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 Aged Care

[redacted]

Fax No. (07) 3273 3277

Dear [redacted]

[redacted]

I refer to my letter to you dated 9 October 2000 cancelling the listing of the above goods, our telephone conversations of 13 and 16 October 2000 in relation to that letter. I apologise for the delay in writing to you but I have been seeking clarification of matters related to these goods.

I have decided to revoke the cancellation of these goods and they remain listed in the Australian Register of Therapeutic Goods (ARTG). However, I have decided to initiate full reviews of these goods to determine their eligibility for listing.

The facts of this case

[redacted] was first listed in the ARTG 21 May 1998. The purpose of the application was to list the ointment for supply in a tube. (The ointment supplied in a jar [redacted] was the subject of an application to list under the grandfathering provisions that existed at the time of commencement of the *Therapeutic Goods Act 1989*.) The application underwent an eligibility review, which was not completed until 4 October 1999 when a proposal to cancel the listing of the goods was issued by the delegate of the Secretary, Ms S. McGregor. On 9 October 2000 I cancelled the listing of the goods because all matters raised in the letter of 4 October 1999 had not been addressed. The goods did not appear to meet the eligibility requirements for listable medicines because the active ingredient was prepared by fermentation, which is not a process permitted under the current definition of a herbal substance. (Regulation 2 of the *Therapeutic Goods Regulations*).

On receipt of the cancellation letter, you contacted me and explained that, in 1991 when you were applying to enter [redacted] jar in the ARTG, you were advised verbally by the TGA that you should list the goods and not register them. I agreed to investigate further and seek additional advice as to the acceptability of fermentation under the definition of herbal substance.

I have been advised that the ingredient in question, *Carica papaya* fresh fruit fermented, does not meet the current definition of herbal substance. Fermentation and precipitation have not

been accepted as preparations of herbal ingredients eligible for listing, as they may chemically transform the herbal material, which may then result in a substance significantly different from the herbal substance on which long term safety may have been based.

However, the Herbal Working Party of the Complementary Medicines Evaluation Committee has been reviewing the regulation of herbal substances, one aspect of which is the definition of herbal substance. A consultation paper from this review is expected in the near future.

I have considered the following evidence

1. The application to list [redacted], dated 21 April 1998.
2. The Notice under Section 30 of the *Therapeutic Goods Act 1989* issued by Ms S. McGregor, dated 4 October 1999.
3. Correspondence between [redacted] and Ms H. Jin, TGA (on file at TGA).
4. The Notice of Cancellation under Section 30(1)(e) of the *Therapeutic Goods Act 1989* issued by Ms C. Bell, dated 9 October 2000.
5. The telephone conversations between [redacted] and Ms C. Bell on 13 and 16 October 2000.
6. Advice from within the Office of Complementary Medicines about the definition of "herbal substance".
7. The entry in the ARTG for [redacted] jar, AUST L[redacted]

Reasons for my decision

You have advised that the formulation of these goods is the same as the formulation of [redacted], which was grandfather listed in the ARTG. You have also advised that those goods were listed and not registered on the verbal advice of the TGA. I cannot confirm that advice but I believe that you should be given a further opportunity to justify why these goods should be listed.

There is a review currently underway of the regulation of herbal substances and this may result in changes to the definition of "herbal substance". Whilst I cannot second guess the outcome of that review, I believe that a final decision on whether Lucas Papaw Ointment meets the definition of a herbal substance should be delayed pending the recommendations of the review.

Please note

Whilst I have revoked my decision to cancel the listing of [redacted] and they therefore remain listed in the ARTG, this should not be taken to mean that they meet all the eligibility requirements for listable medicines.

I note from reviewing the file that concerns had been raised with you in relation to the use of boric acid in the fermentation process (and the residual levels of boron/boric acid in the final product). Boron and boric acid are restricted ingredients in listed medicines because, in certain circumstances, they are scheduled in the Standard for the Uniform Scheduling of Drugs and Poisons. Boric acid is not included in the list of ingredients in the goods with

[redacted], however, it is included as an excipient in the grandfathered product with [redacted]. Concerns were also raised in both the proposal to cancel and the cancellation letter about the therapeutic claims for the goods.

In order to determine the eligibility of the goods to remain listed in the ARTG, I intend to initiate a full review and you will shortly receive a request for information under Section 31 of the Therapeutic Goods Act. I also intend to conduct a full review of the grandfather listed goods with [redacted] to determine their eligibility for listing.

Yours sincerely

Christine Bell

Christine Bell
Manager
Listing Processing and Policy Unit
Office of Complementary Medicines

30 November 2000