AUSTRALIAN SELF-MEDICATION INDUSTRY
BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

Standards Liaison Officer
Food Safety Australia New Zealand
PO Box 7186
Canberra BC ACT 2610

7 August 2002

Dear Sir/Madam

RE: Proposal P235 – Review of Food-Type Dietary Supplements (FTDS)

The Australian Self Medication Industry (ASMI) wishes to thank Food Safety Australia New Zealand (FSANZ) for the opportunity to respond to the above proposal.

ASMI is the peak organisation providing both advocacy and representation for the full spectrum of the non-prescription manufacturing sector, both Over-The-Counter and Complementary Medicines.

Upon review of Proposal P235, difficulties were experienced in clearly identifying exactly what the working definition was for FTDS. Making a delineation on the basis product form alone is not adequate. While tablet, capsule and other associated 'pharmaceutical' dose forms should reasonably be regarded as 'Therapeutic-Type Dietary Supplements' (TTDS), or Complementary Medicines, there are many manufactures who supply on the Australian market powdered FTDS of New Zealand origin, containing substances restricted to therapeutic goods if manufactured in Australia ie chondroitin sulphate. It is certainly unreasonable to argue that this product is a food, even when not making health claims, as they are often marketed with the same livery and branding as tablet and capsule chondroitin sulphate products which have been Listed with health claims under the Therapeutic Goods Act 1989. The consumer is therefore unlikely to make a differentiation of a powdered product as a food and capsule product as a medicine.

It would also be a premature to progress this proposal ahead of the development process for the proposed Australia/New Zealand Joint Agency for regulating medicinal products. While it is assumed that those NZ dietary supplements in 'pharmaceutical' dose form would by default be regulated as medicines, it cannot be taken as a fait accompli, the level of acceptance of these products being regulated as medicines being greatly dependent on the New Zealand governments final acceptance under a joint arrangement.

It is also difficult to be able to differentiate the FTDS on the basis on potential health claims. As yet there has not been an adequate resolution to Proposal P153- Health and Related Claims, and depending on how this proposal may eventually be resolved may significantly impact on what constitutes a FTDS. As any comments received on

FTDS with regards to "health claims" are therefore going to be completely hypothetical, it would therefore be inappropriate to create a separate standard for FTDS using "health claims" as any sort of delineating factor in the absence of a finalised FSANZ policy. This is made more difficult in that a number of potential "health claims" are also "therapeutic claims" currently utilised by medicines, and that there would not a clear delineation of this basis between foods and medicines on the basis of claim alone under Proposal P153.

It needs to be questioned as to what the purpose for FTDS actually is. If the purpose is to be able to make higher-level health claims than is currently possible for other foods, then under the current regime for health claims, this sort of product is arguably a therapeutic good and should be regulated as such. If the purpose were to supplement the diet with substances for nutritional purposes, then there would be no need for health claims for these products greater than 'functional claims' made in context to dietary intake. It could then be questioned as to why there should be a separate and discrete category of foods that are able to contain nutritional substances not available to other foods? The logical conclusion from this that FSANZ need to seriously consider whether the most appropriate way to deal with FTDS, that are not likely to be viewed by consumers as TTDS or Complementary Medicines, is to liberalise the substances and levels of substances able to be used in existing food standards for nutritional purposes. It is appreciated that this may involve significant legislative amendments to all food standards, making this the least favourable solution to dealing with FTDS. It is however the most sensible if FSANZ genuinely seek to minimise the ongoing confusion on the food/therapeutic goods interface, provide equity to all food manufacturers and allow enough flexibility in the Food Code to cope with future innovation.

Section 2.1.1 Market Data

It is important for FSANZ to consider the following points when considering any market scan data provided for this item:

- how can adequate differentiation in market data be made for dietary supplements, especially New Zealand dietary supplements, between those which are FTDS and those that are TTDS? As has been argued in our introduction, such a differentiation cannot be made only on product form.
- how can a differentiation be made between those New Zealand dietary supplements that comply with the New Zealand Dietary Supplements Regulations, and those that do not? As there is little or no compliance activity on illegal product, it is inappropriate that the sales data for these products be considered.
- does the data capture "direct to consumer" in the Australian market by NZ manufacturers?

