or may give consumers more general expectations that the product has been subjected to similar government review for safety and efficacy. A clear and prominent disclaimer may be necessary to indicate that the product has not been evaluated by FDA and is not an approved drug product.

Example 34: An advertisement for an herbal supplement includes strong, unqualified claims that the product will effectively treat or prevent diabetes, heart disease, and various circulatory ailments. The advertiser does not have adequate substantiation for this claim, but includes the DSHEA disclaimer prominently in the ad. In face of the strong contradictory message in the ad, the inclusion of the DSHEA disclaimer is not likely to negate the explicit disease claims made in the ad, and will not cure the fact that the claims are not substantiated.

Example 35: A dietary supplement advertisement makes a number of claims about the benefits of its product for supporting various body functions. The ad also includes the statement, "Complies with FDA notification procedures of the Dietary Supplement Health and Education Act." This statement may suggest to consumers that FDA has authorized the claims made in the ad or that it has reviewed the support for the claims and found the product to be effective. Because there is no review and authorization process for such claims under DSHEA, this would be deceptive.

4. Third Party Literature

Dietary supplement advertisers should be aware that the use of newspaper articles, abstracts of scientific studies, or other "third party literature" to promote a particular brand or product

can have an impact on how consumers interpret an advertisement and on what claims the advertiser will be responsible for substantiating. For purposes of dietary supplement labeling, Section 5 of DSHEA provides an exemption from labeling requirements for scientific journal articles, books and other publications used in the sale of dietary supplements, provided these materials are reprinted in their entirety, are not false or misleading, do not promote a specific brand or manufacturer, are presented with other materials to create a balanced view of the scientific information, and are physically separate from the supplements being sold.

The FTC will generally follow an approach consistent with the labeling approach when evaluating the use of such publications in other contexts, such as advertising. Although the FTC does not regulate the content or accuracy of statements made in independently written and published books, articles, or other non-commercial literature, FTC law does prohibit the deceptive use of such materials in marketing products. The determination of whether the materials will be subject to FTC jurisdiction turns largely on whether the materials have been created or are being used by an advertiser specifically for the purpose of promoting its product. As a practical matter, publications and other materials that comply with the elements of the DSHEA provision, particularly with the requirement that such materials be truthful, not misleading and balanced, are also likely to comply with FTC advertising law.

Example 36: An author publishes a book on the curative properties of an herb. The book title is "The Miracle Cancer Cure." The book does not endorse or otherwise mention any particular supplement brand. The author/publisher does not sell the herbal supplement and does not have any material connection to any marketers of the herb. As non-commercial speech, the book itself would not be subject to the FTC's jurisdiction over advertising. However, if a marketer of the herb referred to the book in advertising materials (for instance, by quoting the title and using excerpts to describe the anti-cancer benefits of its product), such references would likely be considered advertising. The advertiser would be responsible for substantiating any claims about the advertiser's product that are conveyed by these references.

III. CONCLUSION

Marketers of dietary supplements should be familiar with the requirements under both DSHEA and the FTC Act that labeling and advertising claims be truthful, not misleading and substantiated. The FTC approach generally requires that claims be backed by sound, scientific evidence, but also provides flexibility in the precise amount and type of support necessary. This flexibility allows advertisers to provide truthful information to consumers about the benefits of supplement products, and at the same time, preserves consumer confidence by curbing unsubstantiated, false, and misleading claims. To ensure compliance with FTC law, supplement advertisers should follow two important steps: 1) careful drafting of advertising claims with particular attention to how claims are qualified and what express and implied messages are actually conveyed to consumers; and 2) careful review of the support for a claim to make sure it is scientifically sound, adequate in the context of the surrounding body of evidence, and relevant to the specific product and claim advertised.

ENDNOTES

1. The FTC's authority derives from Section 5 of the FTC Act. In addition, supplements have traditionally been regulated under Sections 12 and 15, which prohibit false advertisements, defined as those that are "misleading in a material respect," for foods, drugs, devices or cosmetics.
2. Under DSHEA, supplement marketers are allowed to make two kinds of claims on labeling: 1) health claims specifically authorized by the FDA; and 2) statements of

nutritional support. Health claims — representations about the relationship between a nutrient and a disease or health-related condition — are permitted only if they have been authorized by an FDA finding that there is "significant scientific agreement" to support the claim. The Food and Drug Administration Modernization Act of 1997 (FDAMA) also now allows health claims that are based on "authoritative statements" from certain federal scientific bodies, such as NIH and the National Academy of Sciences. Aside from these authorized claims, supplement marketers are prohibited from making any labeling claim about the diagnosis, mitigation, treatment or cure of a disease. In contrast to health claims, "structure/function" claims, within the broader category of "statements of nutritional support," refer to representations about a dietary supplement's effect on the structure or function of the body for maintenance of good health and nutrition. Structure/function claims are not subject to FDA pre-authorization. A marketer may make these claims in labeling if it notifies FDA and includes a disclaimer that the claim has not been evaluated by FDA and that the product is not intended to diagnose, mitigate, treat, cure, or prevent disease. DSHEA also requires that structure/function claims in labeling be substantiated and be truthful and not misleading. This requirement is fully consistent with the FTC's standard that advertising claims be truthful, not misleading and substantiated.

3. FTC policy statements and other information for businesses and consumers are available on the FTC's Internet home page.

4. As indicated in the Food Policy Statement, the FTC will be "especially vigilant in examining whether qualified claims are presented in a manner that ensures that consumers understand both the extent of the support for the claim and the existence of any significant contrary view within the scientific community. In the absence of adequate qualification the Commission will find such claims deceptive."

5. These principles are articulated in the FTC's Deception Policy Statement and Advertising Substantiation Policy Statement. The FTC also has authority to challenge unfair trade practices. An unfair practice is one that causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or competition. The majority of advertising cases are brought pursuant to the FTC's deception authority.

6. Throughout these examples the terms "advertiser," "marketer," "supplement manufacturer" and "company" are used interchangeably.

7. Additional guidance on the use consumer testimonials is provided in Part C.1. below.

8. Any foreign research submitted to the FTC in the course of an investigation should be presented in English translation and with sufficient detail to allow the agency to evaluate the study.

9. The FTC has provided detailed guidance on this subject in its Guides Concerning Use of Endorsements and Testimonials in Advertising.

Dietary Supplements
statute allows dietary
supplement to claim
w/o pre-approval; structure
& function claims.

they weren't sure how reg.
framework affects them
worked w/ industry.

new guide; doesn't Δ anything

industry has been positive
about this

60 cases over last 10
years; this has no
impact on anything
pending.

MICHELLE RUSK

not doing anything new or
changing standard;
guidance & context —
basic principals.

consulted w/ FDA at a
staff level; center for
food safety

2 agency standards
are consistent.

industry was consulted
in development.

hearing from industry
people that they weren't
clear.

dietary Supplement health
& education act — led
way FDA labeled these
products.

make certain kind of
claims w/o FDA
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Federal Register: April 29, 1998 (Volume 63, Number 82)
Rules and Regulations
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Part VI

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101

Regulations on Statements Made for Dietary Supplements Concerning the
Effect of the Product on the Structure or Function of the Body;
Proposed Rule and Dietary Supplements: Comments on Report of the
Commission on Dietary Supplement Labels; Notice

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
21 CFR Part 101
Docket No. 98N-0044
RIN 0910-AA59

Regulations on Statements Made for Dietary Supplements Concerning
the Effect of the Product on the Structure or Function of the Body

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing regulations defining the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body. The proposed regulations also establish criteria for determining when a statement about a dietary supplement is a claim to diagnose, cure, mitigate, treat, or prevent disease. This action is intended to provide direction to the dietary supplement industry and to respond to guidance on this issue provided by the Commission on Dietary Supplement Labels (the Commission).

DATES: Written comments and recommendations by August 27, 1998.

ADDRESSES: Submit written comments and recommendations to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jeanne Latham, Center for Food Safety and Applied Nutrition (HFS-456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4697.

SUPPLEMENTARY INFORMATION:

I. Introduction

The <Dietary> <Supplement> Health and Education Act of 1994 (the DSHEA) authorizes manufacturers of <dietary> <supplements> to make certain types of statements about the uses of their products. Among the types of permitted statements are certain claims that, prior to enactment of the DSHEA, could have rendered the product a "drug" under the Federal Food, Drug, and Cosmetic Act (the act). Specifically, section 403(r)(6) of the act (21 U.S.C. 341(r)(6)), added by the DSHEA, allows <dietary> <supplement> labeling to bear a statement that "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans" or that "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function." These types of claims are generally referred to as "structure/function claims."

Certain other types of statements about <dietary> <supplements> continue, under the DSHEA, to cause the product to be regulated as a drug. Statements permitted under section 403(r)(6) of the act "may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases," except that such statements may claim a benefit related to a classical nutrient deficiency disease, provided that they also disclose the prevalence of the disease in the United States. Such statements are generally referred to as "disease claims." FDA notes that certain statements that pertain to a disease or health-related condition are permitted on food products, including <dietary> <supplements>. These statements are known as health claims (see section 403(r)(1)(B) of the act) and describe the relationship between a nutrient and a disease or health-related condition. Unlike structure/function claims, health claims must be authorized by FDA before they may be used on the label or in the labeling of a food or <dietary> <supplement> (see section 403(r)(3) and (r)(4) and 21 CFR 101.14 and 101.70). Thus, certain claims about disease may be made for foods and <dietary> <supplements> without causing these products to be regulated as drugs, provided the claim has been authorized for use by FDA in accordance with the applicable regulations. FDA also notes that a <dietary> <supplement> for which only structure/function claims are made in the label or labeling in accord with section 403(r) of the act may nevertheless be subject to regulation as a drug if the agency has other evidence (see 21 CFR 201.128) that the intended use of the product is for the diagnosis, cure, mitigation, treatment, or prevention of disease.

A <dietary> <supplement> manufacturer who wishes to make a permitted structure/function statement under section 403(r)(6) of the act must have substantiation that the statement is truthful and not misleading, and must include in the statement the following disclaimer: "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." The DSHEA requires the manufacturer of a <dietary> <supplement> bearing a statement under section 403(r)(6) of the act to notify FDA, no later than 30 days after the first marketing of the <dietary> <supplement> with the statement, that such a statement is being made for the product. Regulations implementing these requirements were published in the Federal Register of September 23, 1997, and are codified at Sec. 101.93 (21 CFR 101.93) (62 FR 49859 at 49883, September 23, 1997, OMB Control Number 0910-0351).

