

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 20639**

**MEDICAL REVIEW(S)**

## REVIEW AND EVALUATION OF CLINICAL DATA

**NDA 20-639**

**Sponsor: Zeneca**

**Drug: Seroquel (quetiapine)**

**Material Submitted: Safety Update and Response to Approvable Letter**

**Date Submitted: Safety Update (6/30/97); Response to Approvable Letter (7/31/97)**

**Date Received: Safety Update (7/1/97); Response to Approvable Letter (8/4/97)**

**Medical Officer: Andrew Mosholder, M.D.**

### 1. Background

Safety findings from the original Seroquel NDA submission and the 4 month safety update were reviewed in the NDA clinical review. These two sources together provided data on patients exposed to quetiapine in clinical trials through 3/1/96. The sponsor's "pre-approval safety update" submitted 6/30/97, and the sponsor's response to the Seroquel Approvable Letter submitted 7/31/97, provide additional safety data that is the subject of this review.

The sponsor's response to the agency's Approvable Letter will also be reviewed here.

### 2. Updated Clinical Data

The original NDA clinical review covered the sponsor's primary integrated safety database, comprising 2387 quetiapine treated patients who received the drug in Phase II-III clinical trials. This primary integrated database incorporated both the original NDA submission and a four month safety update. The cutoff date for safety data on these 2387 quetiapine patients was 3/1/96.

#### Updated Primary Integrated Database

This submission updates the primary integrated database with a new cutoff date of 11/7/96. Included are data on all adverse experiences, including serious adverse experiences, premature discontinuations and deaths, for 504 quetiapine treated subjects. Of these, 136 are new patients and 368 are previously reported patients with added exposure time. Note that clinical laboratory, vital signs, and EKG data was not updated in this submission. Data on adverse experiences was provided in electronic SAS format. All new safety data was from outpatient uncontrolled trials, and there were no new data from placebo or active control treated patients. The updated primary integrated database does not include any additional Phase I trial data, reportedly because the additional Phase I trials were not yet analyzed.

The table below displays the total number of patients and the exposure in patient years for the primary integrated database, with the new cutoff date of 11/7/96, by treatment group.

TREATMENT GROUP	N	PT-YEARS
Quetiapine	2523	1103.2
Placebo	206	14.6
Haloperidol	320	42.5
Chlorpromazine	100	9.2

The additional quetiapine exposure for this submission amounts to 237.9 patient years. As noted, the exposure for the control groups did not change with this submission.

## Clinical Trials Not Included in the Primary Integrated Database

This submission includes data from 14 trials not incorporated in the primary integrated database, chiefly because they were still ongoing or not yet analyzed. For these studies, the sponsor reported deaths, serious adverse events, and adverse events leading to dropout. While 5 of these trials were described in the NDA clinical review, 9 were new trials.

### Secondary Data Cutoff

In the pre-approval safety update Zeneca provided a listing of all deaths and serious adverse events among quetiapine treated patients during the period 11/8/96 to 5/30/97, with narrative case summaries. Case report forms were also provided for patients who died. These data are not included in the primary integrated database, however, and case report forms were not always available to the sponsor.

### Tertiary Data Cutoff

In the response dated 7/31/97 to the approvable letter, the sponsor provided line listings and narrative summaries for deaths and other serious adverse events occurring from 5/30/97 to 7/15/97. The case report form for the one patient who died was also provided under separate cover (submitted 8/6/97).

### Demographic Profile for primary integrated database

With the updated primary integrated database (n=2523) for quetiapine exposed patients in Phase II-III trials, the percentage composition by age group, gender and racial background changed very little (not more than about 1% in any category). I have not included a revised demographic profile table here, because the overall changes are so minimal, but the interested reader is referred to the sponsor's Table T3.2.7.3.

### Deaths

The following table displays a listing of all deaths among quetiapine treated patients in the safety update period. This table is adapted from the sponsor's electronic submission.

**Table Subjects who died during or within 30 days after discontinuation of trial treatment, 3/1/96 to 7/15/97\***

Trial/center/ subject number	Age (y)	Sex	Last recorded dose (mg/day)	Duration of trial treatment (days)	Primary cause of death
0048/0003/0310*	77	M	500	292	Myocardial infarction; concurrent pneumonia
0048/0007/0712*	64	M	100	252	Aspiration pneumonia; patient with progressive supranuclear palsy
0048/0013/1306*	65	F	175	339	Sepsis, pneumonia, carcinoma of upper esophagus, no autopsy
0048/0013/1310*	81	F	75	189	Sudden death while dancing, deemed "possible cardiopulmonary arrest"
0015/0003/0305	69	M	500	1091	Metastatic pancreatic cancer
0015/0035/3501	47	M	300	1037	Sudden cardiac arrest and death; no autopsy
0048/0001/0105	80	F	50	596	Patient had end stage dementia, was not taking food, liquids or medication, aggressive treatment waived

**Table Subjects who died during or within 30 days after discontinuation of trial treatment, 3/1/96 to 7/15/97<sup>a</sup>**

0048/0002/0207	70	F	300	592	Death from pneumonia following surgery for bowel obstruction
0048/0004/0406	77	M	200	618	Aspiration pneumonia, dysphagia, dementia. Also receiving olanzapine 5 mg/d.
0048/0006/0609	96	M	75	571	Bronchopneumonia in patient with vascular dementia; family elected not to treat pneumonia
H-15-34/1311/H-003	65	M	400	47	Died after febrile illness with respiratory distress; suspected pneumonia
H-15-37/4018/016-001	28	M	75	3	Suicide
H-15-37/4003/012-001	38	m	200	220	Found approximately 10 d after death, body too decomposed for autopsy
H-15-31/0201/013-001 BLINDED (QUETIAPINE OR HALOPERIDOL)	27	F	blinded	57	Suicide
H-15-31/0105/080-001 HALOPERIDOL	55	F	0.75 Haloperidol	1	Sudden death
H-15-31/0402/015-003 HALOPERIDOL	40	M	9 Haloperidol	46	Sudden death (found in bathroom); no autopsy; investigator suspected water intoxication

<sup>a</sup> Additionally, 2 subjects (0048/0001/0102 and 0048/0018/1811) died (aspiration pneumonia and unknown cause, respectively) more than 30 days after discontinuation of quetiapine treatment and 1 subject (0050/0092/0001) committed suicide more than 30 days after discontinuation of blinded treatment (quetiapine or haloperidol).

NA Not applicable.

\*Included in primary integrated database

In my judgement, none of these deaths are directly attributable to the effects of quetiapine. (Drug related dysphagia and aspiration may be contributing factors in the development of pneumonia, however, as discussed in the NDA clinical review.) The following table provides the updated all cause mortality in the primary integrated database.

**Table Overall mortality in the updated integrated Phase II-III database (adapted from sponsor's electronic submission)**

Treatment	Number of subjects	Patient-years exposure <sup>a</sup>	Number of deaths <sup>b</sup>	Crude mortality rate	Mortality per 100 patient-years
Quetiapine	2523	1103.2	12	0.48	1.09
Haloperidol	320	42.5	1	0.31	2.35
Chlorpromazine	100	9.2	0	0.00	0
Placebo	206	14.6	0	0.00	0

<sup>a</sup> Patient-years is defined as the sum of all subjects' days on treatment (duration) divided by 365 days.

<sup>b</sup> Deaths occurring within 30 days after trial treatment ended (excludes one death from Trial 0031, for which treatment assignment remains blinded).

#### Overdose Experience

The sponsor defined overdose to be ingestion of 900 mg or more of quetiapine. In the original database the small number of known overdoses of quetiapine did not point to any unusual toxicity. The following provides a listing of quetiapine overdoses reported in the safety update.