Section 2.4.1 Addition of nutritive substances

Standard 1.3.2- Vitamins and Minerals, is probably too restrictive in the manner of limiting the types and amounts of certain vitamins and minerals available within food groups. It is conceivable that FTDS may contain types and levels of vitamins and minerals currently not allowable in other foods, and that any unique concession provided to FTDS would be an unequitable position to other food manufacturers. There is scope for the limits in this standard, particularly with regards to specific limits set on nutritive substances in types of foods, to be revised significantly.

Foods should not generally contain more than the recommended RDI through use of added nutritive substances. Additionally, any increased allowances of nutritive substances should not necessitate a food to be required to be taken at a specified "dose", and imply a benefit other than nutrition that may otherwise be interpreted as a therapeutic claim.

Section 2.4.2 Special Purpose Foods

The "Primary" function of a Special Purpose food is that it must be used as a food, the "Secondary" function being that it must be formulated for a specific sub-group of the population. Special Purpose Foods are not for general use, therefore it is inappropriate for FTDS to be covered under Special Purpose Food standards.

Section 2.4.3 Formulated Caffeinated Beverages

As a general principle to this standard, which may be applicable to other standards, if a nutritive substance is formulated in a food to a level that necessitates a specific warning statement as would be found in a therapeutic good ie not recommended for pregnant women or a medicine interaction warning, it must be questioned as to whether that formulated ingredient is appropriate for a food.

It needs to be recognised that the creation of the Formulated Caffeinated Beverages standard was done primarily on the basis of addressing a trade issue, and developed through minimising the risk to the consumer. In this regards, ANZFA abandoned certain key principles with regards to the intended purpose of these foods, and created a category of foods based on principles not equitable to other kinds of foods. It would therefore be unacceptable to develop a unique standard for FTDS purely on the premise of "recognising" foods that would not only be illegal for an Australian manufacturer to produce market, but currently do not comply to the New Zealand Dietary Supplements Regulations, despite their presentation as a NZ Dietary Supplement and importation into Australia as such.

Section 2.4.4 Novel Foods

Food-Type Dietary Supplements generally do not meet the definition of a Novel Food on two grounds:

1) a history of consumption by the general New Zealand population would indicate a "tradition" of use;

2) the use of substances that should generally be regarded as suitable only for use in therapeutic goods, as there may be issues with the safe use of these substances on a long-term basis/adlib basis or the use of which conveys an impression of therapeutic health benefits or benefits greater than what may be available through normal dietary intake.

In the latter case, if the presentation of the food product containing such a substance is clearly food-like, and the health benefits are secondary to the primary purpose of the product ie margarine spread, then it may be appropriate to treat the FTDS product as a Novel Food.

It is worth noting that concerns have been raised by ASMI members that individual State Health authorities and the Australian Quarantine Inspection Service do not appear to have a good working understanding of "Novel Foods", and how to recognise a that while a product is a food, and generally allowable for import, may fulfil the criteria of an unapproved Novel Food, and as such should not be allowed to be imported and marketed until that approval has been provided.

Section 2.4.5 Botanicals and Natural Toxicants

There is scope for expanding the currently permitted list of botanical ingredients for use in food provided that the botanicals used are safe for adlib consumption (not dose/serve dependent), and are used only for genuine food additive (flavouring and/or colouring) purposes, and in some circumstances, nutrition.

Such liberalisation however, needs to be balanced to prevent the presence of a herb for which there is not a tradition of culinary use, or the use of a herb for a non-food additive purpose, that may imply certain health benefits to a food. In therapeutic goods, the effective use of an herb may be dictated by plant species, plant part, extraction method and dose. A food using the same herb is not necessarily bound by any of these conventions, and yet may be presented as having similar benefits as a therapeutic good.

It must be stated that the current situation where a non-culinary botanical, animal or plant matter that has no tradition of use, has no *prima facie* evidence of harm, no presumption of safety and not classed by the manufacturer as being novel, cannot continue to have no regulatory control. This situation is unacceptable to the medicines manufacturing industry and has resulted in instances where the substance is not for colour, flavouring or justified nutrition purposes, and implies some additional health benefit ie St Johns Wort Tea. This then relies on the medicines industry to make representation to each State Health department to facilitate action, or get the product classified as an illegal therapeutic good by the TGA.

