

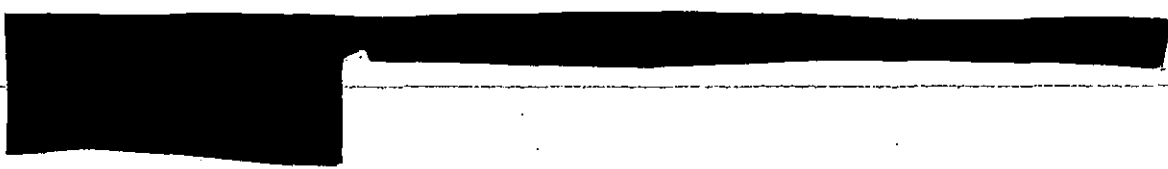
PO Box 100 Woden ACT 2606 Australia  
Telephone: (02) 6232 8444 Facsimile: (02) 6232 8241



13397

ATTENTION: Regulatory Affairs Officer

Dear Sir/Madam



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

I refer to your 'Application to List a New Drug for Supply in Australia' for the above product, which was Listed on the Australian Register of Therapeutic Goods (ARTG) on 21 May 1998 under Section 26A of the *Therapeutic Goods Act 1989*.

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(1)(e). 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 5.2 of the current *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.

no longer  
an issue

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

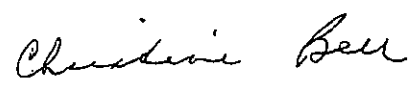
This Decision is an "initial decision" within the meaning of Section 60 of the *Therapeutic Goods Act 1989*. This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes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

**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



Christine Bell  
Delegate of the Secretary

9 October 2000