Table Summary of overdoses with quetiapine 3/1/96-5/30/97

Trial;subject	A g e	S e x	over-dose mg	Concomitant drugs	Comments
0048/0010/1006	79	f	900/d x 14 d		Inadvertent administration by caregiver; no significant effects other than slight hypotension and dizziness
0056/0044/0007	27	f	~1000		Developed Tachycardia, nonspecific T wave changes, Qtc 402 msec; received lavage, recovered
0061/0001/0130	28	f	3000		Treated with charcoal and lavage; experienced sedation, tachycardia (180 bpm) and was administered diltiazem and adenosine; treated in intensive care setting, recovered; no ECG data provided
0053/0521/0001	48	f	5100 or pbo.		Received overdose of quetiapine or placebo due to dispensing error (blind was not broken); pt. asymptomatic
0053/0544/0001	39	m	700-900/d or risperidone 16 mg/d x 1 wk		Dispensing error resulted in overdose; blind not broken; pt. asymptomatic
0054/0253/0001	62	m	10,000 or pbo.		Accidental overdose; blind not broken, pt. slightly hyponatremic (131 mmol/l) but otherwise asymptomatic
0054/0253/0002	57	m	10,000 or pbo.		Accidental overdose; blind not broken, pt. developed dry mouth, urinary retention and incontinence, sedation, hematuria, myoclonus, dry skin, flushing, delirium, no ECG findings. Treated with diazepam; recovered in 2 days.
0053/0573/0001	25	m	1700		Accidental overdose; pt. developed sedation, dizziness, rigidity, lower blood pressure and heart rate. Treated with charcoal and lactulose; recovered in 12 hours.
0056/0008/0002	21	m	18,000 to 20,000	fluoxetine 400-600 mg	Sinus tachycardia, confusion; treated with lavage and IV fluids
0056/0022/0005	26	f	12,000 to 19,200		Treated with gastric lavage, hydration; became obtunded and required intubation; recovered
0056/0044/4410	24	m	2400	risperidone, benztropine	Treated with charcoal; no symptoms or ECG findings. Pt overdosed a second time (see below)
0056/0044/4410	24	m	1900		Second overdose by this patient. Experienced stupor, dysarthria; ECG normal; treated with charcoal, recovered
Not a subject	51	m	200		Family member took patient's medication by mistake; developed hypotension, slurred speech, lethargy, dry mouth, recovered in 7 hrs.
0056/0009/0003	32	m	1800		Sedation noted; treated with lavage and charcoal, recovered within hours

0050/0071/0007	25	f	1000-1200		Developed sopor, tachycardia (140 bpm) and hypotension (85/60); treated with gastric lavage with saline solution, recovered by next day
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The most notable clinical features from the cases above are the prominent sedative effects and anticholinergic effects. The latter is somewhat surprising since quetiapine is not believed to possess much anticholinergic activity.

#### Adverse Events

As the only additional exposure reported was from uncontrolled studies, no information of consequence on the common adverse event profile was provided by the new data. Hence, the focus of this review is on significant adverse events, primarily deaths and other serious adverse events, and in some cases adverse events that lead to dropout. The primary source of information for this section was the sponsor's clinical narrative summaries of the cases; in certain cases the CRF was consulted or the sponsor provided additional information upon my request.

In the following, I will highlight the adverse events of significance by body system. Events referable to the patient's psychiatric illness will not be discussed here.

#### Cardiovascular

Deaths: Patient 0048/0003/0310 died of an MI. Patient 0048/0013/1310 (81 y.o.) died suddenly while dancing. Patient 0015/0035/3501 died suddenly (47 y.o., no autopsy). See table above for details.

Other adverse events: There were 5 cases of syncope or postural hypotension reported among quetiapine treated patients and another 6 such cases among patients who were not unblinded. In addition, there were 2 cases of deep vein thrombophlebitis, 2 cases of angina/chest pain, one case of congestive heart failure, one case of hypotension and left bundle branch block, and one case of arterial thrombosis which required surgery.

Thrombotic adverse events continue to be reported with quetiapine treatment, as was noted in the NDA clinical review; please refer to the discussion there under Cardiovascular system.

Similarly, please refer to the NDA clinical review discussion of syncope/postural hypotension. These new data do not lead me to revise my previous interpretations. The incidence of syncope (i.e., adverse events with this COSTART term found by electronic search) for the updated primary integrated database was 28/2523 quetiapine treated patients (1.1%), compared to 2/420 active control patients (0.5%) and no placebo patients. The median duration of quetiapine treatment at the time of syncope for these patients was 17 days.

#### Gastrointestinal

The following adverse events were reported in patients receiving quetiapine or whose treatment was blinded but could have been receiving quetiapine: bloody diarrhea requiring hospitalization, intestinal obstruction secondary to adhesions, appendectomy for carcinoid tumor of appendix, abdominal pain of unknown cause, esophagitis (3 cases), fecal impaction (2 cases), paralytic ileus, increased liver enzymes, appendectomy, cholecystectomy (2 cases, one of which also involved cirrhosis of unknown cause), gastroenteritis, diarrhea, rectal fistula, hemorrhage from a benign colonic ulcer. One notable case is summarized below, although the randomization code was not broken:

0053/0534/0007

BLINDED 40 y.o. male developed jaundice, increased LFTs (ALT 324 iu/l), hepatopathy, and portal hypertension on day 18 of quetiapine or risperidone. Prior history of hepatitis C, with positive antibodies to hep B and C. Resolved after d/c of treatment

This patient became symptomatic with hepatic dysfunction and recovered after drug was discontinued; however, the patient had evidence of exposure to viral hepatitis.

#### Hemic and Lymphatic

The following adverse events were reported in patients receiving quetiapine or whose treatment was blinded but could have been receiving quetiapine: leukopenia (ANC 1010), pernicious anemia, prolonged bleeding times resulting in postponement of elective surgery, ecchymosis (but with normal platelet count). These new reports do not alter the previous conclusions regarding this body system, in my opinion.

#### Genitourinary

The following adverse events were reported in patients receiving quetiapine or whose treatment was blinded but could have been receiving quetiapine: urinary tract infection (6 cases), pyelonephritis (2 cases), renal calculus, surgery for urethral stricture. In my opinion, a drug related cause of urinary tract infections seems unlikely.

#### Metabolic and Endocrine

The following adverse events were reported in patients receiving quetiapine or whose treatment was blinded but could have been receiving quetiapine: Neuroleptic malignant syndrome and similar events (4 cases, blind unbroken in all 4), weight loss requiring hospitalization, dehydration, acute hypoglycemia of unknown cause, diabetic ketoacidosis. One patient, 0050/0031/0003, whose treatment remained blinded, was withdrawn and treated with thyroid replacement, although the TSH remained normal. Please refer to the NDA clinical review for a discussion of thyroid findings with quetiapine treatment.

#### Musculoskeletal

The following adverse events were reported in patients receiving quetiapine or whose treatment was blinded but could have been receiving quetiapine: fracture of maxilla in a fall, hip fracture (2 cases), bone graft of hip for osteoporosis, fracture of ankle, fracture of radius, herniated lumbar disk. With respect to hip fracture, there was one additional case in the primary integrated database in a patient over age 64 (0048/0008/0801). Please refer to the NDA clinical review for a discussion of falls and fractures, which could be drug related via postural hypotension.

#### Nervous

Deaths (see table above for details): Suicide (patients H-15-37/4018/016-001, H-15-31/0201/013-001 (blinded))

End stage dementia (patient 0048/0001/0105)

The following adverse events were reported in patients receiving quetiapine or whose treatment was blinded but could have been receiving quetiapine: cerebrovascular accident, breast carcinoma metastatic to brain, seizure (12 cases, 5 on quetiapine and 7 blinded), akathisia (4 cases), hypertonia, severe somnolence/stupor (3 cases), tremor, hemiparesis of unknown cause, delirium, ataxia, severe EPS. Please refer to the original NDA clinical review for a discussion of nervous system adverse events. Concerning seizures, Zeneca has agreed to labeling with the incidence of seizures from the previous primary integrated database, i.e., 0.8%, and did not conduct a search to update this incidence.

## Respiratory

Deaths: Pneumonia was involved in the following fatal cases, either as a cause or a complication: 0048/0007/0712, 0048/0013/1306, 0048/0002/0207, 0048/0004/0406, 0048/0006/0609, H-15-34/1311/H-003. See table above for details.

The following adverse events were reported in patients receiving quetiapine or whose treatment was blinded but could have been receiving quetiapine: pneumonia (10 cases), dysphagia (choking on food), respiratory dyskinesia, bronchitis.

As noted in the NDA clinical review, and the draft labeling, dysphagia and aspiration pneumonia may be drug related.

## Dermatological

Two patients underwent surgical removal of skin cancers. One patient had a severe skin allergy:

0051/0216/0007            42 y.o. male hospitalized for photoallergy of skin after 70 days on quetiapine 600 mg/d. Concomitant medications were tropatepine and alprazolam; continued open label quetiapine.

## Special Senses

One patient suffered traumatic retinal detachment (when struck by another patient.)

## Miscellaneous

Deaths: pancreatic carcinoma (0015/0003/0305). Another patient was found dead, and the body was considered too decomposed for autopsy (H-15-37/4003/012-001).

The following adverse events were reported in patients receiving quetiapine or whose treatment was blinded but could have been receiving quetiapine: alcohol intolerance, cellulitis (2 cases), burn injury suffered in kitchen fire, surgery to remove uvula polyp, chronic otitis, breast cancer, fever of unknown origin, leg ulcer, chest pain of unknown etiology, surgical drainage of abscess on arm, food allergy.

In addition, the sponsor reported a case of psuedotumor cerebri in a 14 year old boy receiving quetiapine, the first instance of psuedotumor cerebri in a patient treated with quetiapine. The investigator attributed this to concomitant minocycline (IND safety report 7/28/97).