Diseases, by definition, adversely affect some structure or function of the body, and it is possible to describe most products intended to treat or prevent disease in terms of their effects on the structure or function of the body. The DSHEA, thus, does not authorize the use of all claims that describe the effect of a <dietary> <supplement> on the structure or function of the body. Instead, section 403(r)(6) of the act authorizes only those structure/function claims that describe an effect of a product on the structure or function of the body but that are not also disease claims. Because the distinction between allowable structure/function claims and disease claims is not always obvious, the <dietary> <supplement> industry has requested clarification from FDA on structure/function claims that can be made for <dietary> <supplements> under section 403(r)(6) of the act. To develop clarifying criteria for such claims, FDA has reviewed the notification letters that have been submitted to FDA under section 403(r)(6) of the act. In addition, FDA has reviewed the report of the Commission, which was established by the DSHEA to provide guidance and recommendations for the regulation of label claims and statements for <dietary> <supplements>.

The Commission issued a draft report (the draft report) on June 24, 1997, among other things, the report included the Commission's views on "what constitutes an acceptable statement * * * of the structure/function type" (the draft report, p. 36). The Commission received public comment on the draft report and issued a final report (the report) on November 24, 1997. Guidance in the report "represents advice to specific agencies, groups, or individuals. Guidance should be considered by the identified recipients as they develop or implement activities related to the availability of <dietary> <supplements> in the marketplace" (the report, p. vi).

The Commission's final report contains the following guidance (the guidance) on the scope of permissible structure/function claims:

GUIDANCE

<bullet> While the Commission recognizes that the context of a claim has to be considered on a case-by-case basis, the Commission proposes the following general guidelines:

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1. Statements of nutritional support should provide useful information to consumers about the intended use of a product.
2. Statements of nutritional support should be supported by scientifically valid evidence substantiating that the statements are truthful and not misleading.
3. Statements indicating the role of a nutrient or dietary ingredient in affecting the structure or function of humans may be made when the statements do not suggest disease prevention or treatment.
4. Statements that mention a body system, organ, or function affected by the supplement using terms such as "stimulate," "maintain," "support," "regulate," or "promote" can be appropriate when the statements do not suggest disease prevention or treatment or use for a serious health condition that is beyond the ability of the consumer to evaluate.
5. Statements should not be made that products "restore" normal or "correct" abnormal function when the abnormality implies the presence of disease. An example might be a claim to "restore" normal blood pressure when the abnormality implies hypertension.
6. Health claims are specifically defined under NLEA as statements that characterize the relationship between a nutrient or a food component and a specific disease or health-related condition. Statements of nutritional support should be distinct from NLEA health claims in that they do not state or imply a link between a supplement and prevention of a specific disease or health-related condition.

7. Statements of nutritional support are not to be drug claims. They should not refer to specific diseases, disorders, or classes of diseases and should not use drug-related terms such as "diagnose," "treat," "prevent," "cure," or "mitigate." (The report, pp. 38-39).

The guidance thus focuses on the distinction between allowable structure/function claims and claims that a product can diagnose, treat, prevent, cure, or mitigate disease (disease claims), and makes clear that structure/function claims made for <dietary> <supplements> should not imply treatment or prevention of disease. The guidance also provides examples of types of structure/function claims that do and do not imply disease claims. In its findings, the Commission expressed the view that "guidance by FDA to manufacturers making statements under section 403(r)(6) of the act\1\ is appropriate and helpful in clarifying the appropriate scope of these statements" (the report, p. 38).

\1\ The report refers to statements under section 403(r)(6) of the act as "statements of nutritional support." As noted in a September 23, 1997 final rule regarding labeling claims for <dietary> <supplements>, FDA no longer uses the term "statements of nutritional support" because many of the substances that can be the subject of this type of claim have no nutritional value. Thus, the term "statement of nutritional support" is not accurate in all instances (62 FR 49859 at 49863).

FDA agrees with the Commission that an acceptable structure/function claim must not imply prevention or treatment of disease. FDA believes that the Commission's guidelines provide a useful framework for clarifying the sometimes difficult distinction between structure/function claims and disease claims. Based upon the Commission's advice and the agency's experience in reviewing notification letters submitted under section 403(r)(6) of the act, FDA has developed proposed regulations to define the types of claims that are "disease claims" and thus not acceptable as structure/function claims.

II. Provisions of the Proposed Rule and Guidance

As described in section I of this document, the manufacturer of a <dietary> <supplement> may make a truthful, nonmisleading labeling statement claiming that the product affects the structure or function of the body, unless the statement expressly or implicitly claims an effect on a disease or class of diseases (other than a classical nutrient deficiency disease). Therefore, to determine the scope of structure/function claims that may be made for a <dietary> <supplement>, it is necessary to define the types of claims about the effects of a product that are prohibited disease claims. The proposed rule is designed to provide criteria for determining when a statement about a product constitutes a disease claim.

The agency used several methods and sources to develop the proposed criteria for discerning which categories of labeling statements constitute express or implied claims that a product can diagnose, cure, mitigate, treat or prevent disease. To establish what types of claims the agency had already determined to be disease claims, FDA reviewed the letters it has sent in response to notifications from <dietary> <supplement> manufacturers, listing specific claims the agency regards as disease claims, as well as other regulatory actions taken in response to <dietary> <supplement> claims. FDA also reviewed the Commission Report's guidance on distinguishing structure/function claims and disease claims. In addition, the agency developed a definition of "disease." As described below, the agency relied upon standard medical and legal definitions of disease as a basis for a proposed regulatory definition. The agency then used the proposed definition of disease to generate

workable criteria, by applying the proposed definition to a wide variety of statements currently made by <dietary> <supplement> manufacturers to determine whether the statements claimed an effect on "disease," as tentatively defined. Based upon the information derived from these reviews, the agency developed the general criteria below.

The proposed rule applies only to structure/function claims and disease claims within the meaning of section 403(r)(6) of the act. DSHEA generally, and section 403(r)(6) of the act specifically, apply only to <dietary> <supplements> for human consumption, and were enacted to provide a unique regulatory regime for these products. Thus, the proposed rule is not intended to apply to products other than <dietary> <supplements> for human consumption nor to interpret other provisions of the act.

A. Permitted Structure/Function Claims

Under proposed Sec. 101.93(f), <dietary> <supplement> labels and labeling may bear structure/function statements that are not disease claims within the meaning of proposed Sec. 101.93(g) and that otherwise comply with the notification and disclaimer provisions of Sec. 101.93 (a) through (e), including the requirement that any structure/function statement be substantiated.

B. Definition of Disease

To assist in describing what constitutes a disease claim, the proposed rule contains a definition of "disease." The proposed definition is based on standard medical and legal definitions of the term (Refs. 1, 2, 3 and 4). Under proposed Sec. 101.93(g)(1), a "disease" is any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms. For purposes of this definition, "signs or symptoms" include laboratory or clinical measurements that are characteristic of a disease, such as elevated cholesterol fraction, uric acid, blood sugar, and glycosylated hemoglobin, and characteristic signs of disease, such as elevated blood pressure or intraocular pressure.

To eliminate any inconsistency between this definition of "disease" and the definition of "disease or health-related condition" found in Sec. 101.14(a)(6) and used for purposes of the agency's regulation of health claims, the proposal would also amend Sec. 101.14(a)(6). That section defines "disease or health-related condition" as "damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g. hypertension);

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except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition * * * Under the proposed amendment to 101.14(a)(6), "disease or health-related condition" would be defined, in relevant part, as:

"any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms (including laboratory or clinical measurements that are characteristic of a disease), or a state of health leading to such deviation, impairment, or interruption; except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included within this definition * * *.

FDA believes that the proposed amendment of Sec. 101.14(a)(6) is appropriate because experience since the issuance of the health claims

regulations has shown that the current definition is too narrow in some respects. The term "damage" can be interpreted as limiting the definition to serious or long-term diseases, and as excluding certain conditions that are medically understood to be diseases, such as headaches. The proposed amendment, which covers both "damage" to an organ, part, structure, or system leading to dysfunction, and other deviations from, impairments of, or interruptions of the normal functioning of an organ, part, or system, more accurately covers the range of conditions that are medically understood to be diseases. FDA notes that the definition in Sec. 101.14(a)(6) is intended to cover both diseases and "health-related conditions." As amended, the proposed definition in Sec. 101.14(a)(6) would remain broader than the proposed definition of "disease" in proposed Sec. 101.93(g)(1) because proposed Sec. 101.14(a)(6) includes the phrase "or a state of health leading to such deviation, impairment, or interruption."

C. Criteria for Identifying Disease Claims

Based upon the definition of disease in proposed Sec. 101.93(g)(1), Sec. 101.93(g)(2) of the proposed rule lists criteria for determining whether a statement about a product is a disease claim. To illustrate these criteria, FDA has provided examples of statements that would be considered disease claims under the proposed rule. FDA has also provided examples of statements that would not, by themselves, be considered disease claims. FDA emphasizes that in determining whether a statement about a product constituted a disease claim under these criteria, FDA would also consider the context in which the statement appeared. A statement that by itself would be considered an acceptable structure/function claim could become a disease claim if, in context, an effect on disease were expressed or implied. FDA seeks comment on the examples and the provisions of the proposed rule. To assist the industry, and especially small businesses, if the agency issues a final rule, it will issue an accompanying guidance providing examples of claims that would and would not be considered disease claims under the final rule.

1. Under proposed Sec. 101.93(g)(2)(i), a statement would be considered a disease claim if it explicitly or implicitly claimed an effect on a specific disease or class of diseases. Examples of such disease claims include: "protective against the development of cancer," "reduces the pain and stiffness associated with arthritis," "decreases the effects of alcohol intoxication," or "alleviates constipation." Claims that do not refer explicitly or implicitly to an effect on a specific disease state would not be disease claims under this criterion. Examples include: "helps promote urinary tract health," "helps maintain cardiovascular function and a healthy circulatory system," "helps maintain intestinal flora," and "promotes relaxation." FDA has tentatively concluded that these examples do not contain express or implied references to specific diseases. Instead, they refer broadly to body systems or functions without sufficient reference to specific abnormalities or symptoms to be understood as references to particular diseases.

