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## Dietary Supplements

There is a growing body of evidence that suggests eating a healthy diet may contribute to decreasing one's risk for cognitive decline and dementia. However, there isn't a single food, ingredient or supplement that - through rigorous scientific research - has been shown to prevent, treat or cure Alzheimer's or other dementia. The Alzheimer's Association is aware of a variety of products (including foods and supplements) that claim to be beneficial for people with Alzheimer's. These claims are misleading for several reasons:

- In contrast to “conventional” food and drug products, [dietary supplements](#) are not subject to the Food and Drug Administration's (FDA) rigorous review and regulation process. Because of the [lack of FDA review before the products are marketed](#), the Alzheimer's Association, the medical community and consumers cannot be assured that data (if any) supporting the products' safety and effectiveness have undergone scientific scrutiny. Without, for example, large-scale, controlled clinical testing, it is impossible to make any statements about how well supplements deliver the nutrients they claim to, much less any therapeutic effectiveness perceived or claimed. Conclusions or claims related to the safety and effectiveness remain speculative until randomized, controlled clinical trials are carried out.
- In addition, the [FDA does not currently oversee](#) how dietary supplements are manufactured. It is up to each manufacturer and distributor of dietary supplements to meet all safety and labeling requirements of the Dietary Supplement Health and Education Act of 1994 (DSHEA) and the FDA. Most in the industry act responsibly, but some adulterated or misbranded products have made it to market. Therefore, people with Alzheimer's and their families have no absolute guarantee that supplements contain the ingredients listed on the label in the specified amounts.
- Further, the lack of rigorous research for these products means little (or nothing) is known about the effects, both when taken alone or in combination with approved drugs. For example, often we do not know whether the products will interact with - and possibly decrease - the effectiveness of approved drugs taken for Alzheimer's and other dementia. In fact, there are many known cases in which dietary supplements *do* interact with legitimate, much needed medications, making this a very real concern.

The Alzheimer's Association welcomes [action by the FDA](#) in sending warning letters to companies that are illegally selling dietary supplements that claim to prevent, treat or cure Alzheimer's. To best serve individuals with Alzheimer's and their families, the Alzheimer's Association strongly encourages makers of products that claim to be beneficial for those with Alzheimer's or other dementia to conduct definitive clinical trials.

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## Medical Foods

In the United States, a product can only be considered a medical food if it is designed to treat a condition that has a “distinctive nutritional requirement.” According to the FDA, Alzheimer’s dementia, as currently understood, does not have distinctive nutritional requirements, and therefore, in the United States, no product can legitimately be described as a [medical food for Alzheimer’s](#).

Other countries have different definitions of the term *medical foods*, and products are available for sale as medical foods for Alzheimer’s in several countries. While research on these products may have been conducted in the style of early phase FDA clinical trials, none of these products have been proven to address “nutritional requirements” of people with Alzheimer’s nor to safely or effectively treat the disease.

The Alzheimer’s Association will continue to monitor products that make Alzheimer’s-related claims. The Association will also continue to monitor advances in Alzheimer’s science, including advances relating to nutrition and Alzheimer’s, that may cause the scientific and/or regulatory community to revisit the notion of a dietary supplement or medical food for Alzheimer’s or other dementia.

It’s important that individuals with Alzheimer’s or other dementia, and their caregivers, have conversations with their physicians about all medications, any dietary concerns, and dietary supplements they are taking. This enables the doctor to provide the best advice possible regarding nutrition, and to consider how [dietary supplements may interact with one’s medications](#) and evaluate their potential to cause any unintended side effects.

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