



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

File Number: 2011/009179

Nicole Cockayne
Brain and Mind Research Institute
100 Mallett Street
CAMPERDOWN, NSW 2050

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 Scientific Evaluation (OSE).

Trial Number: 2011/0309
Protocol Number: 12-209/12097

Drug(s):

Drug Active Name	Trade Name	Code Name	Strength
Light Liquid Paraffin			1g
Microcrystalline cellulose			50mg
Omega-3 Marine Triglycerides including EPA and DHA			300mg EPA; 200mg.DHA
sertraline hydrochloride	Setrona		50mg

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.



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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.

James McDonnell
Experimental Products Section
Office of Scientific Evaluation
03 August, 2011



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**Department of Health and Ageing
Therapeutic Goods Administration**

File Number: 2011/009179

**Nicole Cockayne
Brain and Mind Research Institute
100 Mallett Street
CAMPERDOWN, NSW 2050**

CTN Scheme (Drugs): Acknowledgement of Additional Trial Sites

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 Scientific Evaluation (OSE).

Trial Number: 2011/0309
Protocol Number: 12-209/12097
Drug Name(s):

Drug Active Name	Trade Name	Code Name	Strength
Light Liquid Paraffin			1g
Microcrystalline cellulose			50mg
Omega-3 Marine Triglycerides			300mg EPA; 200mg DHA
sertraline hydrochloride	Setrona		50mg

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.

James McDonell
Experimental Products Section
Office of Scientific Evaluation
03 August 2011



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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: 12-209/12097

Trial Number: 2011/0309

Date Acknowledged	Site Name	State
22 June 2011	Brain Mind Research Institute	NSW