2. Proposed Sec. 101.93(g)(1) defines disease as any one of several types of abnormalities that are "manifested by a characteristic set of one or more signs or symptoms." FDA believes that reference to a characteristic set of signs or symptoms, even in the absence of the name of the disease, can be understood as a reference to the disease itself. Under proposed Sec. 101.93(g)(2)(ii), a statement would be considered a disease claim if it explicitly or implicitly claimed an effect (using scientific or lay terminology) on one or more signs or symptoms that are recognizable to health care professionals or consumers as being characteristic of a specific disease or of a number of diseases. Examples of such disease claims include: "improves urine flow in men over 50 years old" (characteristic symptoms of, e.g., benign prostatic hypertrophy); "lowers cholesterol" (characteristic sign of, e.g., hypercholesterolemia); "reduces joint pain"

(characteristic symptom of, e.g., arthritis); and ``relieves headache'' (characteristic symptom of, e.g., migraine or tension headache). In each of these cases, the symptoms described are sufficient to characterize one or more specific diseases. To determine whether a reference to a set of signs and symptoms constituted a disease claim, FDA would interpret the reference in context. Claims of an effect on symptoms that are not recognizable as characteristic of a specific disease or diseases would not constitute disease claims. Examples include: ``reduces stress and frustration,''' ``inhibits platelet aggregation,''' and ``improves absentmindedness.''' In these examples, the signs or symptoms noted may be broadly associated with a number of diseases, but are not, by themselves, sufficient to characterize a specific disease or diseases. If the context did not suggest treatment or prevention of a disease, a claim that a substance helps maintain normal function would not ordinarily be a disease claim. Examples include: ``helps maintain a healthy cholesterol level,''' or ``helps maintain regularity.'''

FDA requests comment on the distinction between maintaining normal function, which is potentially the basis for an allowable structure/function claim, and preventing or treating abnormal function, which is potentially a disease claim. This can be a difficult distinction conceptually, especially if the only reason for maintaining normal function is to prevent a specific disease or diseases associated with abnormal function. According to the report, ``Commission members who were troubled about the wording of structure/function statements suggested that the most problematic wording is seen in statements ostensibly relating to 'normal healthy function' that actually imply the need to remedy an underlying abnormal or unhealthy state * * *'' (the report, pp. 36-37).

The Commission concluded that ``statements that mention a body system, organ, or function affected by the supplement using terms such as ``stimulate,''' ``maintain,''' ``support,''' ``regulate,''' or ``promote'' can be appropriate when the statements do not suggest disease prevention or treatment or use for a serious health condition that is beyond the ability of the consumer to evaluate'' (the report, p. 38). This is consistent with the criterion proposed by FDA. As the report illustrates, however, there can be disagreement about the circumstances in which a reference to maintaining normal function implies disease treatment or prevention. Therefore, FDA welcomes

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comment on the basis for the distinction between maintaining normal function and preventing or treating abnormal function and on factors that help distinguish between claims relating to normal, healthy function that do not imply disease treatment or prevention and those that do. Because of the Commission's concerns that claims relating to maintaining healthy cholesterol levels raise particularly difficult issues (the report, p. 37), FDA seeks comment on these claims.

3. Certain natural states, such as pregnancy, aging, or the menstrual cycle, that are themselves not ``diseases,''' are sometimes associated with abnormalities that are characterized by a specific set of signs or symptoms, and thus meet the proposed definition of disease. Under proposed Sec. 101.93(g)(2)(iii), a statement would be considered a disease claim if it explicitly or implicitly claimed an effect on a consequence of a natural state that presents a characteristic set of signs or symptoms recognizable to health care professionals or consumers as constituting an abnormality of the body, such as toxemia of pregnancy, premenstrual syndrome, or abnormalities associated with aging such as presbyopia, decreased sexual function, Alzheimer's disease, or hot flashes. Claims that did not refer to a recognizable abnormality resulting from a natural state or to its signs or symptoms (e.g., ``for men over 50 years old,''' and ``to meet nutritional needs during pregnancy'') would not be disease claims under this criterion. These examples do not include references to specific abnormalities or

symptoms. FDA thus believes that they would not be understood as references to particular diseases.

4. Various aspects of a product's labeling may be used to express or imply that the product will diagnose, cure, mitigate, treat, or prevent disease. Under proposed Sec. 101.93(g)(2)(iv), a statement would be considered a disease claim if it explicitly or implicitly claimed an effect on disease through one or more of the following factors:

(a) The name of the product (e.g., ``Carpaltum'' (carpal tunnel syndrome), ``Raynaudin'' (Raynaud's phenomenon), ``Hepatacure'' (liver problems)). Names that did not imply an effect on a disease, such as ``Cardiohealth'' and ``Heart Tabs,'' would not constitute disease claims;

(b) Statements about the formulation of the product, including a claim that the product contained an ingredient that has been regulated primarily by FDA as a drug and is well known to consumers for its use in preventing or treating a disease (e.g., aspirin, digoxin, or laetrile). FDA notes that this proposed rule is not intended to interpret section 201(ff)(3)(A) of the act (21 U.S.C. 321(ff)(3)(A)), and that a product may be included in or excluded from the definition of ``<dietary> <supplement>' under that provision regardless of whether the statement made for the product under section 403(r)(6) of the act meets the criteria specified here;

(c) Citation of a title of a publication or other reference, if the title refers to a disease use. For example, labeling for a vitamin E product that included a citation to an article entitled ``Serial Coronary Angiographic Evidence That Antioxidant Vitamin Intake Reduces Progression of Coronary Artery Atherosclerosis,'' would create a disease claim under this criterion;

(d) Use of the term ``disease'' or ``diseased;'' or

(e) Otherwise suggesting an effect on disease by use of pictures, vignettes, symbols, or other means (e.g., electrocardiogram tracings, pictures of organs that suggest prevention or treatment of a disease state, the prescription symbol (Rx), or any reference to prescription use). A picture of a body would not constitute a disease claim under this criterion.

5. Certain product class names are so strongly associated with diagnosis, cure, mitigation, treatment or prevention of a disease or diseases, that a claim that a product belonged to such a class would be understood as a disease claim. Under proposed Sec. 101.93(g)(2)(v), a statement would be considered a disease claim if it claimed that the product belonged in a class of products recognizable to health care professionals or consumers as intended for use to diagnose, mitigate, treat, cure, or prevent a disease (e.g., claims that the product was an ``antibiotic,'' a ``laxative,'' an ``analgesic,'' an ``antiviral,'' a ``diuretic,'' an ``antimicrobial,'' an ``antiseptic,'' an ``antidepressant,'' or a ``vaccine''). The foregoing examples do not constitute an exclusive list of product class names that convey disease claims. Claiming that a product was in a class that is not recognizable to health care professionals or consumers as intended for use to diagnose, mitigate, treat, cure or prevent disease (e.g., an ``energizer,'' a ``rejuvenative,'' a ``revitalizer,'' or an ``adaptogen'') would not constitute a disease claim under this criterion.

6. A statement may imply that a <dietary> <supplement> has an effect on disease by claiming that the effect of the <dietary> <supplement> is the same as that of a recognized drug or disease therapy. A statement may also imply an effect on disease by suggesting that the <dietary> <supplement> should be used as an adjunct to a recognized drug or disease therapy in the treatment of a disease. In both cases, the statement implies that the <dietary> <supplement> is intended for the same purpose as the drug or disease therapy, i.e., for the diagnosis, cure, mitigation, treatment, or prevention of disease. Under proposed Sec. 101.93(g)(2)(vi) and (g)(2)(vii), a statement would be considered a disease claim if it explicitly or implicitly claimed that the product

was a substitute for another product that is a therapy for a disease (e.g., ``Herbal Prozac'') or that it augmented a particular therapy or drug action (e.g., ``use as part of your diet when taking insulin to help maintain a healthy blood sugar level''). A claim that did not identify a specific drug, drug action, or therapy (e.g., ``use as a part of your weight loss plan'') would not constitute a disease claim under this criterion.

7. A statement may contain an express or implied disease claim if it suggests that the product cures, mitigates, treats or prevents a disease or diseases by augmenting the body's own disease-fighting capabilities. Under proposed Sec. 101.93(g)(2)(viii), a statement would be considered a disease claim if it explicitly or implicitly claimed a role in the body's response to a disease or to a vector of disease. A vector of disease is an organism or object that is able to transport or transmit to humans an agent, such as a virus or bacterium, that is capable of causing disease in man. A claim that a product ``supports the body's antiviral capabilities'' or ``supports the body's ability to resist infection'' would constitute a disease claim under this criterion. Infections are well-known disease states that result from the action of pathogenic (disease-causing) microorganisms, such as bacteria and viruses, and are deviations from and impairments of the normal structure and/or function of the body with characteristic signs and symptoms. Claims that a product is intended to affect the body's ability to kill or neutralize pathogenic microorganisms, or to mitigate the consequences of the action of pathogenic microorganisms on the body (i.e., the signs and symptoms of infection) are disease claims because they are claims exclusively associated with the body's ability to prevent or respond to infectious diseases. A more general reference to an effect on a body system that has several functions, only one of which is resistance to disease, would not constitute a disease claim under this criterion (e.g., ``supports the immune system'').

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8. Many adverse reactions to drugs or medical procedures meet the proposed definition of disease because they are abnormalities of structure or function manifested by a characteristic set of signs or symptoms. In addition, the clinical management of adverse events that are consequences of medical intervention is an integral part of the overall medical management of the underlying disease state for which the therapeutic intervention is intended. Therefore, claims that a product is intended to counter adverse events resulting from medical intervention are claims that the product is intended as a part of the treatment program and, as such, are claims that the product is to mitigate, treat, or cure the disease state. Under proposed Sec. 101.93(g)(2)(ix), a statement would be considered a disease claim if it explicitly or implicitly claimed to treat, prevent, or mitigate adverse events associated with a medical therapy or procedure and manifested by a characteristic set of signs or symptoms (e.g., ``reduces nausea associated with chemotherapy,''' ``helps avoid diarrhea associated with antibiotic use,''' and ``to aid patients with reduced or compromised immune function, such as patients undergoing chemotherapy''). A claim that did not mention a therapy for disease (e.g., ``helps maintain healthy intestinal flora'') would not constitute a disease claim under this criterion.

9. Under proposed Sec. 101.93(g)(2)(x), a statement would be considered a disease claim if it otherwise suggested an effect on a disease or class of diseases.

III. Legal Authority

This proposed rule is authorized under sections 201, 403(r), and 701(a) of the act (21 U.S.C. 321, 343(r), and 371(a)).

