

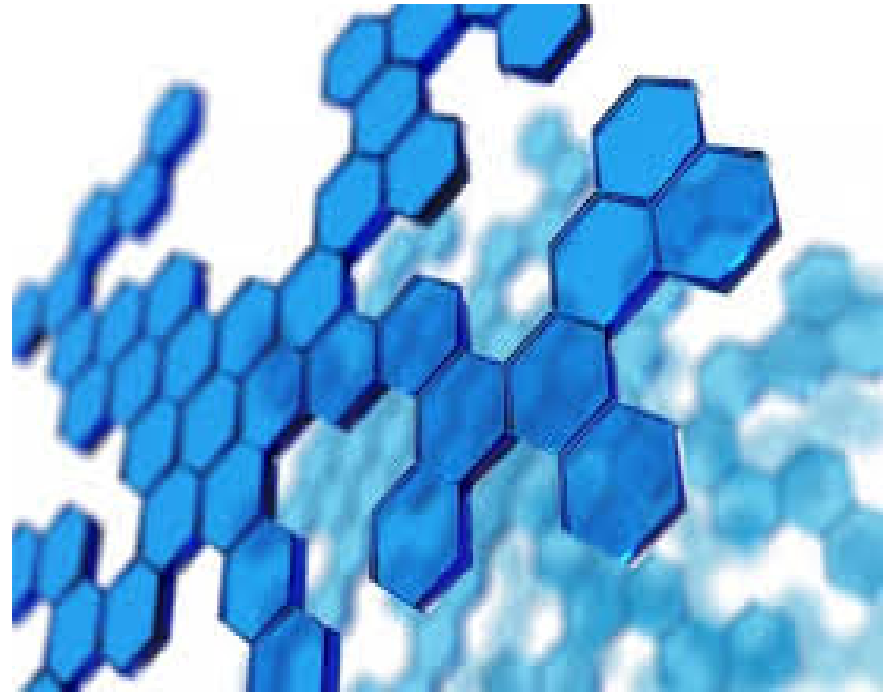
UC DAVIS OFFICE OF RESEARCH

Understanding the Difference: Drugs Dietary Supplements Medical Foods

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Objectives

- Therapeutic Purpose
- Drugs
- Dietary Supplements
- Medical Foods





Therapeutic Purpose

FDA definition of the term *therapeutic purpose* is intended to encompass diagnoses, cure, mitigation, treatment, and prevention of disease.

What Is a Drug?

articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease...

-or-

articles (other than food) intended to affect the structure or any function of the body of man or other animals

What is a Dietary Supplement?

is intended to supplement the diet

and

contains a dietary ingredient that can include vitamins, minerals, herbs and other botanicals, amino acids, other dietary substances intended to supplement the diet,

and

concentrates, metabolites, extracts, or combinations of the preceding types of ingredients.

What is Medical Food?

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.

Minimum Criteria for Medical Food

1. the product must be a food for oral or tube feeding
2. the product must be labeled for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements
3. intended to be used under medical supervision



Name that Compound:

- This consumable compound is a commercially available product that claims to support bone strength. The claim is unsupported by the FDA. A researcher wishes to conduct a clinical investigation on its effect on normal structure and function in humans (e.g. bone mass).
- A researcher has created a compound, with approved food additives and GRAS ingredients, for patients in end stage liver disease for dietary management. They wish to conduct research at their local institution.
- A physician wishes to conduct research on a commercially available consumable compound that claims to lower cholesterol levels. The claim is unsupported by the FDA. This researcher wants to increase daily dosage of this compound in hopes to lower cholesterol levels in patients with >200 cholesterol levels.

Resources

- FDA Guidance for Industry

Investigational New Drug Applications (IND's)-
Determining Whether Human Subject Studies Can
Be Conducted Without an IND

- FDA Guidance for Industry

Frequently Asked Questions About Medical Foods



Questions?
Thank you!

