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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:

- 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.
- 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.



Australian Government

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

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.

A handwritten signature in dark ink, appearing to read 'James McDonnell'.

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



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 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 McDonnell
Experimental Products Section
Office of Scientific Evaluation
03 August 2011



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Department of Health and Ageing
Therapeutic Goods Administration

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 |