TGA THERAPEUTIC GOODS ADMINISTRATION
PO Box 100 Woden ACT 2606 Australia
Telephone: (02) 6232 8444 Facsimile: (02) 6232 8241

Commonwealth Department of Health and Aged Care

Drug Safety & Evaluation Branch
Telephone: 02 6232 8113
Facsimile: 02 6232 8140

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M. D. Edstein
Department of Defence
Australian Army Malaria Institute
Weary Dunlop Drive
Gallipoli Barracks
ENOGGERA QLD 4052

Dear Mr Edstein,

I refer to your application of 11 November 1999 to import Tafenoquine (etaquine) tablets for onward export from Australia to Papua New Guinea to be used in a clinical trial in Australian defence force personnel. There is no tablet formulation containing Tafenoquine (etaquine) registered currently for supply in Australia.

Pursuant to Section 19(1)(b) of the Therapeutic Goods Act 1989, approval is granted for the import into and the export from Australia of up to three thousand (3,000) Tafenoquine (etaquine) tablets for supply for use in a clinical trial in Australian defence force personnel in Papua New Guinea.

It is the responsibility of the exporter to comply with all relevant laws of any other state or national government and any relevant international requirements pertaining to the exportation, importation, supply and use of these products.

The Therapeutic Goods Administration can provide no assurance as to the quality, safety and efficacy in the proposed usage. It should be noted that the proposed clinical use of this drug must be regarded both medico-legally and ethically as experimental.

Permission is given subject to the following:

1. The approval is valid for up to six (6) months from the date of this letter.

2. The total quantity supplied is not to exceed three thousand (3,000) tablets.

3. The approval is for exportation for use in the clinical trial described in your facsimile dated 11 November 1999.

4. You are reminded that you are required to keep records relating to the source of supply, distribution and disposal of this unregistered product, and, if requested by the Secretary of this Department, supply the records to the Secretary.

5. The Commonwealth accepts no responsibility for any defects in the product related to manufacture, distribution or directions for use, including dosage.

This decision is an "initial decision" within the meaning of s 60 of the Therapeutic Goods Act 1989 ("the Act"). 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 letter should be headed "APPEAL UNDER S 60 OF THE THERAPEUTIC GOODS ACT 1989".

Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

The Parliamentary Secretary may either deal with the appeal himself, 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 Tribunal for review of the Minister's/Delegate's decision.

If you require any further assistance concerning this matter please contact me by telephone on (02) 6232 8125 or facsimile on (02) 6232 8112.

Yours sincerely

G.J. Dickson

Dr Grahame Dickson
DELEGATE OF THE SECRETARY

17 November 1999