

Overview of Dietary Supplements

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
January 3, 2001

What is a dietary supplement?

Congress defined the term "dietary supplement" in the Dietary Supplement Health and Education Act (DSHEA) of 1994. A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders. They can also be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet. Whatever their form may be, DSHEA places dietary supplements in a special category under the general umbrella of "foods," not drugs, and requires that every supplement be labeled a dietary supplement. What is a "new dietary ingredient" in a dietary supplement?

The Dietary Supplement Health and Education Act (DSHEA) of 1994 defined both of the terms "dietary ingredient" and "new dietary ingredient" as components of dietary supplements. In order for an ingredient of a dietary supplement to be a "dietary ingredient," it must be one or any combination of the following substances:

- a vitamin,
- a mineral,
- an herb or other botanical,
- an amino acid,
- a dietary substance for use by man to supplement the diet by increasing the total dietary intake (e.g., enzymes or tissues from organs or glands), or
- a concentrate, metabolite, constituent or extract.

A "new dietary ingredient" is one that meets the above definition for a "dietary ingredient" and was not sold in the U.S. in a dietary supplement before October 15, 1994.

What is FDA's role in regulating dietary supplements versus the manufacturer's responsibility for marketing them?

In October 1994, the Dietary Supplement Health and Education Act (DSHEA) was signed into law by President Clinton. Before this time, dietary supplements were subject to the same regulatory requirements as were other foods. This new law, which amended the Federal Food, Drug, and Cosmetic Act, created a new regulatory framework for the safety and labeling of dietary supplements.

Under DSHEA, a firm is responsible for determining that the dietary supplements it manufactures or distributes are safe and that any representations or claims made about them are substantiated by adequate evidence to show that they are not false or misleading. This means that dietary supplements do not need approval from FDA before they are marketed. Except in the case of a

new dietary ingredient, where pre-market review for safety data and other information is required by law, a firm does not have to provide FDA with the evidence it relies on to substantiate safety or effectiveness before or after it markets its products.

Also, manufacturers do not need to register themselves nor their dietary supplement products with FDA before producing or selling them. Currently, there are no FDA regulations that are specific to dietary supplements that establish a minimum standard of practice for manufacturing dietary supplements. However, FDA intends to issue regulations on good manufacturing practices that will focus on practices that ensure the identity, purity, quality, strength and composition of dietary supplements. At present, the manufacturer is responsible for establishing its own manufacturing practice guidelines to ensure that the dietary supplements it produces are safe and contain the ingredients listed on the label.

When must a manufacturer or distributor notify FDA about a dietary supplement it intends to market in the U.S.?

The Dietary Supplement Health and Education Act (DSHEA) requires that a manufacturer or distributor notify FDA if it intends to market a dietary supplement in the U.S. that contains a "new dietary ingredient." The manufacturer (and distributor) must demonstrate to FDA why the ingredient is reasonably expected to be safe for use in a dietary supplement, unless it has been recognized as a food substance and is present in the food supply.

There is no authoritative list of dietary ingredients that were marketed before October 15, 1994. Therefore, manufacturers and distributors are responsible for determining if a dietary ingredient is "new", and if it is not, for documenting that the dietary supplements it sells, containing the dietary ingredient, were marketed before October 15, 1994. For more detailed information on new dietary ingredients, go to: <http://www.cfsan.fda.gov/~dms/ds-ingrd.html>.

What information must the manufacturer disclose on the label of a dietary supplement?

FDA regulations require that certain information appear on dietary supplement labels. Information that must be on a dietary supplement label includes: a descriptive name of the product stating that it is a "supplement;" the name and place of business of the manufacturer, packer, or distributor; a complete list of ingredients; and the net contents of the product.

In addition, each dietary supplement (except for some small volume products or those produced by eligible small businesses) must have nutrition labeling in the form of a "Supplement Facts" panel. This label must identify each dietary ingredient contained in the product.

Must all ingredients be declared on the label of a dietary supplement?

