MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

NEW ZEALAND FOOD SAFETY AUTHORITY

03 December 2007

Dear Sir / Madam

This letter is being sent to organisations involved in the manufacture, distribution and advertising of dietary supplements in New Zealand in order to:

- inform businesses of planned changes to the Dietary Supplements Regulations 1985 that are expected to come into effect in early 2008;
- emphasise the importance of ensuring that the supply and promotion of products is compliant with current legislation; and
- advise the sector of a planned compliance review and enforcement programme.

Amended Dietary Supplements Regulations 1985

In February 2007 the New Zealand Food Safety Authority (NZFSA) issued a consultation paper (www.nzfsa.govt.nz/consultation/dietary-supplements/index.htm) on proposals to amend the Dietary Supplements Regulations 1985 (DSR). The outcome of the consultation process is that Cabinet has agreed that the DSR should be amended to:

- exclude food-type dietary supplements from coverage under the DSR and instead regulate them as supplemented foods - initially under an interim Standard and later under a Joint Standard developed through the Food Standards Australia New Zealand process;
- require sponsors of therapeutic-type dietary supplements to enter details about their products into a database to be administered by the Ministry of Health (Medsafe); and
- transfer responsibility for administration of therapeutic-type dietary supplements from NZFSA to the Ministry of Health.

It has also been agreed that the recommended daily dose of folic acid permitted in dietary supplements will be raised from 300 micrograms to 500 micrograms, but only for products made in compliance with Good Manufacturing Practice for medicines.

Please note that therapeutic claims in relation to products that remain under the amended DSR will continue to be prohibited.

The amended DSR are expected to come into force in early 2008. A transition period of six months will be provided to give businesses time to comply with the new requirements in relation to the database of products to be administered by Medsafe. Further, more detailed, information will be sent to you when it becomes available.

Compliance with current legislation

Medsafe and the NZFSA are concerned at the level of non-compliance with the DSR and the Medicines Act 1981 and the potential risks for consumers that arise as a consequence. The

most significant area of non-compliance is in relation to therapeutic claims being made for products that are being supplied as dietary supplements. Therapeutic claims are permitted for medicines but are not permitted in respect of dietary supplements. Companies wishing to make therapeutic claims in respect of their products are positioning their product as a medicine and must therefore apply for and obtain Ministerial consent for the product's distribution as a medicine before the product can be lawfully sold.

Guidance is available on the Medsafe and NZFSA websites (www.medsafe.govt.nz and www.nzfsa.govt.nz) to assist companies ensure they are compliant with the applicable legislation. If you need assistance determining claims that are appropriate for a dietary supplement or seeking approval for your product as a medicine, there are also a number of regulatory consultants whose contact details are available through Medsafe (www.medsafe.govt.nz).

If a product is presented as a medicine and is being sold or distributed without Ministerial consent, there can be significant consequences, including seizure of stock and prosecution when enforcement action is taken against companies who are supplying non-compliant products.

Please make yourselves familiar with the requirements of the legislation and undertake a compliance review of your products and promotional activities to identify any corrective actions you may need to take.

Compliance review and enforcement programme

There are many products on sale in New Zealand that are positioned at the Food/Medicine interface. NZFSA and Medsafe will shortly commence a pro-active compliance review to identify companies and products that are in breach of the Dietary Supplements Regulations and/or the Medicines act 1981. Appropriate follow-up action will then be taken.

A similar review and enforcement programme will also be undertaken by Medsafe in respect of topical products at the medicines/cosmetic interface and the companies who supply these to ensure compliance with the Medicines Act. This programme will commence in January 2008.

If you want to discuss any aspect of this review programme or the amendments to the DSR, please contact either Medsafe for therapeutic products (0800 266-380) or NZFSA for food products (0800 693-721)

Yours faithfully

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