## Additional Clinical Data on Cases Reviewed in NDA Clinical Review

In response to our request (fax 6/5/97), Zeneca provided additional clinical information on certain cases of serious adverse events for which the originally submitted information was incomplete (submissions dated 6/19/97 and 6/16/97). On balance, this additional clarifying information does not provide evidence of additional adverse drug reactions to quetiapine. Briefly, the information provided is as follows:

0013/0016/1605: This patient had a DVT which was attributed to concomitant oral contraceptives; her anemia was determined to be iron deficiency.

0012/0091/9143: This 46 year old man who developed a left ventricle thrombus and a resulting cerebrovascular accident did in fact have a history of myocardial infarction with a residual left bundle branch block, although Zeneca did not include this information originally.

0048/0002/0201: This patient developed acute renal failure and anemia while on quetiapine, among other disorders; he apparently had a history of chronic renal failure and the sponsor attributes his acute renal failure to multifactorial causes. No specific cause for the anemia was stated but Zeneca denied that there was any evidence of hemolysis.

0012/0019/1903: No other cause of this patient's renal failure was found, and the investigator attributed it to quetiapine; however, the patient was not rechallenged with the drug.



0048/0004/0405: No additional information on this patient's anemia was available; apparently the investigator ignored it.  
0015/0005/0502: The patient's anemia was attributed to cancer chemotherapy, which was not made clear in the original submission.  
0014/0046/4609: This patient was hospitalized for his anemia, and was found to have gastritis; he was treated with folate. The case report form was submitted but provided little additional information.

**Conclusions:** The additional safety data in the pre-approval safety update and the final safety update submitted after the approvable letter do not substantively alter the previous conclusions about quetiapine safety. If desired, the sponsor could be asked to update the incidence of key adverse events such as seizures and syncope, which was not done for these submissions.

### **3. Zeneca's Response to the Approvable Letter**

#### **Labeling**

I have the following comments on the sponsor's counter-proposals to the approvable letter labeling. Regarding the interaction with phenytoin cited under Clinical Pharmacology, I favor retaining the cross-reference to the Dosage and Administration section; Zeneca's proposal is to delete the cross-reference. Under Clinical Trials, I favor retaining the description of the possible age interaction, which Zeneca proposed to delete. For the precaution about cataracts, Zeneca has proposed deleting the recommendation for periodic slit lamp exams and replacing it with a recommendation for "careful ocular examination." The sponsor's response has been reviewed by our ophthalmology consultant, Dr. Wiley Chambers, who disagrees. (Dr. Chambers explained to me in a telephone conversation that a routine examination of the eye with a handheld ophthalmoscope does not permit thorough visualization of the lens, partly because the bright light constricts the pupil and partly because the instrument cannot focus effectively on the lens.) Regarding cholesterol elevations, Zeneca has declined to conduct further analyses of these data on the grounds that the samples were non-fasting and therefore are not definitive.

Zeneca proposes a recommended dose range of 300-400 mg/d (the agency's interpretation was that the target dose should be 400-450 mg/d). In my opinion, this is a matter of judgement, as I do not believe the clinical trial data are precise enough to distinguish whether 300 or 400 mg daily should be the target dose. The sponsor has revised the "Other Events..." table as requested.

**Post-Marketing Studies:** Zeneca has agreed to conduct the studies requested in the approvable letter, but has not submitted any proposals.

**World Literature Update:** Zeneca conducted a literature search covering the period 4/16/96 through 7/14/97, using their in-house library database, and provided abstracts of publications pertaining to quetiapine. Dr. Lisa Arvanitis from Zeneca has certified that there are no publications that would adversely affect conclusions about the safety of quetiapine. My own review of the abstracts provided leads me to the same conclusion. There is some new information about the pharmacology of the drug, however: Seeman and associates (Japanese Journal of Pharmacology 71(3):187-204, 1996) provided  $K_i$  values for quetiapine binding to human dopamine and serotonin receptors (see page 215 of submission). The values they obtained were 78 nM for D2, 3000 nM for D4 and 2500 nM for 5HT2A. The proposed labeling has IC50 values; these appear to be the first  $K_i$  values reported for the compound. Additionally, Zeng and associates concluded that quetiapine has almost no effect at the muscarinic m4 receptor (European Journal of Pharmacology 1997:321(3):349-354, on page 238 of the submission).

**World Regulatory Update:** Seroquel has neither been approved nor rejected for marketing elsewhere. A number of foreign applications are pending.

### **4. Conclusions and Recommendations**

The additional clinical data provided by Zeneca subsequent to the NDA clinical review do not substantively

alter the previous conclusions about quetiapine safety or efficacy. I recommend approval of the drug, with appropriate revisions to the sponsor's draft labeling.

*Andrew Mosholder* 8/19/97

Andrew Mosholder, M.D.  
Medical officer, Division of Neuropharmacologic Drug Products

NDA 20-639  
Div File  
HFD-120:Laughren/Hardeman/Mosholder

8-21-97

I agree that this NDA can now be approved. However, we have not reached agreement on the issue of labeling language for extracts, and I will forward a package that includes our originally proposed language. See memo to file for more detailed response.

Thomas P. Laughren, MD  
TL, PDA

## 8A LIST OF INVESTIGATORS

All investigators who received trial drug shipment up to the secondary data cutoff date (1 March 1996) are included in the following list:

NAME/ADDRESS	TRIAL NUMBER/ CENTER***	TYPE OF TRIAL**	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT FORMS*
Addington, Donald E.N., MD Foothills Hospital 1403-29th Street NW Calgary, Alberta T2N 2T9 CANADA	5077IL/0013:0019	D-B Comp	1.117/1, 1.148/1, 1.308/1	1.398/1	CANDA
	5077IL/0013:0019	O-L E	1.262/1	1.442/274	CT Report
Ahnkund, Dr. N.G. Vuxen Psyk Mottagningen Vallonvagen 15 612 00 Finspang SWEDEN	5077IL/0014:0058	D-B Comp	1.243/1 1.354/1	1.431/1	CANDA
	5077IL/0014:0058	O-L E	1.262/1	1.442/274	CT Report
Alphs, Larry D., MD, PhD Lafayette Clinic 951 East Lafayette Avenue Detroit, MI 48207 USA  Detroit VA Medical Center Southfield and Outer Drive Allen Park, MI 48101 USA	5077IL/0006:0004 (APS 0-A31-1/0004)	D-B Comp	1.132/1, 1.301/1	1.384/1	CANDA
Anderson, Cheryl, PharmD University of Texas Health Science Center at San Antonio San Antonio State Hospital Clinical Pharmacy Programs 7703 Floyd Curl Drive San Antonio, TX 78284 USA	5077US/0001:0009 <sup>11</sup> (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Anderson, Dr. T. Psyk Kliniken Universitetssjukhuset 901 85 UMea SWEDEN	5077IL/0014:0060	D-B Comp	1.243/1 1.354/1	1.431/1	CANDA
	5077IL/0014:0060	O-L E	1.262/1	1.442/274	CT Report
Apter, Jeffrey T., MD Princeton Biomedical Research 256 Bunn Drive, Suite 6 Princeton, NJ 08540 USA	5077IL/0015:0001	D-B Comp	1.171/1, 1.314/1	1.408/1	CANDA
	5077IL/0015:0001	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0048:0001	O-L	1.258/1	1.442/272	CANDA
Aschauer, Dr. H.H. Psychiatrische Universitätsklinik Wahringer Gurtel 18-20 A-1090 Wien AUSTRIA	204636/0008:0027 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA

See footnotes on Pages 53 and 54.

