

Overview of Medical food with specific emphasis of its labeling requirements in US and Australia

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ABSTRACT

Purpose: A food that are specially formulated and intended for the dietary management of a disease that has distinctive nutritional needs that cannot be met by normal diet alone is known as medical food. Medical food is newly developed products for mostly genetic disease and have advantage over allopathic medicines as they have lesser side effects and easily acceptable by patients. Now a days Medical food is growing industry and have a wide opportunity in pharmaceutical industry because of low cost compare to allopathic medicines as it do not require pre-market approval. It is also known as alternative medicines.

Method: In different countries medical food is regulated under different name like in US it is regulated under Medical food while in Australia it is regulated under name of food for special dietary use. Medical food must meet distinctive nutritional requirement for particular disease state and administered under the supervision of physician and contain ingredient that are generally consider as a safe as per GRAS (generally recognized as safe). Medical food regulation is required to because it is newly developed therapy.

Result and conclusion: This article includes general information of medical food, how it differ from drug and dietary supplements, its concept, general regulatory requirements, current marketing scenario and labeling requirements in US and Australia. In US medical food is regulated by FDA (food and drug administration) and in Australia it is regulated by FSANZ (food standard Australia and New Zealand).

KEYWORDS: US, Regulatory requirements, Australia, Medical food, Food for special dietary purpose.

INTRODUCTION

Definition [1]

Medical foods are defined as “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.”

General criteria for medical food [2]

- Specifically for management of disctintive nutrient needs, resulting from a specific clinical condition and Specially formulated and processed; not naturally occurring.
- For patient which cannot normally take or metabolize ordinary food or those whose distinctive dietary needs cannot be met through normal diet.
- Used under medical supervision and for patients receiving ongoing medical care.

General requirements of medical food [3]

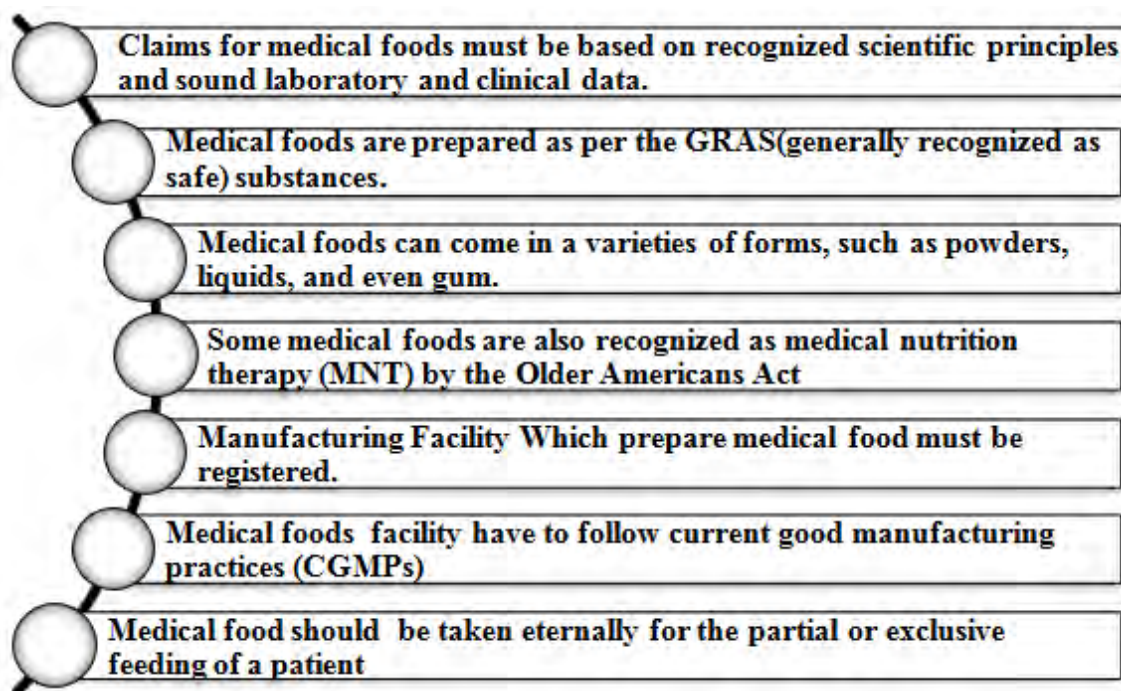


Figure 1: General requirements of medical food[3]

History [4]

