TGA THERAPEUTIC GOODS ADMINISTRATION
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Commonwealth Department of Health and Ageing

[redacted]

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Attention: Regulatory Affairs Officer

Dear Sir / Madam

[redacted]

Notice under Section 30(1) 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(1)(e) 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

The formulation details declared in the application to list the medicine indicate that the medicine contains *Saccharum officinarum* stem extract concentrate as an active ingredient. The sponsor indicated in subsequent correspondence that this ingredient was 'sugar cane wax alcohols' as included in the product name. As a result of this information the TGA requested the certificate of analysis of the active ingredient which indicated that the substance is different from the substance which the TGA evaluated and approved as 'sugar cane wax alcohols' for use in listed medicines. The compositional guideline for the TGA's 'sugar cane wax alcohols' (August 2001) indicates that it contains 60-70% octacosanol and 10-15% triacontanol. The ingredient in this medicine although referred to as 'sugar cane wax alcohol' contains only 20% octacosanol, the major component being triacotanol which makes up 46% of the

material. Therefore, the active ingredient in this medicine does not meet the TGA's compositional guideline for 'sugar cane wax alcohols'.

In addition the review of the manufacturing process of this extract indicates that the substance may not be considered a 'herbal substance' in accordance with the definition in the Therapeutic Goods Regulations (the 'Regulations'). The manufacturing process provided by the sponsor includes a step where the wax is soaked in an alkaline solution, then filtered to remove the impurities. Advice from the TGA Laboratory indicates that this is most likely a saponification step, whereby the esters in the wax are chemically converted into free alcohols and fatty acids. This type of chemical conversion is not consistent with the Regulations definition of a 'herbal substance' which is as follows:

> ***Herbal substance*** *means all or part of a plant or substance (other than a pure chemcial 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.*

Given the above, the active ingredient in this medicine does not appear to be a herbal substance nor the same substance evaluated by the TGA as 'sugar cane wax alcohols'. Therefore, the medicine is not eligible for listing and the certification provided under Section 26A(2)(a) of the Act is incorrect.

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 declared in the ELF application to list the medicine;
3. The TGA's draft compositional guideline for Sugar cane wax alcohols (August 2001);
4. The information in relation to the manufacturing process provided by the sponsor on 17 January 2002 in response to the TGA's request for information;
5. The sponsor's correspondences of 25 January 2002 providing the certificate of analysis of the active ingredient *Saccharum officinarum* dry stem extract concentrate;
6. The sponsor's correspondences of 7 May 2002 providing further information in relation to the manufacturing process of the active ingredient; and
7. The TGA Laboratory's advice in relation to the manufacturing process provided by the sponsor for the active ingredient *Saccharum officinarum* dry stem extract concentrate.

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*".

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

5th June 2002