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 Ageing

[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 details for this product refers to 62.5mg of *Glycine max* seed germ extract concentrate (160:1) in 70% ethanol and water, equivalent to 25mg of isoflavones. The review 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 Regulations. The current definition of herbal substance included in the Therapeutic Goods Regulations (the 'Regulations') is as follows:

Herbal substance means all or part of a plant or substance (other than a pure chemical 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.

The manufacturing process of this extract includes two purification steps (or precipitation steps) which are used to remove insoluble impurities. This type of process is not consistent with the 'Regulations' definition of herbal 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.

In making this decision I have reviewed the following evidence

1. The *Therapeutic Goods Act 1989* and its regulations;
2. The formulation details of the product entered in the ARTG; and
3. The information in relation to the manufacturing process provided [redacted] on 31 October 2002, and by [redacted] on 13 December 2002 in response to the TGA's request for information.

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

Michael Wiseman
Delegate of the Secretary
28th January 2003

Cc:
Fax: [redacted]