TGA Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Woden Telephone: (06) 289 1555. Fax: (06) 289 8709
Symonston Telephone: (06) 232 8444. Fax: (06) 232 8605

COMMONWEALTH DEPARTMENT OF HEALTH AND FAMILY SERVICES

[redacted]

Dear Sir/Madam

[redacted]

Notice of Cancellation under Section 30 (2)(ba) of the Therapeutic Goods Act 1989

These goods, which have been entered in the Australian Register of Therapeutic Goods (ARTG) following the submission of an *Application to List a New Drug or to Vary the Particulars of a Listed Drug for Supply in Australia* under the provisions of Section 26A of the Therapeutic Goods Act 1989, have been reviewed for eligibility for listing.

It has been determined that these goods are not eligible for listing in the ARTG for supply in Australia **and they have been cancelled from the ARTG under the provisions of Section 30 (2)(ba).** The basis for this decision is given below:

- *Prunus anneniaca* may contain amygdalin/laetrile as well as hydrocyanic acid. Amygdalin is included in Appendix C of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP), which prohibits possession, sale, supply and use. You need to provide sufficient information in Item 24 of the content of amygdalin/laetrile to demonstrate that the product is not subject to the SUSDP. Therefore the certification provided under Section 26A (2)(b) is incorrect.

- "Hordeum vulgare seed powder germinated, fried" is included in Item 19 as an active ingredient. The status of this ingredient in the ARTG is as a food excipient only, stated in *TGA Approved Terminology for Drugs.* The ingredient (common name barley) can only be listed in the application as an excipient. Therefore the certification under Section 26A(2)(h) is incorrect.

- "Triticum aestivum seed powder fermented and dried" is included in Item 19 as an active ingredient. The status of this ingredient in the ARTG is as a food excipient only, stated in *TGA Approved Terminology for Drugs.* The ingredient (common name wheat) can only be listed in the application as an excipient. Therefore the certification under Section 26A(2)(h) is incorrect.

- You have failed to respond to the Notice under Section 30 of the Therapeutic Goods

Act 1989, dated 26 August 1996, which gave you opportunity to address these matters in relation to these goods.

Cancellation is effective from the date of this notification and you are requested to return the Certificate of Listing to the Head, ARTG.

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** ("the ACT"). 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 Family Services
Parliament House
CANBERRA ACT 2600

This letter should be headed "APPEAL UNDER SECTION 60 OF THE THERAPEUTIC GOODS ACT 1989".

The Parliamentary Secretary (Senator Woods) may either deal with the appeal himself, or send it to be dealt with by one of the Ministers'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 Tribunal for review of the Ministers's/Delegate's decision.

Yours faithfully

Laurayne Bowler

Laurayne Bowler
Delegate of the Secretary
26 September 1996

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COMMONWEALTH DEPARTMENT OF HEALTH AND FAMILY SERVICES

COMMONWEALTH OF AUSTRALIA
THERAPEUTIC GOODS ACT 1989
NOTICE UNDER SECTION 30(6)(b): CANCELLATION OF LISTING OF GOODS
IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

Pursuant to Section 30 (6)(b) of the Therapeutic Goods Act 1989, notice is hereby given that the listing in the Australian Register of Therapeutic Goods (ARTG), of the goods specified below was cancelled on 25 September 1996. The listing was cancelled under Section 30(2)(ba) of the said Act, because the application contains insufficient information to confirm that the goods are safe for the purposes for which they are to be used and the information included in the application is incorrect. Particulars of the cancellation are as follows:

SPONSOR: [redacted]

ARTG NAME OF GOODS **ARTG NUMBER** [redacted]

[redacted]

dated this 16th day of September 1996

Laurayne Bowler

Laurayne Bowler
Delegate of the Secretary
to the Department of Health & Family Services