National Institutes of Health
Office of Dietary Supplements

Background Information: Dietary Supplements

Fact Sheet for Consumers

What is a dietary supplement?

As defined by Congress in the Dietary Supplement Health and Education Act, which became law in 1994, a dietary supplement is a product (other than tobacco) that

- is intended to supplement the diet
- contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and other substances) or their constituents
- is intended to be taken by mouth as a pill, capsule, tablet, or liquid
- is labeled on the front panel as being a dietary supplement

What is a new dietary ingredient?

A new dietary ingredient is a dietary ingredient that was not sold in the United States in a dietary supplement before October 15, 1994. The U.S. Food and Drug Administration (FDA) requires specific safety information (https://www.fda.gov/food/dietary-supplements/new-dietary-ingredients-ndi-notification-process) from a manufacturer intending to market a dietary supplement containing a new dietary ingredient. This information is not required for older dietary supplement ingredients.

Are dietary supplements different from foods and drugs?

Although dietary supplements are regulated by the FDA as foods, they are regulated differently from other foods and from drugs. Whether a product is classified as a dietary supplement, conventional food, or drug is based on its intended use. Most often, classification as a dietary supplement is determined by the information that the manufacturer provides on the product label or in accompanying literature, although many food and dietary supplement product labels do not include this information.

What claims can manufacturers make for dietary supplements and drugs?

The types of claims that can be made on the labels of dietary supplements and drugs differ. Drug manufacturers may claim that their product will diagnose, cure, mitigate, treat, or prevent a disease. Such claims may not legally be made for dietary supplements.

The label of a dietary supplement or food product may contain one of three types of claims (https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements): a health claim, nutrient content claim, or structure/function claim. Health claims describe a relationship between a food, food component, or dietary supplement ingredient and reducing risk of a disease or health-related condition. Nutrient content claims describe the relative amount of a nutrient or dietary substance in a product. A structure/function claim is a statement describing how a product may affect the organs or systems of the body and it cannot mention any specific disease. Structure/function claims do not require FDA approval, but the manufacturer must provide FDA with the text of the claim within 30 days of putting the product on the market. Product labels containing such claims must also include a disclaimer that reads, "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease."

How does FDA regulate dietary supplements?

In addition to regulating label claims, FDA regulates dietary supplements in other ways. Supplement ingredients sold in the United States before October 15, 1994, are not required to be reviewed by FDA for their safety before they are marketed because they are presumed to be safe based on their history of use by humans. For a new dietary ingredient (one not sold as a dietary supplement before 1994) the manufacturer must notify FDA of its intent to market a dietary supplement containing the new dietary ingredient and provide information on how it determined that reasonable evidence exists for safe human use of the product. FDA can either refuse to allow new ingredients into or remove existing ingredients from the marketplace for safety reasons.

Unlike drug products, there are no provisions in the law for FDA to approve dietary supplements for safety or effectiveness before they reach the consumer. Once a dietary supplement is marketed, FDA has to prove that the product is not safe in order to restrict its use or remove it from the market. In contrast, before being allowed to market a drug product, manufacturers must obtain FDA approval by providing convincing evidence that it is both safe and effective.

The label of a dietary supplement product is required to be truthful and not misleading. If the label does not meet this requirement, FDA may remove the product from the marketplace or take other appropriate actions.

What information is required on a dietary supplement label?

FDA requires that certain information appear on the dietary supplement label.

General information

- Name of product (including the word supplement or a statement that the product is a supplement)
- Net quantity of contents
- Name and place of business of manufacturer, packer, or distributor
- Directions for use

Supplement Facts panel

- Serving size, list of dietary ingredients, amount per serving size (by weight), percent of Daily Value (%DV), if established
- If the dietary ingredient is a botanical, the scientific name of the plant or the common or usual name standardized in the reference *Herbs of Commerce* (1992 edition) and the name of the plant part used
- If the dietary ingredient is a proprietary blend (i.e., a blend exclusive to the manufacturer), the total weight of the blend and the components of the blend in order of predominance by weight

Other ingredients

- Nondietary ingredients such as fillers, artificial colors, sweeteners, flavors, or binders listed by weight in descending order of predominance and by common name or proprietary blend

The label of the supplement may contain a cautionary statement but the lack of a cautionary statement does not mean that no adverse effects are associated with the product.

Does a label indicate the quality of a dietary supplement product?

It is difficult to determine the quality of a dietary supplement product from its label. The degree of quality control depends on the manufacturer, the supplier, and others in the production process.

In 2007, FDA issued Good Manufacturing Practices (GMPs) for dietary supplements, a set of requirements and expectations by which dietary supplements must be manufactured, prepared, and stored to ensure quality. Manufacturers are now expected to guarantee the identity, purity, strength, and composition of their dietary supplements. For example, the GMPs aim to prevent the inclusion of the wrong ingredients, the addition of too much or too little of a dietary ingredient, the possibility of contamination (by pesticides, heavy metals such as lead, bacteria, etc.), and the improper packaging and labeling of a product.

Are dietary supplements standardized?

