U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
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The latest version of this guidance issued in May 2007. Below is an earlier version.

Medical Foods

What is a Medical Food?

A medical food is prescribed by a physician when a patient has special nutrient needs in order to manage a disease or health condition, and the patient is under the physician's ongoing care. The label must clearly state that the product is intended to be used to manage a specific medical disorder or condition. An example of a medical food is a food for use by persons with phenylketonuria, i.e., foods formulated to be free of the amino acid phenylalanine.

Medical foods are not meant to be used by the general public and may not be available in stores or supermarkets. Medical foods are not those foods included within a healthy diet intended to decrease the risk of disease, such as reduced-fat foods or low-sodium foods, nor are they weight loss products.

How Does FDA Oversee Medical Foods?

Until recently, medical foods received little attention. But the number and types of foods marketed as medical foods are increasing. While FDA is working to more clearly define and regulate medical foods, specific requirements for the safety or appropriate use of medical foods have not yet been established. Medical foods do not have to include nutrition information on their labels, and their claims do not need to meet specific standards.

Currently, FDA is exploring ways to more specifically regulate medical foods. This might include safety evaluations, standards for claims, and requiring specific information on the labels. In order to do this, FDA must first propose rules for medical foods. After publication of such a proposal, a public comment period would occur during which individuals and organizations write to offer their comments for changes to the proposed rules.

Where can I get more information about FDA's role in overseeing medical foods?

In November of 1996, FDA published a type of document known as an "advanced notice of proposed rulemaking" (ANPR). This document contains FDA's current thinking about how to best develop rules for medical foods.

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