IV. Effective Date and Implementation Plan

The agency proposes that any final rule based on this proposal will become effective 30 days after the date of publication of the final rule in the Federal Register. However, for a product marketed by a small business (as defined below) that was on the market as of the date of publication of the final rule, the agency is proposing to allow an additional 17 months within which claims made about such product as of the date of publication of the final rule must be brought into compliance with the final rule, provided that the small business has notified FDA of the claim as required by section 403(r)(6) of the act and Sec. 101.93(a) and that FDA has not objected to the claim. A ``small business'' for purposes of this proposal is a business with total annual revenues of less than \$20 million. For all other products that were on the market as of the date of publication of the final rule, the agency is proposing to allow an additional 11 months within which claims made about such products as of the date of publication of the final rule must be brought into compliance, again provided that the firm has notified FDA of the claim as required by section 403(r)(6) of the act and Sec. 101.93(a) and that FDA has not objected to the claim. Any product that is marketed for the first time after publication of the final rule, and any new claims made for an existing product for the first time after publication of the final rule, will be expected to be in compliance beginning 30 days after publication of the final rule.

During the pendency of this rulemaking, manufacturers will continue to be under an obligation to comply with section 403(r)(6) and other applicable provisions of the act and applicable regulations. FDA will continue to respond to notifications submitted under section 403(r)(6) of the act, and the agency will continue to enforce that provision and all other applicable legal requirements.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(h), (k) and 25.34(f) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Economic Impacts

A. Benefit--Cost Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approach which maximizes net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). According to Executive Order 12866, a rule is significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of \$100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. Because it raises novel policy issues, FDA finds that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

In addition, FDA has determined that this rule does not constitute a significant rule under the Unfunded Mandates Reform Act of 1995 requiring cost-benefit and other analyses. A significant rule is defined in Section 1531(a) as ``a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of \$100,000,000 (adjusted annually for inflation) in any 1 year * * *''.

Finally, in accordance with the Small Business Regulatory Enforcement Fairness Act, the administrator of the Office of

Information and Regulatory Affairs of the Office of Management and Budget has determined that this proposed rule is not a major rule for the purpose of Congressional review.

There are several different types of products that may be considered to be <dietary> <supplements>. These products include but are not limited to vitamin and mineral supplements, herbal products, and products that contain other similar nutritional substances. Estimates of the number of <dietary> <supplements> are approximate because no one source collects information on all types of <dietary> <supplements>. In fact, until the DSHEA, there was no agreed upon definition of a <dietary> <supplement>. Some sources include only <dietary> <supplements> of vitamins and minerals, others include herbals or botanicals, and still others include other types of products that may or may not be <dietary> <supplements>, such as sports nutrition products and "functional foods," a term for which there is no regulatory definition. FDA's preliminary estimate of the number of such products is approximately 29,000. FDA's estimate of the number of stockkeeping units (skus), a more accurate count of the number of labels, is approximately 75,000.

In its analysis of the rule establishing nutrition labeling requirements for <dietary> <supplements> (62 FR 49826 at 49843), FDA provided an estimate of the number of <dietary> <supplement> firms. According to Dun's Market Identifiers (Ref. 5), there are approximately 250 manufacturers of vitamin and mineral products. According to Nutrition Business Journal (Ref. 6), the <dietary> <supplement> industry includes 850 supplement manufacturing companies. The Journal reports 1995 industry revenues at \$4.5 billion. The Journal's estimate of 850 firms is an overestimate of the <dietary> <supplement> industry as defined by FDA because it includes homeopathic products, which are drugs by statutory definition, and "functional

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foods" and sports nutrition products, which may be either conventional foods or <dietary> <supplements> depending on how they are marketed and used. Although the Journal does not break down the number of firms by the type of <dietary> <supplement> produced, it does specify that 250 firms produce herbal or botanical products.

For purposes of determining the costs of regulation, FDA has used 850 as an upper bound estimate of the number of firms. As a lower bound estimate, FDA has used 500 (250 vitamin/mineral firms plus 250 herbal/botanical firms). Since publication of the nutrition labeling final rule in September 1997 (62 FR 49826), FDA has not been challenged on these estimates. Therefore, the same range of estimates is used in this analysis.

In this proposed rule, FDA is clarifying the distinction between disease claims and structure/function claims in <dietary> <supplement> labeling. If the proposed rule becomes final, any firm currently making a claim that was not previously classified as a disease claim but is classified as a disease claim by the rule will be required to change the claim to an acceptable structure/function claim, remove the claim from labeling, petition and be granted permission to carry a health claim, or bear the consequences of being classified as an unapproved drug. FDA has received approximately 2,300 notifications of structure/function claims and has sent objection letters for approximately 150 of the notifications. FDA believes that those firms have made the necessary changes to make their claims come into compliance. FDA has estimated the number of additional notifications to which it would have objected under the criteria in this proposed rule. Using conservative, worst-case estimates, FDA estimated that it would have objected to approximately 60 additional notifications. The firms making these 60 products will have to change their claims if the proposal becomes final; these firms would bear the costs of this proposed rule.

FDA is aware that, despite the notification requirements in section 403(r)(6) of the act and Sec. 101.93(a), some firms that have not sent notifications are in fact marketing products whose labeling contains

structure-function claims. If the labels contain claims that are unacceptable under the criteria FDA is proposing to adopt, and if the firms change those labels in response to this proposed rule, then the costs of those labeling changes can be attributed to the rule.

1. Costs

Only those firms who must change their labeling will bear the costs of this rule. Categories of costs for relabeling include administrative, analytical, printing, and inventory disposal. FDA will first estimate compliance costs for the 60 products for which the agency has received notifications of claims that would be classified as disease claims under the criteria in the proposed rule. These costs will be the lower-bound costs of the proposed rule. FDA will then estimate the compliance costs for the products for which FDA has not received notification, but whose labeling contains claims that would be classified as disease claims under the criteria in the proposed rule. The sum of the compliance costs for the two categories of products will be the upper-bound costs of the proposed rule.

a. Lower-bound Estimate

The administrative costs associated with a labeling regulation result from the incremental administrative labor expended in order to comply with a regulation. FDA estimates administrative costs at approximately \$425 per firm for a 1-year compliance period and approximately \$320 for an 18-month compliance period. Longer compliance periods decrease administrative effort because firm executives often delegate downward decisions that are less immediate. FDA will assume that the number of firms affected by the proposed rule is proportional to the number of labels affected. FDA therefore estimates the number of firms affected by multiplying the upper-bound estimate of total firms in the industry by the fraction of the labels in violation, or $850 \times (60/2,300) = 22$. Total administrative costs are estimated to be \$7,040 ($22 \times \$320$) with an 18-month compliance period and \$9,350 ($22 \times \$425$) with a 1-year compliance period.

Based on an average of the estimates provided in comments to earlier rules, FDA estimates that the average redesign cost for a 1-year compliance period is \$1,700 per <dietary> <supplement> label. Redesign costs associated with an 18 - month compliance period are typically 3/4 of those for a 1 year compliance period, or \$1,300 per <dietary> <supplement> label. Therefore, FDA estimates total redesign costs to be \$102,000 ($60 \times \$1,700$) for a 12-month compliance period and \$78,000 ($60 \times \$1,300$) for an 18-month compliance period.

FDA received information from an earlier rule affecting the entire <dietary> <supplement> industry indicating that inventory disposal costs would be \$8 million for an 18-month compliance period and \$15 million for a 12-month compliance period. FDA has some experience suggesting that some firms will experience minimal inventory disposal costs due to the rapid frequency with which they change labels or move product. Because FDA is assuming that 0.08 percent ($60/75,000$) of the industry will incur costs as a result of this rule, total inventory disposal costs are estimated to be \$6,400 ($0.0008 \times \$8$ million) for an 18-month compliance period and \$12,000 ($0.0008 \times \$15$ million) for a 12-month compliance period.

FDA has estimated the impact of the proposed regulation and has determined that, for a 1-year compliance period, lower-bound total costs would be approximately \$123,400. Alternatively, if FDA were to provide 18 months for compliance, lower-bound total costs would be approximately \$91,400. The components of lower-bound total costs are shown in the following table.

Cost Category	12-month compliance	18-month compliance
Administrative	\$9,400	\$7,000
Redesign	\$102,000	\$78,000
Inventory	\$12,000	\$6,400

Total	\$123,400	\$91,400
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b. Upper-bound Estimate

Some manufacturers of <dietary> <supplements> may not have notified FDA that their product labels contain structure-function claims. Because these manufacturers have not complied with the existing legal requirement to notify FDA of the claims they are making for their products, FDA believes that it is unlikely that they would change their labels to comply with new regulations defining acceptable structure/function claims. However, to ensure that all possible costs are considered in this impact analysis, the agency is including costs that might be incurred by such manufacturers as an upper bound on its estimate of the costs of this proposed rule. Based on visual observation of <dietary> <supplements> sold in retail establishments (grocery, drug, and health food stores), FDA estimates that up to 30 percent of all labels contain structure-function claims. FDA therefore estimates that up to 22,500 ($0.3 \times 75,000$) <dietary> <supplement> labels may contain structure-function claims. Although it is uncertain how many of these labels contain claims that would be disease claims under the proposed rule, if the proportion of all labels containing such claims is the same as the proportion of notifications containing such claims, then there may

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be up to 585 ($60/2,300$) $\times$ 22,500 labels that would need to be changed if the proposed rule becomes final. Subtracting the 60 unacceptable labels for which FDA has received notifications leaves about 525 additional labels that may be affected by the rule.

Based on its model of food labeling compliance costs, FDA assumes that compliance costs per label double with each halving of the compliance period (Ref. RTI Final Report, "Compliance Costs of Food Labeling Regulations"). The cost per label for a 12-month compliance period is approximately \$2,000 ($\$123,400/60$). The compliance period for claims for which no notification has been received is 30 days. Based on the model, FDA expects that compliance costs will double as the compliance period falls from 12 to 6 months, and double again as the compliance period falls to 3 months. Although the model does not predict compliance costs for periods shorter than 3 months, FDA assumes that as the compliance period falls from 3 months to 30 days, compliance costs are likely to double again. Estimated costs per label should therefore be approximately 8 times ($2 \times 2 \times 2$) higher for a compliance period of 30 days than for a compliance period of 12 months. FDA therefore estimates compliance costs per label for current structure-function claims for which no notification has been received to be \$16,000 ($8 \times \$2,000$). The total costs for 525 label changes would be \$8.4 million ($525 \times \$16,000$). Although FDA believes that it is very unlikely that all of these label changes would be made, the upper-bound total cost of this proposed rule is the sum of the costs for the 60 unacceptable claims for which notifications have been received and the costs of the additional unacceptable claims. The total cost will thus range between approximately \$0.1 million and \$8.5 million.

