TGA THERAPEUTIC GOODS ADMINISTRATION
PO Box 100 Woden ACT 2606 Australia
Telephone: (02) 6232 8444 Facsimile: (02) 6232 8241
ABN 40 939 406 804

Commonwealth Department of Health and Aged Care

The Managing Director

[redacted]

Attention: Regulatory Affairs Officer

Dear Sir / Madam

[redacted]

Notice under Section 30(1)(e) of the *Therapeutic Goods Act 1989*
Cancellation of listing

This medicine, which was listed in the Australian Register of Therapeutic Goods (ARTG) under the provisions of Section 26A of the *Therapeutic Goods Act 1989* (the 'Act'), has been reviewed for eligibility for listing.

It has been determined that this medicine is not eligible for listing in the ARTG for supply in Australia, Therefore, the listing of this medicine has been cancelled from the ARTG under the provisions of Section 30(1)(e). The basis for this decision is given below:

- The formulation detail of the medicine refers to 75mg of *Glycine max* seed dry extract concentrate (160:1) in 70% ethanol, equivalent to 30mg of standardising component isoflavone glycoside.. The evaluation of the submitted data detailing the manufacturing process of the ingredient indicates that the extract is not considered a herbal substance in accordance with the definition in the Regulation. The current definition of herbal substance as described in the Regulation to the Therapeutic Goods Act is as follows:

  ***Herbal substance** means all or part of a plant or substance (other than a pure chemcial or substance of bacterial origin):*
  (a) that is obtained only by drying, crushing, distilling, extraction, expressing, comminuting, mixing with water, ethanol, glycerol or aqueous ethanol; and
  (b) that is not subjected to any other treatment or process other than a treatment or process that is necessary for its presentation in a pharmaceutical form.

  Glycine max seed extract in this medicine cannot be considered to be herbal substance as the process of manufacturing this extract is in fact a purification process. The extract is passed through a resin and the substances of interest are

adsorbed onto the resin. The resin is washed, eluted with an aqueous ethanol gradient and the fractions of interest containing isoflavones are then concentrated. This is a purification step of the sort that might occur in the manufacture of a drug substance. Therefore the goods are not eligible for listing and the certification provided under Section 26A(2)(a) of the *Therapeutic Goods Act of 1989* is incorrect.

The cancellation is effective from the date of this notice. You are requested to return the Certificate of Listing to the Manager, Listing Processing and Policy Unit. Sponsors are reminded that under Section 20 of the *Therapeutic Goods Act 1989*, it is an offence to supply goods not entered in the ARTG. Supply should cease immediately.

Appeal under Section 60 of the *Therapeutic Goods Act 1989*

This Decision is an "initial decision" within the meaning of Section 60 of the *Therapeutic Goods Act 1989*. This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister for Health and Aged Care
Parliament House
CANBERRA ACT 2600

The appeal to the Minister should be headed "Appeal under Section 60 of the *Therapeutic Goods Act 1989*".

The Parliamentary Secretary may either deal with the appeal personally or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the *Administrative Appeals Tribunal Act 1975*, you may appeal to the Administrative Appeals Tribunal for review of the Minister's / Delegate's decision.

Yours faithfully

Allison Rosevear
Delegate of the Secretary
18 September 2001

Cc: [redacted]
Fax: [redacted]