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Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

File Number: 04/453 16

Royal Melbourne Hospital
C/- Post Office
ROYAL MELBOURNE HOSPITAL VIC 3050

Attention: Dr C O'Donnell, Orygen

ack sent to
address on
folio # 132.

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: 2004/306
Protocol Number: 2004.026
Drug Name(s): folic acid
vitamin B12
vitamin B6

Sighted: *J. Wable*
(D. Wable)
date: 13.7.2004

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

12/07/04



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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: Royal Melbourne Hospital

Protocol Number: 2004.026

Trial Number: 2004/306

<u>Date Acknowledged</u>	<u>Site Name</u>	<u>State</u>
12-JUL-04	ORYGEN Youth Health	VIC