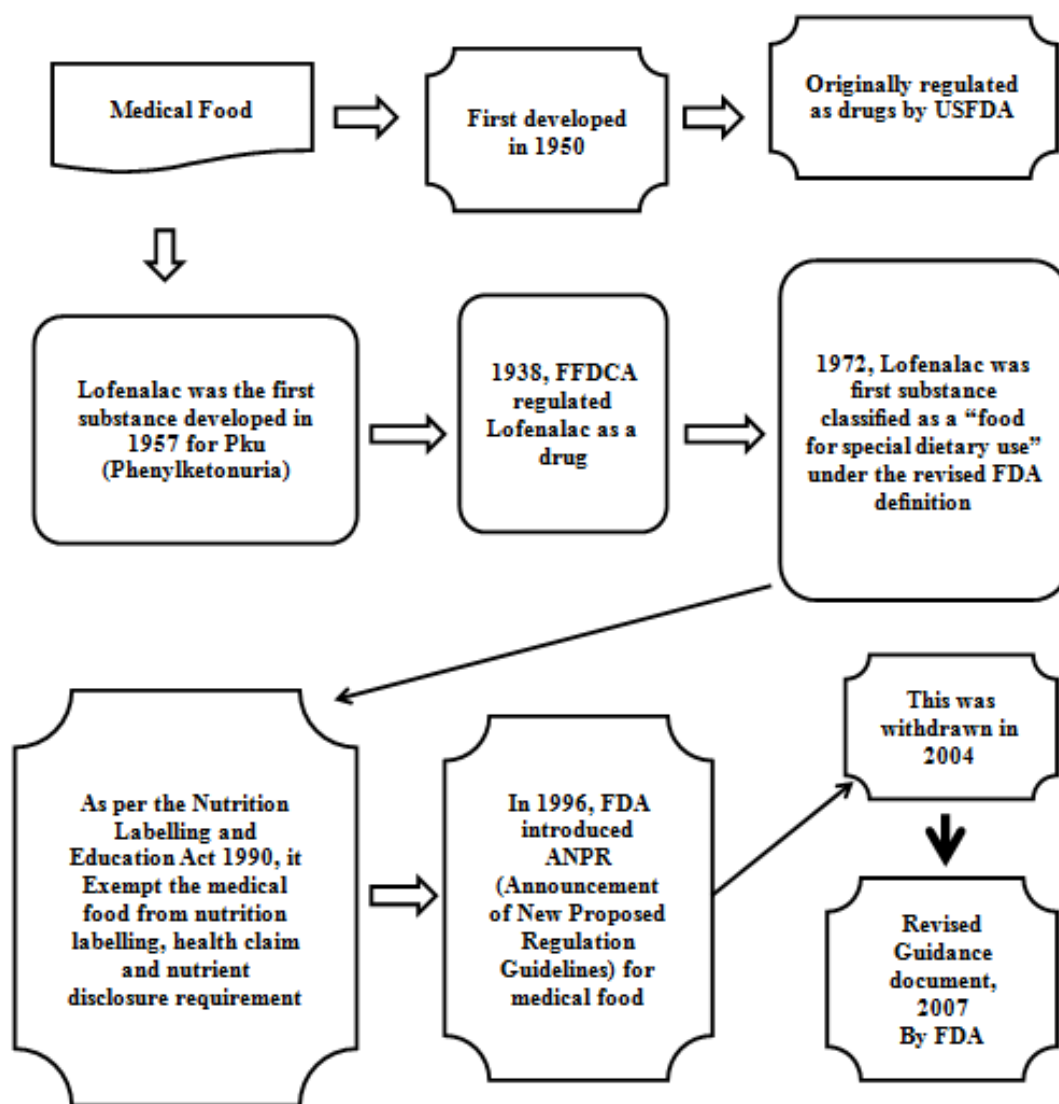


Figure 2: History of medical food [4]

Medical Food market [5]

Active companies: Many companies are moving into the medical foods area, including large food and healthcare companies such as Nutricia, Nestle and Abbott Laboratories, and smaller companies specializing in medical foods such as Targeted Medical Pharma and PamLab.

Market trends: Medical foods are becoming recognized products, particularly in the United States, less so elsewhere. This is seen through the organization of a Medical foods conference in 2011, hosted by the National Organization of Rare Diseases (NORD).

Factors influencing the market: Rise in aging population, Shift to enteral nutrition, Demand for personalized medicine, Business benefits

Examples

Axona (Accera): Axona was developed by Accera (USA) as a medical food to provide the necessary nutrients for patients with Alzheimer’s disease (AD).

