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ENTERAL NUTRITION

MANUFACTURERS ASSOCIATION

- Abbott Australasia
- Nestle Australia
- Novartis Consumer Healthcare
- Nutricia Australia

SUBMISSION TO ANZFA

PROPOSAL

P242-FOODS FOR SPECIAL MEDICAL PURPOSES

5 DECEMBER 2001

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Section 1

Executive Summary

This is a joint submission on behalf of the Food for Special Medical Purpose (FSMP) Marketers (Industry) of Australia and New Zealand (ANZ). The companies represented are Abbott (Australia & NZ), Nestlé (Australia and New Zealand), Novartis (Australia & NZ) and Nutricia (Australia and NZ).

Background

Industry believes it has been lawfully and responsibly marketing FSMP products for over 30 years and there has been no evidence of market failure that would justify the need for regulation. Most products are sold to hospitals under state, regional or individual hospital tenders or through retail pharmacy with or without Pharmaceutical Benefits Scheme (PBS) subsidy on doctor's prescription. Companies act ethically to maintain their reputation with the various tender committees, the PBS and individual health professionals.

The FSMP industry is a global industry. Many of the conditions requiring FSMPs are very rare and manufacturers only manufacture a product for rare conditions in one factory and distribute to over 100 individual countries. The amount each individual country requires would not justify individual formulation and labeling. In many cases the minimum batch size would be much larger than the requirement for ANZ

The products usually have long manufacture lead times. When there is an unexpected surge in demand this can usually be met quickly from factory's stockholding of international product or product could be borrowed from another country. The factory would not be holding reserve stocks of special formulations for individual countries.

Industry supplies a large range of oral and enteral feeds for patients with conditions that prevent the use of normal foods. Such patients are usually anorexic and industry supplies a range of products with milk, soup or fruit juice type presentations in a wide range of flavours and textures to overcome flavour fatigue. Ready to feed products have short shelf lives and despite using international products industry struggles to maintain supply without excessive write off of expired product. Due to the small size of the Australasian market it would be impossible to maintain a comprehensive range of these products with separate ANZ formulations.

One of the major advantages of international formulations is that they are able to be subject to extensive initial research and clinical trials and once introduced the health professional will have confidence in the knowledge that the formulation is being used internationally not just in ANZ.

Regulation

Industry strongly favours "minimal regulatory control" as described in ANZFA's Option 2. ANZ does not have the population base to support a prescriptive standard. The most relevant prescriptive standard is the EU standard for FSMPs. However the EU has a population of 375million compared with ANZ's population of 24 million. Prescriptive standards would result in greatly increased prices. Many products would be deleted from the market in ANZ. This would be a major threat to the health and wellbeing of many patients who have need for FSMP. Prescriptive standards delay innovation and compliance with new trends in nutritional care.

Industry believes that Co-regulation as described in ANZFA's Option 3 is possible and workable. However Industry believes it is neither required nor justifiable and would be a waste of resources of Government,

Industry and Health Professionals. There has been no evidence of market failure and any additional level of regulation will add to costs and distract industry from servicing the needs of its customers.

For a FSMP to be successfully marketed in Australia it is currently subject to a large amount of regulation and control.

1. It is a requirement under the Food or Health Acts of the Australian States and Territories and New Zealand that food for sale must be safe. Safety would also relate to the level of nutrients in the products being appropriate for the use of the product, in the case of these foods. Even though there is no particular standard for Foods for Special Medical Purposes, this fundamental requirement is currently complied with.

2. It is also a breach of the food acts, fair trading legislation, the Trade Practices Act in Australia and the Fair Trading Act in New Zealand to make false and misleading claims about food in either the food label or other publications such as leaflets.

3. Most products are manufactured to meet FSMP Standards in the EU or USA where there is a large population to consume the products and the market size can sustain regulations.

4. Most products are either sold through the Pharmaceutical Benefits Scheme that has an expert nutritional subcommittee that reviews the suitability of the products or the products are purchased by institutions through hospital, regional or state tender boards that have expert committees to evaluate them.

