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Present scenario of medical food with specific emphasis on its registration procedure in US and Australia

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ABSTRACT

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. 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. 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 [1]
- Specifically for management of disctintive nutrient needs, resulting from a specific clinical condition and Specially formulated and processed; not naturally occuring.
- 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 [1]**

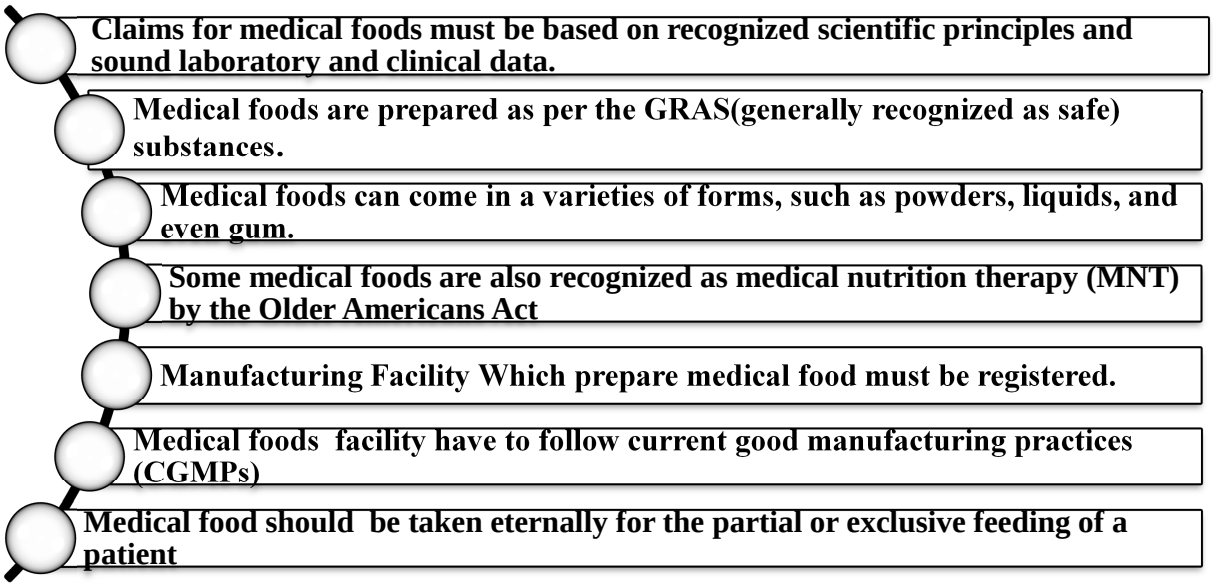

Figure 1: General requirements of medical food[3]

For medical food registration in US registration of food facility is required while in Australia product registration is required.

A. Registration of Food Facilities regulations[1]

- The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directs the Food and Drug Administration (FDA), as the food regulatory agency of the Department of Health and Human Services, to take additional steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies.
- To carry out certain provisions of the Bioterrorism Act, FDA has established new regulations requiring that:
  - Food facilities are registered with FDA, and
  - FDA be given advance notice on shipments of imported food.
- These regulations go into effect on December 12, 2003.
- Food Facility Registration Requirement
- Domestic and foreign facilities that manufacture, process, pack, or hold food, as defined in the regulation, for human or animal consumption in the U.S. must register with FDA by December 12, 2003.
- Food facility registration will help FDA to:
  - Determine the location and source of a potential bioterrorism incident or an outbreak of
  - food-borne illness; and Quickly notify facilities that may be affected
- There is no fee for registration or updates to a registration.

Facilities Must Register [2]

- If your facility is in one of following food industry sectors, you must register your facility with FDA by December 12, 2003.
  - Domestic and foreign manufacturers or processors
  - Domestic and foreign packers
  - Domestic and foreign storage operations

Table 1: It shows facility that must register

If...	Then
A foreign facility that manufactures, processes, packs or holds food sends it to another foreign facility for further manufacturing/processing or packaging before the food is exported to the U.S.	Only the second foreign facility is required to register.
The second foreign facility performs only a minimal activity, such as putting on a label	Both facilities must register.
Any foreign facility packs or holds food after the last foreign manufacturer/processor of the food	The foreign packer or holder Must register.

Facility that do not have to register[3]