This situation does have certain public health implications in that these non-traditional, non-culinary ingredients often do not have sufficient paediatric safety data to remove any health concerns that may arise though ad lib food usage by a child.

<u>Questions on added substances</u>

Most of these questions have been addressed in the previous section.

Single and Mixed Foods

Single-ingredient mixed foods can be acceptable provided the primary purpose is as a food – however, if the suggested serving size or frequency of a particular substance is sufficient to convey an implied therapeutic action ie chondroitin sulphate powder, ispagula husk powder, then such foods should be classified as therapeutic goods.

The example provided of conjugated linoleic acid as being a single substance is incorrect, as this is a chemically synthesised substance that contains mixed octadecadienoic acid isomers as a result of the manufacturing process

There would be no general objection to allow a "mixture of foods", provided this was achieved by bringing those FTDS under existing food standards, and that the primary purpose of the food could not be interpreted for "therapeutic use". It must also be recognised that this may constitute making the product a "Novel Food".

Novel Foods

Permission to allow substances that might otherwise be classed as Novel must only occur on a case by case basis, which could occur through a "grandfathering" type of application rather than a full application, providing there was adequate consultation with key food and medicines stakeholders, and bodies such as ERPIM (External Reference Panel on Interface Matters). Approval could be granted provided there were no sustainable objections. If such an approach were taken there would need to be a predictable and transparent process devised.

Section 2.4.7 Labelling and Claims

<u>Questions on Labelling</u>

1) What labelling statements are considered important..?

There should not be any unique label statements for FTDS that are beyond or different to existing categories of food (allowing for specific exemptions).

2) How should underpinning criteria be set…?

Where there are no Australian RDI's, and overseas RDI could be used, provided this is referenced on the label.

3) Is the labelling of products with general advisory statements?

It can be argued that should specific advisory statements be required to prevent consumption by vulnerable population groups, then the substance should not be used in a food, unless the target group of the warning involves a specific food allergy or condition.

4) Are there other substances, specific to FTDS?

Any specific FTDS substance warnings should be determined by nutritionist-based policy from FSANZ- however there should be an equity in labelling requirements between foods and therapeutic goods when an ingredient common to both require a warning statement.

5) The nutrition information requirements…?

FTDS should be required to carry a Nutrition Information Panel as do all other foods (except for those foods subject to special exemption).

6) If health claims are permitted….?

With regards to nutritive substances, it may be regarded as inappropriate for a food to make a "nutrition function" claim without at least 10-25% of the RDI. The criteria for claims stronger than this encounter a number of significant problems.

In figure 3, page 28 of the consultation document, a delineation is made between nutrition claims (nutrient content and nutrient function), health claims (enhanced function and risk reduction claims) and therapeutic claims.

The fundamental error with such delineation is that it does not properly represent health claims as existing on a continuum of claims that potentially overlap. For example, the defining of enhanced function claims and risk reduction claims as not being therapeutic claims is erroneous, as many therapeutic goods carry such claims already and are clearly regarded as therapeutic claims.

This re-emphasises the import of having an equitable system of evidence substantiation to that of therapeutic goods for comparable claims, should health claims in food become implemented. It also indicates that there needs to be a shift in mind set from considering only the risk management of a food making health claims to considering the management of the food based on the level of promise behind the health claim. This is particularly relevant where the nature of the claim may result in changes in consumer behaviour towards their use of medication that may be necessary to manage serious health conditions.

It is of critical importance that there be an effective national "watchdog" approach to managing non-compliance of foods with regards to ingredients and health claims. This approach needs to encompass not just issues of public health concern, but also technical breaches of the Food Code that result in the erosion of consumer confidence and compromise the integrity of the food and therapeutic goods industry.

Furthermore, it is essential that at the very minimum that a post-market system be in place to make formal advertising complaints on health claims in food like that for therapeutic goods under the Therapeutic Goods Advertising Code Council.

An additional area FSANZ may need specific management criteria is the emergence of Novel Claims. These may be health claims for traditionally used foods for which the intended ad lib usage confers a health benefit that may not be able to be replicated if the substance was to be made into a medicinal dose form ie cranberry juice for use in Urinary Tract Infections.

7) If so, is the contextual statement….?

