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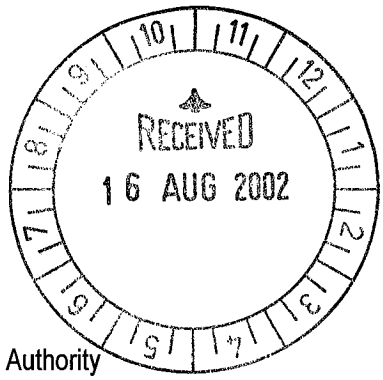

Standards Liaison Officer
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ENTERED IN DATABASE
19/8/02

14th August 2002

Submission from Blackmores Ltd –
"Proposal P235 Review of Food-Type Dietary Supplements"

Thank you for the opportunity to provide comment on the proposal.

Blackmores' comments will be of a more general nature at this stage till the Draft Assessment Report is available later this year.

Blackmores supports the establishment of a new regulatory model for food-type dietary supplements (FTDS) in conjunction with the repeal of the New Zealand Dietary Supplements Regulations (NZDSR). With the proposed new joint trans-tasman agency for therapeutic products also being progressed the need to harmonise this area is also critical for industry.

Blackmores supports a risk-based regulatory framework to minimise any threats to public health and safety. FTDS, in general, are at the high-risk end of the food supply and must be regulated using an appropriate risk management strategy.

Blackmores believes the most appropriate regulatory option is 2bi and believes that a new vertical standard within Part 1.5 of Volume 2 of the Food Standards Code (FSC) is the most suitable regulatory option. Blackmores believes it is not in the interests of either consumers or industry to open up the wider food supply to the inclusion of any substance that may be classified as an adjunct to the diet i.e. a dietary supplement. Consideration must be given to the public health and safety consequences of such an outcome. For this reason Blackmores supports a specific standard for FTDS to ensure there are adequate controls in place to characterise and regulate FTDS.
Failing option 2bi being accepted Blackmores believes in the main most FTDS could be incorporated into the Novel Food Standard 1.5.1 of Volume 2 of the FSC. Since many FTDS are non-traditional foods and have been specifically developed as functional type foods they should be subject to controls consistent with this approach.

Comments of a more specific nature follow:

1 Interface with medicines
Blackmores believes that in developing a new model for FTDS it is critical that the food / medicine interface be clarified and understood by all stakeholders. There must be a commitment by both the Australian and New Zealand governments to provide resources to ensure timely enforcement of any breaches.

2 Presentation of FTDS
Blackmores believes that in order to appropriately differentiate FTDS from medicines, FTDS must be presented as a food. We do not support any permission to allow FTDS to be in a "pharmaceutical" format such as tablets or capsules. Foods presented in this way are often confused with medicines.

There are many cases currently where capsules / tablets are passed off as foods and they enter the complementary medicine market via the back door. Since it is likely the intent of the product was to be a de-facto medicine anyway then the presentation of future FTDS must prohibit those formats already established in the medicines arena. Presentations likely to mislead or confuse should automatically progress these products to the therapeutic products area where they are subject to tighter regulatory control. In addition the definition of FTDS should also capture "what is the intent of the FTDS?". If the intent of the FTDS is to promote the food for a therapeutic use then the product is a therapeutic good and should be regulated as such. This is particularly problematic should products contain herbal substances when the use of those herbs is mainly for medicinal reasons. Since very few herbs would have a culinary / flavouring usage in FTDS there is the need to question why they are being added to supplements if not to take advantage of consumer awareness of those herbs for specific therapeutic use.

3 Safety of substances

Blackmores believes it is critical in the development of a new model to take into consideration safety issues relating to the indiscriminate use of ingredients that may have potentially adverse public health and safety consequences.

Blackmores believes it is not appropriate to permit the addition of any substance to food unless that substance has been adequately assessed for safety within the context of that food. In order to facilitate this Blackmores believes:

- The inclusion of vitamins and minerals as per the National Health and Medical Research Council's Recommended Dietary Intake (RDI's) table should be permitted in FTDS provided the level of fortification does not exceed 50% of the RDI.
- The inclusion of other macronutrients such as protein, fats, fibre etc should be permitted in FTDS in reasonable levels as a supplement to the diet.
- The use of any other substance is subject to assessment by Food Standards Australia New Zealand (FSANZ) for safety.
- There should be a "negative" list of substances that should not be permitted in FTDS due to safety concerns. This is particularly relevant to herbal substances. This list should at a minimum be drawn from the current prohibitions in the FSC and Therapeutic Goods Regulations.