5. The health professional recommending the products belong to Australian professional societies with international affiliations that are involved in evaluating nutritional needs and trends for their patients. Such groups include Australia Society for Parenteral and Enteral Nutrition, Australian Society of Paediatric Gastroenterology and Nutrition, Australian Society of Inborn Errors of Metabolism, Australian Society of Immunology and Clinical Allergy and various special interest groups of the Dietitcians Association of Australia.

6. The development of many products is instigated by international experts or they are consulted and involved in clinical trials. It is very difficult to gain health professional acceptance of a new product concept without clinical trial data or the endorsement of an expert.

7. Industry members monitor the activities of their competitors and draw their attention to any health or safety issues that may arise. If satisfaction is not achieved these matters can be referred to the ACCC, tender committees or Health Professional bodies.

Industry believes therefore that there is regulatory control over these products already in Australia and New Zealand.

Definition of Medical

It is important that the warning statement on the label be "Use under medical supervision or similar words". This would cover the EU standard that requires the exact words "use under medical supervision" but still allow for some variation for products from other areas. Otherwise all products from Europe would need to be relabelled. This would be expensive for some products and impossible for others.

If health professionals other than doctors are to supervise the use of FSMPs this should be clarified in the definition of "Medical" in the standard but not on the label. The standard could say: "Medical" includes doctors, dietitians, pharmacists, and nurses.

FSMPs are Not Pharmaceutical Products

The TGA's definition of therapeutic goods excludes "(e) goods for which there is a prescribed standard in the Australian New Zealand Food Code as defined in subsection 3(1) of the Australian New Zealand Food Authority Act 1999." This will therefore exclude FSMPs

Prior to 20th September 1995 a number of FSMPs were classified as Therapeutic Goods. Because of classification problems regarding selenium the TGA and the then NFA agreed the products should no longer be classified as therapeutic and should be standardised in the food code as FSMPs. This overcame the problem of poisons schedule listing for selenium as foods are exempt from the schedule. (see Appendix A of the schedule).

FSMPs should be subject to their own standards and if these conflict with other sections of the Food Code or TGA regulations then the Food Code or the TGA regulations should be amended to exempt FSMPs.

Reference to a Disease State

Many FSMPs currently contain a statement of use such as "For the dietary management of phenylketonuria". This is not a therapeutic or prophylactic claim and is used in conjunction with the words "Use under medical supervision". The statement of use is required under the EU FSMP standard and is considered by Industry and Health Professionals to be a very important final check to ensure the patient is receiving the correct product. Industry considers this to be a very important health and safety issue.

There are precedents for using the name of a disease or condition on the label of a food. Standard A8 of Volume 1 requires foods containing aspartame to be labelled with the statement: "Phenylketonuric: Contains Phenylalanine". A similar statement is required by standard 1.2.3 of Volume 2 of the Food Standards Code for foods containing aspartame.

Which is your preferred regulatory option for FSMP and why?

Industry favours Option 2. – *"No specific standard(s) for FSMP in Volume 2; recognition of FSMP by provision of definition, application of generic standards and provisions and where relevant, exemption from generic prohibitions".*

Within this exemption, there needs to be provision made for manufacturers to detail on the label the type of disease or physiological condition for which the product is intended. There are currently no specific standards for these types of food. Although there are no standards for these foods, their compositional aspects are often controlled through the tendering system of the various health departments. Where there is no such tendering system within a State Health Department, then the products that are provided are the same ones that have been approved through another State or Territory Health Department tendering system.

While currently working outside of any specific standards, Industry would like it noted that there is no evidence of market failure under this modus operandi. Furthermore, agreement by the various State Health Departments has been confirmed directly over the years and endorsed through product specifications published by Tender Boards.

However, Industry sees the formulation of a FSMP category under ANZFA as providing some benefits, one being the publication of a standard as a reference point for Australian Quarantine and Inspection Service (AQIS). The current lack of a standard has been known to cause delays and expense for Industry as the importing process through AQIS is unnecessarily prolonged and complicated.

The stringency of Options 4&5 is unacceptable and Industry believes that these options would result in withdrawal of many products, a lessening of competition and pricing increases of most lines.

Industry believes that a self regulatory code of practice as outlined in Option 3 would be a waste of resources as there is no market failure.

