



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

File Number: 09/11640

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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 Office of Prescription Medicines (OPM).

Trial Number: 2010/0011
Protocol Number: 12091

Drug(s):

Drug Active Name	Trade Name	Code Name	Strength
sertraline hydrochloride	Zoloft	N/A	25-100mg

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 additional site.
- ii. the representative of the Ethics Committee for each additional site has certified that the Committee is constituted and operates in accordance with the NHMRC "National Statement on Ethical Conduct in Human Research" 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 "CTN Scheme (Drugs): Trial Completion Advice" is enclosed. Please fill out and return this form after the Clinical Trial has completed.

Joseph Croke
Experimental Drugs Section
Office of Prescription Medicines
21 January, 2010



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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: 14195 - University of Sydney

Protocol Number: 12091

Trial Number: 2010/0011

Date Acknowledged	Site Name	State
08 January 2010	The University of Sydney - Brain & Mind Research Institute	NSW