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| OUR REF | : | | DATE | : 24 March 2003 |
| YOUR REF | : | | | |
| TO | : | Food Standards Australia New Zealand | | |
| ATTENTION | : | | FAX NO | : (02) 6271 2278 |
| COPY | : | | | |
| SUBJECT | : | Submission - P242 Draft Assessment Report - Foods for Special Medical Purposes | No. OF PAGES (Including this page) | : 6 |



Dear Madam/Sir,

Following is the submission from Nestlé Australia Ltd and Nestlé New Zealand Limited. Thank you for the extension to the time permitted to allow for us to prepare the submission.

Regards,
**Nestlé Australia Ltd**

[redacted]

Robyn Banks
Regulatory Affairs and Nutrition Manager
Oceania

**SUBMISSION TO THE REQUEST FOR COMMENT ON THE DRAFT ASSESSMENT REPORT FOR FOODS FOR SPECIAL MEDICAL PURPOSES – PROPOSAL P242**

This submission is made on behalf of **Nestlé Australia Ltd** and **Nestlé New Zealand Ltd.** Nestlé is a manufacturer and importer of a wide variety of foods for the Australian and New Zealand markets. Some of the brand names belonging to Nestlé include MAGGI, NESCAFE, MILO, NESTLE PETERS, PAPA GUISEPPI'S, LEAN CUISINE, SUNSHINE, NESTLE GOLD MEDAL, CARNATION, ROWNTREE, LIFESAVERS, ALLENS, KANDYLAND, MINTIES, INTERNATIONAL ROAST, COFFEE-MATE, MASTERCRAFT, IDEAL, BEARBRAND, SWEETACRES, THOMY, VIOLET CRUMBLE, WALCO, ANDRONICUS, ALPEN BLEND, BACI, CROSSE & BLACKWELL, VITARI, GOLD BLEND, BUITONI, PERRIER, VITTEL, WONKA and KIT KAT. The two products Nestlé markets in the category of foods for special medical purposes are MODULEN IBD, intended for people with Crohn's disease and BUILD-UP Hospital Formula with Fibre.

**GENERAL COMMENTS:**

Nestlé also supports the submissions provided by the Australian Food and Grocery Council and also the submission provided by the Australia New Zealand Enteral Nutrition Manufacturers Association. Nestlé has provided input into these submissions. Nestlé also offers the following comments.

Nestlé is concerned with the direction of the proposed standard, particularly regarding the compositional requirements for the products. The proposed levels will mean that the two products that Nestlé markets in Australia will potentially be removed from the Market because the costs for reformulation will be too cost-prohibitive, if indeed the manufacturing factory will agree to a change in formulation for one small market.

**3 REGULATORY PROBLEM:**

It is stated that the lack of a regulation for these foods means uncertainty for health professionals and consumers in being assured of appropriate and consistent information on their safe and effective use. Consumers of these foods would not necessarily be aware that there has been no standard for these foods and would consider that the basic requirements are that they are provided with safe food. This is indeed the basic requirement for all manufacturers and suppliers of food.

The document states that the products need to be safe and effective in meeting the needs of the target population and that there are potential risks to both the target and the non-target population if the products are consumed inappropriately. It is also stated here that these foods are generally consumed under direct supervision of a health professional and are unlikely to be purchased or consumed by the general population, and the risks were presumed to be small. There has been no evidence provided showing incorrect

consumption of these products and the basic requirement is that food is safe under the Food Acts of the States and Territories and New Zealand.

## 5 ISSUES:

### 5.2 Definition of FSMP:

The Codex definition has been proposed for adoption. We recommend that the modification to this definition as proposed in the ANZENMA submission be adopted.

### 5.3 Distribution and Access:

It is determined here that there is little evidence suggesting that there is a problem or an increased risk to public health and safety from the current unrestricted access to Foods for Special Medical Purposes (FSMP)

Nestlé agrees that it is not necessary to change the distribution and access arrangements for these products.

### 5.3.2 Advertising of FSMP:

It is stated here that there is no evidence that the FSMP industry is unethically advertising products to the general public. FSANZ also states here that there are significant public health and safety risks associated with unsupervised and inappropriate use of FSMP by consumers. Earlier within the document it was stated that there is little evidence to suggest that there are problems and an increased risk to public health and safety from the current unrestricted use of these products. The restriction on the advertising and promotion to the public is not warranted as it is already acknowledged that there is no evidence of market failure.

The assessment has also not considered that support groups for particular conditions would also allow for advertising in their publications. Our preference is to have no restrictions imposed on advertising.

### 5.4 Composition of FSMP

The compositional levels proposed will mean that the two Nestlé products that are sold within Australia would not be compliant under this new standard. These products are manufactured in specific factories under a single formulation for distribution around the world. This would mean that the products are likely to be removed from sale, as the supply of such a limited amount of product especially for Australia would be cost-prohibitive. It is very likely that the manufacturing factories will refuse to manufacture a country specific formulation, even if it is decided to continue with the product in Australia.

MODULEN IBD (for people with Crohn's diseases) will not meet the requirements for niacin and magnesium with difficulties occurring with the upper limit for vitamin A within which we operate. BUILD-UP Hospital Formula with Fibre will not meet the requirements for niacin, vitamin B12, folate, biotin and magnesium with difficulties occurring with the upper limit for vitamin A within which we operate.

There are currently 536 patients listed on the Australian paediatric Crohn's database. This does not represent all of the paediatric Crohn's patients however. There are 5.3 new cases per 100,000 on average each year, which equates to 210 new cases a year.

The prevalence of Crohn's disease in the adult population is estimated to be over 10,000. The incidence of new cases is estimated at the rate of 5 per 100,000 head of population. On average, there are 770 new cases of Crohn's disease for people 15 years and over each year.