NAME/ADDRESS	LOCATION IN APPLICATION				
	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT FORMS*
Ashcroft, G.W., Professor Department of Mental Health University Medical Buildings Foresterhill Aberdeen, England AB9 2ZD UK	50771L/0005: UK-0005	O-L	1.254/1	1.439/272	CANDA
Asserson, Dr. S. Helleveien 65 Sandviken Sykehus 5035 Bergen NORWAY	50771L/0014:0043	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	50771L/0014:0043	O-L E	1.262/1	1.442/274	CT Report
Avnon, Dr. M. Psychiatric Center Doar NA Chefer Shaar Menashe ISRAEL	50771L/0012:0046	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	50771L/0012:0046	O-L E	1.262/1	1.442/274	CT Report
Ayuso, Prof. Hospital Clinico Universitario Servicio de Psiquiatria San Carlos Madrid SPAIN	204636/0007:0011	D-B Comp	1.217/1, 1.348/1	1.415/1	CANDA
Azorin, Prof. J.M. C.H.U. La Timone Clinique de Psychiatrie Rue Saint-Pierre 13385 Marseille Cedex 4 FRANCE	50771L/0012:0033	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	50771L/0012:0033	O-L E	1.262/1	1.442/274	CT Report
Baker, Robert Special Studies Center South 2, Ward 4B 1601 Mayview Road Bridgeville, PA 15017 USA	50771L/0031:0009:	D-B Comp	1.261/333	1.442/273	CANDA
Ballus-Pascual, Dr. C. Servicio de Psiquiatria Hospital Clinico y Provincial Villarreal 170 08036 Barcelona SPAIN	204636/0007:0014	D-B Comp	1.217/1, 1.348/1	1.415/1	CANDA
	50771L/0014:0054	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
Banki, Dr. C. Department of Psychiatry Regional Neuropsychiatric Institute Nagykallo, PO Box 37 H-4321 HUNGARY	50771L/0012:0092	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	50771L/0012:0092	O-L E	1.262/1	1.442/274	CT Report

NAME/ADDRESS	LOCATION IN APPLICATION				
	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT FORMS*
Bark, Nigel, MD Bronx Psychiatric Center Ward 19 - Research 1500 Waters Place Bronx, NY 10461 USA	5077IL/0031:0006	D-B Comp	1.261/333	1.442/273	CANDA
Barnes, T.R.E., Dr. Horton Hospital Long Grove Road Epsom Surrey KT19 8PZ UK	204636/0008:0001 <sup>16</sup> (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Bartko, Dr. G. Department of Psychiatry South-Pest Hospital Budapest Koves, ut 2-4 H 1204 HUNGARY	5077IL/0012:0091	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0091	O-L E	1.262/1	1.442/274	CT Report
Bassi, Dr. M. Servizio di Salute Mentale Via Berenini 153-43036 Fidenza ITALY	5077IL/0012:0074	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0074	O-L E	1.262/1	1.442/274	CT Report
Bastani, Bijan, MD Portage Path Community Mental Health Center, 340 South Broadway Street Akron, OH 44304 USA	5077IL/0015:0034	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0034	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0048:0002	O-L	1.258/1	1.442/273	CANDA
Beau, Dr. J. Center Hospitalier Malartic 1141 Rue Royale Malartic Quebec J0Y 1Z0 CANADA	5077IL/0012:0062	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0062	O-L E	1.262/1	1.442/274	CT Report
Bech, Prof. Per Hellerod Sygehus Helsevej 2 3400 Hillerod DENMARK	5077IL/0005: UK-0017	O-L	1.254/1	1.439/272	CANDA
	5077IL/0014:0018	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
Beckers, Dr. G. Medister Jagersdreef 100 2950 Kapellen BELGIUM	5077IL/0012:0023	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0023	O-L E	1.262/1	1.442/274	CT Report

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT FORMS*
Belmaker, Prof. R.H. Psychiatric Center PO Box 4600 Beer Sheva ISRAEL	5077IL/0012:0045	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0045	O-L E	1.262/1	1.442/274	CT Report
Benkert, Prof. O. Psychiatric Clinic Mainz GERMANY	5077IL/0005:UK-020	O-L pilot	1.254/1	1.439/272	CANDA
Bennie, Dr. E. Department of Psychology Leverdale Hospital 510 Crookston Road Glasgow G53 7TU UNITED KINGDOM	204636/0008:0002 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0014:0064	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0064	O-L E	1.262/1	1.442/274	CT Report
Bent, Dr. E. SPDC Oost Bredesodelaan 54 Postbox 50 2080 AB Santpoort-Zuid NETHERLANDS	5077IL/0014:0033	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0033	O-L E	1.262/1	1.442/274	CT Report
Frederik Van Eeden Stichting Amsterdam NETHERLANDS					
Bern, Dr. P.H. C.H. des Chanoux Hotel Dieu 71018 Macon Cedex FRANCE	204636/0007:0031	D-B Comp	1.217/1, 1.348/1	1.415/1	CANDA
	5077IL/0012:0032	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0032	O-L E	1.262/1	1.442/274	CT Report
Bitter, Dr. I. Semmelweis Medical University Balassa utca 6H-1083 Budapest HUNGARY	204636/0008:0017 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0014:0035	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0035	O-L E	1.262/1	1.442/274	CT Report
Bjorling, Dr. G. Psyk Mottagningen Fyren Drottninggatan 461 33 Trollhattan SWEDEN	5077IL/0014:0057	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0057	O-L E	1.262/1	1.442/274	CT Report
Bjoch-Thorsen, Dr. G.R. Psykiatrisk Avdeling Sentraljukehuset i Rogalad 4011 Stavanger NORWAY	5077IL/0014:0042	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0042 <sup>13</sup>	O-L E	1.262/1	1.442/274	CT Report
Bobon, Prof. D. Clinique Notre Dame des Anges Rue Vanderveelde 67 4000 Glain BELGIUM	5077IL/0005:UK-008	O-L pilot	1.254/1	1.439/272	CANDA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F ORMS*
Borison, Richard L., MD, PhD Medical College of Georgia Dept of Psychiatry & Health Behavior 1515 Pope Avenue Augusta, GA 30912-3800 USA  Psychiatry Service 116A-U Augusta VA Medical Center One Freedom Way Augusta, GA 30910 USA	5077IL/0006:0008 <sup>3</sup> (APS 0-A31-1/0008)	D-B Comp	1.132/1, 1.301/1	1.384/1	CANDA
	5077IL/0013:0001	D-B Comp	1.117/1, 1.148/1, 1.306/1	1.398/1	CANDA
	5077IL/0013:0001	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0015:0002	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0002	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0031:0001	D-B Comp	1.261/333	1.442/273	CANDA
	5077IL/0044:0001	Clin Pharm	1.90/1	1.377/1	NA
	5077IL/0045:0001 5077IL/0045:0001	Clin Pharm O-L E	1.108/1 1.262/1	1.381/1 1.442/274	CANDA CT Report
Botte, Dr. Psychiatric Hospital of Manage 7170 Manage BELGIUM	204636/0007:0035	D-B Comp	1.217/1, 1.348/1	1.415/1	CANDA
Bowden, Charles L., MD Department of Psychiatry Audie L. Murphy Veterans Memorial Hospital 7400 Merton Minter Boulevard San Antonio, TX 78284 USA	5077US/0001:0002 (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Boza, Ramon, MD VA Medical Center  Department of Psychiatry 1201 NW 16th Street Miami, FL 33125 USA	5077IL/0015:0022 <sup>4</sup>	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0022 <sup>4</sup>	O-L E	1.262/1	1.442/274	CT Report
Braconnier, Dr. A. Centre de L'Eau Vive 6 Avenue du Gal de Gaulle 91450 Soisy-sur-Seine FRANCE	5077IL/0012:0037	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0037	O-L E	1.262/1	1.442/274	CT Report
Bredbacka, Dr. P.E. Paijat Hame Central Hospital Keskussairaalankatu 7 15 850 Lahti FINLAND	5077IL/0014:0023	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0023 <sup>13</sup>	O-L E	1.262/1	1.442/274	CT Report
Brown, Walter A., MD Clinical Programs Ltd. 4 Richmond Square Providence, RI 02906 USA	5077IL/0015:0031	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0031	O-L E	1.262/1	1.442/274	CT Report

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F ORMS*
Buchkremer, Prof. G. Psychiatrische Universitätsklinik 72076 Tubingen Osianderstrasse 22 72076 Tubingen GERMANY	5077IL/0012:0050	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0050	O-L E	1.262/1	1.442/514	CT Report
Burns, Prof. T. Department of Mental Health Sciences Jenner Wing Cranmer Terrace Tooting London SW17 0RE UNITED KINGDOM	5077IL/0012:0015	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0015	O-L E	1.262/1	1.442/274	CT Report
Susse, Erhard, MD Psychopharmacology Research Training Center Hamilton Psychiatric Hospital 100 West 5th Street Hamilton, Ontario L9C 3N6 CANADA	5077IL/0031:0007	D-B Comp	1.261/333	1.442/273	CANDA
Canive, Jose M., MD VA Medical Center Building 1 2100 Ridgecrest Drive, SE Albuquerque, NM 87108 USA  VA Medical Center 3695 Hot Springs Boulevard Las Vegas, NM 87701 USA	5077IL/0015:0003	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0003	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0031:0002	D-B Comp	1.261/333	1.442/273	CANDA
Carman, John S., MD Brawner Psychiatric Institute 3180 Atlanta Street SE Smyrna, GA 30080 USA  Carman Research 4000 Cumberland Parkway Building 100, Suite A Atlanta, GA 30339 USA	5077IL/0006:0002 (APS 0-A31-1/002)	D-B Comp	1.132/1, 1.301/1	1.384/1	CANDA
	5077IL/0015:0030	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0030	O-L E	1.262/1	1.442/274	CT Report