Yes, ingredients not listed on the "Supplement Facts" panel must be listed in the "other ingredient" statement beneath the panel. The types of ingredients listed there could include the source of dietary ingredients, if not identified in the "Supplement Facts" panel (e.g., rose hips as the source of vitamin C), other food ingredients (e.g., water and sugar), and technical additives or processing aids (e.g., gelatin, starch, colors, stabilizers, preservatives, and flavors). For more details, see: <http://www.cfsan.fda.gov/~lrd/fr97923a.html>.

Are dietary supplement serving sizes standardized or are there restrictions on the amount of a nutrient that can be in one serving?

Other than the manufacturer's responsibility to ensure safety, there are no rules that limit a serving size or the amount of a nutrient in any form of dietary supplements. This decision is made by the manufacturer and does not require FDA review or approval.

Where can I get information about a specific dietary supplement?

Manufacturers and distributors do not need FDA approval to sell their dietary supplements. This means that FDA does not keep a list of manufacturers, distributors or the dietary supplement products they sell. If you want more detailed information than the label tells you about a specific product, you may contact the manufacturer of that brand directly. The name and address of the manufacturer or distributor can be found on the label of the dietary supplement.

Who has the responsibility for ensuring that a dietary supplement is safe?

By law (DSHEA), the manufacturer is responsible for ensuring that its dietary supplement products are safe before they are marketed. Unlike drug products that must be proven safe and effective for their intended use before marketing, there are no provisions in the law for FDA to "approve" dietary supplements for safety or effectiveness before they reach the consumer. Also unlike drug products, manufacturers and distributors of dietary supplements are not currently required by law to record, investigate or forward to FDA any reports they receive of injuries or illnesses that may be related to the use of their products. Under DSHEA, once the product 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 or removal from the marketplace.

Do manufacturers or distributors of dietary supplements have to tell FDA or consumers what evidence they have about their product's safety or what evidence they have to back up the claims they are making for them?

No, except for rules described above that govern "new dietary ingredients," there is no provision under any law or regulation that FDA enforces that requires a firm to disclose to FDA or consumers the information they have about the safety or purported benefits of their dietary supplement products. Likewise, there is no prohibition against them making this information available either to FDA or to their customers. It is up to each firm to set its own policy on disclosure of such information. For more information on claims that can be made for dietary supplements, see (<http://www.cfsan.fda.gov/~dms/hclaims.html>).

How can consumers inform themselves about safety and other issues related to dietary supplements?

It is important to be well informed about products before purchasing them. Because it is often difficult to know what information is reliable and what is questionable, consumers may first want to contact the manufacturer about the product they intend to purchase (see previous question "Where can I get information about a specific dietary supplement?"). In addition, to help consumers in their search to be better informed, FDA is providing the following sites: *Tips For The Savvy Supplement User: Making Informed Decisions And Evaluating Information* --

<http://www.cfsan.fda.gov/~dms/ds-savvy.html> (includes information on how to evaluate research findings and health information on-line) and Claims That Can Be Made for Conventional Foods and Dietary Supplements -- <http://www.cfsan.fda.gov/~dms/hclaims.html>, (provides information on what types of claims can be made for dietary supplements).

What is FDA's oversight responsibility for dietary supplements?

Because dietary supplements are under the "umbrella" of foods, FDA's Center for Food Safety and Applied Nutrition (CFSAN) is responsible for the agency's oversight of these products. FDA's efforts to monitor the marketplace for potential *illegal* products (that is, products that may be unsafe or make false or misleading claims) include obtaining information from inspections of dietary supplement manufacturers and distributors, the Internet, consumer and trade complaints, occasional laboratory analyses of selected products, and adverse events associated with the use of supplements that are reported to the agency.

Does FDA routinely analyze the content of dietary supplements?

In that FDA has limited resources to analyze the composition of food products, including dietary supplements, it focuses these resources first on public health emergencies and products that may have caused injury or illness. Enforcement priorities then go to products thought to be unsafe or fraudulent or in violation of the law. The remaining funds are used for routine monitoring of products pulled from store shelves or collected during inspections of manufacturing firms. The agency does not analyze dietary supplements before they are sold to consumers. The manufacturer is responsible for ensuring that the "Supplement Facts" label and ingredient list are accurate, that the dietary ingredients are safe, and that the content matches the amount declared on the label. FDA does not have resources to analyze dietary supplements sent to the agency by consumers who want to know their content. Instead, consumers may contact the manufacturer or a commercial laboratory for an analysis of the content.