Through its member companies, Industry can demonstrate successful self regulation in other areas of health:

- Marketing in Australia of infant Formulas Agreement (MAIF) (Nutricia, Nestle & Abbott)
- Pharmaceutical Manufacturers' Association Code of Practice (Abbott & Novartis)
- Weight Management Code of Practice (Novartis)

With experience in self regulation, Industry is suggesting if a code of practice is required it be a voluntary Group to ensure that FSMP products are only promoted to Health Professionals and formulations are appropriate. A Board would be formulated to comprise Industry Members and an Independent Member. In the case of disputes or breaches of protocol, it is proposed that arbitration be handled by an independent council comprising a Health Care Professional, Industry representative and an independent chair person. The Health Professional would be a person with technical skills who could represent both health professionals and consumers.

Industry accepts the definition of Medical Foods as tabled in ANZFA Consultation Meetings with Industry, Summary Notes, 23-24 July 2001 with a few minor additions:

- *Medical foods should be used under medical supervision and labelled with a statement to this effect.*
- *Medical foods are*
  a) a food that may or may not be fortified
  b) enterally (or otherwise) administered
  c) involve medical supervision I.e. Physician, Dietitian, Pharmacist etc.
  d) indicated for the management of special dietary needs that exist because of a disease, physiological condition or treatment
  e) for patients with special dietary needs by virtue of disease, inborn error or chronic medical need, has limited or impaired capacity to ingest, digest and absorb or metabolise.

Industry is adamant that the scope of products include foods that may or may not be fortified but are used

for special medical purposes e.g. thickened foods for dysphagia as possible exclusion from the standard may result in exclusion from the Australian market.

Option 2 provides a means of 'legitimising' these products within the regulatory framework without over-regulating a category of foods that is quite widespread in its application and consumer need.

There has been no evidence of market failure, except for the issue of labelling when the imported products are inspected under the Imported Food Programme. Sufficient information is currently provided to Health Professionals and consumers to ensure the appropriate use of the product occurs. This is just not in the format specified for general foods in the Food Standards Code. These products are recommended or prescribed to consumers and are used under the supervision of health professionals, either medical practitioners or dietitians. These products are used in hospitals or are either supplied to the consumer in an at-home situation by means of a prescription or are available directly from pharmacies or pharmacy consumer distribution outlets. These products are not promoted to consumers and access is limited with products not being freely available in the general retail outlets. The cost of these products is usually such that consumers would not purchase them unless they require the products for the specific condition for which they are intended.

Some of the products that are available in this category of foods may only be provided to one patient in the whole of Australia or New Zealand. There is generally only one manufacturing factory for these types of products within individual companies. It is neither cost effective nor practical to provide country specific labelling or country specific formulations for these products. Generally the amounts of products sold do not allow for country specific labels or composition of products. If specific labelling and formula compositions are required, then some products will no longer be available for consumers that are ill or require specific dietary management for their condition.

- **In responding you may wish to consider the following questions:**
  - What are the costs and/or benefits for health professional/consumers in relation to accurate and meaningful information, changes to supply and costs in response to regulatory measures, potential for misleading consumers, risk to public health and safety etc?
  - What are the costs and/or benefits for industry in relation to compliance, market supply and distribution, labelling and composition, and product quality and safety etc?
  - What are the costs and/or benefits for government in relation to administration and enforcement, on the health and disability care system, and risk to public health and safety etc?

Cost of Compliance to Full Regulation:
If a specific formulation is required for Australia and New Zealand, current products will more than likely require reformulation. The reformulation of products will generally require manufacturers to conduct production trials. The cost for production trials is in the order of $55,000. These costs would need to be factored into the cost of the product. If there is only a small number of products sold each year (say 5,000 units) and if the costs were amortised over the cost of the product for 3 years, the additional costs to a unit of product due to trials would be $3.67.

The cost for overlabelling would be higher for these products than for normal products due to the smaller number of labels required. For example, one manufacturer has recently overlabelled a similar product to a Food for Special Medical Purposes.