Standardization is a process that manufacturers may use to ensure batch-to-batch consistency of their products. In some cases, standardization involves identifying specific chemicals (known as markers) that can be used to manufacture a consistent product. The standardization process can also provide a measure of quality control.

Dietary supplements are not required to be standardized in the United States. In fact, no legal or regulatory definition exists in the United States for standardization as it applies to dietary supplements. Because of this, the term standardization may mean many different things. Some manufacturers use the term standardization incorrectly to refer to uniform manufacturing practices; following a recipe is not sufficient for a product to be called standardized. Therefore, the presence of the word standardized on a supplement label does not necessarily indicate product quality.

What methods are used to evaluate the health benefits and safety of a dietary supplement?

Dietary supplements are not required by federal law to be tested for safety and effectiveness before they are marketed, so the amount of scientific evidence available for various supplement ingredients varies widely. Some ingredients in dietary supplements have been carefully evaluated. For example, scientists know that calcium and vitamin D are important for keeping bones strong and reducing bone loss. Other supplements, such as many herbal products, need more study to determine their value.

Scientists can use several approaches to evaluate dietary supplements for their potential health benefits and risks. They may investigate history of use, conduct laboratory studies using cell or tissue cultures, and experiment with animals. Studies on people (for example, individual case reports, observational studies, and clinical trials) provide the most direct evidence of a dietary supplement's effects on health and patterns of use.

What are some additional sources of information on dietary supplements?

Medical libraries are one source of information about dietary supplements. Others include web-based resources such as PubMed and FDA (http://www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm109760.htm). For general information on botanicals and their use as dietary supplements please see Background Information About Botanical Dietary Supplements.

Disclaimer

This fact sheet by the National Institutes of Health (NIH) Office of Dietary Supplements (ODS) provides information that should not take the place of medical advice. We encourage you to talk to your health care providers (doctor, registered dietitian, pharmacist, etc.) about your interest in, questions about, or use of dietary supplements and what may be best for your overall health. Any mention in this publication of a specific product or service, or recommendation from an organization or professional society, does not represent an endorsement by ODS of that product, service, or expert advice.

Glossary

adverse effect
: An unwanted side effect.

amino acid
: A chemical building block of protein.

association
: A relationship between two conditions or states such that if one is present, the other is likely to be present as well. An association between two conditions or states, however, does not necessarily imply a cause and effect relationship. The terms association and relationship are often used interchangeably.

bacteria
: Single-celled organisms that are too small to be seen without a microscope. Bacteria are found everywhere and may be helpful or harmful.

binder
: An inactive ingredient (one that has no medicinal effect on the body, such as starch, salt, or sugar) used to hold together the contents of a pill or tablet.

botanical
: Having to do with plants or plant parts, or dietary supplement products made from plants.

calcium
: A mineral found throughout the body. Calcium is needed for healthy bones and teeth, for nerves and enzymes to function properly, and for blood clotting. Calcium is found in some foods, including milk, yogurt, and cheese, and in Chinese cabbage, kale, broccoli and fortified foods, such as many drinks, tofu, and cereals.

capsule
: A gelatin shell containing a dose of medicine, a vitamin, or other dietary supplement.

case report
: A detailed record of the diagnosis, treatment, and follow-up of an individual patient. Case reports also contain some information about the patient (such as age, gender, and ethnic origin).

cell
: The individual unit that makes up the tissues of the body. All living things are made up of one or more cells, which are the smallest units of living structure capable of independent existence.

clinical trial
: A type of research study that uses volunteers to test the safety and efficacy (the ability to produce a beneficial effect) of new methods of screening (checking for disease when there are no symptoms), prevention, diagnosis, or treatment of a disease. Also called a clinical study.

constituent

A component, part, or ingredient of a larger whole. For example, valerenic acid and valepotriate are constituents of the dietary supplement valerian.

control

In a clinical trial, the group of participants that does not receive the new treatment being studied. This group is compared with the group receiving the new treatment, to see whether the new treatment works. In an observational study, the controls are participants who do not have a particular health condition; the control group is compared with the group of participants who do have the condition to see if certain factors (such as diet, activity level, or use of dietary supplements) may be associated with developing or preventing the condition.

conventional food

Edible substances, excluding organic food, genetically modified food, functional food, and dietary supplements.

cure

To heal or restore health; a treatment to restore health.

Daily Value

DV. A term used on a food or dietary supplement label that tells you how much of a particular nutrient (such as calcium) one serving of the food or supplement provides. DVs are given as percentages and help you compare one product with another. For example, a food that lists 40% DV for calcium would provide much more calcium than another food that lists 10% DV for calcium. For each nutrient, there is one DV for all people aged 4 years and older. DVs are established by the U.S. Food and Drug Administration.

diagnose

The process of using signs and symptoms to identify a disease.

dietary supplement

A product that is intended to supplement the diet. A dietary supplement contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and other substances) or their components; is intended to be taken by mouth as a pill, capsule, tablet, or liquid; and is identified on the front label of the product as being a dietary supplement.

drug

Any substance (other than food) that is used to prevent, diagnose, treat, or relieve symptoms of a disease or abnormal condition. Also, a substance that alters mood or body function or that can be habit-forming or addictive, especially a narcotic.

effectiveness

In medicine, the ability of an intervention (for example, a drug, surgery, or a dietary supplement) to produce the desired beneficial effect under the usual conditions of care by a health care provider.

evidence

Information used to support the use of a particular screening procedure, treatment, or preventive measure. In medicine, evidence needed to determine effectiveness is provided by laboratory research, clinical trials, and other studies.

filler

An inactive ingredient (one that has no medicinal effect on the body, such as lactose or starch) that is used to provide consistency and uniformity in the size and weight of a pill or tablet.

