

EZTREK[®]

DIFFERENCES BETWEEN

Drugs, Medical Foods & Dietary Supplements

DRUG – VS - MEDICAL FOOD

A drug is defined as:

- A substance recognized by an official pharmacopoeia or formulary.
 - A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
 - A substance (other than food) intended to affect the structure or any function of the body.
- The term **medical food**, as defined in section 5 (b) of the [Orphan Drug Act](#) (21 U.S.C. 360ee (b) (3)) is "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.**"

DIETARY SUPPLEMENTS

- The law defines dietary supplements in part as products taken by mouth that contain a "dietary ingredient." Dietary ingredients include vitamins, minerals, amino acids, and herbs or botanicals, as well as other substances that can be used to supplement the diet.
- **Dietary supplements are not intended to treat, diagnose, cure, or alleviate the effects of diseases.**

MEDICAL FOOD

- The term **medical food**, as defined in section 5 (b) of the [Orphan Drug Act](#) (21 U.S.C. 360ee (b) (3)) is "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.**"