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Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

File Number: 05/62563

AUSTRALIAN NATIONAL UNIVERSITY
Centre for Mental Health Research

AUSTRALIAN NATIONAL ACT 0200
Attention: Janine Walker

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: 2005/483

Protocol Number: 2004/188

Drug Name(s): folic acid/vitamin B12

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).

N. Andersson

Natasha Andersson
Experimental Drugs Section
Drug Safety & Evaluation Branch

09/09/05



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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: **AUSTRALIAN NATIONAL UNIVERSITY**

Protocol Number: **2004/188**

Trial Number: **2005/483**

<u>Date Acknowledged</u>	<u>Site Name</u>	<u>State</u>
09-SEP-05	Australian National University - Centre for Mental Health Research	ACT
	University of Sydney - Brain and Mind Research Unit	NSW