Food and Drug Administration

FDA, Department of Health and Human Services. FDA is the Federal government agency responsible for ensuring that foods and dietary supplements are safe, wholesome and sanitary, and that drugs, medical devices, cosmetics, and food are honestly, accurately

and informatively represented to the public. FDA regulates dietary supplements under a different set of regulations than those covering conventional foods and drug products (prescription and over-the-counter). The dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to get FDA approval before producing or selling dietary supplements.

health claim

A statement on a food or dietary supplement product label that describes a relationship between a food, food component, or dietary supplement ingredient and the reduction in risk of developing a disease or health-related condition. For example: "Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect."

herb

A plant used in cooking, in tea, and for medicinal purposes.

herbal

Having to do with or made from medicinal or edible plants.

ingredient

In a dietary supplement, an ingredient is a component of the product, such as the main nutrient (vitamin, mineral, herb, amino acid, or enzyme) or any binder, color, filler flavor, or sweetener. In herbal supplements, the common name and Latin name (the genus and species) of the plant is given in the ingredient list. On a dietary supplement label, the ingredients are listed by weight, with the ingredient used in the largest amount first on the list and the ingredient used in the least amount at the end of the list.

label

When referring to dietary supplements, information that appears on the product container, including 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 each dietary ingredient contained in the product. Supplements must also include directions for use, nutrition labeling in the form of a Supplement Facts panel that identifies each dietary ingredient contained in the product and the serving size, amount, and active ingredients.

laboratory study

Research done in a laboratory. A laboratory study may use cells in test tubes or animals to find out if a drug, procedure, or other treatment is likely to be safe and useful. Laboratory studies usually take place before any testing is done in humans.

medical history

Information about a person’s health, such as allergies, illnesses, surgeries, medications, immunizations, and the results of tests and physical exams. It may also include information about health habits, such as diet and exercise, and health information about current and past illnesses of one’s parents and other close family members.

mineral

In nutrition, an inorganic substance found in the earth that is required to maintain health.

mitigate

To make milder or less painful.

nutrient

A chemical compound in food that is used by the body to function and maintain health. Examples of nutrients include proteins, fats, carbohydrates, vitamins, and minerals.

nutrient content claim

A statement on a food or dietary supplement product label that describes the amount of a

nutrient or dietary substance in a product. Examples of nutrient claims for dietary supplement products include fortified, high, rich in, excellent source of, good source of, and high potency.

prevent
: To stop from happening.

proprietary
: A product or technique that is developed and owned by a company or individual, cannot be used by others without approval, and may be protected by patent or copyright.

quality control
: A system to ensure that consistency and uniformity are maintained in the manufacturing of a product.

regulate
: To govern, make uniform, and bring under the control of a rule, principle, or legal system. In the United States, the FDA has the authority to regulate dietary supplements.

risk
: The chance or probability that a harmful event will occur. In health, for example, the chance that someone will develop a disease or condition.

standardization
: A process manufacturers may use to ensure batch-to-batch consistency of their products and to provide a measure of quality control. Dietary supplements are not required to be standardized in the United States. Some manufacturers use the term incorrectly or to mean different things and the presence of the word "standardized" on a supplement label does not necessarily indicate a level of product quality.

structure/function claim
: A statement on a food or dietary supplement label that describes how a product may affect the organs or systems of the body; a specific disease cannot be mentioned. Structure/function claims do not require FDA approval, but the manufacturer must provide the FDA with the text of the claim within 30 days of putting the product on the market. Labels must also include a disclaimer that reads, "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease." For example: "Calcium builds strong bones."

supplement
: A nutrient that may be added to the diet to increase the intake of that nutrient. Sometimes used to mean dietary supplement.

tissue
: A group or layer of cells in a living organism that work together to perform a specific function.

treat
: To care for a patient with a disease by using medicine, surgery, or other approaches.

uniformity
: The quality of being consistently the same and not varying or fluctuating in color, size, weight, composition, or any other physical feature.

vitamin
: A nutrient that the body needs in small amounts to function and maintain health. Examples are vitamins A, C, and E.

vitamin D
: A nutrient that is obtained from the diet and can be made in the skin after exposure to sunlight. Vitamin D acts as a hormone. It helps to form and maintain strong bones, maintain normal blood levels of calcium and phosphorus, and increase calcium absorption; it also helps to maintain a healthy immune system and control cell growth.

Vitamin D is found in some foods, including some types of fatty fish, and milk and breakfast cereals that are fortified with vitamin D.

Updated: March 11, 2020 History of changes to this fact sheet