NAME/ADDRESS	LOCATION IN APPLICATION				
	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT FORMS*
Caroli, Dr. F. Hospital Sainte Anne Pavillon Benjamin Ball 1 Rue Cabanis 75674 Paris Cedex 14 FRANCE	204636/0007:0026	D-B Comp	1.217/1, 1.348/1	1.415/1	CANDA
	50771L/0012:0043	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	50771L/0012:0043	O-L E	1.262/1	1.442/274	CT Report
Casacchia, Prof. M. Universita dell'Aquila Ospedale Santa Maria di Collemaggio 67100 L'Aquila ITALY	50771L/0012:0077	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	50771L/0012:0077	O-L E	1.262/1	1.442/274	CT Report
Casey, D.E., MD Chief, Psychiatric Research Pharmacology Psychiatry Service 116A VA Medical Center Portland, OR 97207 USA	50771L/0005: US-0005 (APS 9-976-1)	O-L pilot	1.254/1	1.439/1	CANDA
Cervera, Dr. S. Servicio de Psiquiatria Clinica Universitaria de Navarra Avenida Pio XII S/N 31080 Pamplona SPAIN	50771L/0012:0086	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	50771L/0012:0086	O-L E	1.262/1	1.442/274	CT Report
Chabannes, Dr. J.P. C.H.S. de Bassans BP 1126 73011 Chambéry Cedex FRANCE	50771L/0012:0041	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	50771L/0012:0041	O-L E	1.262/1	1.442/274	CT Report
Chiles, John, MD University of Texas Health Science Center at San Antonio Department of Psychiatry 7703 Floyd Curl Drive San Antonio, TX 78284-7792 USA	50771L/0015:0013a	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	50771L/0015:0013 <sup>b</sup>	O-L E	1.262/1	1.442/274	CT Report
Chinchilla, Dr. A. Servicio de Psiquiatria Hospital Ramon y Cajal Ctra Colmenar KM 9100 Madrid SPAIN	50771L/0012:0084	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	50771L/0012:0084	O-L E	1.262/1	1.442/274	CT Report
Clerc, Dr. G. C.H.S. de Pontorson 50170 Pontorson FRANCE	50771L/0012:0040	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	50771L/0012:0040	O-L E	1.262/1	1.442/274	CT Report

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT FORMS*
Cookson, Dr. I. Department of Psychiatry Defton General Hospital Smithdown Road Liverpool UNITED KINGDOM	204636/0007:0023	D-B Comp	1.217/1, 1.348/1	1.415/1	CANDA
Cooper, Dr. S.J. Department of Therapeutics and Pharmacology Whitta Medical Building Queens University of Belfast 97 Lisburn Road Belfast, Northern Ireland UNITED KINGDOM	204636/0008:0028 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Copolov, Prof. D.L. Mental Health Research Institute of Victoria Oak Street Parkville Victoria 3052 AUSTRALIA	5077IL/0014:0001  5077IL/0014:0001	D-B Comp  O-L E	1.243/1, 1.354/1  1.262/1	1.431/1  1.442/274	CANDA  CT Report
Corrigan, Dr. F.M. Department of Psychiatry Argyll & Bute Hospital Barbuie Road Lochgilphead Argyll Scotland UNITED KINGDOM	5077IL/0012:0017  5077IL/0012:0017	D-B Comp  O-L E	1.225/1, 1.350/1  1.262/1	1.423/1  1.442/274	CANDA  CT Report
Corrigan, Mark, MD Clinical Research Unit Edgerton Building Dorothea Dix Hospital 809 Ruggles Drive Raleigh, NC 27603 USA	5077US/0001:0007 (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Covelli, Dr.G. Ospedale Bolognini Via Paderno 1-24068 Seriate ITALY	5077IL/0012:0067  5077IL/0012:0067	D-B Comp  O-L E	1.225/1, 1.350/1  1.262/1	1.423/1  1.442/274	CANDA  CT Report

NAME/ADDRESS	LOCATION IN APPLICATION				
	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT FORMS*
Crabtree, Brian L., PharmD VA Medical Center 1500 East Woodrow Wilson Avenue Jackson, MS 39216-5199 USA  University of Mississippi Medical Center 2500 North State Street Jackson, MS 39216 USA	5077US/0001:0006 <sup>4</sup> (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Creaven, Dr. F. St. Mary's Psychiatric Hospital Caslebar County Mayo EIRE	204636/0008:0023 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Csemansky, John G., MD Washington University School of Medicine Department of Psychiatry 4940 Children's Place St. Louis, MO 63110 USA	5077IL/0015:0004  5077IL/0015:0004 5077IL/0031:0003	D-B Comp  O-L E D-B Comp	1.171/1, 1.314/1 1.262/1 1.261/333	1.406/1  1.442/274 1.442/273	CANDA  CT Report CANDA
Daniel, David G., MD Neuropsychiatric Services of Greater Washington, Inc. 8404-P Seven Corners Place Falls Church, VA 22044 USA	5077IL/0013:0024  5077IL/0013:0024	D-B Comp  O-L E	1.117/1, 1.148/1, 1.306/1 1.262/1	1.398/1  1.442/274	CANDA  CT Report
Darcourt, Prof. G. Clinique de Psychiatrie et de Psychologie Medicale C.H.U. Hopital Pasteur 30 Avenue de la Voie Romaine BP 69 06002 Nice Cedex FRANCE	5077IL/0005: UK-0003 204636/0008:0005 (5077US/0001) 5077IL/0012:0030  5077IL/0012:0030	O-L pilot  D-B Comp D-B Comp O-L E	1.254/1  1.137/1, 1.303/1, 1.225/1, 1.350/1 1.262/1	1.439/272  1.389/1 1.423/1 1.442/274	CANDA  CANDA CANDA CT Report
Daubenton, Dr. F. Medical School University of Capetown Ronderbosch SOUTH AFRICA  Valkenberg Hospital Private Bag X1 Observatory 7935 SOUTH AFRICA	204636/0007:0038    5077IL/0014:0047  5077IL/0014:0047	D-B Comp    D-B Comp O-L E	1.217/1, 1.348/1   1.243/1, 1.354/1 1.262/1	1.415/1    1.431/1 1.442/274	CANDA    CANDA CT Report

