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

Commonwealth Department of Health and Aged Care

Contact Officer: Hongxia Jin
Telephone: (02) 6232 8901

[redacted]

ATTENTION: Regulatory Affairs Officer

Dear Sir/Madam

[redacted]

Notice under Section 30 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 **in relation to the following criteria only:**

1. Eligibility of the ingredients disclosed in the application for listing in the ARTG for supply in Australia;

2. Eligibility of the therapeutic claims disclosed in the application for listing in the ARTG for supply in Australia in terms of the Therapeutic Goods Advertising Code, as well as the presence of required warning/cautionary statements.

On the basis of this assessment, it has been determined that these goods are not eligible for listing in the ARTG for supply in Australia **and it is suggested they not be supplied**. The basis for this decision is given below:

- The goods are not eligible for listing because the formulation contains the active ingredient *Carica papaya* fruit fresh **fermented**. The fermentation process is not included in the herbal substance definition (*Therapeutic Goods Regulations)* as one of the designated acceptable processing methods in obtaining a herbal substance. In consequence this ingredient is not eligible for inclusion in listable drug products. Therefore the certification provided under Section 26A(2)(a) is incorrect;

- The indication recommending this product for topical application on **burns** is unacceptable because there is no entry in item 27 or 28 indicating that the label would include additional information required by the *Guidelines for Applicants*, July 1995 (page 67) for a burn treatment product. Please note that the burn claim should be limited to minor burns only. Therefore the certification provided under Section 26A(2)(b) is incorrect; and

- The indication recommending this product for topical application on **whitlow** contravenes Clause 4 of the *Therapeutic Goods Advertising Code* (TGAC). Whitlow may be a symptom of herpes simplex virus infection or subungual melanoma that are prohibited by the TGAC. Therefore the certification provided under Section 26A(2)(d) is incorrect.

You are hereby given notice that it is proposed to cancel the listing of these goods in accordance with Section 30(1)(e) and Section 30(2)(ba). You are advised that cancellation will not take effect for 30 days from the date of this letter so as to allow you to make a submission to establish the eligibility of these goods for listing in the ARTG for supply in Australia, or to submit *an Application to List a New Drug or to Vary the Particulars of a Listed Drug for Supply in Australia* to address the above matter. You may also submit an appeal to the Parliamentary Secretary to the Minister for Health and Aged Care under Section 60 of the *Therapeutic Goods Act 1989* in accordance with the procedure detailed below. If I receive advice within 30 days of the date of this letter that the above appeal has been submitted, cancellation will not take effect until the outcome of this appeal is known.

At the end of the 30 day period a decision will be made based on the information received. **If you decide to submit an application to correct the matter identified, we ask that you attach the enclosed gold coloured sheet with your application to facilitate appropriate action.**

It is suggested that if the matter is one that can be addressed by the submission of an application to vary this product that you take this course of action rather than listing another product. This will reduce the possibility of you being invoiced for an annual charge for the product which may be cancelled from the ARTG in the near future as well as for the new product. If you need to list a new product in the ARTG to correct the matter identified, you should also cancel the old entry from the ARTG as soon as possible for the same reason.

You should advise the above contact officer in writing of the TGAIN allocated to the new application to allow confirmation that corrective action is taking place. Failure to do this could lead to cancellation of this product from the ARTG even though an application to address the above matter has been submitted. Any questions concerning the contents of this letter should also be addressed to the above contact officer.

You should take note of the fact that under the revised listing arrangements introduced in June 1996 with the changes to the *Therapeutic Goods Act 1989*, only the information contained within the application submitted through the Electronic Lodgement Facility (ELF) was taken into consideration when conducting this assessment.

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

This letter 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 sincerely

S McGregor

Sharyn McGregor
Delegate of the Secretary
4 October 1999