Printing of 1900 labels (including artwork set-ups)	$1500
Labour for overstickering @ $0.25/can	$475
Replacement of shippers	$190
Total cost	$2165
Cost per unit (exclusive of GST)	$1.14

The total additional cost per unit, in this case, would be $4.81 due to regulatory changes.

Where products are imported for individual patients, the cost for overlabelling becomes even more excessive. This cost may then be prohibitive for the consumer. Often consumers use these food products for an extended period of time, so the overall added cost could be quite substantial.

- How would the costs and/or benefits change under the other proposed regulatory options?
- Do you agree with the identified costs and benefits as outlined in Attachment 5 of this report? Please provide quantitative data, where possible, to support your response.

Evaluation of Other Options:

Industry would not accept Option 3 based on Option 4.This option is described as being co-regulation. However, within the option it provides for full regulation with the enforcement of the regulation being the responsibility of industry. Full regulation would mean that there would be both labelling and compositional requirements for these products. This Option would merely be Option 4 with the government's responsibility for enforcement being shifted. Where there is full regulation, it is the Government's duty to enforce the legislation. The Industry Code of Practice in this case would merely state that industry members must comply with the requirements of the specific standard for Foods for Special Medical Purposes

It would not be possible to introduce prescriptive standards that would cover products currently being imported from Europe, USA and other areas.

There is also a requirement for minimal effect on competition. Full regulation again will have an impact on this because there will be less products in the market, therefore a less competitive market.

Any regulation that is developed must be scientifically based to address the needs of public health and safety. There is no evidence that public health and safety is compromised by the lack of a standard for these products at the moment. Indeed the development of regulation could impact on the public health and safety of some of these special consumers because some products would not be available if full regulation is implemented.

The Authority must fully estimate the net benefit to the community if full regulation is imposed for this category of food.

If Option 5 is implemented, there is even less scope available for these special consumers to be provided with the products they require. Pre-market clearance will extend the timeframe in which a particular consumer is able to obtain a product that has not previously been required by other consumers. Consumers are unable to plan the times that they may need a particular food for special medical purposes. This would be a critical situation with respect to the introduction of full regulation with or without pre-market notification, but is relevant to all foods for special medical purposes. It should not be overlooked, however, that these critical situations would occur if the regulations were more than the minimum effective regulation. Consumers and health professionals would not benefit from this sort of situation. The cost to the consumer can be their health. Public health and safety would not be served with such a set of circumstances.

In relation to industry as a whole, if a regulatory system other than full regulation was introduced:

- To what extent would the industry be prepared to be responsible for enforcement and monitoring of, for example, a code of practice?
- What level of resource (funding and human resources) of enforcement and reporting arrangements could the industry sustain?
- What level of resource of monitoring and reporting arrangements could the industry sustain?

Industry Code of Practice:
The Authority is required to comply with the Government policy of minimum effective regulation. There is no evidence of market failure under current (minimum).

In assessing the need for regulation, the Authority must assess whether there has been market failure within this category of food. The regulatory impact assessment must demonstrate that the benefits derived from the regulation exceed the costs of the regulation

Industry does not believe it needs a Code of Practice, as there are currently no problems that industry's current informal arrangements cannot control. However if an Industry Code of Practice is required then we offer the following.

There are examples of other Industry Codes of Practice in similar areas working quite well. The area of Complementary Medicines has such a situation where some enforcement occurs through a Committee set up particularly for that reason. Another example is the Committee set up to oversee the APMAIF agreement for the marketing of infant formula. A Code of Practice for the foods for special medical purposes industry would be simpler to enforce than the Code of Practice on Nutrient Claims, for example, because the industry contains a small number of players and it is therefore easier to ensure that all manufacturers/distributors comply with the requirements of a Code of Practice.

Before agreeing or committing to such an arrangement Industry would need to consider the financial and resource implications of an industry controlled self-regulatory programme, especially as it does not perceive that there are any difficulties with the current situation for these products

- **Should FSMP be regulated as special purpose foods and why?**

FSMP are sufficiently different from "normal foods" in their formulation and use and the manner in which they are to be regulated to require a separate chapter from normal foods. I.e. **Chapter 4 Foods for Special Medical Purposes.** The concept of normal foods is introduced in the Codex definition of FSMP in the ANZFA assessment report.