2. Benefits

Most of the benefits from this rule will come from the reduced uncertainty associated with structure/function claims in <dietary> <supplement> labeling. Some manufacturers of <dietary> <supplements>, as shown by the submission of a significant number of notifications for purported structure/function statements that are clearly disease claims, are uncertain about what constitutes an acceptable structure/function claim. This proposed rule establishes clarifying criteria that will reduce and perhaps eliminate this uncertainty.

FDA cannot quantify the benefits from this proposed rule. Because of the uncertainty about what constitutes an acceptable structure/function claim, some manufacturers of <dietary> <supplements> may have

hesitated to attempt to make structure/function claims. These clarifying criteria will enable those firms to go forward with those claims. To the extent that the lack of these claims has caused consumers to seek out the information from other sources, this rule will benefit consumers by reducing the cost of searching for information and ensuring that the information provided to consumers is appropriate.

Manufacturers who were considering making claims that would be considered unacceptable will be provided with clear criteria showing that the claims are unacceptable. As evidenced by notifications of structure/function claims already received by FDA, several firms have had to bear the cost of redesigning labeling to incorporate the changes recommended by the agency. By providing criteria to firms before they submit notifications to FDA, this rule will reduce costs to firms by reducing the probability of having to redo labels. Government costs will also be lessened by reducing the number of letters informing firms of inappropriate label statements.

3. Regulatory Alternatives

FDA considered, but did not adopt, other regulatory options. First, the agency considered treating a statement about a <dietary> <supplement> as a disease claim only if the statement included an express reference to a specific disease. This option would have resulted in a significantly larger number of permitted claims for <dietary> <supplements>, and reduced costs for <dietary> <supplement> manufacturers. FDA did not adopt this option for several reasons. First, it would be inconsistent with FDA's longstanding policy of considering both express and implied claims when determining whether a product falls within various definitions under the act. Second, it would be inconsistent with the interpretation of "disease claims" that FDA has used in administering section 403(r)(6) of the act prior to issuing this proposed rule. Finally, because many implied claims, e.g., claims that list the symptoms of a disease without naming the disease, are well-understood by consumers as disease treatment or prevention claims, this option would be inconsistent with the intent of section 403(r)(6).

Second, FDA considered treating any mention of an abnormality of the structure or function of the body as a disease claim, even if the abnormality was not characterized by a set of signs or symptoms recognized as a disease. This option would have resulted in a significantly smaller number of permitted claims for <dietary> <supplements>, and greater costs for <dietary> <supplement> manufacturers. FDA did not adopt this option because section 403(r)(6) of the act prohibits only claims of an effect on a disease. Because not all abnormalities are recognized by health professionals or consumers as diseases, this option would have been overbroad, and would have prevented manufacturers from making claims permitted by the statute.

Finally, FDA considered taking no new regulatory action. This option would have resulted in no immediate change in the number of permitted claims, and no costs for <dietary> <supplement> manufacturers. FDA rejected this option because there is substantial confusion among <dietary> <supplement> manufacturers and consumers about what types of claims are permitted for <dietary> <supplements>, and the agency has been called upon to provide clarification of permitted and prohibited claims. In the absence of direction from the agency, an increasing number of products in the marketplace carry express and implied disease claims, misleading consumers and creating unfairness to those manufacturers who have attempted to comply with advice from FDA.

B. Small Entity Analysis

According to the Regulatory Flexibility Act, the definition of a small entity is a business independently owned and operated and not dominant in its field. The Small Business Administration (SBA) has set size standards for most business categories through use of four-digit Standard Industrial Classification (SIC) codes. <Dietary> <supplements> of vitamins and minerals are included in the industry group Pharmaceutical

Preparations (SIC 2834); a business in that classification is considered small if it has fewer than 750 employees. According to Dun's Market Identifiers, there are approximately 250 producers of vitamin and mineral supplements, of which 200 have fewer than 750 employees. The remaining <dietary> <supplement> products--mainly herbs, other botanicals, and amino acids--do not fit in any classification, but come closest to the industry groups Food Preparations Not Elsewhere Classified (SIC 2099) and Medicinal Chemicals and Botanical Products (SIC 2833). The SBA size standards are 500 or fewer employees for food preparations and 750 or fewer employees for medicinal and botanical products.

According to Nutrition Business Journal (Ref. 6), 11 of the 850 <dietary> <supplement> manufacturing firms have

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total revenues over \$100 million, accounting for 53 percent of total sales; 30 firms have sales revenues between \$20 and \$100 million, accounting for 28 percent of industry sales; and 809 firms have sales under \$20 million, accounting for 19 percent of industry sales. The 809 firms in the under \$20 million category have an average sales revenue of \$800,000 and will be considered small by FDA.

No employment data are available for some of these firms. Many of the firms are in the SIC codes 2833 and 2834, however. According to Dun's Market Identifiers, no firms for which both employment and sales data are available in SIC code 2833 have less than \$20 million in annual sales and more than 500 employees. Indeed, 96% of the firms in that sales category have fewer than 100 employees. By contrast, over 90% of the firms in SIC codes 2833 and 2834 (vitamin and minerals sub-category) with annual sales greater than \$100 million have more than 750 employees. If the relationship between sales and employment for SIC codes 2833 and 2834 holds for other sectors of the <dietary> <supplement> industry, then the proportion of firms with sales under \$20 million should be approximately the same as the proportion of firms with fewer than 500 employees, an employment category that is classified as small for any SIC code involving the manufacture of foods, chemicals and kindred or allied products. FDA concludes therefore that as many as 809 firms in the <dietary> <supplement> industry, or 95 percent of firms, could be considered small (sales under \$20 million). As stated previously in this analysis, 809 small firms may be an overestimate because it counts firms that produce homeopathic products, which are drugs, and sports nutrition products and "functional foods," which may be either foods or <dietary> <supplements>. If there are as few as 500 <dietary> <supplement> firms, there may be 475 small <dietary> <supplement> firms.

Because virtually all firms affected by this rule will be classified as small under SBA standards, FDA assumes that small entities will bear 100 percent of the costs. Because per firm labeling costs are probably burdensome for small firms and because the costs of this rule are borne entirely by small firms, FDA tentatively concludes that this rule will result in a significant economic impact on a substantial number of small entities. In section VI. A. of this document, entitled Benefit--Cost Analysis, FDA estimated that, as a lower-bound, 22 firms would be affected by this proposed rule and that the lower-bound costs with a compliance period of 12 months would be approximately \$123,400, or about \$5,600 per small firm. FDA estimated upper-bound costs, \$8.5 million, by adding the costs of changing 525 additional labels (with a 30-day compliance period) to the lower-bound costs. If the number of additional firms affected is proportional to the number of additional labels changed, the upper-bound number of firms affected by this proposed rule is 215, for an upper-bound average cost of about \$40,000 per small firm.

The Regulatory Flexibility Act requires agencies to examine regulatory alternatives that would minimize the impact on small entities. FDA considered exempting small entities from this rule, which would eliminate the costs borne by small entities. FDA rejected this

option for several reasons. First, the agency has no authority to exempt small entities from their statutory obligations, and this proposed rule merely clarifies a statutory requirement. Second, as described above, virtually all manufacturers covered by this proposal are small entities. Exempting small entities would thus eliminate the benefits of the proposed rule. Finally, some of the benefits of the rule, such as reducing the uncertainty associated with structure/function claims and reducing the probability of having to re-do labels, will accrue to small entities.

FDA has examined the impact of different compliance periods and has determined that extending the compliance period from 12 to 18 months for firms that have notified the agency of a claim and have not received an objection reduces the burden on small entities in this category. Extending the compliance period from 12 to 18 months reduces lower-bound estimated costs borne by small firms by \$32,000, and average costs per firm would fall from \$5,600 to about \$4,200. Extending the compliance period beyond 18 months could provide additional relief to these small entities. Based on FDA's experience with the <dietary> <supplement> industry, however, the agency believes that labels are changed more often than every 18 months; therefore, FDA believes that this additional relief would be small. FDA has tentatively concluded that the compliance period for those firms whose products contain structure/function claims but who have not complied with the legal requirement to notify FDA of those claims should not be extended.

VII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Comment Request

Interested persons may, on or before August 27, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Dorland's Illustrated Medical Dictionary, 28th Edition, W.B. Saunders Co., Philadelphia, p. 478, 1994.
2. Stedman's Medical Dictionary, 26th Edition, Williams & Wilkins, Baltimore, p. 492, 1995.
3. The Encyclopedia Americana, International Edition, Grolier Inc., Danbury, p. 168, 1985.
4. Black's Law Dictionary, 6th Edition, West Publishing Co., St. Paul, p. 467, 1990.
5. Dun's Market Identifiers, Knight-Ridder Information, Inc., Mountain View, CA, 1998.
6. Nutrition Business Journal, 1(1):15, 16, 1996.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is

proposed that 21 CFR part 101 be amended as follows:

PART 101--FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 101.14, as currently in effect, is amended by revising paragraph (a)(6) to read as follows:

Sec. 101.14 Health claims: general requirements.

(a) * * *

(6) Disease or health-related condition means any deviation from, impairment

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of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms (including laboratory or clinical measurements that are characteristic of a disease), or a state of health leading to such deviation, impairment, or interruption; except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition (claims pertaining to such diseases are thereby not subject to this section or Sec. 101.70).

* * * * *

3. Section 101.93, as currently in effect, is amended by revising the section heading and by adding paragraphs (f) and (g) to read as follows:

Sec. 101.93 Certain types of statements for <dietary> <supplements>.

* * * * *

(f) Permitted structure/function statements. (1) <Dietary> <supplement labels or labeling may, subject to the requirements of this section, bear statements that describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, but may not bear statements that are disease claims under paragraph (g) of this section.

(g) Disease claims. (1) Definition of disease. For purposes of 21 U.S.C. 343(r)(6), a ``disease'' is any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms, including laboratory or clinical measurements that are characteristic of a disease.

