

Medical Food

Medical food refers to specially formulated and processed products intended for the dietary management of a disease or condition that has distinctive nutritional needs that cannot be met by a normal diet alone. These foods are used under medical supervision and are regulated differently from conventional foods and drugs.

Key Features of Medical Foods

- 1. Intended for Specific Diseases or Conditions** – Designed for patients with specific metabolic needs due to a disease (e.g., Alzheimer's disease, chronic kidney disease, or metabolic disorders like phenylketonuria).
- 2. Used Under Medical Supervision** – Requires medical oversight to ensure appropriate use.
- 3. Distinct Nutritional Requirements** – Addresses dietary deficiencies or special nutritional needs that cannot be met by normal food intake.
- 4. Regulated but Not a Drug** – In the U.S., medical foods are regulated under the **Orphan Drug Act of 1988** and must comply with FDA requirements, but they do not require premarket approval like drugs.

Examples of Medical Foods

- **PKU formulas** (Phenylketonuria): Low-protein foods for individuals with PKU who cannot metabolize phenylalanine.
- **Ketogenic diet formulas**: Used in the management of epilepsy.
- **Lofenalac®**: A formula for infants with phenylketonuria.
- **Axona®**: A medical food formulated for Alzheimer's disease.
- **Nepro® with Carb Steady**: Designed for patients with kidney disease.
- **VSL#3®**: A high-potency probiotic used in inflammatory bowel disease.

How Medical Foods Differ from Dietary Supplements and Functional Foods

Category	Definition
Medical Food	Specifically formulated for disease management and requires medical supervision.
Dietary Supplement	Contains nutrients or bioactive compounds but is not meant for disease-specific dietary management.
Functional Food	Regular food with added benefits (e.g., fortified cereals, probiotic yogurt).

Regulations

Medical foods are not subject to the same **FDA premarket approval process** as drugs but must meet:

- **Good Manufacturing Practices (GMPs)**
- **Labeling Requirements**
- **Nutritional Guidelines for Disease-Specific Conditions**

Related Links

- [FDA Medical Foods Overview](#)
- [PubMed - Research on Medical Foods](#)

From:

<https://neurosurgerywiki.com/wiki/> - **Neurosurgery Wiki**

Permanent link:

https://neurosurgerywiki.com/wiki/doku.php?id=medical_food

Last update: **2025/02/08 10:11**