NAME/ADDRESS	LOCATION IN APPLICATION				
	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT FORMS*
Daumer, Dr. J. C.H.S. Charcot Secteur Adulte 2W 56854 Cuadan FRANCE	5077IL/0012:0039	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0039	O-L E	1.262/1	1.442/274	CT Report
Davidson, M., MD Psychiatry Service 116A VA Medical Center 130 West Kingsbridge Road Bronx, NY 10468 USA	5077IL/0005: US-0004 (APS 0-991-1)	O-L pilot	1.254/1	1.439/272	CANDA
de Beaupaire, Dr. R. C.H.S. du Bon Sauveur Pavillon Pere Jamet 93 Rue Caponiere 14032 Caen FRANCE	5077IL/0012:0044	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0044	O-L E	1.262/1	1.442/274	CT Report
De Bieker, Dr. E. Psychiatrisch Ziekenhuis St. Lucia Ankerstraat 91 9100 Sint Niklaas BELGIUM	5077IL/0014:0010	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0010 <sup>13</sup>	O-L E	1.262/1	1.442/274	CT Report
Debuick, Dr. R. Service de Psychiatrie Hopital Brugmann Place A Van Gehuchten 4 1020 Bruxelles BELGIUM	5077IL/0014:0066	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0066 <sup>13</sup>	O-L E	1.262/1	1.442/274	CT Report
DeCherney, G. Stephen, MD Medical Research Institute of Delaware 4755 Ogletown-Stanton Road Newark, DE 19718 USA	5077IL/0007:0007	Clin Pharm	1.97/1	1.378/328	NA
DeNayer, Dr. A.R. Service de Psychiatrie Hopital Ste-Therese Rue Trieu Kaisin 134 6061 Montignies Sur Sambre BELGIUM	5077IL/0014:0067	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0067	O-L E	1.262/1	1.442/274	CT Report
DeSilva, Dr. M.S.L. Department of Mental Health Heatherwood Hospital London Road Ascot Berkshire SI5 8AA UNITED KINGDOM	204636/0008:0009 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.384/1	CANDA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Diamond, Bruce: PhD Psychiatry Service 116A Augusta VA Medical Center One Freedom Way Augusta, GA 30911 USA	5077IL/0006:0008 <sup>3</sup> (APS 0-A31-1/0008)	D-B Comp	1.132/1, 1.301/1	1.384/1	CANDA
Dickson, Ruth, MD Clinical Pharmacology Unit Medical Research Department ZENECA Pharmaceuticals Mersey, Alderley Park Macclesfield, Cheshire SK10 4TG UNITED KINGDOM	5077IL/0013:0023 <del>3</del>	O-L E	1.262/1	1.442/274	CT Report
Didi, Dr. R. C.H.S. La Chartreuse 1 Bd Chanoine Kir 21033 Dijon Cedex FRANCE	5077IL/0012:0004	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0004	O-L E	1.262/1	1.442/274	CT Report
Dierick, Dr. G. Ziekenhuis Reigerlo Reigerlo 10 8730 Beernem BELGIUM	5077IL/0012:0024	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0024	O-L E	1.262/1	1.442/274	CT Report
Dierick, Dr. M. St. Camillus Institute Beukenlaan 20 9051 Sint Denijs-Westrem BELGIUM	5077IL/0005: UK-0018	O-L pilot	1.254/1	1.439/272	CANDA
	204636/0007:0009	D-B Comp	1.217/1 1.348/1	1.415/1	CANDA
Dietzel, Dr. M. Psychiatrische Universitätsklinik Währingergürtel 18-20 A-1090 Wien AUSTRIA	204636/0008:0012 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.384/1	CANDA
Doane, Joseph C. Beasler Clinical Research Unit 900 Osceola Drive West Palm Beach, FL 33409 USA	5077IL/0018:0001	Clin Pharm	1.98/1	1.379/1	NA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Donovan, A. J. G., MA, MB, BChir, DA Clinical Pharmacology Unit ZENECA Pharmaceuticals Mereside, Adderly Park Macclesfield, Cheshire SK10 4TG UNITED KINGDOM	5077IL/0025:000125	Clin Pharm	1.96/1	1.378/208	NA
Dott, Sharon G., MD University of Texas Medical Branch Department of Psychiatry and Behavioral Sciences 1014 Texas Avenue Galveston, TX 77555-0428 USA	5077IL/0013:0017 5077IL/0013:0017 5077IL/0015:0005 5077IL/0015:0005 5077IL/0031:0004	D-B Comp O-L E D-B Comp O-L E D-B Comp	1.117/1, 1.148/1, 1.308/1 1.262/1 1.171/1, 1.314/1 1.262/1 1.261/333	1.398/1 1.442/274 1.408/1 1.442/274 1.442/273	CANDA CT Report CANDA CT Report CANDA
Dries, Dr. P.J.T. Delta Ziekenhuis der Gemeente Rotterdam Albrandswaardsedijk 74 3172 AA Poortugaal NETHERLANDS	5077IL/0014:0031 5077IL/0014:0031	D-B Comp O-L E	1.243/1, 1.354/1 1.262/1	1.442/273 1.442/274	CANDA CT Report
Dubinsky, Richard M., MD Associate Professor of Neurology University of Kansas Medical Center 3901 Rainbow Boulevard Kansas City, KS 66160-7314 USA	5077IL/0024:00016 (Part B) 5077IL/0024:00019	Clin Pharm O-L E	1.129/377 1.262/1	1.383/169 1.442/274	NA CT Report
Duboc, Dr. G.E. C.H.S. de Navarre Rue de Conches 27022 Evereux Cedex FRANCE	5077IL/0012:0042 5077IL/0012:0042	D-B Comp O-L E	1.225/1, 1.350/1 1.262/1	1.423/1 1.442/274	CANDA CT Report
Ebert, Dr. D. Psychiatrische Klinik und Poliklinik Schwabachanlage 6 91054 Erlangen GERMANY	5077IL/0012:0056 5077IL/0012:0056	D-B Comp O-L E	1.225/1, 1.350/1 1.262/1	1.423/1 1.442/274	CANDA CT Report
Eccleston, Prof. D. Department of Psychiatry Royal Victoria Infirmary Queen Victoria Road Newcastle-upon-Tyne NE1 4LP UNITED KINGDOM	5077IL/0005: UK-0006	O-L pilot	1.254/1	1.439/272	CANDA
Eichelman, Burr S., MD, PhD Department of Psychiatry Temple University School of Medicine 3401 Broad Street Philadelphia, PA 19140 USA	5077US/0001:0004 <sup>10</sup> (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Emsley, Prof. R.A. Department of Psychiatry Faculty of Medicine University of Stellenbosch PO Box 19063 Tygerberg 7505 SOUTH AFRICA	204636/0007:0037	D-B Comp	1.217/1, 1.348/1	1.415/1	CANDA
	5077IL/0014:0050	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0050 <sup>13</sup>	O-L E	1.262/1	1.442/274	CT Report
Ereshefsky, Larry, PharmD University of Texas Health Science Center at San Antonio San Antonio State Hospital Clinical Pharmacy Programs 7703 Floyd Curl Drive San Antonio, TX 78284 USA	5077US/0001:0009 <sup>11</sup> (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0017:0005	Clin Pharm	1.100/1	1.379/231	CANDA
	5077IL/0017:0005	O-L E	1.262/1	1.442/274	CT Report
Eriksson, Dr. L. Psyk Kliniken Liljhagens Sjukhus Box 3005 S 42203 Hisings Backa SWEDEN	5077IL/0014:0065	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0065 <sup>13</sup>	O-L E	1.262/1	1.442/274	CT Report
Erkwoh, Dr. R. Psychiatrische Klinik der RWTH Pauwelsstrasse 30 52057 Aachen GERMANY	5077IL/0012:0016	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
Ermentini, Prof. A. Universita de Brescia Ospedale Civile Piazza Spedali Civile 25123 Brescia ITALY	5077IL/0012:0068	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0068	O-L E	1.262/1	1.442/274	CT Report
Fabre, Louis F., Jr., MD, PhD Research Testing, Inc. 5503 Crawford Street Houston, TX 77004 USA  Fabre Research Clinics, Inc. 5503 Crawford Street Houston, TX 77004 USA	5077US/0002:0001	Clin Pharm	1.103/1	1.380/1	NA
	5077IL/0004 (APS 9-398-1)	Clin Pharm	1.83/1, 1.130/1, 1.300/1 1.254/1	1.375/1	NA
	5077IL/0005: US-0001 (APS 0-398-2)	O-L pilot		1.439/272	CANDA
	5077IL/0008:0001	Clin Pharm	1.82/1	1.374/1	NA
	5077IL/0015:0007	D-B Comp	1.171/1, 1.314/1 1.262/1	1.406/1	CANDA
	5077IL/0015:0007 <sup>27</sup>	O-L E	1.79/69	1.442/274	CT Report
	5077IL/0016:0001	Clin Pharm	1.104/1	1.372/1	CANDA
	5077IL/0020:0001	Clin Pharm	1.90/1	1.380/104	NA
5077IL/0044:0003	Clin Pharm		1.377/1	NA	
Faltus, Mudr. F. Psychiatricka Klinika Ke Karlovu 11 128 21 Praha 2 CZECH REPUBLIC	204636/0008:0015 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0014:0015	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0015	O-L E	1.262/1	1.442/274	CT Report

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Farmer, Mildred, MD Clinical Studies, Florida 780 94th Avenue North, Suite 102 St. Petersburg, FL 33702 USA	5077IL/0048:0011	O-L	1.258/1	1.442/272	CANDA
Faustman, William O., PhD Stanford VA Mental Health Clinical Research Center, Unit 4C2 and 4B2 DVA Medical Center 3801 Miranda Avenue Palo Alto, CA 94304 USA	5077US/0001:0014 <sup>12</sup> (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Fenton, Prof. G.W. Department of Psychiatry University of Dundee Ninewells Hospital Dundee DD1 9SY UNITED KINGDOM	5077IL/0012:0014  5077IL/0012:0014	D-B Comp  O-L E	1.225/1, 1.350/1  1.262/1	1.423/1  1.442/274	CANDA  CT Report
Ferguson, Dr. B.G. Department of Psychiatry Mapperley Hospital Porchester Road Nottingham NG6 6AA UNITED KINGDOM	204636/0007:0004  5077IL/0012:0003  5077IL/0012:0003	D-B Comp  D-B Comp  O-L E	1.217/1, 1.348/1  1.225/1, 1.350/1  1.262/1	1.415/1  1.423/1  1.442/274	CANDA  CANDA  CT Report
Ferguson, James M., MD Pharmacology Research Corporation Suite 350 448 East 6400 South Salt Lake City, UT 84107 USA	5077IL/0013:0018  5077IL/0013:0018 5077IL/0015:0006  5077IL/0015:0006 5077IL/0031:0021 5077IL/0048:0003	D-B Comp  O-L E D-B Comp  O-L E D-B Comp O-L	1.117/1, 1.148/1, 1.306/1  1.262/1  1.171/1, 1.314/1  1.262/1  1.261/333  1.258/1	1.398/1  1.442/274 1.406/1  1.442/274  1.442/273  1.442/272	CANDA  CT Report CANDA  CT Report CANDA CANDA
Ferreira, Dr. L.M. Hospital Magalhaes Lemos Servicio Povoá Vila do Conda Estrada da Circumvalacao 4100 Porta PORTUGAL	5077IL/0012:0082  5077IL/0012:0082	D-B Comp  O-L E	1.225/1, 1.350/1  1.262/1	1.423/1  1.442/274	CANDA  CT Report
Ferrey, Dr. C.H. Emile Roux rue de Docteur Roux 95600 Eaubonne FRANCE	204636/0007:0028	D-B Comp	1.217/1, 1.348/1	1.415/1	CANDA
Fleischhacker, Prof. W.W. Biological Psychiatry Research Unit Department of Psychiatry Innsbruck University Clinic Anichstrasse 35 A-6020 Innsbruck AUSTRIA	204636/0008:0011 (5077US/0001) 5077IL/0012:0027	D-B Comp  D-B Comp	1.137/1, 1.303/1  1.225/1, 1.350/1	1.389/1  1.423/1	CANDA  CANDA



