



JANSSEN-CILAG

Janssen-Cilag Pty. Ltd.
A.C.N. 000 129 975

00/388

Tuesday, 5 September 2000

SENT BY EXPRESS POST

EDG, Drug Safety and Evaluation Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia

RE

08 SEP 2000

Drug Safety and
Evaluation Branch

Dear Sir/Madam

**Re: Clinical Trial Notification for
Protocol RIS-AUS-9**

I enclose a completed Clinical Trial Notification Form and TGA Credit Card Authorisation for \$200.00 for the above mentioned trial. This is a single site study.

Please note that the original expected start date was 16/8/2000, the trial is now expected to start on the 14/9/2000

Should you require further information please contact me on (02) 8875 3218

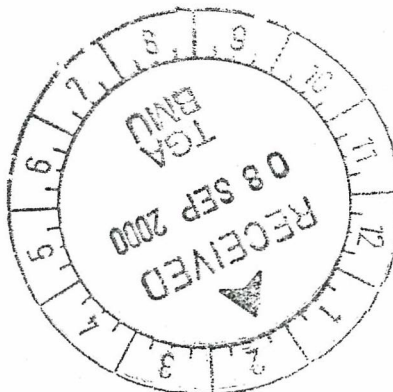
I would appreciate formal TGA acknowledgment of the notification by fax on (02) 8875 3225.

Yours faithfully

Claire Methven

Claire Methven
Project Manager, Clinical Research

Enc: CTN Form
TGA Credit Card Authorisation



Therapeutic Goods Act 1989

00/388



Therapeutic
Goods
Administration

Commonwealth Department of
Health and
Family Services

Clinical Trial of Drugs

DSEB 8.3 September 1997

Notification to the DRUG SAFETY AND EVALUATION BRANCH of an approval by a sponsor or other body or organisation to use a therapeutic good in a clinical trial:

- under the Clinical Trial Notification (CTN) Scheme for Drugs; or
- at one or more additional sites for a Clinical Trial previously reported under the Clinical Trial Notification (CTN) Scheme for Drugs.

Notification Type (Select One Only)

New CTN trial (single site) ☒

Additional CTN site (single) ☐

New CTN trial (multiple sites) ☐

Additional CTN sites (multiple) ☐

Use of Restricted Goods

Does this trial involve the use of any drug as an abortifacient or for "post-coital" or "emergency" contraception in women, or the use of a progesterone antagonist or a vaccine against human chorionic gonadotrophin for any purpose? Yes ☐ No ☒

Sponsor's Certification

I certify that all details contained within this form are true and accurate and that all required information and signatures have been included. The Sponsor named in Section 1 of this form is taking responsibility for the overall conduct of the trial.

Name (Print) JANE VIERTEL

Position CLINICAL RESEARCH MANAGER

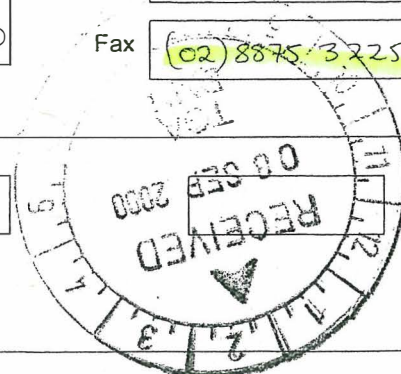
Signature  6 17 100

Phone (02) 8875 3336

Fax (02) 8875 3225

Office use only

\$



140107

Commercial - in - Confidence
Clinical Trial of Drugs - Trial and Drug Details

Sponsor Details (to be completed by sponsor)

Sponsor's name

Enterprise ID code
(If known)

2 Trial Details (to be completed by sponsor)

Protocol Number

If adding a Site
- Clinical Trial Number

Complete for a New Trial only: (If notifying additional sites go to Section 4 "Site Details")

Title and aim of
Trial/Study

Trial Type: (check one that is applicable or describe)

Phase 1 ☐

Phase 2 ☐

Phase 3 ☒

Bioavailability ☐

Other (describe) ☐

This Trial: (check any that are applicable)

is placebo controlled ☒

involves gene therapy ☐

is also being conducted in other countries ☐

involves use of an unregistered device ☐

**Trial expected
start**

**Trial expected
completion**

3 Drug Details (to be completed by sponsor for a New Trial only) (list all drugs being trialled including all comparators)

1 Active name

Trade name

Code name

Dosage form

Strength

Biological
origin ☐

2 Active name

Trade name

Code name

Dosage form

Strength

Biological
origin ☐

3 Active name

Trade name

Code name

Dosage form

Strength

Biological
origin ☐

Commercial - in - Confidence

Clinical Trial of Drugs - Trial and Drug Details


If there is more than one site, please complete a copy of this page for each site.

4 Trial Site Details (to be completed by the sponsor)	Site expected start	14/09/2000 16/08/2000
Site name	The PACE Clinic, Department of Psychiatry, University of Melbourne/MHSY	
Site address	35 Poplar Road, Parkville, Victoria	
	Postcode 3052	

5 Ethics Committee Details (to be completed by Ethics Committee responsible for monitoring trial)		
EC name	NORTH WESTERN MENTAL HEALTH BEHAVIOURAL & PSYCHIATRIC RESEARCH & ETHICS COMMITTEE	
EC address	SUNSHINE HOSPITAL, 176-190 FURLONG RD. ST. ALBANS, VIC.	
	Postcode 3021	

Ethics Committee Certification

I certify that the abovenamed Ethics Committee operates in accordance with the NH&MRC Statement on Human Experimentation and Supplementary Notes and has considered this clinical trial and provided advice to the body or organisation conducting the trial.

Name (Print)	DR. TOM PEYTON	Position	CHAIRMAN
Signature	 01 09 00	Phone	9365-1681
		Fax	9364-3792


6 Approving Authority Details (to be completed by the body, organisation or institution approving the conduct of the trial at this site)

Authority name	Professor Patrick McGorry		
Authority address	PACE Clinic/MH-SKY, Ricketts Bag 10 Parkville 35 Poplar Rd Parkville Postcode 3052		

Approving Authority Certification

I, the undersigned

- am authorised to represent the body, organisation or institution responsible for approving the conduct of the trial at the above named site;
- give approval in accordance with item 3 of Schedule 5A of the Therapeutic Goods Regulations for this trial to proceed; and
- undertake that the use of the drug will comply with all relevant Commonwealth and State or Territory legislation.

Name (Print)	P. D. MCGORRY	Position	Professor/Director
Signature	 19/7/00	Phone	03 93422800
		Fax	03 93422941