Putting the products in Chapter 4 reflects Industry's belief that these products are currently outside the Foods Standards Code and are not therefore subject to current prohibitions of the code. As the products are outside the code they do not require positive permission for the addition of nutritive substances and therefore are not "unlawful" at the point of sale.

In support of our position we attach a letter of 20th September 1995 from Mr. G.M. James, Director Compliance Branch, Therapeutic Goods Administration. We interpret the words "not standardized within the Food Standards Code" to mean the products are not subject to the Code including its current prohibitions.

- **Should FSMP be required to conform to the existing Standards as listed above? Please explain.**

No. The existing standards listed will not be relevant to FSMPs. If any matter need be controlled this could be achieved by a clause in the FSMP standard which may if necessary make reference to certain parts of existing standards.

- **What do you consider are the necessary components of a definition for FSMP?**

The definition needs to define the types of products, the conditions for which they are requtired and restrict their usage to "under medical supervision".

• Is the Codex definition for FSMP appropriate in the Australian and New Zealand context?

The definition suggested by Industry in more complete.

• What types of products should be encompassed by a definition of FSMP?

The products would be as follows:

- Tube feeds
- Oral feeds
- Liquid, solid, semi solid or thickened liquids
- Feeds which are nutritionally complete and capable of being the sole source of nutrition
- Supplements.
- Modules.
- Very Low Calorie Diet (VLCD)

In all cases the products would be use for patients who have the medical conditions described in the industry definition and only used under medical supervision as defined in the definition of FSMPs.

• Should "use under medical supervision" be a defining feature of FSMP? If so, why?

Yes. As this is the essential nature of the products and it will prevent other products incorrectly using this standard to avoid the restriction of other standards. However there should be some flexibility in the actual words to cover the variation between various overseas standards.

• Does the term "Food for Special Medical Purposes" appropriately and accurately reflect the meaning and intent of the proposed regulatory standard? If not, then what would be a more suitable term for this standard?

Yes. It is essential for continued availability of product that the Australasian standards reflect the key elements of the regulations of the major areas of uniform regulations that have target populations at least 20 times larger than the Australasian population.
The costs of making special products for Australasia only would be a burden to the health system or individual patients which they should not be made to bear.

• Are there any health and safety risks to consumers associated with the composition of FSMP? Please explain.

FSMP products fall into two groups. The first is formulated to meet the needs of patients who have their intake of certain essential nutrients restricted as they have difficulty in ingesting or metabolising these nutrients. These patients are monitored regularly to ensure that they do not become deficient in the restricted nutrient. If non-monitored patients are consuming the products they may become deficient in these nutrients. It is essential that consumers receive the correct product for their condition.

It is also essential that the consumer can have reasonable access to these products in emergency situations or for long term use. A patient on a life long diet should not be required to obtain doctors prescription for modified food products they require on a daily basis.

The second group are products that are modified to meet different needs such as increased energy density or thicker consistency but are unchanged in the amount of essential nutrients they supply compared to their unmodified counterparts, or are fortified with extra nutrients. Long term consumption of these products will not cause nutrient deficiencies in consumers irrespective of their medical need for the product.

- Relative to the risk, should FSMP have compositional regulation?

No. The industry currently works in a compositional framework that is acceptable to Healthcare Professionals. Products are usually imported from parent companies in either USA or Europe who are meeting the internationally recognised standards of the country of manufacture. Therefore no additional regulations are required.

- If so, then
  - What nutritive requirements apply to FSMP and in what framework (e.g. standards for all FSMP, product specific standards, or other alternatives) should this regulation exist?

N/A

- Should the definition of nutritive substances be clarified to extend beyond a potentially narrow definition of nutritional purpose for the purpose of permitting added substances to FSMP? If so, how should that purpose be defined?

N/A

- Should more nutritive (and other) substances be permitted additions for FSMP? If so, what criteria should be considered (e.g. safety)?

N/A

- How should 'nutritionally complete' be defined in the context of FSMP?

