NSW Food Authority

Proposal 242
FOODS FOR SPECIAL MEDICAL PURPOSE

CONSULTATION PAPER – NOVEMBER 2011

Summary

The NSW Food Authority is in general agreement with the proposal, although would like to see some further alignment with EU and US requirements that improve clarity over the identification of Food for Special Medical Purposes (FSMPs). Further detail is provided below.

Specific Issues

1. Definition

The NSW Food Authority notes that the definition for FSMPs has been revised. The definition now makes reference to the terms "*food for special medical purposes*" and "*medical food*" to align with the terms used in Europe and United States respectively. To remove any ambiguity over these terms we would recommend that the terms are listed along with the relevant overseas legislation for example, "a **dietary food for special medical purposes** as defined by the Article 1 2(b), Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes" and "a **medical food** as defined by 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b)(3)" (see US 21 CFR 101.9(j)(8)). This would provide the requisite clarity and understanding of the terms and result in less misinterpretation of what is represented as a FSMP.

2. Prescribed Name

The Authority notes "the revised definition now relates to how FSMPs are represented at the point of sale so they can be identified and distinguished from other food products". To enable the identification and control of products misrepresented as FSMPs, the Standard should include the requirement for the label to carry a prescribed name. To assist in reduced costs to industry, it is suggested that the Standard be consistent with the international regulations in that regard, requiring either "food for special medical purposes", "dietary foods for special medical purposes" or "medical food", depending on the place of export and respective regulation.

ENDS

NSW Food Authority

Proposal 242
FOODS FOR SPECIAL MEDICAL PURPOSE

CONSULTATION PAPER – NOVEMBER 2011 and examples regarding the revised FSMP definition

Summary

Further to our comment on the FSANZ Consultation Paper November 2011 the NSW Food Authority has compiled international examples of regulatory actions based on compliance with the statutory definitions of this category of foods.

Definition

The NSW Food Authority notes that the definition for FSMPs has been revised. The definition now makes reference to the terms "*food for special medical purposes*" and "*medical food*" to align with the terms used in Europe and United States respectively, but does not reflect the international category definer for this category of products: "to be used under medical supervision".[1] The respective European Directive and US statute do not define the phrase; a review of the relevant case law in those jurisdictions should elucidate judicial treatment of the undefined concept and assist in any attempt to define the concept for application in Australia and New Zealand.

---

[1] European Directive 1999/21/EC defines "dietary foods for special medical purposes" means a category of foods for particular nutritional uses specifically processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feedings of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically-determined nutrient requirements, who dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two."

In the United States, medical food is defined by section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b)(3) see US CFR 101.9(j)(8)(i)-(v) defines medical food "is a food 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. A food is subject to nutrition labelling exemption only if: (i) it is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube; (ii) it is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary food stuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone; (iii) It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation; (iv) It is intended to be used under medical supervision; and (v) it is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food."

Evidence indicates the FDA has relied upon the statutory definition for 'medical foods' to adequately identify, limit and control what foods can be represented as 'medical foods' and benefit from the lack of approval for the high level health claims used in the sale and advertising. The definition as currently drafted in P242: "A food for special medical purposes means a food that is represented as being a) for the dietary management of a disease, disorder, or medical condition …" would allow for a wider than intended range of foods to be represented as FSMP in Australia and New Zealand due to the absence of the statutory definer, 'use under medical supervision'. The following provide examples of the types of foods represented as 'medical foods' but subsequently regulated by the FDA using a suitably narrow statutory definition:

- On 1 November 2010 Bioenergy, Inc was warned its Corvalen®, Corvalen® Chewable Wafers, and Corvalen M® products were misbranded as they were labelled and marketed as medical foods for the conditions of fibromyalgia, chronic fatigue syndrome, and cardiovascular disease but did not meet the statutory definition of a medical food.[2]
- The FDA issued a warning letter to Nestle HealthCare Nutrition on 3 December 2009 for the internet promotion of 'BOOST Kid Essentials Nutritionally Complete Drink' as a 'medical food' for the medical condition 'failure to thrive' and also for 'pre/post surgery, injury or trauma, chronic illnesses'. The FDA warned Nestle the product was misbranded as a medical food but did not meet the statutory definition of a medical food.[3]
- On 2 November 2009, Pan American Laboratories was warned the label on 'Neevo caplets' was false and misleading in that the product is labeled and marketed as a medical food but did not meet the statutory definition of a medical food.[4]
- On a September 28, 2007, in a warning letter issued to Efficas Inc., FDA claimed that one of the company's products for allergies and asthma did not meet the definition of a medical food because "although asthma and allergies are diseases, neither has distinct nutritional requirements that are based on recognized scientific principles and established by medical evaluation."[5]

ENDS

[2] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm232086.htm
[3] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm194121.htm
[4] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm191841.htm
[5] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076519.htm