Is It Really FDA Approved?

✓ Does Approve
✗ Does Not Approve

"FDA approved": Maybe you saw the words on a company's Web site or in a commercial promoting a new product or treatment. Some marketers may say their products are "FDA approved," but how can you know for sure?

An FDA Web page serves as a gateway to information about approvals of FDA-regulated products: *www.fda.gov/opacom/7approvl.html*

You can search for FDA approval information by product type.

FDA is responsible for protecting the public health by regulating human and animal drugs, biologics (e.g. vaccines and cellular and gene therapies), medical devices, food and animal feed, cosmetics, and products that emit radiation.

But not all of these products undergo premarket approval—a review of safety and effectiveness by FDA experts and agency approval *before* a product can be marketed. In some cases, FDA's enforcement efforts focus on products after they are already on the market. This is determined by law.

The following facts can shed light on when the term "FDA approved" is appropriate after such a determination is made by the agency.

✗ FDA does not approve companies.

FDA does not "approve" health care facilities, laboratories, or manufacturers. FDA does inspect product manufacturers to verify that they comply with good manufacturing practices.

Owners and operators of domestic or foreign food, drug, and most device facilities are required to register with FDA. Blood and tissue facilities also must register with the agency.

Mammography facilities must be FDA certified. Mammography facilities are required to display their FDA certificates where patients can see them. The certificate indicates that the facilities have met stringent standards and can provide quality mammography.

✓ FDA approves new drugs and biologics.

New drugs and biologics must be proven safe and effective to FDA's satisfaction before companies can market them. FDA does not develop or test products; FDA experts review the results of laboratory, animal, and human clinical testing done by manufacturers.

If FDA grants an approval, it means the agency has determined that the benefits of the product outweigh the risks for the intended use.

✓ ✗ FDA uses a risk-based, tiered approach for regulating medical devices.

FDA classifies devices according to risk. Only the highest-risk devices, such as mechanical heart valves and implantable infusion pumps, require FDA approval before marketing. To receive FDA approval for these devices, the manufacturer must demonstrate that its devices provide a reasonable assurance of safety and effectiveness.

Moderate-risk medical devices (e.g., dialysis equipment and many types of catheters) are cleared for marketing based on an FDA determination that they are substantially equivalent to an already legally marketed device of the same type.

FDA has exempted certain low-risk medical devices (e.g., certain bandages) from premarket review when they are for the same use and of the same technology.

✓ FDA approves additives in food for people.

FDA field investigators inspect food companies, examine food shipments from abroad, and collect samples. Laboratory scientists analyze samples. Compliance officers recommend legal action and follow through on enforcement issues. What undergoes premarket approval? New food additives and color additives must be approved before they can be used in foods. These additives are considered food under the law.

New food additives, including substances added intentionally to food and substances that may migrate to food because they contact food (e.g., food packaging) must be shown to be safe to FDA's satisfaction before companies can market them.

Companies that want to add new additives to food bear the responsibility of providing FDA with information demonstrating that the additives are safe. FDA experts review the results of appropriate tests done by companies to ensure that the additive is safe for its intended use.

An approved food additive must be used in compliance with its approved uses, specifications, and restrictions. Certain food ingredients, such as those with a long history of safe use in food, do not require premarket approval.

✓ FDA approves drugs and additives in food for animals.

FDA is responsible for approving drugs and food additives given to, or used on, over one hundred million pets, plus millions of poultry, cattle, swine, and minor animal species. (Minor animal species include animals other than cattle, swine, chickens, turkeys, horses, dogs, and cats.)

FDA does not approve pet food, but rather approves the food additives that are used in pet food. FDA has the authority to take action against pet food products that are in violation of the law.

✓ FDA approves color additives used in FDA-regulated products.

This includes those used in food, dietary supplements, drugs, cosmetics, and some medical devices. These color additives (except coal-tar hair dyes) are subject by law to approval by the agency, and each must be used only in compliance with its approved uses, specifications, and restrictions.