The meaningful addition of substances must also be considered. Miniscule amounts of ingredients that consumers believe have some health benefit deceive and mislead consumers. Levels of any supplement must have some meaningful basis as well as being safe to consume. Excessive fortification is also likely to produce adverse effects on public health and safety since the exposure to these ingredients is higher. All these factors must be taken into account when assessing the safety of ingredients to be incorporated into FTDS.

4 Health Claims

Blackmores awaits the outcomes of Proposal153 for further developments on permission of health claims. In principle Blackmores does not support health claims on foods unless they are adequately substantiated and assessed to ensure their validity.

5 Labelling

Blackmores supports the appropriate labelling of any FTDS to ensure that consumers have adequate information regarding the product. This labelling should contain at a minimum full disclosure of the supplemental ingredients including the amount present in the food. In addition where products contain substances that have been evaluated by other government agencies, for e.g. the Therapeutic Goods Administration (TGA), and require safety warnings, then those same warnings should be required on FTDS. Since the amount consumed of any one FTDS will largely be uncontrolled it is critical that consumers are made aware of any safety risks. It is also appropriate to ensure these foods are labelled with a prescribed name to differentiate them from other general purpose or special foods and that they carry some information about the amount that should be consumed within the context of the total diet.

6 Notification of products to FSANZ

Blackmores strongly supports a mandatory notification system for FTDS intended for marketing in Australia and New Zealand. This system would establish a central register of FTDS products, what they contain, what their intent is and their directions for use. The ongoing monitoring of these products and ingredients would minimise adverse public health and safety benefits. The system could operate as a notification system and FSANZ would inform a company of any safety concerns within a statutory time frame. If no response is received then the product is suitable for sale, if there are questions or concerns these can be raised directly with the company. All notifications could be held on the FSANZ web site so that industry and consumers alike are aware the product is cleared for marketing. This register will also ensure there is a level playing field with complementary medicines that may contain similar ingredients. Complementary medicines are required to undergo a pre-market assessment prior to entering the marketplace. It is equitable to ensure that all products that the public consume are safe and of good quality.

7 Manufacturing standards

It is critical that any products consumed as an adjunct to the diet are manufactured under an appropriate level of good manufacturing practice. A minimum standard will help ensure products are safe for their intended purpose and of good quality. This will instil consumer confidence in this growing area of functional foods. Without adequate standards of manufacturing and processing consumers may be put at risk.

8 Quality of ingredients

Blackmores strongly supports rigorous controls on the supplementary ingredients placed into FTDS. Consumers expect that products with a perceived health benefit will be of good quality. Quality also has a direct correlation to safety of the product since appropriate quality standards aim to minimise contaminants and impurities. This is especially so in the area of herbals where it is necessary to be aware of types of preparations and their appropriate usage.

9 Transition arrangements

Blackmores strongly supports a minimum transition period for lawful existing products in either country to conform to the new FTDS standard. Those products in tablet / capsule form should transition over to therapeutic products and be subject to those controls. The remainder of lawful products that are "true" foods should be required to comply with any new standard within 2 years of operation. Two years is consistent with the transition period currently for foods covered under Volume 1 of the FSC. During this transition period products would be required to enter their details on the register and be subject to an assessment by FSANZ. Products considered currently unlawful would either need to modify their composition or presentation in order to comply with any new standard.

10 Advertising of FTDS

Blackmores strongly supports a co-regulatory system of advertising controls to ensure that FTDS are responsibly promoted, especially to vulnerable consumer groups. An advertising code containing key principles should ensure that products are not embellished with health / therapeutic claims. Any such code must be supported by government, industry and professional groups to ensure it is adhered to. A suitable starting point could be the New Zealand Advertising Standards Authority's Code for the Advertising of Food.

11 Single and Mixed foods

Blackmores does not support the creation of a FTDS standard that would permit single foods unless they have been assessed for safety. The reason many of these foods would be marketed as FTDS is to by-pass the therapeutic goods regulations. This is currently the case now for several single ingredient products. The intent of the food must be examined and if they are being developed to promote a particular health benefit then they are more appropriately regulated as medicines. In adopting a notification system for FTDS FSANZ will have the opportunity to raise any concerns about these foods in conjunction with them entering the marketplace.

The wider use of supplementary ingredients in general purpose foods must also be closely examined. It would not be appropriate to permit the fortification of staple food items with certain substances since these foods are consumed by the population as a whole and may present some risk for certain groups. The development of a unique FTDS standard that is specific and does not permit cross supplementation will minimise any safety risks to the public.

Blackmores woud be pleased to provide any further information as required and we look forward to the Draft Assessment Report in due course.

Regulatory Affairs Manager
Blackmores Ltd