Lofenalac: Lofenalac was developed by Mead Johnson Nutrition designed for PKU

Table 1: Difference between pharmaceutical drug, medical food and dietary supplements. [5]

	Drugs	Medical foods	Dietary supplements
IND required	Yes	No	No(need for health claims)
Pre-market scientific testing	Preclinical and clinical studies (phases I, II, III)	Medical evaluation in patients with the specific disease being targeted	No
Ingredients	Mostly synthetic, can be nutritional	Nutritional, not in ordinary diet	Nutritional
NDA/BLA required Claims	Yes Negotiated with FDA and dependent on pivotal clinical trial data	No Dietary management of a specific disease	No Support healthy functions
Intended target population	Diseased - for patients with a specific indication or symptoms	Diseased - for meeting nutritional requirements of a specific diseased population	Normal, healthy adults
Safety and pharmacovigilance	Need to establish through clinical trials and post market surveillance	GRAS and post market surveillance	General expectation of safety and through monitoring of consumer complaints
Physician supervision	Required if prescription drug, not for OTC medications	Required	No
Dosing Distribution	Any Hospitals, retail pharmacies	Oral or enteral Hospitals, retail pharmacies	Oral Health food stores, mass market

MATERIAL AND METHOD (WORK DONE)

OVERVIEW OF LABELING REQUIREMENTS OF MEDICAL FOOD AS PER US.

Labeling requirements apply to medical food in US is regulated by FDA (food and drug administration) [6].

Medical foods are foods and, therefore, their labeling must comply with all food labeling requirements except for those specific requirements from which medical foods are exempt.

Medical foods must contain the following mandatory label information:

- A statement of identity (the common or usual name of the product) (21 CFR 101.3),
E.g. Axona used for Alzheimer disease
- An accurate statement of the net quantity of contents (21 CFR 101.105),
- The name and place of the manufacturer, packer, or distributor (21 CFR 101.5)
- The complete list of ingredients, listed by their common or usual name, and in descending order of predominance by weight (21 CFR 101.4).
- In addition, all words, statements, and other information required by or under authority of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to appear on a label or labeling of a medical food must appear with prominence and conspicuousness (21 CFR 101.15).
- The label must be in English, except that, for medical foods distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English (21 CFR 101.15(c)(1)).
- If a label bears any representation in a foreign language, then all mandatory label information must be repeated in each foreign language used on the label (21 CFR 101.15(c)(2)).
- Medical foods also must be labeled in conformance with the principal display panel requirements (21 CFR 101.1), the information panel requirements (21 CFR 101.2), and the misbranding of food requirements (21 CFR 101.18).

- **Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) [7].**

Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) also apply to medical food.

- FALCPA requires food manufacturers to label food products that contain protein from a major food allergen in one of two ways.
 - The first option for food manufacturers is to include the name of the food source in parenthesis following the common or usual name of the major food allergen in the list of ingredients in instances where the name of the food source of the major allergen does not appear elsewhere in the ingredient statement.
 - The second option is to place the word "Contains" followed by the name of the food source from which the major food allergen is derived, immediately after or adjacent to the list of ingredients, in font size that is no smaller than the font size used for the list of ingredients.
- FALCPA requires that food manufacturers label the food products that contain ingredients, which include a flavoring, coloring, or incidental additive that are, or contain, a major food allergen should be in plain English to identify the allergens.
- FALCPA states that the manufacturer of medical food must file petition to the Secretary of Health and Human Services for an exemption either through a petition process or a notification process.
- The petition process requires scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that possess a risk to human health.
- The notification process must include scientific evidence (including the analytical method used) that demonstrates that the food ingredient (as derived by the production method specified in the notification) does not contain allergenic protein.
- If either the petition or the notification is granted by the Secretary, the result is that the ingredient in question is not considered a "major food allergen" and is not subject to the labeling requirements.
- If ingredient is consider as "major food allergen" it is subjected to the labeling requirements.
- **OVERVIEW OF LABELING REQUIREMENTS FOR MEDICAL FOOD AS AUSTRALIA [8].**

Medical food labeling is regulated in Australia by FSANZ (food standard Australia New Zealand) which is co-regulation authority of Australia and New Zealand

Australia New Zealand food standards code –standards 2.9.5- food for special medical purpose is guideline for labeling of medical food in Australia

Subdivision 1: Outline of requirements

Labeling and related requirement

- Each medical food must contain label on their package.
- The label must comply with the requirements of Subdivision 2 (General labelling requirements).
- The requirements of Subdivision 3 (Labelling requirements for inner package) apply instead of Subdivision 2 if the package is an inner package.
- The requirements of Subdivision 4 (Information requirements for transformation outers) apply instead of Subdivision 2 to transportation outer.
- To avoid doubt, this division does not apply to a food for special medical purposes that is not in a package.