MODULEN IBD helps modulate the inflammatory reactions of Crohn's disease. There is a high re-occurrence rate with Crohn's disease and many patients require multiple courses of MODULEN IBD throughout the year. The standard as proposed will mean that this product will no longer be available to these people.

The business impact for just these 2 products if the proposed compositional levels were adopted would be $250,000, as these would no longer be supplied to the Australian market.

**5.5 Labelling:**

It is recommended in the assessment that the mandatory statement for the products to be used under medical supervision is contained under a heading 'Important Notice'. The inclusion of 'Important Notice' does not allow for the flexibility and consistency with international regulations. This is not required by Codex standards. The assessment that current practices are not creating public health and safety concerns would mean that there is no justification to deviate from current practices. This heading is also not required in the USA. The inclusion of this statement would mean that many products manufactured overseas and supplied around the world would not comply with the standard if the heading 'Important Notice' were not included on the labels.

The requirement to include the number of serves per pack is not appropriate for some forms of product eg tube-feeds. The mandatory requirement to include this needs to be reassessed. The Codex standard (180-1991) acknowledges that it is not always necessary to include a serve size under clause 4.5.6. There is a precedent within the Food Standards Code (Infant Formula standard) that does not need the nutritional information to be provided on a serving size basis. It would not be inconsistent then if the serving size were not required on foods for special medical purposes.

The requirement to label that a product poses a health hazard when consumed by individuals who do not have the disease, disorder or medical condition for which the

product is intended is not always a true statement and would be considered a breach of the Trade Practices Act. Often, all family members can use foods that are provided for people with specific conditions, in that the foods are safely modified for consumption.

It is extremely difficult for manufacturers to include side effects, contraindications and product-drug interactions. These products are food, not drugs. It is the responsibility of the supervising medical professional to determine how the food and drug interaction needs to be managed. This proposed requirement is far in excess of what is required under international standards and needs to be deleted. The labelling assessment at attachment 3 takes the requirements of the Codex standard for these foods out of context. The Codex standard (180-1991) requires 'a complete statement concerning adequate precautions, known side effects, contraindications and product-drug interactions **where applicable. It also permits the information to be provided separately from the package.** This was not acknowledged nor allowed for in the drafting of the standard.

## 10 CONCLUSION AND RECOMMENDATION:

It is stated that option 2 provides greater benefits for all affected parties and that this option provides continued access to greater assurance of safe, quality products. Option 2 is concluded as harmonising between Australia and New Zealand and also internationally where appropriate. However, in the areas where it is considered inappropriate to harmonise internationally, some products are likely to be deleted thereby having a tremendous impact on those consumers that require the product. For Nestlé, this would mean the deletion of the 2 products that we market.

The reasons for adopting the standard as proposed includes that the standard assures the regulatory control commensurate with the assessed level of risk. At certain stages of the assessment paper, it is stated that there are no problems with the current practices for the distribution and access of these products.

We support the position of the Australia New Zealand Enteral Nutrition Manufacturers Association in that the best option for the continued and safe supply of these products is option 2 from the then ANZFA Initial Assessment Report of October 2001. Option 2 the October 2001 Report allowed for recognition in volume 2 of the Food Standards Code with minimal regulatory control.

## 11 IMPLEMENTATION AND REVIEW:

We recommend that the implementation time be extended to 4 years to allow for the reformulation of the products if the proposed standard is adopted without modification. The time taken to gain approval from other countries for reformulation and the actual trials and assessment of the efficacy of the reformulated is likely to require extra time than is proposed by FSANZ. Due to the shelf-life, the special nature and slow turnaround of some of these products, we recommend that the stock-in-trade for these be extended to 2 years rather than the standard 12 months stated in the standard.

**DRAFT VARIATIONS TO THE FOOD STANDARDS CODE:**

[2] – definition of warning statement – (f) should refer to clause 8 rather than clause 9.
[7] & [8] – refers to the variation of volume 2 – there is actually no volume 1, so is the mention of volume 2 here relevant?

Standard 2.9.5:

Modify the definition for Foods for Special Medical Purposes to include the recommendations of the NZENMA submission.

The definition for protein may not be the most appropriate way for measuring the protein. This form of measuring protein is not provided for in other standards. Other legislation does not require a specific level for protein nor do they provide for it to be measured in this way. This may create a barrier to trade and may require reformulation of some types of products, for example, those based on soy protein. Soy protein might be a necessary for of protein for those people that might have an intolerance or allergy to milk and milk products.

The more restrictive nature for minimum and maximum levels of vitamins and minerals means that products manufactured for worldwide distribution will need to be reformulated or they will be removed from sale in Australia and New Zealand because it would be too cost-prohibitive to continue selling. Also the differences between the proposed requirements for vitamins and minerals and that required by international standards will also mean that products will need to be reformulated. The cost of manufacturing small amounts of product to an exclusive formulation for Australia and New Zealand (which are very small markets) would mean a large increase in the selling price. It may also be that the manufacturing factory will refuse to manufacture a specific product because of the increased costs to manufacture and the disruption to operational aspects of the manufacturing facility. Sometimes the amount that would be required for the Australian and New Zealand markets is far smaller than the amount of product that is needed to just settle down the processing equipment used to manufacture the products.

Clause 7(4) requires foods to be expressed as prepared for consumption. This may not always be relevant for all types of products, for example, thickeners.

We support the position of NZENMA in relation to the mandatory advisory statements and the additional labelling statements as written in clause 10(1).

**Nestlé Australia Ltd**

[redacted]

Robyn Banks
Regulatory Affairs and Nutrition Manager
Oceania