Is it legal to market a dietary supplement product as a treatment or cure for a specific disease or condition?

No, a product sold as a dietary supplement and promoted on its label or in labeling* as a treatment, prevention or cure for a specific disease or condition would be considered an unapproved--and thus illegal--drug. To maintain the product's status as a dietary supplement, the label and labeling must be consistent with the provisions in the Dietary Supplement Health and Education Act (DSHEA) of 1994.

*Labeling refers to the label as well as accompanying material that is used by a manufacturer to promote and market a specific product.

Who validates claims and what kinds of claims can be made on dietary supplement labels?

FDA receives many consumer inquiries about the validity of claims for dietary supplements, including product labels, advertisements, media, and printed materials. The responsibility for ensuring the validity of these claims rests with the manufacturer, FDA, and, in the case of advertising, with the Federal Trade Commission.

By law, manufacturers may make three types of claims for their dietary supplement products: health claims, structure/function claims, and nutrient content claims. Some of these claims describe: the link between a food substance and disease or a health-related condition; the intended benefits of using the product; or the amount of a nutrient or dietary substance in a product. Different requirements generally apply to each type of claim, and are described in more detail at the following site: (<http://www.cfsan.fda.gov/~dms/hclaims.html>).

Why do some supplements have wording (a disclaimer) that says: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease"?

This statement or "disclaimer" is required by law (DSHEA) when a manufacturer makes a structure/function claim on a dietary supplement label. In general, these claims describe the role of a nutrient or dietary ingredient intended to affect the structure or function of the body. The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; they are not approved by FDA. For this reason, the law says that if a dietary supplement label includes such a claim, it must state in a "disclaimer" that FDA has not evaluated this claim. The disclaimer must also state that this product is not intended to "diagnose, treat, cure or prevent any disease," because only a drug can legally make such a claim.

How are advertisements for dietary supplements regulated?

The Federal Trade Commission (FTC) regulates advertising, including infomercials, for dietary supplements and most other products sold to consumers. FDA works closely with FTC in this area, but FTC's work is directed by different laws. For more information on FTC, go to: <http://www.ftc.gov/bcp/menu-health.htm>. Advertising and promotional material received in the mail are also regulated under different laws and are subject to regulation by the U.S. Postal Inspection Service.

How do I, my health care provider, or any informed individual report a problem or illness caused by a dietary supplement to FDA?

If you think you have suffered a serious harmful effect or illness from a product FDA regulates, including dietary supplements, the first thing you should do is contact or see your healthcare provider immediately. Then, you and your health care provider are encouraged to report this problem to FDA.

Your health care provider can call FDA's MedWatch hotline at 1-800-FDA-1088, submit a report by fax to 1-800-FDA-0178 or on-line at: <http://www.fda.gov/medwatch/report/hcp.htm>. The MedWatch program provides a way for health care providers to report problems believed to be caused by FDA-regulated products such as drugs, medical devices, medical foods and dietary supplements.

You, or anyone, may report a serious adverse event or illness directly to FDA if you believe it is related to the use of any of the above-mentioned products, by calling FDA at 1-800-FDA-1088, by fax at 1-800-FDA-0178 or reporting on-line at: <http://www.fda.gov/medwatch/report/consumer/consumer.htm>.

FDA would like to know when you think a product caused you a serious problem, even if you are not sure that the product was the cause, or even if you do not visit a doctor or clinic. In addition to communicating with FDA on-line or by phone, you may use the postage-paid MedWatch form available from the FDA Web site.

NOTE: The identity of the reporter and/or patient is kept confidential.

For a general, not serious, complaint or concern about food products, including dietary supplements, you may contact the consumer complaint coordinator at the local FDA District Office nearest you. See the following Web address for the telephone number:

<http://www.fda.gov/opacom/backgrounders/complain.html>.

For more recent information on Dietary Supplements

See <http://www.cfsan.fda.gov/~dms/supplmnt.html>