

About health claims for drugs and dietary supplements

This fact sheet was developed by the Alzheimer's Association Clinical Issues and Interventions Work Group, a team of consulting physicians and specialists. The content is provided for your information only and does not represent an endorsement of any product by the Alzheimer's Association.

Products that claim to offer various kinds of health benefits include prescription drugs, nonprescription drugs sold “over the counter” (OTC), and dietary supplements (also called “nutraceuticals”). The U.S. Food and Drug Administration (FDA) regulates these products under two different legal frameworks: (1) prescription and nonprescription medicines are regulated as drugs and (2) dietary supplements are considered a special class of foods. This fact sheet provides information to help people with dementia and their families understand these different regulations and learn how to evaluate health-related claims of products marketed to treat Alzheimer's disease and related disorders.

How does the FDA regulate prescription drugs?

The FDA regulates prescription medications through a rigorous review and approval process designed to ensure their safety and effectiveness. The FDA must approve any substance marketed as a drug in the United States, and only FDA-approved drugs can claim to treat, cure, or prevent disease. In order to win approval, a manufacturer must demonstrate that a product is safe as well as effective for the condition that it claims to benefit. This process involves extensive preliminary research and a three-phase series of progressively larger clinical trials in human participants. Phase I trials, which typically enroll small numbers of healthy volunteers, are designed to provide preliminary evidence of safety. Drugs that fail to meet acceptable safety standards are not permitted to advance to Phase II and Phase III trials—larger studies designed to test effectiveness.

Many Phase II and III trials compare the effectiveness of a drug to a placebo—an inactive treatment designed to be indistinguishable from the experimental drug. The placebo

and drug are each given to a portion of the people enrolled in the trial, with neither researchers nor participants knowing who is receiving either preparation. Use of a placebo helps investigators distinguish the true medicinal effects of a drug from beneficial effects that may occur due to participants' expectations that a drug will help them.

Results of Phase II and Phase III clinical trials help determine if the investigational treatment is (1) more effective than not receiving any treatment or (2) more effective than the current standard treatment. The FDA usually requires at least two large, scientifically convincing Phase III studies demonstrating effectiveness before granting approval. In addition to reviewing data confirming effectiveness, the FDA closely monitors the production of drugs to ensure purity, potency, and consistency of dosage.

Drugs are tested and approved for specific symptoms or conditions, and manufacturers are allowed to label and market drugs only for these approved purposes. For example, all drugs currently marketed specifically to treat Alzheimer symptoms are approved for particular stages. The manufacturers cannot market the drugs for other stages of the disease or to treat other types of dementia.

However, once a medication has been approved for a specific purpose, licensed physicians may use their clinical judgment to prescribe the drug for other symptoms or illnesses. For example, some doctors may prescribe drugs approved for mild to moderate Alzheimer's for later stages or for other dementias, even though these medications have not, in most cases, been formally tested for these uses. Because unapproved uses are not mentioned in the drug's labeling, this practice is called “off-label” prescribing. Insurance plans with drug benefits may refuse to cover medications prescribed off-label.

How does the FDA regulate nonprescription drugs?

Many medications, including painkillers, cold remedies, and sleep aids, are available “over the counter” (OTC) without a doctor’s prescription. New drugs developed for sale OTC as well as new uses for currently marketed OTCs are reviewed and approved by the FDA under the same standards governing prescription drugs. Some prescription drugs may also be approved for OTC marketing. One example is ibuprofen, now marketed OTC under such brand names as Motrin® and Advil®. Drugs that were historically available without prescription before the FDA gained regulatory authority over these products were subjected to a comprehensive review process beginning in 1972. The FDA has completed final review and determined approved uses for almost all OTC drugs now marketed. Consumers should always read labels carefully and make their physicians aware of any OTCs they may be taking. Some OTCs can interact with other OTCs or with prescription drugs, including approved Alzheimer medications.

How does the FDA regulate dietary supplements (nutraceuticals)?

Dietary supplements include such preparations as vitamins, minerals, herbal products, amino acids and enzymes. The FDA’s current authority to regulate these products is spelled out in the Dietary Supplement Health and Education Act (DSHEA) of 1994, which establishes supplements as a special category of foods. Under DSHEA, a company is responsible for ensuring that any supplements it manufactures are safe and that any claims that it makes about their health effects are supported by “adequate evidence.” However, the FDA has no authority to review these claims or the evidence that they are based on, and the products are not approved by the agency.

Because supplements are not FDA approved and are not considered drugs, they may not claim to treat, cure or prevent any disease or condition. However, nutraceuticals are permitted to claim that they have beneficial effects on “structures” or “functions” of the body. The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims. For example, a manufacturer may claim, based on “adequate evidence,” that a product “enhances the

function of the brain in older individuals” but not that it “prevents Alzheimer’s disease.” If a supplement features a statement about structure or function benefits, the label must also include a disclaimer alerting consumers that the FDA has not evaluated this claim.

Although the FDA tries to enforce these standards within the limits of the agency’s resources and regulatory authority, there are important cautions to keep in mind when evaluating claims about vitamins, herbal preparations and other nutraceuticals:

- Effectiveness and safety are unknown. A company is not required to provide the FDA with the evidence on which it bases its claims for safety and effectiveness.
- Purity is unknown. The FDA has no authority over supplement production. It is a manufacturer’s responsibility to develop and enforce its own guidelines for ensuring that its products are safe and contain the ingredients listed on the label in the specified amounts.
- Bad reactions are not routinely monitored. Manufacturers are not required to report to the FDA any problems that consumers experience after taking their products. The agency does provide voluntary reporting channels for manufacturers, health care professionals, and consumers, and will issue warnings about products when there is cause for concern. To file a report, consumers and health care professionals can call the FDA’s MedWatch hotline at 1.800.332.1088.
- The FDA has no jurisdiction over advertising. This responsibility lies with the Federal Trade Commission (FTC).

How will federal agencies meet the challenge of growing consumer interest in nontraditional therapies?

In their quest for relief from disease and discomfort, people spend billions of dollars annually on dietary supplements and other nontraditional treatments. In an effort to create a rigorous framework for evaluating the effectiveness of nontraditional therapies, the U.S. government has created the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health. NCCAM’s mandate is to investigate selected nutraceuticals and other treatments according to the same

rigorous process used to establish the safety and effectiveness of drugs. These investigations will provide scientific data that will offer consumers a basis for making intelligent assessments of the value of these treatments.

Where can I get more information?

For more information about the importance of placebos in clinical research, see Tamar Nordenberg's article "The Healing Power of Placebos" in the January–February 2000 issue of *FDA Consumer*, also available online at http://www.fda.gov/fdac/features/2000/100_heal.html.

For more information about dietary supplements, a Web site hosted by the FDA Center for Food Safety and Applied Nutrition provides an overview of the regulatory framework governing supplements and answers to frequently asked questions at: <http://vm.cfsan.fda.gov/~dms/supplmnt.html>.

Another site hosted by the FDA Center for Food Safety and Applied Nutrition discusses the health claims that manufacturers can make about conventional foods and dietary supplements at: <http://www.cfsan.fda.gov/~dms/hclaims.html>.

The Web site of the National Center for Complementary and Alternative Medicine at the U.S. National Institutes of Health is at: <http://nccam.nih.gov/>.

The Alzheimer's Association is fighting on your behalf to give everyone a reason to hope. For more information about Alzheimer research, treatment and care, please contact the Alzheimer's Association.

Contact Center **1.800.272.3900**
TDD Access **1.312.335.8882**
Web site **www.alz.org**
e-mail **info@alz.org**
Fact sheet updated **October 13, 2004**