

Medical Foods

According to the U.S. Food and Drug Administration (FDA), Alzheimer's disease does not have "distinctive nutritional requirements" as currently understood, and therefore, in the U.S., 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 effectively treat the disease.

MEDICAL FOODS, DIETARY SUPPLEMENTS AND "NUTRACEUTICALS"

The Alzheimer's Association is aware of several non-drug products that claim to be beneficial for people with Alzheimer's disease. These include dietary supplements, so-called "nutraceuticals," and products that claim to be medical foods for Alzheimer's. These products concern the Association for several reasons:

- In contrast to approved drugs, the products have not undergone the FDA's rigorous review. Because of the lack of FDA review before the products are marketed, the Alzheimer's Association cannot be assured that data (if any) supporting the products' safety and effectiveness have undergone scientific scrutiny. Their effectiveness is, therefore, difficult for the Association to assess.
- In addition, the FDA does not oversee how they are manufactured. Thus, people with Alzheimer's and their families have no guarantee that they 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 of products marketed as dietary supplements, nutraceuticals or medical foods for Alzheimer's, 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 conditions.

To best serve individuals with Alzheimer's disease and their families, the Alzheimer's Association strongly encourages makers of products that claim to be beneficial for those with Alzheimer's to conduct definitive clinical trials that will establish their products' effectiveness.

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.

Note: The U.S. FDA does not have a regulatory definition for "nutraceutical" and doesn't recognize them as a legitimate category of products. Rather, they are dietary supplements that often make general or specific health claims that have not been approved by the FDA.

- **FOR MORE INFORMATION**

For information on treatments for Alzheimer's disease and other dementias, visit the Alzheimer's Association website:

http://www.alz.org/research/science/alzheimers_treatment_horizon.asp

- To learn about Alzheimer's and dementia clinical trials and to use Alzheimer's Association TrialMatch, visit:

http://www.alz.org/research/clinical_trials/find_clinical_trials_trialmatch.aspx

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