

Medical Foods

As the leading voluntary health organization in Alzheimer care, support and research, the Alzheimer's Association takes seriously its role of communicating to the public information about new treatments for Alzheimer's disease.

Five drugs for Alzheimer's have been approved by the U.S. Food and Drug Administration (FDA). To obtain FDA approval, a drug must undergo the agency's rigorous, multi-year, multi-phase evaluation process, which ensures its safety and effectiveness. As an added measure, the FDA oversees how approved drugs are manufactured to ensure purity. When a drug is approved by the FDA, the Association can state with confidence that the drug has met standards of safety and effectiveness.

The Association is aware of several products containing dietary supplements or agents naturally produced by the body that claim to beneficially affect Alzheimer's. These products, as well as associated claims, have not been reviewed by the FDA. The manufacturers of some of these products intend to market them as "medical foods." This is a subject of concern as the Association strives to fulfill its mission of providing the public with scientifically accurate information about treatments for Alzheimer's.

A medical food is defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

Federal regulation 21CFR101.9(j)(8) requires that a product meet all of the following criteria to be considered a medical food.

1. It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube.
2. It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone. The product label specifies that the product is for the dietary management of a medical disorder, disease or condition.
3. It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation.
4. It is intended to be used under medical supervision, and is labeled as such.
5. It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

Labels for medical foods cannot make drug claims or state that the product alleviates symptoms because medical foods are not drugs. Such claims can be grounds for possible enforcement action.

In contrast to FDA-approved drugs, no pre-market review process exists for medical foods. Instead, they are regulated after they have become available to consumers. However, new products do not always come to the attention of the FDA.

The FDA has established a compliance program for medical foods. The objectives of this program are to obtain information on manufacturing processes and quality assurance and to collect samples for nutritional analysis and analysis for microbes such as *Salmonella* and *Staphylococcus*. If violations are found, the FDA can take action.

Historically, medical foods have developed to address the needs of individuals with inherited errors of metabolism, such as phenylketonuria (PKU), in which an individual is born with low levels of an enzyme necessary to convert a particular type of amino acid into another type of amino acid after protein has been consumed. PKU and other errors of metabolism are quite rare.

Because medical foods do not undergo premarket FDA review, the Association cannot be assured that data supporting their effectiveness (if such data exist) have undergone scientific scrutiny. In light of the lack of rigorous scientific data to substantiate the use of medical foods, the effectiveness of medical foods is difficult for the Association to assess. Unlike PKU, no clear role for medical foods exists at this time for Alzheimer's disease, as Alzheimer's does not have "distinctive nutritional requirements, based on recognized scientific principles." Current evidence does not document the efficacy of a medical food that substitutes for or supplements a balanced diet. The Association encourages a healthy diet rich in nutrients, as well as physical, social and mental activity, as steps to support brain health.

Much is unknown about the effects of medical foods, both when taken alone and in combination with drugs. Whether medical foods will interact with and possibly decrease the effectiveness of drugs taken for Alzheimer's and other conditions is not known, although makers of medical foods may claim that they can be used with drugs prescribed by one's physician.

The Association recognizes the growing market presence of medical foods and will continue to monitor new products that make Alzheimer claims. The Association will also continue to monitor advances in Alzheimer science, including advances relating to nutrition and Alzheimer's that may cause the scientific community to revisit the notion of a medical food for Alzheimer's.

Companies researching or selling medical foods are allowed to exhibit or advertise at Association scientific meetings (for example, ICAD) and in the Association journal as corporate entities. They are not, however, allowed to exhibit, promote or dispense products. Companies whose sole product is a medical food or who have a common product and corporate name are not allowed to present or advertise.

To best serve individuals with Alzheimer's disease and their families, the Alzheimer's Association strongly encourages makers of medical foods that claim to affect Alzheimer's to conduct definitive clinical trials that will establish their products' effectiveness. Until then, consumers should become familiar with their individual insurance plans to determine whether coverage for medical foods is included. Because medical foods are not drugs, insurance coverage may vary considerably. A decision to purchase products that may not be effective and may not be covered by insurance should be made carefully.

— Adopted by the Alzheimer's Association Medical and Scientific Advisory Council, March 2009