- Private residences of individuals, even though food may be manufactured/processed, packed, or held in them.
- Non-bottled water drinking water collection and distribution establishments and structures, such as municipal water systems.
- Transport vehicles that hold food only in the usual course of their business as carriers.
- Farms — i.e., facilities in one general location devoted to growing and harvesting crops (washing, trimming outer leaves, and cooling produce are part of harvesting) and/or raising animals (including seafood). The term "farm" also includes facilities that manufacture/process, pack, or hold food, provided that all food used in those activities is grown, raised, or consumed on that farm or another farm under the same ownership.
- Restaurants — i.e., facilities that prepare and sell food directly to consumers for immediate consumption, including pet shelters, kennels, and veterinary facilities that provide food directly to animals. Facilities that provide food to interstate conveyances, such as commercial aircraft, or central kitchens that do not prepare and serve food directly to consumers, are not restaurants for purposes of the rule.
- Retail food establishments, such as groceries, delis, and roadside stands, that sell food directly to consumers as their primary function, meaning that annual food sales directly to consumers are of greater dollar value than annual sales to other buyers.
- Nonprofit food facilities, which are charitable entities that meet the terms of § 501(c)(3) of the Internal Revenue Code and that prepare or serve food directly to the consumer or otherwise provide food or meals for consumption by humans or animals in the U.S. This includes central food banks, soup kitchens, and nonprofit food delivery services.
- Fishing vessels that harvest and transport fish. Such vessels may engage in practices such as heading, eviscerating, or freezing fish solely to prepare the fish for holding on board the vessel and remain exempt.
- Facilities regulated exclusively and throughout the entire facility by the U.S. Department of Agriculture, that is, facilities handling only meat, poultry, or egg products.
- Registration is required only once for each food facility. However, if required registration information about your facility changes, you must update the registration.

If fail to register

- Failure to register your facility, update required elements, or cancel registration in accordance with this regulation is a prohibited act under the Federal Food, Drug, and Cosmetic Act. The Federal government can bring a civil action against persons who commit a prohibited act, or it can bring a criminal action in Federal court to prosecute persons who are responsible for the commission of a prohibited act, or both.
- If a foreign facility is required to register but fails to do so, food from that facility that is offered for import into the U.S. is subject to refusal. The food may be held within the port of entry, unless directed elsewhere by FDA or the Customs and Border Protection Service (CBP).
- FDA plans to issue enforcement guidance on the agency's policies regarding refusals of imported food or holds of imported food.

Process of Registrating facility[4]

- Registrants must use Form 3537 to register or update a registration. This form is available online and in paper form
- A business with multiple facilities may also register on CD-ROM. FDA will process paper and CD-ROM submissions in the order received.

Information required for registration

- Facility name, address, phone number, and emergency contact phone number
- Parent company name, address, and phone number (if applicable)
- Name, address, and phone number of the owner, operator, or agent in charge

- All trade names the facility uses
- Applicable food product categories, as listed on the registration form
- Name, address, and phone number of a foreign facility's U.S. agent, and phone number of the facility's emergency contact if it is someone other than the U.S. agent
- Certification that the information submitted is true and accurate and that the person submitting it is authorized to do so.

Optional information requested

- Facility fax number and email address
- Preferred mailing address, if different from that of the facility
- Fax number and email address of the owner, operator, or agent in charge of the facility
- Fax number and email address of the parent company (if applicable)
- For a foreign facility: the fax number and email address of its U.S. agent Type of activity conducted at the facility (i.e., processing, packing, etc.).
- Form 3537 (where they are marked optional), or in section 11b (where all food categories listed are optional)
- Type of storage (if it's a holding facility)
- Whether the facility manufactures/processes, packs, or holds most or all of the product categories identified in 21 CFR 170.3
- Approximate dates of operation (if the facility's business is seasonal).

Update Registration Information[5]

If any of the required information on your registration form changes — for example, if there is a new operator, agent in charge, or U.S. agent — the owner, operator, or agent in charge, or an individual authorized by one of them, must notify FDA within 60 days.

Cancellation of registration

If your facility goes out of business or comes under new ownership, you must cancel its registration within 60 days using Form 3537a.

If registration is confirmed and any change in registration

Table 2: It shows If change in registration

If	Then
Required registration info changes	Must notify FDA within 60 days (online or by mail or fax).
There is change in ownership	The former owner must cancel registration within 60 days and the new owner must re-register
Facility goes out of business	Cancel registration
A domestic facility fails to register	The Federal government can bring a civil or criminal action against the owner, operator, or agent in charge. However, FDA will use discretion in enforcing the regulation during the comment period (75 days).
A foreign facility fails to register and then tries to import food into US	The food will be held at the port of entry, unless otherwise directed to register and then by FDA or CBP

Product application for medical food in Australia[6]

Rules/Regulations for licensing and registration: Therapeutic goods regulations

Responsible Regulatory authorities for Registration of medical food: Therapeutic Good Administration (TGA)

Regulatory Requirements for Registration:

A. Product Application

Product application should include

- The number or name of the application or proposal
- Applicant name and contact details including: position, address, telephone number, fax and email address
- For organizations, the level at which the submission was authorized.

Submission may have greater impact if it:

- Comments on the issues raised and any possible options

- Provides as much supporting evidence as possible e.g. groups or individuals who may be affected, data on the impact of the proposed decision, relevant technical information
- Is written with regard to the policy framework FSANZ must have regard to.

Your submission should:

- Be simple, clear and concise
- Be supported by relevant, reputable and current data where possible
- Use appropriate and specific case examples
- Include a brief summary, especially if the submission is lengthy.

Where possible, submissions should contain scientific evidence rather than conjecture to back up any assertions as FSANZ is required to use the best scientific evidence available in its decision-making processes. If no scientific or other validated evidence is provided by a submitter, FSANZ will still have regard to those comments, but may not be able to give those comments the same weighting as that given to scientific evidence.