(2) Disease claims. FDA will find that a statement about a product claims to diagnose, mitigate, treat, cure, or prevent disease (other than a classical nutrient deficiency disease) under section 403(r)(6) of the act if it meets one or more of the criteria listed in this paragraph (g)(2). In determining whether a statement is a disease claim under these criteria, FDA will consider the context in which the claim is presented. A statement claims to diagnose, mitigate, treat, cure, or prevent disease if it claims, explicitly or implicitly, that the product:

(i) Has an effect on a specific disease or class of diseases;

(ii) Has an effect, using scientific or lay terminology, on one or

more signs or symptoms that are recognizable to health care professionals or consumers as being characteristic of a specific disease or of a number of different specific diseases;

(iii) Has an effect on a consequence of a natural state that presents a characteristic set of signs or symptoms recognizable to health care professionals or consumers as constituting an abnormality of the body;

(iv) Has an effect on disease through one or more of the following factors:

(A) The name of the product;

(B) A statement about the formulation of the product, including a claim that the product contains an ingredient that has been regulated by FDA as a drug and is well known to consumers for its use in preventing or treating a disease;

(C) Citation of the title of a publication or reference, if the title refers to a disease use;

(D) Use of the term ``disease'' or ``diseased''; or

(E) Use of pictures, vignettes, symbols, or other means;

(v) Belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease;

(vi) Is a substitute for a product that is a therapy for a disease;

(vii) Augments a particular therapy or drug action;

(viii) Has a role in the body's response to a disease or to a vector of disease;

(ix) Treats, prevents, or mitigates adverse events associated with a therapy for a disease and manifested by a characteristic set of signs or symptoms; or

(x) Otherwise suggests an effect on a disease or diseases.

Dated: April 22, 1998.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

FR Doc. 98-11294 Filed 4-24-98; 4:27 pm

BILLING CODE 4160-01-F

Extension of Comment Period August 26, 1998

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Hypertext updated by dms/ear 1998-SEP-10

GLAVINE WINS NL'S CY YOUNG AWARD 1,6C

2ND FOR BRAVES' ACE
DENNIS RODMAN AND CARMEN ELECTRA: A MARRIAGE MADE IN VEGAS 4C



Says he's married and proud of it. 4C

WEDNESDAY, NOVEMBER 18, 1998

NEWSLINE

A QUICK READ ON THE NEWS

WALL STREET: Dow Jones industrial average drops 24.97 points to 8986.28; Nasdaq index climbs 16.84 to 1878.52; 30-year Treasury bond yield rises to 5.30%, 1.4B.

► Japan's Nikkei average is up 154 points to 14,567 at midday; yen is 121 per dollar; Hong Kong's Hang Seng index is up 170 points to 10,318 early today.

GUN CONTROL: The Brady law is expanding to cover shotguns and rifles, yet the cry against background checks this time around is muted. 3A.

Students bear bigger burden



Heavy lifting: Janero Marchany, left, and Candice Home lug their gear to school in Columbia, Md. Officials are expressing concern over the size and weight of students' luggage. 11D.

IRAQ CONFLICT: Weapons inspectors fly to Baghdad and fighter jets begin flying back to U.S. bases. 14A.

SKY JAMS: Delays loom on horizon, as FAA attempts to overhaul air traffic system, experts say. 21A.

RISE IN COLLEGE COSTS: Federal grant money is covering less when it comes to tuition. 3A.

HISTORIES: Volunteers helping Americans learn whether relatives emigrated through Ellis Island. 17A.

EDITORIAL: House leadership, Rep. Bob Livingston, R-La. In USA TODAY's opinion, "Who better to lead the party that promised to change Washington into changing the way Washington gets elected?" 26A.

MONEY: Microsoft ordered to change software that uses Sun Microsystems' Java language. 1B.

► Car engine light illuminates emissions debate. 1B.

► DaimlerChrysler merger begins with need for speed. 1B.

SPORTS: Penalties get Kansas City linebacker Derrick Thomas suspended for game. NFL. 1C.

► Hampton University coaches charged with theft. 1C.

LIFE: Dinosaur nesting ground found in Argentina. 1D.

► Spirit can still move some long-gone composers. 8D.

► Smoking among college students jumps 28%. 10D.

► New surgery helps golfer Greg Norman's game. 11D.

COMING FRIDAY

College hoops
Basketball bonus section looks at top-ranked Duke, men's and women's previews.

Duke's Trajan Langdon AP

Written by John O. Buckley

Crossword	12D
Editorial/Opinion	26-27A
Lotteries	15C
Marketplace Today	12D
State-by-state	11A
Stocks	4, 8-11B

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USA TODAY

ENOUGH IN THE USA TO FIRST IN DAILY READERS

Rate cut may be last for now

Who will be MVP? The impossible choice

Two USA TODAY writers make the case for their favorite

MARK MCGWIRE
Average: .299
Home runs: 70
RBI: 147
His 70 homers shattered baseball's most cherished record and helped restore faith in a troubled sport. His team missed playoffs.

SAMMY SOSA
Average: .308
Home runs: 66
RBI: 158
His hitting and run production helped lead the Cubs to playoffs; his grace during home run chase touched millions.

Cast your vote at www.usatoday.com. Final results Thursday

Top photo of McGwire by AP Wirephoto; Sosa photo by AP Wirephoto. USA TODAY Top photo of Sosa by Steve Russell. USA TODAY Bottom photo by Beth A. Sander AP

COVER STORY Thursday's pick will ignite controversy for the ages

Who was better? Samson or Hercules? King Kong or Godzilla? Muhammad Ali or Joe Louis? That's the kind of choice that faced a panel of 32 sportswriters when voting for this year's Most Valuable Player Award in the National League.

The tightly-held results of that no-win situation will be announced Thursday afternoon. Whoever wins — the St. Louis Cardinals' Mark McGwire or the Chicago Cubs' Sammy Sosa — some fans are sure to be outraged, because both had seasons that rank among the best in baseball history. (Indeed, it will stir far more talk than the American League MVP, which is expected to go today to the Texas Rangers' Juan Gonzalez.)

Throughout the summer and early fall, McGwire and Sosa held the nation's spotlight as they chased Yankee great Roger Maris' single-season mark of 61 home runs, one of the most revered records in sports.

Hal Bodley on why Sosa should win 2A
Tom Weir on why McGwire should win 2A

The case for McGwire: His 70 home runs shattered Maris' record and he mesmerized fans with some of the longest homers ever. For Sosa: He topped McGwire for runs batted in, batting average, runs scored and his — and the Cubs made the playoffs.

Guidelines provided to the voters, two from each city with a National League team, leave little specific direction: "There is no clear-cut definition of what most valuable means."

Tough choices and controversy aren't new to MVP voting.

In 1941, American League voters had to choose between Joe DiMaggio, who had a record 56-game hitting streak, and Ted Williams, who batted .406. DiMaggio, playing for the league champion Yankees, won handily.

In 1947, Williams lost again to DiMaggio, in

Please see COVER STORY next page ►

DOLL-SIZE WONDERLAND 1D

American Girls (\$82 each), coming to Chicago



Fed's 1/4-point reduction is third in two months

By Beth Belton and Rich Miller
USA TODAY

The Federal Reserve cut interest rates Tuesday for the third time in under two months and hinted that it might be the last reduction for a while.

The quarter-percentage-point cut was designed to protect the economy from the global financial crisis and ensure that the USA's 7½-year economic expansion continues into next year, economists say.

In explaining its action, the Fed said in a statement that financial markets remain unsettled, although they're not as shaky as they were just a few weeks ago. Experts say the statement signals that the central bank is likely to hold rates steady until its first meeting of 1999 on Feb. 23.

The statement does strongly hint that the Fed has done enough until it meets next February, said Allen Sinai, chief economist for Boston-based Primark Decision Economics.

The Fed Tuesday trimmed the federal funds rate that banks charge each other for overnight money and the discount rate it charges on overnight loans to the banks.

The former now stands at 4½%, its lowest level in more than four years; the latter stands at 4½%.

The rate cut will mean lower borrowing costs for consumers and companies and should provide a boost to confidence ahead of the critical holiday shopping season, experts say.

Major banks quickly matched the Fed's move and lowered their prime lending rate to 7¼% from 8%. The prime serves as benchmark for a wide variety of rates on everything from credit cards to home equity loans.

Stock prices initially bounded after the central bank's announcement but then fell back on talk that this may be the last rate cut for a while, traders said. The Dow Jones industrial average closed 25 points lower at 8986.

Experts described the Fed rate cut as insurance against renewed turmoil in financial markets. And, they added, with inflation so low, that insurance doesn't cost much.

The government said Tuesday that consumer prices rose 0.2% last month for a year-on-year rate of just 1.5%.

Experts said the rate cut should prove helpful to struggling emerging market economies such as Brazil's that are saddled with hundreds of billions of dollar-denominated debt.

Brazil is facing a tough time persuading banks and investors to keep credit lines open after its agreement last week on a \$42 billion rescue with the International Monetary Fund.

► Fed's timing, 1B
► Brazil's challenge, 2B



► Monica on tape, 4A

GOP tries to expand hearings

By Wendy Koch
USA TODAY

WASHINGTON — Republicans prepared Tuesday to call more witnesses in upcoming House impeachment proceedings as Monica Lewinsky's voice was heard for the first time on the nation's airwaves.

With only the third impeachment hearings in U.S. history set to begin Thursday, partisan tempers flared on the House Judiciary Committee over the inquiry's scope and handling.

White House counsel Charles Ruff asked for more time to cross-examine independent counsel Ken Starr, the leadoff witness, who has said that Clinton committed 11 possibly impeachable offenses. Ruff sought 90 minutes; he had been offered 30 minutes.

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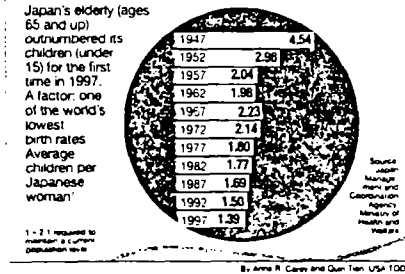
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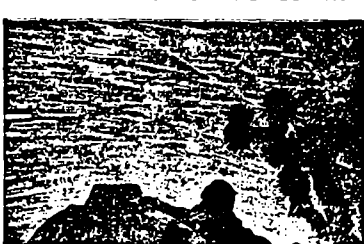
USA SNAPSHOTS®

A look at statistics that shape the nation

Japan's falling birth rate



Satellites weather dust storm



Sky show: A meteor streaks across background stars over California's Joshua Tree National Park in this 30-minute exposure early Tuesday. The shower was less intense than expected. 3A.

Rate cut may be last for now

Fed's 1/4-point reduction is third in two months to expand GOP tries to expand hearings

By Beth Belton
and Rich Miller
USA TODAY

The Federal Reserve cut interest rates Tuesday for the third time in under two months and hinted that it might be the last reduction for a while.

The quarter-percentage-point cut was designed to protect the economy from the global financial crisis and ensure that the USA's 7 1/2-year economic expansion continues into next year, economists say.

In explaining its action, the Fed said in a statement that financial markets remain unsettled, although they're not as shaky as they were just a few weeks ago. Experts say the statement signals that the central bank is likely to hold rates steady until its first meeting of 1999 on Feb. 2-3.

