TGA Therapeutic Goods Administration

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COMMONWEALTH DEPARTMENT OF HUMAN SERVICES AND HEALTH

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The Managing Director

[redacted]

Dear Sir/Madam

APPLICATION REFUSAL

[redacted]

I refer to your 'Application to List a New Drug or to Vary the Particulars of a Listed Drug for Supply in Australia' dated 13 December 1995 to list the above product in the Australian Register of Therapeutic Goods (ARTG).

Your application has been assessed and, under the provisions of Section 26(1) of the *Therapeutic Goods Act 1989*, it has been decided to refuse listing of the above product in the ARTG for the following reason:

- I am not satisfied that the goods are eligible for listing (Section 26.(1)(c) in that I am unable to determine whether the ingredient *Vaccinium myrtillus herb fr. extract (30:1) in 70%E:W* is a herbal substance as defined in the Therapeutic Goods Regulations.

  Your company was sent two requests under the provisions of Section 31 of the Therapeutic Goods Act 1989, on 21 March 1996 and 7 May 1996, seeking information to be able to determine this in relation to this and another ingredient. A response (dated 14 May 1996) was only received in relation to the other ingredient indicating that it had been incorrectly entered in the listing application and that it is an ingredient which the TGA has already determined is a herbal substance. No similar response was received in relation to the abovementioned ingredient. The product specification I discussed with [redacted] in March is not adequate evidence. If you are using an ingredient which the supplier has already cleared with the TGA you should quote the 'HC' number obtained from the supplier in the listing application.

  You have therefore not complied with the request made under Section 31 (see Section 26.(1)(b).

Appeal under Section 60 of the Therapeutic Goods Act 1989

The refusal of your application 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, and you wish to lodge an appeal against the decision, you may do so by writing to the Minister and requesting a reconsideration of the decision, as provided by Section 60 of the Act. The appeal should be made in writing within 90 days after the decision first comes to your notice or to the notice of your company, and should be sent to the following address:

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".

Should you be dissatisfied with the Minister's reconsideration of the decision then, subject to the *Administrative Appeals Tribunal Act 1975*, you may apply to the Administrative Appeals Tribunal for a review of the reconsidered decision.

Should you wish to reapply for inclusion of this product in the ARTG, a new 'Application to List a New Drug or to Vary the Particulars of a Listed Drug for Supply in Australia' should be submitted and directed, as usual, to the Business Management Unit (BMU), together with the appropriate fee.

Yours faithfully

Laurayne Bowler

Laurayne Bowler
Delegate of the Secretary
27 May 1996