



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

**OUR REF: RCU11968**

Garry Vereb  
Apricot Seeds  
28 Maryland Street  
Stafford Heights  
Queensland 4053

Dear Garry,

It has come to the attention of the Therapeutic Goods Administration that you are importing, advertising and supplying the following products in Australia for human therapeutic use:

Megazyme Forte;  
Vitamin B – 15 Pangamic Acid;  
Preven – CA;  
AHCC (Active Hexose Correlated Compound); and  
Complete Liquid Multi Vitamin Plus.

You should be aware that these products, when presented with claims for therapeutic use, may be classified as a Therapeutic Good, requiring entry in the Australian Register of Therapeutic Goods (ARTG) prior to import, export, manufacture or supply for human therapeutic use.

Our records indicate that these products are not included in the ARTG in respect to you or your company as required by law. You are therefore to cease importation, advertising and supply immediately of these products, together with any other unregistered or unlisted product, which is not exempted from this requirement.

You are to provide **written** confirmation within 5 working days of receipt of this letter that importation, advertising and supply will cease until such time as the products have been included in the ARTG for human therapeutic use.

Application forms for Listing or Registration of Therapeutic Goods are available from the TGA Publications Office at the above address or by phoning 1800 020 653. Further information on the TGA is available from the Internet website [www.tga.gov.au](http://www.tga.gov.au)

## Legislation:

I would draw your attention to the following legislative provisions contained in Therapeutic Goods Act 1989.

Under Section 19B of the Therapeutic Goods Act 1989, it is an offence for a person who is a sponsor of therapeutic goods, to intentionally import, export, manufacture or supply the goods in Australia for use in humans unless those goods are listed or registered in the ARTG in respect to the importer, or the goods are exempt goods or are subject of an approval or authority under Sections (18A) (19) or (19A) of the Act.

"Sponsor" includes persons who import or arrange for the importation of therapeutic goods, or who manufacture or arrange for another person to manufacture the goods for supply.

Sponsors are subject to the requirements of the Act if they are trading corporations or, in the case of individuals and corporations generally, trade goods between Australia and another country or among States within Australia.

The maximum penalty upon conviction is Imprisonment for 5 years or a fine of \$440,000 or both for an individual, or a fine of \$2,200,000 for a corporation in respect of each offence.

Please also note that Section 19D of the Therapeutic Goods Act 1989, may also subject sponsors of therapeutic goods not included in the Australian Register of Therapeutic Goods to the civil penalties provisions contained in the legislation. Contravention of a civil penalty can attract maximum fines of \$550,000 for individuals and \$2,750,000 for a body corporate.

In addition, it is an offence for a person to advertise a therapeutic good, which is not included in the ARTG. It is also an offence for a person to make a claim by any means, that the person or another person can arrange the supply of therapeutic goods (not being exempt goods) that are not listed or registered in the ARTG. The maximum penalty upon conviction in this instance is \$6,600 for a person or \$33,000 for a corporation in respect of each offence.

Yours sincerely



Daniel Black  
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Therapeutic Goods Administration

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