"The statement does strongly hint that the Fed has done enough until it meets next February," said Allen Sinai, chief economist for Boston-based Primark Decision Economics.

The Fed Tuesday trimmed the federal funds rate that banks charge each other for overnight money and the discount rate it charges on overnight loans to the banks.

The former now stands at 4 3/4%, its lowest level in more than four years; the latter stands at 4 1/2%.

The rate cut will mean lower borrowing costs for consumers and companies and should pro-

vide a boost to confidence ahead of the critical holiday shopping season, experts said.

Major banks quickly matched the Fed's move and lowered their prime lending rate to 7 3/4% from 8%. The prime serves as benchmark for a wide variety of rates on everything from credit cards to home equity loans.

Stock prices initially bounded after the central bank's announcement but then fell back on talk that this may be the last rate cut for a while, traders said. The Dow Jones industrial average closed 25 points lower at 8986.

Experts described the Fed rate cut as insurance against renewed turmoil in financial markets. And, they added, with inflation so low, that insurance doesn't cost much.

The government said Tuesday that consumer prices rose 0.2% last month for a year-on-year rate of just 1.5%.

Experts said the rate cut should prove helpful to struggling emerging market economies such as Brazil's that are saddled with hundreds of billions of dollar-denominated debt.

Brazil is facing a tough time persuading banks and investors to keep credit lines open after its agreement last week on a \$42 billion rescue with the International Monetary Fund.

► Fed's timing, 1B
► Brazil's challenge, 2B

By Wendy Koch
USA TODAY

WASHINGTON — Republicans prepared Tuesday to call more witnesses in upcoming House impeachment proceedings as Monica Lewinsky's voice was heard for the first time on the nation's airwaves.

With only the third impeachment hearings in U.S. history set to begin Thursday, partisan tempers flared on the House Judiciary Committee over the inquiry's scope and handling.

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Government to set guidelines for dietary supplement ads

By Jayne O'Donnell
USA TODAY

Federal regulators will announce guidelines today that they hope will force more truthful advertising of vitamins, herbal products and other dietary supplements.

The Federal Trade Commission (FTC) is alerting the booming supplement industry that it continues to require extensive proof that products do what is claimed in advertising.

FTC investigators say companies often don't have proof to back up claims of benefits.

"If we can get the principal part of the industry into com-

pliance, then we can focus on going after the bad actors," says Jodie Bernstein, FTC consumer protection chief.

About 100 million consumers use diet supplements, such as the popular St. John's Wort, Gingko Biloba and androstenedione, the product made famous by baseball's Mark McGwire last summer. Advertising of the products is up more than 30% from 1997.

Supplement makers asked the FTC to clarify the rules. Since a 1994 law stripped the Food and Drug Administration of some control over supplements, the FTC has increased its scrutiny, going after supple-

ment makers 34 times for misleading ads. In the previous 12 years, the commission brought just 26 cases.

Supplement companies say it's never been clear how much substantiation is needed. Annette Dickinson of the Council for Responsible Nutrition, an industry trade group, says the guidelines still leave the FTC a lot of discretion.

Some say it's needed. "Diet supplements are advertised as cure-alls for every ailment known to man," says Bruce Silverglade of consumer advocacy group Center for Science in the Public Interest. "It's a very difficult market to police."

backup information
primary
person on
issue

Tom Friedman

Frenzied Lobbying Leads Up To House GOP Voting Today

By JULIET EILPERIN
Washington Post Staff Writer

With his ear attached to the phone, Rep. J.C. Watts (R-Okla.) scavenges his desk for the small slips of white paper containing home numbers of his colleagues. He tells one member that he's "a great American" for agreeing to support his bid for a GOP leadership post; then he's onto another line so he can persuade the Iowa Republican Party chairman to lobby Iowa lawmakers on his behalf.

Even as he's talking, Watts's eyes widen, and he motions frantically to an aide who has been entertaining Weekly Standard editor Fred Barnes on another line for several minutes. "Fred!" he cries out in a horse whisper; the aide nods reassuringly. There's still time to woo the conservative pundit, whose views are closely monitored by some House Republicans.

Watts and other hopefuls will find out whether their frenzied lobbying pays off this morning, when the 223 incoming GOP members of Congress meet behind closed doors to pick their new leaders. While Bob Livingston (La.) has sewed up the votes to succeed Newt Gingrich as House speaker, the fate of other leaders—including Majority Leader Richard K. Armey (Tex.)—remained very much in doubt yesterday.

Following the party's disappointing election results two weeks ago,

there's been no shortage of ideas about what's needed to revitalize congressional Republicans. Conservatives say party leaders must return to a more forceful message of tax cuts and other longtime GOP themes, while moderates say the party needs

"It's very retail. It's very personal. Members want to know how you are going to accommodate them."

—Werner Brandt, lobbyist

to take the hard edge off its image. Many of the leadership challengers themselves gripe about the lack of any coherent message from the GOP congressional hierarchy.

But in the end, lawmakers say, today's secret balloting will turn less on such grand themes and more on mundane, garden-variety political factors: networking, personal favors and

superior organizational skills aimed at lining up the necessary votes.

"It's very retail. It's very personal," said Preston Gates lobbyist Werner Brandt, a former senior House aide. "Members want to know how you are going to accommodate them."

Handicapping the key contests remained hazardous. Armey was fighting to save his job against Reps. Jennifer Dunn (Wash.) and Steve Largent (Okla.). Although he has alienated assorted GOP factions with his brusque approach, Armey was benefiting from the apparent failure of either challenger to develop broad backing across the GOP caucus. Some members were still trying to draft Rep. J. Dennis Hastert (Ill.) into the race.

Meanwhile, Watts claimed he had amassed enough votes to defeat Rep. John A. Boehner (Ohio) as chairman of the Republican Conference, who chairs the regular House GOP meetings and develops the party's message. Boehner aides predictably disputed this estimate, and lawmakers expect the race to be close.

Usually leadership races last for at least a year, perhaps two, giving lawmakers ample time to line up the necessary votes. Indeed, Livingston greased his likely ascension by traveling the country on behalf of his colleagues, doling out campaign funds to allies in case Gingrich decided to step down.

Armey has spent much of the past

year trying to damp down discontent with his leadership, using the powers of incumbency to woo unlikely supporters. Sources said he has lined up support, for instance, from moderate Mark Foley (Fla.) by vowing to help Foley obtain a seat on the Ways and Means Committee; Armey also personally intervened to block a Wall Street magnate from running ads criticizing Foley for his support of the sugar industry.

But for others, the battle to get into leadership has been more seat-of-the-pants, with the normal timetables for even junior posts accelerated because of the GOP's setback at the polls and Gingrich's surprise resignation. And in this compact campaign schedule, members and their staffs have done everything from enlisting celebrity allies—Largent's staff hoped Denver Bronco quarterback John Elway would call Colorado members on behalf of the former football star—to spreading dirt about their opponents.

National Republican Congressional Committee chairman John Linder (Ga.), who is battling to keep his post, decried such attacks in an impassioned letter he distributed to House Republicans last week.

"This obsession with false rumor-mongering and spin and counter-spin is what's standing in the way of our Conference's success," he wrote. "It has stymied our progress, sidetracked us, and sidelined our agenda for nearly four years. It's a sickness

that so consumes the time and energy of our Conference and there's no focus left for an agenda—an agenda that tells the American people what we're for and what it means to them."

Even being assured of having one vote can be tricky, however, and candidates spend the bulk of their time figuring out whether their colleagues are telling the truth. It is the ultimate political test, and it takes several steps to find the answer.

First, the candidate calls a member to ask for his or her vote and rates the response on a scale of one to five: "one rock solid, five absolutely not," according to one senior House aide. Then the lawmaker asks a group of close supporters, known as a "whip team," to further assess this response. Asking a member from a politician's home state, or from a similar ideological wing of the party, to call the same colleague is a good way to coax out a more frank response. Finally, the candidate enlists someone from Washington's lobbying community to make a call.

"This is where you often get the honest answer—find out what he's saying to his fund-raiser," the senior aide said. "When you get your four bases touched, then you make your count."

But the personal touch is also necessary, and leadership aspirants go to great lengths to track down their wandering colleagues. "I found one member pheasant hunting," recalled Sue Myrick (N.C.), who is running for conference vice chairman. "I found one in Scotland, one in Bermuda."

Of course, some members are not exactly eager to be found. One Republican confessed that while he has already decided to support Rep. Thomas M. Davis III (Va.) in his bid to become chairman of the Republican fund-raising committee, he was in no rush to inform Linder.

"Do I want to tell John Linder that I'm against you, John?" the lawmaker asked. "On the list of things I've got to do today, that's not a high priority."

There are other reasons for avoiding those sorts of conversations. One junior Republican, who asked to remain unidentified, told Linder last week that he would be supporting Davis for the NRCC post. A few days later, the lawmaker's staff called the NRCC to find out when their boss could address the incoming freshman class about how to solidify political support back home.

"We were told by Linder's staff, essentially, [that if] we're not backing Linder, we're not needed at freshman orientation," said the lawmaker's chief of staff.

See HOUSE, A5, Col. 1

The Washington Post

WEDNESDAY, NOVEMBER 18, 1998

FTC to Reaffirm Standards For Dietary Supplement Ads

By DAVID BROWN
Washington Post Staff Writer

The Federal Trade Commission today will formally remind the burgeoning "dietary supplement" industry that it can't advertise a product's health benefits—or even hint it has one—without having good scientific evidence to back up the claim.

Furthermore, advertisements for herbal preparations, vitamins, minerals and over-the-counter hormones can't exaggerate the results of research studies, nor can they rely on shoddy experiments simply because they bear the imprimatur of science, the agency makes clear in a 26-page booklet for marketers.

The FTC regulates the advertising of drugs, supplements and medical devices, while the Food and Drug Administration regulates the labeling of those products. The new guidelines describe in detail the FTC's standards for evaluating supplement ads, but doesn't alter them.

The supplement industry had \$12.8 billion in sales last year. Vitamins and minerals accounted for 50 percent of that figure, and herbal and botanical products about 30 percent. Companies spent about \$180 million advertising supplements in 1997, up 34 percent from the previous year.

"The purpose is to clarify for the industry how to make accurate claims," said Jodie Bernstein, director of FTC's bureau of consumer protection. "The ultimate purpose is to ensure that consumers have complete and accurate information about these products so they can make intelligent choices."

Since 1984, the agency has brought 60 cases against supplement manufacturers for deceptive advertising. Most ended in

"consent decrees" in which companies admitted no wrongdoing but nevertheless agreed to stop doing what the FTC complained about. Subsequent violations of decrees have brought fines, including one for \$2.4 million in 1994.

