

# Pharmaceutical Applications of Nutraceuticals and its Dietary Supplements

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## Perspective

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### Regulation

**Canada:** A nutraceutical can be marketed as either a food or a drug under Canadian law; the terms "nutraceutical" and "functional food" have no legal distinction, referring to "a product isolated or purified from foods that is generally

### ABOUT THE STUDY

A nutraceutical is a pharmaceutical alternative that purports to provide physiological benefits. Nutraceuticals are largely unregulated in the United States because they are classified by the Food and Drug Administration (FDA) as dietary supplements and food additives under the authority of the Federal Food, Drug, and Cosmetic Act. Because nutraceuticals are unregulated, they are sold based on marketing hype rather than actual clinical evidence. There is no compelling evidence that nutraceuticals are effective.

sold in medicinal forms not usually associated with food is demonstrated to have a physiological benefit or provide protection against chronic disease."

**USA:** The term "nutraceutical" is not defined by law in the United States. A product is classified as a drug, dietary supplement, food ingredient, or food based on its ingredients and marketing claims.

**Other sources:** There are significant product quality issues on the global market. Although international nutraceuticals may claim to use organic or exotic ingredients, a lack of regulation may jeopardize product safety and effectiveness. Companies seeking a high profit margin may manufacture unregulated products in foreign countries using low-quality or ineffective ingredients.

### **Classification of nutraceuticals**

Nutraceuticals are food-derived products that are claimed to provide additional health benefits in addition to the basic nutritional value found in foods. Products may claim to prevent chronic diseases, improve health, delay the ageing process, increase life expectancy, or support the structure or function of the body, depending on the jurisdiction.

**Dietary supplements:** The term "dietary supplement" was defined in the United States by the Dietary Supplement Health and Education Act (DSHEA) of 1994: "A dietary supplement is a product taken by mouth that contains a 'dietary ingredient' intended to supplement the diet." Vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandular and metabolites are examples of 'dietary ingredients' in these products. Dietary supplements can also be extracts or concentrates, and they come in a variety of forms, including tablets, capsules, soft gels, gel caps, liquids, and powders."

Dietary supplements do not need to be approved by the FDA before being marketed, but companies must register their manufacturing facilities with the FDA and follow Current Good Manufacturing Practices (cGMPs). Dietary supplements, with a few well-defined exceptions, may only be marketed to support the structure or function of the body and may not claim to treat a disease or condition, and must include a label that states: "These statements have not been evaluated by the Food and Drug Administration." The purpose of this product is not to diagnose, treat, cure, or prevent any disease." The FDA has reviewed and approved a health claim as an exception. In those cases, the FDA also specifies the exact wording that is permitted.

**Functional foods:** Functional foods are fortified or enriched during processing and then marketed to consumers as providing some benefit. Milk may contain additional complementary nutrients, such as vitamin D.

Functional foods are defined by Health Canada as "ordinary food that has components or ingredients added to give it a specific medical or physiological benefit, other than a purely nutritional effect." All functional foods in Japan must meet three established criteria: they must be (1) present in their naturally occurring form, rather than a capsule, tablet, or powder; (2) consumed in the diet on a daily basis; and (3) regulate a biological process in the hopes of preventing or controlling disease.

### **Applications**

Nutraceutical products can be considered non-specific biological therapies used to promote general well-being, control symptoms, and prevent malignant processes. The term "nutraceutical" combines the two words of "nutrient," which is a nourishing food component, and "pharmaceutical," which is a medical drug. They contain a high concentration of bioactive compounds, derived from a natural source and have physiological benefits and aid in the prevention and treatment of disease. Nutraceuticals even include everyday foods like pre- and probiotics, fortified cereals, processed foods, and beverages.