Subdivision 2: General labeling requirement

The label on a package of food for special medical purposes must include the following information –

- A name or a description of the food sufficient to indicate the true nature of the food;
E.g. lofenalac use for phenyketonuria
- The lot identification of the food;
- Directions for the use of the food or the storage of the food, or both, if the food is of such a nature to require directions for health or safety reasons;
- The minimum or average energy content expressed per given quantity of the food;
- The average quantity or minimum quantity, expressed per given quantity of the food, of
 - Protein, fat and carbohydrate; and
 - Any vitamin, mineral or electrolyte present in the food, if the vitamin, mineral or electrolyte has been added to the food.

Mandatory statements

The label on a package of food for special medical purposes must include the following statements –

- A statement which indicate the effect that the food must be used under medical supervision;
- A statement indicating, if applicable, any precautions and contraindications associated with consumption of the food;
- A statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition, for which the food has been formulated.
- A statement describing the properties or characteristics which make the food appropriate for the medical purpose.
- If the food has been formulated for a specific age group—a statement indicating that the food is intended for the persons within the specified age group;
- A statement indicating whether or not the food is suitable for use as a sole source of nutrition.

Mandatory declaration

A declaration of the presence in a food for special medical purposes of any of the substances like fish and fish products, egg and egg products, milk and milk products, to this clause is required if the substance is present as an ingredient; an ingredient of a compound ingredients; or a food additive or component of a food additives; or a processing aid or component of a processing aid.

Date of making of food.(1.2.5)

If a label on a package of food for special medical purposes is required to include a use-by date under Standard 1.2.5, the words ‘Expiry Date’, or words to similar effect, may be used instead of the words ‘Use By’.

Lactose claims in relation to food for special medical purposes

If a claim in relation to the lactose content of a food for special medical purposes is made, the label on the package of food must include the average quantity of the lactose and galactose in the food, expressed per given quantity of the food.

Claims in relation to gluten content of food for special medical purposes

If a claim is made in relation to the gluten content of a food for special medical purposes, the label on the package of food must include the average quantity of the gluten in the food, expressed per given quantity of the food.

Legibility requirements (1.2.9)

Unless otherwise expressly permitted by this Code, each word, statement, expression or design prescribed to be contained, written or set out in a label must, wherever occurring, be so contained, written or set out legibly and prominently such as to afford a distinct contrast to the background, and in the English language. Words should be clear enough to read.

Subdivision 3: Labelling requirements for inner package

The inner label must include:

- A name or a description of the food sufficient to indicate the true nature of the food; and
- The lot identification of the food; and
- A declaration of the presence in the food of any of the substances (eggs, milk products etc) if the substance is present;
 - As ingredient; or
 - As ingredient of a compound ingredients; or
 - A food additive or component of food additives; or a processing aid or component of a processing aid.

Subdivision 4: Information requirements for transformation outers

If packages of food for special medical purposes are in a transportation outer, then there must be a label on the transportation outer that includes –

- A name or a description of the food sufficient to indicate the true nature of the food; and
- The lot identification of the food; and
- The name and business address in Australia or New Zealand of the supplier of the food, unless that information is provided in documentation accompanying the food for special medical purposes.

RESULT:**Difference between medical food labelling requirements in US and Australia.**

Table 2: difference between medical food labelling in US and Australia

	Us	Australia
Regulatory authority	Food and drug administration (FDA)	Food standard Australia New Zealand (FSANZ)
Regulatory body	Labelling requirements are regulated by FDA only	Australia and New Zealand combinely regulate labelling requirement in Australia
Regulatory guidelines	Two guidelines are available in US for labelling (Food labelling requirements, Food Allergen Labelling and Consumer Protection Act of 2004)	Only one guideline is available for labelling (Australia New Zealand food standards code –standards 2.9.5- food for special medical purpose)
Division in guideline	No subdivision are available	Four subdivision are available
For allergens	Specific guideline is available	No specific guideline is available
Regulation of label	Regulated by normal food only	Regulated by food for special dietary use

CONCLUSION

Medical foods are designed to be a component of an overall disease management plan. Medical foods are a distinct class of FDA-regulated therapeutic agents that meet the distinctive nutritional requirements or metabolic deficiencies of a particular disease state, are formulated to be consumed or administered under the Physician's supervision and contain ingredients that are generally recognized as safe (GRAS). Medical food will be helpful to maintain good health in the future; it has been convincingly beneficial for their intended purposes when consumed as part of a generally well-balanced and healthful diet. This article gives basic knowledge about medical food and general regulatory requirements needed for labelling in US and Australia. This article also shows the major difference in labeling requirement of medical food in US and Australia. Thus article will be useful for the manufacturer of the medical food to prepare label according to US and Australia.

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