"We are not tightening our standards, and not relaxing them either," said Michelle K. Rusk, a lawyer at the agency. The warning that a vitamin seller must be prepared to substantiate things said in an ad "is the same standard that applies to any advertiser making a health-related claim, whether it's for a food, a drug or a device," she said.

Annette Dickinson, an official at the Council for Responsible Nutrition, a trade group for supplement makers, said the FTC has made a substantial effort to publicize its standards in recent years. She said some companies have been surprised to learn that claims that even hint a product will benefit a consumer have to be backed up.

In the booklet, the FTC gives an example that shows how strict this standard is. If an advertiser states that 90 percent of cardiologists regularly take a certain vitamin, the company must have "adequate support" not only for that statistic, but for the "implied claim that the product offers some benefit for the heart."

Nonverbal suggestions that a supplement can treat or prevent a disease must be defensible, the agency said. If an ad for an herbal preparation that "boosts the immune system" contains pictures of people coughing and sneezing, there has to be evidence that the substance acts specifically against colds. (Advertisers don't have to cite the evidence in the advertisement, only have it on hand if the FTC comes asking for it.)

Although not regulated like drugs, many dietary supplements are advertised with obvious appeal to their drug-like actions.

A recent issue of the journal *Alternative & Complementary Therapies*, for example, contained an ad for a substance called glucosamine sulfate, accompanied by the statement in large type: "Joints need dietary support, especially for people with osteoarthritis." On its Web site, the manufacturer had the journal abstract of a randomized clinical trial of the substance.

The ad for a substance called BioPectin said the material "may be particularly helpful for inhibiting the spread of defective prostate cells." A call to the manufacturer brought a fax summarizing studies of pectin's effect on metastatic prostate cancer in rats.

Robert
The Washington Post Moore
WEDNESDAY, NOVEMBER 18, 1998 205
4605.

Michelle
Rusk.

Supplements dodge regulation

OUR VIEW And consumers take the risk of unproven, untested products.

When is chicken soup not chicken soup? When there's money to be made by touting a faddish cold remedy among otherwise routine ingredients. Then it's an "herbal supplement," immune from regulation that keeps food safe.

When is margarine not margarine? When it's a hot new product from Europe that promises big profits from a cholesterol-panicked nation. Then it's called a "dietary supplement in food form" and may escape regulation as well.

These word games are among the latest efforts to exploit a hole in consumer protection laws. If a company can avoid calling a product a food or a drug, it can evade rules that bar unsubstantiated claims and unproven products.

The same exception lets makers of the muscle candy creatine peddle their product to teen athletes and body builders even though there's no safety assurance. As USA TODAY reported recently, win-crazed high school coaches are shamelessly recruited as creatine pushers.

In this neverland where no testing for safety or effectiveness is required, the booming diet supplement industry has tripled — from \$4 billion a year in 1990 to \$12 billion now. No wonder big names like McNeil Consumer Products, Lipton, Kellogg and Monsanto are looking for a piece of the action.

Hain, the country's largest natural-foods company, has a whole new line of soups with echinacea, St. John's wort and other allegedly medicinal herbs. McNeil is trying to market a spread laced with a pine tree fiber that supposedly kills cholesterol. In Finland, it sells for six times the price of ordinary margarine, and they can't keep it on the shelves.

Labeled as soups or margarine they'd be subject to the laws protecting the public from untested food additives. And they'd need scientific studies for health claims. An independent study published Thursday, for example, found that echinacea, at least outside chicken soup, apparently has little effect on colds. As "supplements," back-door health claims can be made without proof or safety testing.

Creatine exemplifies what can happen when word of mouth and hucksterism propel such an unregulated product. Thousands of athletes swear by it for strength and endurance. But it's also caused diarrhea, dehydration, muscle cramping and tearing — and been suspected of worse. Effect of long-term use: unknown.

Big names like football's John Elway and baseball's Brady Anderson endorse it. Home run champ Mark McGwire uses it, along with other more controversial supplements. But there's enough concern that at least 21 professional teams tell their players not to use it.

And the industry is notorious for lax controls. A study of ginseng supplements at Rochester Institute of Technology found some contained as much as 50% caffeine. An analysis of 10 St. John's wort products for the *Los Angeles Times* found one was an automatic overdose and three had half the claimed amount.

The last time the federal Food and Drug Administration tried to bring more consumer protection to this world of amateur medication, it lost big-time. The industry and its friends in Congress carved out an even wider exemption for its activities.

Folk-remedy soups, tree-fiber margarine and other products may be OK. But no one knows for sure — or what's coming next. Until Congress escapes industry control, consumers may play Russian roulette at the store.

They pose no risk to health

OPPOSING VIEW And they don't need any more government regulation.

By Michael Q. Ford

As the nation's largest trade association for manufacturers of dietary supplements, we naturally follow news about our industry with great interest. Whether it's the latest issue of the *Journal of the American Medical Association* supporting the effectiveness of certain herbal remedies or a supplement-taking athlete breaking records, our products make headlines. With this attention has come greater scrutiny of dietary supplements resulting in questions about safety and a call for greater regulation. There are two faulty assumptions in this diagnosis: that dietary supplements are unsafe, and that more regulation is the cure.

► First, where is the evidence that supplements are unsafe? The Food and Drug Administration (FDA) has tracked adverse reactions to dietary supplements since 1993 and has a total of approximately 2,500 in its database.

Many of these reports are anecdotal and, by the FDA's admission, there is "no certainty that a reported adverse event can be attributed to a particular product or ingredient." With over 100 million Americans using supplements,

this number is minuscule by comparison.

► Second, does regulation equal safety? According to a study published in April by a leading medical journal, in a single year reactions to prescription medications caused more than 100,000 deaths and 2.2 million injuries. This statistic led USA TODAY to conclude that "too few consumer protections exist" in the way prescription drugs are "marketed, prescribed and monitored." Obviously the rigorous regulation prescription medications undergo has not prevented adverse drug reactions from becoming the fourth leading cause of death in this country.

It is probably not surprising that a trade organization would believe that the agency charged with its regulation — the FDA — does not need greater enforcement power over its members. However, it is also the opinion of Dr. Jane Henney, the recently appointed FDA commissioner. During confirmation hearings, she was quoted as saying the current law "provides adequate statutory authority to protect the public health."

Dietary supplements have been and will continue to be a safe, well-regulated way for consumers to improve and maintain health.

Michael Q. Ford is executive director of the National Nutritional Foods Association.

PATENTS

Policy Shift Opens Door for Medicinal Herbs

By TERESA RIORDAN

Three years ago, the U.S. Patent Office published new guidelines that loosened its standards for granting certain medically related patents.

The biotechnology sector, in particular, had sought such a change, complaining that the Food and Drug Administration should determine whether a potential drug was safe and effective. The Patent Office, it argued, should stick to deciding whether something was novel enough to deserve a patent.

Under old standards for granting so-called utility patents, the Patent Office took a critical view of medicinal claims, often refusing to issue a patent if the applicant could not prove a drug's usefulness. Biotechnology companies contended that without patent protection in the first place, they could not get financing for clinical testing to prove claims.

But biotechnology companies are not the only ones to benefit from the policy shift.

A recent informal database search suggests that herbal entrepreneurs are forging ahead with patent applications that a few years ago the Patent Office would have turned down cold. Five years ago, only a handful of patents appear to have been granted for herbal preparations with medicinal purposes. So far in 1998, at least a dozen such patents have been issued.

"I'm a little bit amazed by some of these," said Colin Sandercock, a partner at the law firm of Foley & Lardner in Washington. "What you're seeing is the Patent Office taking the position that in light of the new guidelines, they are not going to challenge the efficacy of the claimed treatment."

Many of the new patents, Sandercock said, are very limited in scope, and might be easily and legally circumvented should they prove to be popular. "With the keen interest in vitamins and herbal remedies, many people are probably getting patents primarily for a marketing edge," he said.

Here are a few patents granted this year under the new rules:

A New Application for Ancient Herbs

An herbal patent issued last week appears to be rather sweeping in its claims for the use of herbs in treating HIV, leukemia and various forms of hepatitis.

The patent was jointly granted to Shie-Ming Hwang, a chemist in Columbus, Ohio; his cousin Hsiu-Hsien Tsai, a physician in Taiwan, and Pai-Chu Kung, a pharmacist and Tsai's wife.

Tsai, who was trained in Western medicine, became frustrated with poor results when using interferon to treat patients with Hepatitis B, Hwang said. So Tsai turned to traditional Chinese herbal medicine, concocting a powder of 11 herbs that was mixed with water and taken several times a day.

"It's not a formal clinical trial, but it appeared to significantly lower levels of Hepatitis B," Hwang said.

Subsequent laboratory testing suggests that the herbal combination

may help patients with HIV and leukemia. But how is it that the use of these herbs, which have been used for thousands of years in Chinese medicine, can be patented? The answer appears to be that the three inventors have come up with a new use for the ancient herbs.

Hwang, Tsai, and Kung received patent 5,837,257.

Combining Herbs for Weight Loss

St. Johnswort has attracted considerable attention for its reputed success in combating depression. And ephedrine, an herb known for its amphetamine-like qualities, has developed a reputation for accelerating weight loss.

Brian Haveson, of Yardley, Pa., contends that the two herbs, when taken together, act synergistically to suppress appetite and burn calories. A patent he received for a combination of the herbs cites a small, unpublished study as evidence. In that study, a dozen overweight individuals lost eight pounds in six weeks by taking both St. Johnswort and ephedrine twice a day, according to the patent.

Haveson received patent 5,798,101 for his herbal combination.

Herbal Substitute for a Nicotine Patch

Plantago, a weed known as common plantain, has been extolled for centuries for its healing properties. Since the 1920s, this herb has also been reputed to suppress the desire of smokers to reach for a cigarette.

Mary Cody, of Boonton Township, N.J., has invented the herbal answer to the nicotine skin patch: a transdermal version of Plantago. Rather than delivering nicotine slowly to the bloodstream, though, it delivers an extract of the herb.

Ms. Cody received patent 5,716,635.

Giving Chew Toys an Herbal Punch

Cats have appreciated catnip for millennia. But it has never held much allure for dogs. Enter valerian, until now mostly known for its putative sedative power over humans.

Vsande Childers-Zadah, of West Palm Beach, Fla., has patented the use of valerian root in chew toys and food treats for pets. Valerian is irresistible to both dogs and cats, the patent contends.

Childers-Zadah received patent 5,786,382.
END