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FOR INFORMATION

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EXPERT GROUP ON VITAMINS AND MINERALS: FOLLOW UP ACTION WITH INDUSTRY

Executive summary

1. When the Board discussed the report of the Expert Group on Vitamins and Minerals (EVM) on 8 May 2003 it agreed that, where food supplement products are currently recommending doses higher than the Safe Upper Levels or Guideline Levels agreed by the EVM, the Agency should take forward discussions with industry on reformulation and/or advisory label statements. Officials have met the three major trade associations several times since June of last year and discussions are now finished for the time being. The discussions were constructive and we have managed to secure agreement for most of the nutrients where problems were identified.
2. Copies of the agreed advisory statements / reformulations and accompanying cover note are attached to this information note.
3. The Agency's position, as well as that of the industry, is set out in the footnotes to the attached documents, which are to be published on the Agency's website. For beta-carotene and manganese the issues will be revisited if relevant new evidence comes to light. For phosphorus the wording of the advisory statement will be reconsidered following receipt of advice from the COT.
4. This advice to industry was published on the Agency's website on Tuesday 18 May and reflects consumer advice already on the website.

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FOOD SUPPLEMENTS: LABEL ADVISORY STATEMENTS AND SUGGESTED REFORMULATIONS

This note introduces advice that applies to some food supplements containing high levels of vitamins and minerals. The advice covers advisory statements to be included on labels and, in a limited number of cases, suggests reformulation. The advice has been agreed by the Food Standards Agency and food supplements industry representatives following publication of the report of the UK's Expert Group on Vitamins and Minerals (EVM) in May 2003 (available at <http://www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf>). The aim of the advice is to protect consumers by providing information which will alert them to the potential for adverse effects, and enable them to make informed choices.

The EVM was a group of independent experts established in 1998 to review the safety of food supplements containing high levels of vitamins and minerals. EVM's membership was drawn from four existing advisory committees along with two experts nominated by consumer and industry organisations. Four observers to the Group represented the main interest groups of consumers, the food and health food industries and complementary medicine.

The majority of food supplement products on the UK market contain amounts of vitamins and minerals that are well below the safe upper levels set by the EVM. However, a small number of products contain higher amounts, which could cause adverse effects in some individuals. These are some products containing vitamin C, iron, calcium, magnesium, nickel, beta-carotene, nicotinic acid, zinc, manganese, phosphorus, vitamin B6. In these cases the Food Standards Agency considered that providing information to consumers is necessary to enable them to make informed choices, and embarked upon discussions with industry representatives with the objective of providing this information on product labels. The result of these successful discussions is the list of advisory label statements and, for three vitamins, suggested reformulations, attached as the Annex.

The recommendations in the Annex have been agreed on the basis of the scientific evidence considered by the EVM and may be amended in future in the light of new information. This approach is seen as an important element of the safety-based regulation of food supplements, as it demonstrates a risk management approach which both protects consumer health and enables informed consumer choice.

The Food Standards Agency will make this advice available on its website at **www.food.gov.uk** and will send it to the European Commission, the European Food Safety Authority and other Member States in order to inform further EC discussions on safety-based regulation of food supplements in due course. The Council for Responsible Nutrition, the Health Food Manufacturers Association, and the Proprietary Association of Great Britain will disseminate the advice and make it widely known to their memberships.

Food Standards Agency, Council for Responsible Nutrition, Health Food Manufacturers' Association, Proprietary Association of Great Britain, May 2004

ANNEX: LABEL ADVISORY STATEMENTS AND RE-FORMULATIONS IN RESPONSE TO EVM'S FINDINGS, MAY 2004

Nutrient	Threshold to trigger statement (recommended daily amount)	Label advisory statement/reformulation
Vitamin C	> 1000 mg	"[This amount of Vitamin C]* may cause mild stomach upset in sensitive individuals."
Iron	> 20 mg	"[This amount of Iron]* may cause mild stomach upset in sensitive individuals"
Calcium	> 1500 mg	"[This amount of Calcium]* may cause mild stomach upset in sensitive individuals."
Magnesium	> 400 mg	"[This amount of Magnesium]* may cause mild stomach upset in sensitive individuals."
Nickel	All nickel-containing products	"[Nickel]* may cause a skin rash in sensitive individuals."
Beta-carotene	1) > 7 mg 2) See footnote ¹	1) Encourage reformulation to ≤ 7 mg/day. 2) Label statement: "[Beta-carotene]* should not be taken by heavy smokers."
Nicotinic acid	> 20 mg	1) Encourage reformulation to nicotinamide. 2) If nicotinic acid is used, label statement: "[This amount of Nicotinic acid]* may cause skin flushes in sensitive individuals".
Zinc	> 25 mg	Label statement: "Long term intake [of this

* For single nutrient products, the words in square brackets may be deleted.

¹ The Food Standards Agency considers that the labels of all food supplements containing beta-carotene should carry the advisory statement "[Beta-carotene]* should not be taken by heavy smokers." Industry considers that this should only be on products recommending a daily amount > 7mg. This footnote is for information here; it will not appear on labels.

		amount of zinc]* may lead to anaemia”.
Manganese	See footnote ²	Label statement: “Long term intake [of this amount of manganese]* may lead to muscle pain and fatigue”.
Phosphorus	> 250 mg	Label statement: “[This amount of Phosphorus]* may cause mild stomach upsets in sensitive individuals.” ³
Vitamin B6	> 10 mg > 100 mg	Label statement: “Long term intakes [of this amount of vitamin B6]* may lead to mild tingling and numbness” Encourage reformulation to lower daily amount.

Notes:

- a) No vitamins are completely stable and they deteriorate at different rates. Amounts of vitamins are added to food supplements during manufacture to compensate for losses during shelf life. For very labile nutrients, such as vitamin C, the threshold values above refer to the declared amount and manufacturers will strive to use only the necessary quantities in the products to ensure 100 per cent of the declared value at the end of shelf-life.
- b) The Food Standards Agency view is that all sources of nutrients in a product should be taken into account when declaring the quantities of nutrients and deciding if the trigger level for an advisory statement has been exceeded.

² The Food Standards Agency considers that the labels of all food supplements recommending a daily amount greater than 0.5mg manganese should carry this advisory statement. Industry considers that this statement could only be justified on products recommending a daily amount greater than 4mg. This footnote is for information here; it will not appear on labels.

³ The Food Standards Agency wants a second sentence “Long term intake [of this amount of phosphorus] may weaken bones” to be included in the advisory statement for phosphorus. Industry does not agree that inclusion of the second sentence is warranted. The Agency has asked the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) to look in detail at the effects of phosphate intake on parathyroid hormone and bone metabolism including new data on phosphate regulation. The wording of the advisory statement will be reconsidered following receipt of COT advice. This footnote is for information here; it will not appear on labels.

- c) These advisory statements are based on current evidence and are subject to change in the light of new evidence and advice.
- d) The timings of label changes should take place as soon as possible after May 2004 but may be made to coincide with other new labelling requirements.