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

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[redacted]

Attention: Regulatory Affairs Officer

Dear Sir / Madam

[redacted]

Notice under Section 30(2) 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(2)(a) of the Act.

Cancellation is effective from the date of this notice and 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.

Reason for this decision

A notice under Section 30(2)(a) of the Act proposing to cancel the product listing within 30 days was issued on 16 July 2002 following the review of the manufacturing process of the active ingredient *Glycine max* seed extract concentrate. *Glycine max* is a listable herbal substance and certain extracts and preparations of this herb are also eligible for listing because they are sufficiently similar in chemical profile to the raw herb so as to allow the known safety of the raw herb to be extrapolated to the extract or preparation. However, the

review of the submitted data detailing the manufacturing process of the *Glycine max* seed extract concentrate indicate that this extract is not considered a "herbal substance" in accordance with the definition in the Therapeutic Goods Regulations (the 'Regulations') which 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 a precipitation step in that "The molasses is held in a suitable holding vessel for a minimum required time allowing the isoflavones to precipitate from the mother liquid." This type of process is not consistent with the Regulations' definition of a herbal substance. Therefore it appears that the final extract may not resemble the raw herb material in chemical composition and profile and subsequently the safety of the final product is unknown. Given the above, the TGA is unable to determine if the safety of the medicine is acceptable and also if the active ingredient *Glycine max* seed extract concentrate is eligible for inclusion in a listable medicine. Therefore, the TGA is unable to determine if the safety of the medicine is acceptable and also if the certification provided under Section 26A(2)(a) of the Act, that the medicine is eligible for listing, is correct.

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 medicine entered in the ARTG; and
3. The information in relation to the manufacturing process provided by your regulatory consultant, [redacted] from [redacted] on 16 April 2002 in response to the TGA's request for information; and subsequent information provided on 25 July 2002, 12 August 2002 and 29 August 2002.

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 Ageing
> Parliament House
> CANBERRA ACT 2600

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

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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
24th September 2002

Cc: [redacted]
Fax: [redacted]