Not all products need to be nutritionally complete. When a nutritionally complete product is needed patient should be able to consume product indefinitely and at the same time meet all the relevant RDIs. Micronutrients should be included eg. selenium, chromium and molybdenum.

- If not, then what alternatives can be utilised to ensure nutritive quality and safety levels are maintained for FSMP?

For may years our industry has been operating successfully using clinical trials/studies, or efficacy studies developed/produced by our parent companies. All formulations are developed due for clinical need and are thoroughly researched before entering the Australian market. Compositional requirements in all instances meet the EU or the US compositional standards. Market forces and tender committees would prevent companies marketing products to health professionals that did not meet the patients' needs.

- Does a public health and safety risk exist in the unrestricted access to FSMP?

Yes for this reason Industry is recommending that products should only be available under medical/healthcare supervision.

- Are there any situations in which you believe ANZFA should restrict the sale of FSMP?

The only restrictions should be for the promotion of these products directly to the consumer. Restricting access by consumers can also be a health and safety issue when consumers run out of product. In some cases direct supply is the safest supply. This would however be in the overall context of regular medical supervision. An example of this would be a patient requiring home enteral nutrition on discharge from hospital.

- If so, then where should FSMP be available and in what manner should they be accessed? Should product labelling reflect any restriction on access, e.g. "Pharmacy only product"?

Available through hospitals, nursing homes, pharmacies or mail order under medical supervision.
The only product labelling restriction should be: "Use under medical supervision".
The definition of "medical supervision would include doctors, dietitians, pharmacists, and nurses.

- If not, then what measures (if any) should be placed on the sale of FSMP?

N/A

- Should FSMP be exempt from the various horizontal labelling standards in Volume 2? If so, which ones and why?

Industry supports exemption from many of the Food Standards on the basis that the products involved are not General Foods by composition nor targeted at Consumers directly

Industry accepts the need to comply with Public Health & Safety requirements provided for by horizontal labelling standards and will supply Product Information sheets containing this information to accompany the product. For long term or contract customers the information sheets would be supplied and kept up to date by company sales personnel.

- If FSMP were to be required to comply with all generic labelling requirements in Volume 2, what cost would there be to industry in terms of re-labelling of products? (Please quantify if possible)

Industry estimates that 99% of FSMP product units sold in Australia/NZ are imported. Of these 95% would not comply with ANZFA current general labelling requirement and would require relabelling or over sticking. The cost of this exercise would be minimised by performing the task within Australia/NZ (lower labour costs) and this could trigger increase AQIS Imported Food Programme inspection prior to Release for Sale of the goods or an arrangement whereby the goods are held in bond, labelled, and then released by AQIS.

The actual cost of re-labelling assuming use of a sticker plus labour to repack and apply, is estimated at $0.25 cents/unit. Automated re-labelling is unlikely to be attractive due to the variety of container shapes, tetrabriks with straws attached, round bottles, cans and 'ready to hang' bottle enteral feeds etc etc .

Industry estimates a total of 9-10 million units are sold per annum. Relabelling of individual containers within Australia/NZ would therefore cost an additional $2.5 –3.0 million. p.a. an increase of approximately 8-10% on C.O.G.'s to be passed on to health system ,in the main. (90% of this product being sold to hospital or hospital pharmacy or through retail pharmacy on the PBS.)

- Should FSMP be labelled with contact details of the product supplier

For products for inborn errors of metabolism most companies have a policy of analysing the product after the label has been attached to the packed product to ensure the correct product is in the correctly labelled container. If local over labelling of the product with the name of the product and country specific details including details of the local supplier were mandated, the product could require revalidation post over labelling. With the extra cost and delay – there would be instances where incorrect product supplied to compromised patients could result in death.

In all cases, the status quo provides for a local supply contact, through Product Information Leaflets supplied with products. In all cases the product itself is labelled with the name of the Manufacturing Company abroad who is a parent or associate company of the local supplier.

