



Therapeutic
Goods
Administration

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Commonwealth Department of
Health and
Family Services

File Number: 00/42050

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Janssen-Cilag P/L
Locked Bag 2070
NORTH RYDE NSW 1670
Attention: Ms Claire Methven

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: 2000/388
Protocol Number: RIS-AUS-9
Drug Name(s): risperidone

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 Statement on Human Experimentation and Supplementary Notes, 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 Aged Care 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).

Rhonda Whybrow
Experimental Drugs Section
Drug Safety & Evaluation Branch

12/09/00



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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: Janssen-Cilag P/L

Protocol Number: RIS-AUS-9

Trial Number: 2000/388

<u>Date Acknowledged</u>	<u>Site Name</u>	<u>State</u>
12-SEP-00	The PACE Clinic - Department of Psychiatry - University of Melbourne/MHSY	VIC