All nutrition function and health claims in food must be made in context of the total diet.

8) Should FTDS regulated as foods be required…?

As ASMI do not believe that there is sufficient justification for the establishment of a separate standard for FTDS, any prescribed names or advisory statement should be unnecessary.

9) Are instructions regarding dosage…?

Instructions for specific dosage are not appropriate for any food unless it is required to meet the nutrition needs of a subgroup of the population, such as for a Special Purpose Food, or unless it meets the evidence requirements for a Novel Food.

10) Are there any other general labelling issues..?

No other issues identified.

Section 4 Regulatory Options

Based on Figure 4 p 33 of the consultation document, ASMI favour a Horizontal approach to resolving the issue (option 2a)

Option 1 – Status Quo is not acceptable as it undermines the regulatory standards required of Australian manufacturers of "dietary supplement" products required to meet GMP, while NZ Dietary supplements do not.

Option 2a- Full Regulation- full regulatory provisions within Volume 2, and the cessation of provision for production or importation of FTDS under the NZDSR.- a horizontal approach is adopted based on the premise that the policy bases of particular standards are reviewed and amended/expanded. This would have the affect of allowing for the manufacture of many of the FTDS not currently addressed by Volume 2, and opening up the food supply generally to more liberal permissions under regulated provisions.

Option 2b- Vertical approach- separates FTDS as discrete products- is not acceptable for reasons specified throughout this response.

Option 3 – Co-regulation – not acceptable as it is dependent on full participation of food industry in Industry Codes of Practice, which will not occur. It also relies on an efficient and transparent food compliance system on a national level that also does not currently exist.

Section 5 Impact Analysis

Nowhere has the OTC and Complementary Medicines industry been identified as an affected stakeholder. As these FTDS potentially sit on the interface between foods and medicines, especially in context to possible future allowances for health claims, these products have considerable potential to detrimentally affect these industries if standards for FTDS are implemented which encroach into the area of therapeutic goods.

The regulatory objective of ensuring that FTDS products facilitate consumers making informed choices makes an assumption of consumer understanding of a distinct group of nutritional products between foods and medicines, that are regulated as foods but may convey benefits similar to that of medicines. As has already been stated, the differentiation between FTDS and TTDS cannot easily be made on form or claim, and it is therefore unlikely that the consumer will easily be able to discern the two.

A significant number of manufacturers of complementary medicines, or TTDS, use a pharmaceutical GMP and meaningful therapeutic claims to establish the identity of these product in the Australian market place. To introduce a separate standard of goods that cannot be easily discerned from therapeutic goods, but without the guarantees on manufacturing quality, evidence and protective surveillance by a national authority serves to undermine the integrity of the Australian medicines manufacturing sector and dilute consumer confidence. By encompassing these products under existing food standards with suitable regulatory controls will provide greater clarity on the foods/medicines interface and ensure reasonable consumer expectations with regards to the products they purchase.

The assertion that Australian industry is somehow at a disadvantage through lack of FTDS standards with regards to exporting to markets such as South-East Asia is misleading, and assumes that these importing regions currently make a clear distinction between FTDS and TTDS. Currently Australian therapeutic goods manufacturers export significant quantities of “dietary supplements” (as complementary medicines), where the assurances of quality under our system of GMP manufacture are viewed as a beneficial attribute. To create a separate FTDS standard whereby the delineation between foods and medicines is not readily recognisable runs the risk of lower quality products that could be viewed as TTDS being exported, which may pose risks to the reputation and viability of our medicines exports industries, which as of first quarter 2001 was at 1.8 billion dollars (source Working Paper No. 2001/10 - A Statistical Analysis of Australia's Exports, ABS).

To expect this proposal not to discriminate against any sector of industry is a worthy ideal but present practicalities. Any amendment to the food code that facilitates standards for FTDS should not be used as a mechanism for legitimising illegal products that currently do not comply with the New Zealand Dietary Supplement Regulations, despite presenting themselves as such in order to access the Australian market. Inevitably those manufacturers who unreasonably exploit the lack of regulatory compliance in New Zealand and Australia on technical breaches to the Food Code should not be expect to accommodated.

I trust that be above comments are useful to your considerations. [redacted]

Yours sincerely

[redacted]
Regulatory and Technical Manager