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 Ageing

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[redacted]

Attention: Regulatory Affairs Officer

Dear Sir / Madam

[redacted]

Notice under Section 30(1)(e) 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). The basis for this decision is given below:

- The formulation details entered on the Register for this product indicates that it contains 185mg of *Paullinia cupana* seed ext. dry conc. (10.0: 1) in 60% E:W. The equivalent amount of caffeine is declared at 66.60mg. *Paullinia cupana* is a listable herbal substance and extracts and preparations of this herb prepared by conventional extraction processes which may be standardised to naturally occurring substances such as caffeine are also eligible for listing. The conventional extraction processes produce extracts and preparations that are sufficiently similar in chemical profile to the raw herb so as to allow the known safety of the raw herb to be extrapolated to the final preparation. However, the review of the submitted data detailing the manufacturing process of *Paullinia cupana* indicates that the preparation is "...dry-blended with caffeine and dicalcium phosphate to an activity of 36% caffeine". Therefore the extract in the medicine does not resemble the raw herb material in chemical composition and profile and subsequently the safety of the final product is unknown. In addition, caffeine is not a listable active ingredient and is therefore not eligible for inclusion in a listed product. Given the above, the TGA is unable to determine if the safety of the medicine is acceptable. Therefore, this medicine is not eligible for listing and the certification provided under Section 26A(2)(a) of the Act is incorrect.

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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.

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

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

24 September 2002

Cc:
Fax: [redacted]