In the approval process, FDA evaluates safety data to ensure that a color additive is safe for its intended purposes.

✗ FDA does not approve cosmetics.

Examples of cosmetics are perfumes, makeup, moisturizers, shampoos, hair dyes, face and body cleansers, and shaving preparations.

Cosmetic products and ingredients do not require FDA approval before they go on the market, with one exception: color additives (other than coal tar hair dyes.) Cosmetics must be safe for their intended use and properly labeled.

FDA field investigators inspect cosmetic companies, examine imports, and collect samples for analysis. FDA may take action against non-compliant products, or against firms or individuals who violate the law.

✗ FDA does not approve medical foods.

A medical food is used for the dietary management of a disease or health condition that requires special nutrient needs. An example of a medical food is a food for use by persons with phenylketonuria, a genetic disorder.

FDA does not approve individual food labels before food products can be marketed. But FDA regulations require nutrition information to appear on most foods, including dietary supplements.

A person with this disorder may need medical foods that are formulated to be free of the amino acid phenylalanine. A medical food is intended for use under the supervision of a physician.

Medical foods do not have to undergo premarket approval by FDA. But medical food firms must comply with other requirements, such as good manufacturing practices and registration of food facilities. Medical foods do not have to include nutrition information on their labels, and any claims in their labeling must be truthful and non-misleading.

✗ FDA does not approve infant formula.

FDA does not approve infant formulas before they can be marketed. However, manufacturers of infant formula are subject to FDA's regulatory oversight.

Manufacturers must ensure that infant formula complies with federal nutrient requirements. Manufacturers are required to register with FDA and provide the agency with a notification before marketing a new formula.

✗ FDA does not approve dietary supplements.

Unlike new drugs, dietary supplements are not reviewed and approved by FDA based on their safety and effectiveness. Most dietary supplements that contain a new dietary ingredient (a dietary ingredient not marketed in the United States before October 15, 1994) require a notification to FDA 75 days before marketing.

The notification must include the information that was the manufacturer or distributor's basis for concluding that the dietary supplement will reasonably be expected to be safe. After dietary supplements are on the market, FDA evaluates their safety through research and adverse event monitoring.

✗ FDA does not approve the food label, including Nutrition Facts.

FDA does not approve individual food labels before food products can be marketed. But FDA regulations require nutrition information to appear on most foods, including dietary supplements. Also, any claims on food products must be truthful and non-misleading, and must comply with any special requirements for the type of claim.

Manufacturers are required to provide the serving size of the food and information about the nutrient content of each serving on the "Nutrition Facts" panel of the food label (or on the "Supplement Facts" panel for dietary supplements.)

✗ FDA does not approve structure-function claims on dietary supplements and other foods.

Structure-function claims describe the role of a food or food component (such as a nutrient) that is intended to affect the structure or function of the human body. One example is "calcium builds strong bones."

Dietary supplement firms that make structure-function claims on labels or in labeling must submit a notification to FDA. This notification must be submitted no later than 30 days after marketing the dietary supplement with the structure/function claim. Additionally, the notification must include the text of the claim, as well as other information, such as the name and address of the notifier. FDA does not require conventional food manufacturers to notify FDA about their structure-function claims.

Structure-function claims on dietary supplements carry a disclaimer stating that the claim has not been reviewed by FDA, and that the product is not intended to diagnose, treat, cure, or prevent any disease. Conventional foods are not required to carry such a disclaimer.

Misuse of FDA's logo may violate federal law.

FDA's logo should not be used to misrepresent the agency nor to suggest that FDA endorses any private organization, product, or service.

This article appears on FDA's Consumer Health Information Web page (*www.fda.gov/consumer*), which features the latest updates on FDA-regulated products. Sign up for free e-mail subscriptions at *www.fda.gov/consumer/consumerenews.html*.

For More Information

Protect Your Health
Joint FDA/WebMD resource
www.webmd.com/fda

Approvals of FDA Regulated Products
www.fda.gov/opacom/7approvl.html