- If changes could not be made on product labels

Industry believes that there is sufficient information leaflets supplied with Product Information, to enable the supplier and local distributor to be traced. Dissemination of information containing product details to those using the product should be mandatory; all product supplied currently has extensive product information available with it and there is insufficient label space to communicate all of the product attributes to ensure efficacious usage. Product information will typically include macro, micro nutrient composition, specific protein, fat, carbohydrate profiles, osmolarity, fatty acid profiles, energy distribution profiles etc as required according to the physical condition of the patient targeted with the specific formulation - this level of detail cannot often be communicated on existing pack surface area.

- Should FSMP comply with the requirements of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations? If so, why? If FSMP were only available under medical supervision, is it reasonable that the medical practitioner should consider the appropriateness of the product from supporting information and label declarations may be not required?

Section 1.2.3 Mandatory Warning and Advisory Statements and Declarations should be complied with using local Product Information publications, which are distributed with the product. A Medical Practitioner or other health professional would then take control of recommending the product based on the patient's history. Current warning statements in the Food Code will not cover enough detail to ensure the product will be the correct product for the consumer.

There are numerous factors for a health professional to consider in selecting a product for a patient, only some of these factors are covered in health warnings. The ANZFA list of allegens for instance is shorter than Nutricia's list and neither list would fit on many of the containers. Some warning statements say not to use for certain conditions except under medical advice. This is redundant when the label of a FSMP says "use under medical supervision". ANZFA warning statements are unique to Australia. There would not be sufficient space on many packs and to use them would require relabelling. The best solution is for all the information to be supplied to the health professional for evaluation and recommendation accordingly.

- How can FSMP be labelled to support the market of specialised products for people with specific conditions, but to prevent the misuse of FSMP, or the marketing of inappropriate products? Should FSMP carry the warning "Use only under medical supervision"? (Please state reasons for agreeing/disagreeing). What alternative statements/means could be appropriate to inform consumers that these products are not suitable for consumption by the general public?

Together with mandatory labelling 'Use under Medical Supervision' the environment for marketing of such products can be effectively controlled. A Medical Food product is unlikely to be attractive for consumers and the general public if such a statement is prominent and obvious. In addition, the graphical representation on existing products is unlikely to be attractive to the general public.

- Should FSMP be permitted to make reference to particular disease states? If so, why?

FSMP by their nature must make reference to by association with a medical condition or disease state rather than any direct therapeutic or prophylactic claim; and given that communication is targeted at health professionals, they would identify with the terminology making categorisation of the product according to specific needs, easier. The name of the condition on the pack also allows the patient or carer to make a final check that they have been supplied the correct product. This is often CRITICAL to medical professionals in providing the link between metabolic need and clinical indication of a disorder. To remove reference of disease or disorders from the pack introduces an unacceptable element of risk to the patient and the practitioner – eg a patient with phenylketonuria who requires a product free of phenylalanine but high in tyrosine may be incorrectly administered a product containing phenylalanine but free of tyrosine intended for a patient with tyrosinemia if the container was not labelled with the condition. Administration or recommendation of unsuitable formulations could cause mental retardation or death. This raises the issue of professional liability for medical practitioners as well as the supply company if an incident occurred.

• Is the definition of "convincing" appropriate for the substantiation of Health Claims in FSMP?
The substantiation of suitability of the nutritional profile of a particular product must be based on accepted nutritional science, i.e. structure/function of particular nutrients. The substantiation of any synergistic effects of combination ingredients is often validated by clinical trial and in this regard the definition of "convincing" as suggested under 1.5.4 Health Claims is acceptable to industry. If Country specific formulation and labelling compliance at the point of import were required (as opposed to over labelling at the Country of destination) it is estimated that up to **70% of the product range (by SKU) would likely be deleted due to the unfavourable costs of production overseas.** Higher volume "standard" lines would continue to be supplied albeit it at elevated costs. Special lines indicated for 2 in 10 patient needs, e.g. short bowel syndrome example Vivonex TEN, would be taken off the market and would then need to be imported by specialists on a scheme similar to the 'orphan drug' scheme. This could compromise the health of some patients. We have seen already examples of this with the withdrawal of Portagen®, an MCT oil based product; there were no equivalents available when the local sponsor ceased operations; patients and recommenders were left without alternatives and forced to make their own special importation arrangements for small volumes at highly escalated costs with excessive administration hurdles.