Registration procedure

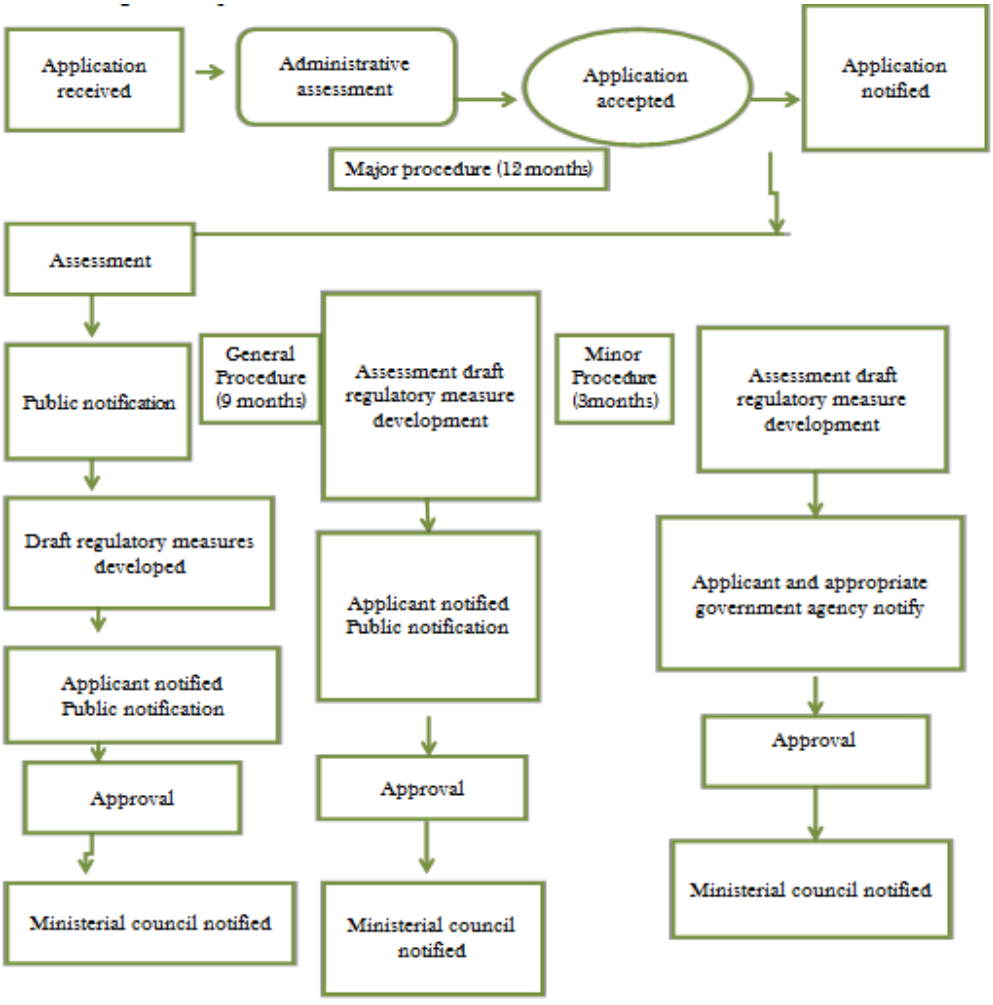

Fig 2: It shows Registration process according to FSANZ

There are three types of registration process by FSANZ

1. **Major procedure**: This include application which required more than 1050 hrs for fully assessment.

Eg. Derive of new food standard.

2. **Minor procedure:** Include the application which required 175 hrs for fully assessment.
Eg. Correcting typographical error
3. **General procedure:** Two types of general procedure
- **General procedure 1**: Required 500hrs for assessment of application

Eg. Minor change in label requirements
- **General procedure 2:** Required 800hrs for assessment of application

Eg.Changing compositional requirement for a food.

RESULTS

Registration procedure of medical food is different in US and Australia as in US form number is given while in Australia online registration is there. After application of medical food registration in Australia we can also get license in New Zealand. Facility registration is there in US while in Australia Product application is given. Product application is divided in 3 parts according to application assessment time.

Table No.3: Difference in registration procedure of medical food in US and Australia

	US	Australia
Registration process	Simple (not divided)	Divided into 3 procedure General Minor Major
Registration documents	More detail documents are required	The number or name of the application or proposal Applicant name and contact details including: position, address, telephone number, fax and email address For organizations, the level at which the submission was authorized.
Registration requirements	Labelling requirements GMP Facility registration FDA compliance program	Labeling requirements GMP Product registration Post market surveillance

CONCLUSION

Medical food provides the nutritional requirements to the disease patient which cannot be provided by normal diet. Registration procedure for medical food is different in two country as in US facility registration is required where in Australia product registration is there. Specific form number is given in Us while in Australia there is no form number is given for product registration. This article helps manufacturer, seller, distributor to understand the requirement of registration in US and Australia.

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