



**THERAPEUTIC
GOODS
ADMINISTRATION**

PO Box 100 Woden ACT 2606 Australia
Telephone: (02) 6232 8111 Facsimile: (02) 6232 8112

Commonwealth Department of
Health and
Ageing

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File Number: 03/26996

Astrazeneca Pty Ltd
Po Box 131
NORTH RYDE NSW 1670
Attention: Ms. Mahogany Fox

CTN Scheme (Drugs): Acknowledgement of New Trial

Your notification to conduct a clinical trial under the Clinical Trial Notification (CTN) Scheme, pursuant to Schedule 5A of Regulation 12 of the Therapeutics Goods Regulations, has been received by the Drug Safety and Evaluation Branch (DSEB).

Trial Number: 2003/273
Protocol Number: AU-SEA-0003
Drug Name(s): quetiapine fumarate

It is noted that:

- i. the approval of the goods for this trial was given in accordance with Item 3 of Schedule 5A of the Therapeutic Goods Regulations by the body or organisation conducting the trial at each site.
- ii. the representative of the Ethics Committee for each site has certified that the Committee is constituted and operates in accordance with the NH&MRC "National Statement on Ethical Conduct in Research Involving Humans", has considered this clinical trial, and has provided advice to the body or organisation conducting the trial.

The Therapeutic Goods Administration has not carried out an assessment of the quality, safety or efficacy of any drug product in relation to this notification.

Please note that, in the event that the Secretary of the Commonwealth Department of Health and Ageing becomes aware that to undertake or continue the clinical trial would be contrary to the public interest, the Secretary has the authority to direct that use of the drug product(s) for this clinical trial must cease.

A form for "CTN Scheme (Drugs): Trial Completion Advice" is enclosed. Please fill out and return this form after the Clinical Trial has completed.

Please direct enquiries to the Experimental Drugs Section on (02) 6232 8106 (phone) or (02) 6232 8112 (fax).

Elizabeth Armer
Experimental Drugs Section
Drug Safety & Evaluation Branch

30/05/03



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CTN Scheme (Drugs): Clinical Trial Site List

This document lists all sites acknowledged to date for the following clinical trial:

Sponsor: **Astrazeneca Pty Ltd**

Protocol Number: **AU-SEA-0003**

Trial Number: **2003/273**

<u>Date Acknowledged</u>	<u>Site Name</u>	<u>State</u>
30-MAY-03	University of Melbourne - ORYGEN Research Centre	VIC