TGA THERAPEUTIC GOODS ADMINISTRATION
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Commonwealth Department of Health and Ageing

Contact Officer: Diana Toakley
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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

The above medicine is listed in the Australian Register of Therapeutic Goods (ARTG) under the provisions of section 26A of the *Therapeutic Goods Act* 1989 (the 'Act').

I am a delegate of the Secretary for the purposes of section 30 of the Act.

Cancellation

I have cancelled the listing of this Medicine from the ARTG in pursuant to paragraph 30(1)(e) of the Act from the date of this notice.

Sponsors are reminded that under Section 20 of the Act, it is an offence to supply goods not entered in the ARTG. You are also requested to return the Certificate of Listing to the Manager, Listing Processing and Policy Unit.

Evidence before me in making this decision

The formulation details of the medicine refers to 1mg of *Camellia sinensis* leaf extract dry concentrate (200:1) in 70% ethanol/water, standardised to 300mcg of *camellia sinensis catechins (of camellia sinensis)*. A review of the submitted data detailing the manufacturing process of *Camellia sinensis* extract in this medicine indicates that the extract is not considered a "herbal substance" in accordance with the definition in the Therapeutic Goods Regulations (the ' Regulations'). The current definition of herbal substance included in the Regulations is as follows:

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

The manufacturing process of the extract includes an "absorption" step through resins. This type of purification process is not consistent with the 'Regulations' definition of a herbal substance.

Camellia sinensis 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) 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. Given the type of purification step involved in the manufacture of *Camellia sinensis* extract, the final extract in the medicine may not resemble the raw herb material in chemical composition and profile. The medicine is therefore not eligible for listing and the certification provided under Section 26A(2)(a) of the Therapeutic Goods Act of 1989 is incorrect.

Relevant Legislation

Subsection 30(1) of the Act relevantly provides that the Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included on the Register, cancel the registration or listing of the goods if :

(e) in the case of a medicine listed under section 26A, it appears to the Secretary that any of the certifications under paragraph 26A(2)(a), (e) or (g) are incorrect or (if applicable) the requirements under subsection 26A(3) are not fulfilled.

Under paragraph 26A(2)(a) of the Act, the applicant must certify that:

(a) the medicine is eligible for listing

In making this decision I have reviewed the following evidence

- The information held in the ARTG for this medicine.
- The Therapeutic Goods Act 1989.
- The Therapeutic Goods Regulations 1990.

Review Rights

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

Tanya Hwang
Delegate of the Secretary
8 September 2003

Cc:
Fax: [redacted]