NAME/ADDRESS	LOCATION IN APPLICATION				
	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Franks, S., Dr. Department of Psychiatry Gordon Hospital 126 Vauxhall Road London SW1 UK	204636/0008:0001 <sup>18</sup> (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Fujii, Dr. Yasuo Yamanashi Prefectural Northern Hospital 3314-13 Kamijomimamiwari Asahi-cho Nirasaki-shi Yamanashi JAPAN	H-15-21:5 H-15-22:32 H-15-23:32	O-L O-L O-L	1.282/377 1.282/402 1.282/435	1.442/275 1.442/276 1.442/277	CANDA CANDA NA
Fukui, Dr. Yoshihisa Sankokai Second Kitayama Hospital 161 Iwakurakamigura-tyo Sakyou-ku Kyoto-shi Kyoto JAPAN	H-15-21:12 H-15-22:38 H-15-23:38	O-L O-L O-L	1.282/377 1.282/402 1.282/435	1.442/275 1.442/276 1.442/277	CANDA CANDA NA
Fukushima, Prof. Yutaka Hirosaki University School of Medicine 53 Honamathi Hirosaki-shi Aomori JAPAN	H-15-22:6 H-15-23 <sup>13</sup>	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Gabriele, William F., Jr., MD, PhD Department of Psychiatry University of Kansas Medical Center 3901 Rainbow Boulevard Kansas City, KS 66160-7314 USA	5077IL/0024:0001 <sup>9</sup> (Part B) 5077IL/0024:0001 <sup>9</sup>	Clin Pharm O-L E	1.129/373 1.282/1	1.383/169 1.442/274	NA CT Report
Gagliano, Prof. C.A. Department of Psychiatry University of Orange Free State PO Box 339 Bloemfontein 9300 SOUTH AFRICA	5077IL/0005: UK-0011 204636/0007:0017 5077IL/0014:0046 5077IL/0014:0046	O-L pilot D-B Comp D-B Comp O-L E	1.254/1 1.217/1, 1.348/1 1.243/1, 1.354/1 1.262/1	1.439/272 1.415/1 1.431/1 1.442/274	CANDA CANDA CANDA CT Report
Gaussares, Dr. C. C.H.S. Charles Perrens 121 Rue de la Bechade 33076 Bordeaux Cedex FRANCE	5077IL/0012:0038 5077IL/0012:0038	D-B Comp O-L E	1.225/1, 1.350/1 1.262/1	1.423/1 1.442/274	CANDA CT Report

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Geretsegger, Dr. C. Landes-Nervenklinik Salzburg Ignaz-Harrer Strasse-79 5020 Salzburg AUSTRIA	5077IL/0012:0028	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0028	O-L E	1.262/1	1.442/274	CT Report
Gerlach, Dr. J. Sankt Hans Hospital 4000 Roskilde DENMARK	5077IL0014:0019	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
Gerner, Robert H., MD 11500 West Olympic Boulevard Suite 635 Los Angeles, CA 90068 USA	5077IL/0015:0008	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0008 <sup>27</sup>	O-L E	1.262/1	1.442/274	CT Report
Gewirtz, George, MD Department of Psychiatry Columbia University School of Medicine NY State Psychiatric Institute 722 West 168th Street New York, NY 10032 USA	5077IL/0006:0009	D-B Comp	1.132/1, 1.301/1	1.384/1	CANDA
	(APS 0-A31-1/009) 5077IL/0013:0003 <sup>14</sup>	D-B Comp	1.117/1, 1.148/1, 1.306/1	1.398/1	CANDA
	5077IL/0013:0003 <sup>14</sup>	O-L E	1.262/1	1.442/274	CT Report
Gladson, Michael, MD DeKalb Medical Center 2701 North Decatur Road Decatur, GA 30033 USA	5077US/0001:0017 (204636/0008) <sup>15</sup>	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Grace, Jeffrey, MD Buffalo Psychiatric Center 400 Forest Avenue Buffalo, NY 14213 USA	5077IL/0013:0014	D-B Comp	1.117/1, 1.148/1, 1.306/1	1.398/1	CANDA
	5077IL/0013:0014	O-L E	1.262/1	1.442/274	CT Report
Gross, Lawrence S., MD Los Angeles County USC Medical Center Adult Psychiatric Outpatient Clinic 1937 Hospital Place Los Angeles, CA 90033 USA	5077IL/0015:0009	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0009 <sup>27</sup>	O-L E	1.262/1	1.442/274	CT Report
Guimon, Dr. Hospital Cival de Basurto Servicio de Psiquiatria Avenida de Montevideo Bilbao SPAIN	204636/0007:0015	D-B Comp	1.217/1, 1.348/1	1.415/1	CANDA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Gutierrez, Dr. M.- Servicio de Psiquiatria Hospital Santiago C/Olaguibel S/N Vitoria SPAIN	5077IL/0012:0087	D-B Comp	1.225/1 1.350/1	1.423/1	CANDA
	5077IL/0012:0087	O-L E	1.262/1	1.442/274	CT Report
Hallstrom, C., Dr. Department of Psychiatry Charing Cross Hospital London UK	204636/0008:0001 <sup>18</sup> (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Hamner, Mark B., MD VA Medical Center, 116A Inpatient Psychiatry 5BN 109 Bee Street Charleston, SC 29401-5799 USA	5077IL/0006:0010 (APS 0-A31-A010)	D-B Comp	1.132/1, 1.301/1	1.384/1	CANDA
	5077IL/0013:0004	D-B Comp	1.117/1, 1.148/1, 1.308/1	1.398/1	CANDA
	5077IL/0013:0004	O-L E	1.262/1,	1.442/274	CT Report
	5077IL/0015:0010	D-B Comp	1.171/1 1.314/1	1.408/1	CANDA
	5077IL/0015:0010 <sup>27</sup> 5077IL/0031:0005	O-L E D-B Comp	1.262/1 1.261/333	1.442/274 1.442/273	CT Report CANDA
Hanada, Prof. Masanori Kinki University School of Medicine 377-2 Onohigashi Osakasayama-shi Osaka JAPAN	H-15-22:46	O-L	1.282/402	1.442/276	CANDA
	H-15-23 <sup>13</sup>	O-L	1.282/435	1.442/277	NA
Hansen, J. Psykiatrihospital i Dianalund DE Sallserj 35 Dianalund Z5 DENMARK	5077IL/0014:0022	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
Hart, Prof. G.A. Department of Psychiatry University of Witwaterstrand 7 York Road Parktown 2193 Johannesburg SOUTH AFRICA	204636/0007:0016	D-B Comp	1.217/1, 1.348/1,	1.423/1	CANDA
	5077IL/0014:0045	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0045	O-L E	1.262/1	1.442/274	CT Report
Hasegawa, Dr. Youichi Keiyukai Sankei Hospital 3-29-1 Aoba-cho Higashimurayama-shi Tokyo JAPAN	H-15-22:23	O-L	1.282/402	1.442/276	CANDA
	H-15-23:23	O-L	1.282/435	1.442/277	NA
Hashimoto, Dr. Atsutaka Eiwakai Kaizuka Sanatorium 497 Mori Kaizuka-shi Osaka JAPAN	H-15-22:50	O-L	1.282/402	1.442/276	CANDA
	H-15-23:50	O-L	1.282/435	1.442/277	NA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Hauge, Dr. L. Psykiatrisk Avdeling Innerred Sykeus 7600 Levanger NORWAY	5077IL/0014:0041	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0041	O-L E	1.262/1	1.442/274	CT Report
Hayano, Dr. Taizo Wakayama Prefecture Goryo Hospital 31 Syo Oaza Kibi-tyo Arita-gun Wakayama JAPAN	H-15-21:18	O-L	1.282/377	1.442/275	CANDA
	H-15-22:56	O-L	1.282/402	1.442/276	CANDA
	H-15-23:56	O-L	1.282/435	1.442/277	NA
Hellebuyck, Dr. H. Psych Centrum Heilig Hart Poperingseweg 16 8900 Ieper BELGIUM	5077IL/0014:0011	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0011	O-L E	1.262/1	1.442/274	CT Report
Hertzman, Marc, MD North Arundel Hospital Dept of Psychiatry 301 Hospital Drive Glen Burnie, MD 21061-5803 USA	5077IL/0013:0011	D-B Comp	1.117/1, 1.148/1, 1.306/1	1.398/1	CANDA
	5077IL/0013:0011	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0048:0004	O-L	1.258/1	1.442/272	CANDA
Herz, Marvin I., MD University of Rochester Strong Ties Annex Department of Psychiatry 1650 Elmwood Avenue Rochester, NY 14620 USA  Rochester Psychiatric Center 1111 Elmwood Avenue Rochester, NY 14620 USA	5077IL/0013:0005	D-B Comp	1.117/1, 1.148/1, 1.306/1	1.398/1	CANDA
	5077IL/0013:0005	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0015:0C11	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0011	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0031:0024	D-B Comp	1.261/333	1.442/273	CANDA
Hikichi, Dr. Akiyoshi Social Security Hiroshima Citizen's Hospital 7-33 Moto-mati Naka-ku Hiroshima-shi Hiroshima JAPAN	H-15-22:61	O-L	1.282/402	1.442/275	CANDA
	H-15-23 <sup>13</sup>	O-L	1.282/435	1.442/277	NA
Hippius, Prof. H. Psychiatrische Klinik der Universitat Munchen Nubaumstrasse GERMANY	5077IL/0005: UK-0021	O-L pilot	1.254/1	1.439/272	CANDA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Hirakawa, Dr. Hiroyuki Koseikai Harakawa Hospital 1076 Miyama-cho Hachiohji-shi Tokyo JAPAN	H-15-22:21 H-15-23:21	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Hirano, Dr. Takashi Aomori Prefecture Central Hospital 33-2 Aza-isono Ohaza-tsukurimithi Aomori-shi Aomori JAPAN	H-15-22:8 H-15-23 <sup>13</sup>	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Hirsch, Prof. S.R., BA, MPhil, MD, FRCP, FRCPsych Department of Psychiatry Charing Cross Hospital Fulham Palace Road London W6 8RF UNITED KINGDOM	50771L/0005: UK-0001 204638/0008:0001 (5077US/0001) 50771L/0012:0001 50771L/0012:0001	O-L pilot D-B Comp D-B Comp O-L E	1.254/1 1.137/1, 1.303/1 1.225/1, 1.350/1 1.262/1	1.439/272 1.389/1 1.423/1 1.442/274	CANDA CANDA CANDA CT Report
Hirschfeld, Robert, MD Department of Psychiatry and Behavioral Sciences University of Texas Medical Branch 1014 Texas Avenue Galveston, TX 77550 USA	50771L/0006:0005 (APS 0-A31-1/0005)	D-B Comp	1.132/1, 1.301/1	1.384/1	CANDA
Holsboer, Prof. F. Max Planck Institute Munchen GERMANY	50771L/0005: UK-0019	O-L pilot	1.254/1	1.439/272	CANDA
Holt, P., MRCP, Dip Pharm Med Dip Pharm Med Leicester Clinical Research Centre 72 Hospital Close Leicester LE 5 4WW UNITED KINGDOM	50771L/0026	D-B bio- equivalence	1.94/1	1.378/1	NA
Igarashi, Dr. Yoshio Zenwakai Chichibu Central Hospital 1404 Ohaza-terao Thithibu-shi Saitama JAPAN	H-15-21:2 H-15-22:28 H-15-23:28	O-L O-L O-L	1.282/377 1.282/402 1.282/435	1.442/275 1.442/276 1.442/277	CANDA CANDA NA
Ikawa, Prof. Genro Nara Medical University 840 Shijyo-tyo Kashihara-shi Nara JAPAN	H-15-22:54 H-15-23 <sup>13</sup>	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA

NAME/ADDRESS	LOCATION IN APPLICATION				
	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Ikegami, Dr. Mamoru Sanjyokai Sogo Hospital Higashikori Hospital 1-24-34 Higashikori Hirakat-shi Osaka JAPAN	H-15-21:14	O-L	1.282/377	1.442/275	CANDA
	H-15-22:44	O-L	1.282/402	1.442/276	CANDA
	H-15-23:44	O-L	1.282/435	1.442/277	NA
Invernizzi, Prof. G. Universita Degla Studi di Milano Ospedale Maggiore Policlinico Via F Sforza 35-20122 Milano ITALY	5077IL/0012:0075	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0075	O-L E	1.282/1	1.442/274	CT Report
Ishii, Dr. Toshiki Kora Hospital 107 Kora Hikami-tyo Hikami-gun Hyogo JAPAN	H-15-22:13	O-L	1.282/402	1.442/276	CANDA
	H-15-23:13	O-L	1.282/435	1.442/277	NA
Iwama, Dr. Hisayuki Kiyose Hospital 3-10-5 Takeoka Kiyose-shi Tokyo JAPAN	H-15-22:16	O-L	1.282/402	1.442/276	CANDA
	H-15-23:13	O-L	1.282/435	1.442/277	NA
Iwamura, Dr. Hisashi Geisei Hospital 4268 Washokukou Geisei-mura Aki-gun Kochi JAPAN	H-15-22:64	O-L	1.282/402	1.442/276	CANDA
	H-15-23:64	O-L	1.282/435	1.442/277	NA
Iwao, Dr. Yoshiro Iwaokai Tokyo Kaido Hospital 1-4-5 Suehiro-chu Ohme-shi Tokyo JAPAN	H-15-22:13	O-L	1.282/402	1.442/276	CANDA
	H-15-23:13	O-L	1.282/435	1.442/277	NA
Izquierdo de la Torre, Dr. J. Servicio de Psiquiatria Hospital Clinico de Salamanca Paseo de San Vicente 108 Salamanca SPAIN	5077IL/0012:0088	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0088	O-L E	1.282/1	1.442/274	CT Report

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Jacobson, Dr. O: Kas Glostrup NDR Ringven 2600 Glostrup DENMARK	5077IL/0014:0020	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
Janka, Dr. Z. Department of Psychiatry Szentgyorgi Albert Medical University, PF 397 H-6701 Szeged HUNGARY	5077IL/0014:0037 5077IL/0014:0037	D-B Comp O-L E	1.243/1, 1.354/1 1.262/1	1.431/1 1.442/274	CANDA CT Report
Jaskiw, George, MD Director, Geriatric Psychiatry Division of Psychiatry 116A(B), VA-Medical Center 10000 Brecksville Road Brecksville OH 44141 USA	5077IL/0017:0002 5077IL/0017:0002	Clin Pharm O-L E	1.100/1 1.262/1	1.379/231 1.442/274	CANDA CT Report
Javitt, Daniel, MD, PhD Bronx Psychiatric Center Ward 19 - Research 1500 Waters Place Bronx, NY 10461 USA	5077IL/0031:0006	D-B Comp	1.261/333	1.442/273	CANDA
Jolley, A., Dr. Department of Psychiatry St Bernards Wing Ealing hospital Uxbridge Road Southall Middlesex UB1 3EU UK	204636/0008:0001 <sup>16</sup> (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Jones, Barry, MD Psychopharmacology Research Training Center Hamilton Psychiatric Hospital 100 West 5th Street Hamilton, Ontario L9C 3N6 CANADA	5077IL/0031:0007 <sup>5</sup> 5077IL/0015:0027 <sup>26</sup> 5077IL/0015:0027 <sup>26</sup>	D-B Comp D-B Comp O-L E	1.261/333 1.171/1, 1.314/1 1.262/1	1.442/273 1.406/1 1.442.274	CANDA CANDA CT Report
Karson, Craig N., MD VA Medical Center North Little Rock Division 116A/NLR Department of Psychiatry 2200 Fort Roots Drive North Little Rock, AR 72114-1706 USA Arkansas State Hospital 4313 North Markham Street Little Rock, AR 72205 USA	5077US/0001:0012 <sup>17</sup> (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Kasper, Prof. A. Psychiatrische Universitätsklinik Währinger Gurtel 18-20 Wien AUSTRIA	5077IL/0014:0006	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0006	O-L E	1.262/1	1.442/274	CT Report
Kato, Dr. Akira Meiwakai Biwako Hospital 1-8-5 Sakamotohonnmati Otu-shi Shiga JAPAN	H-15-21:13	O-L	1.282/377	1.442/275	CANDA
	H-15-22:36	O-L	1.282/402	1.442/276	CANDA
	H-15-23 <sup>13</sup>	O-L	1.282/435	1.442/277	NA
Katsura, Dr. Kunio Hoseikai Ozone Hospital 2-6-4 Hounan-tyo Higasi Toyonaka-shi Osaka JAPAN	H-15-22:41	O-L	1.282/402	1.442/276	CANDA
	H-15-23 <sup>13</sup>	O-L	1.282/435	1.442/277	NA
Keck, Paul E. Jr., MD University of Cincinnati College of Medicine Biological Psychiatry Center 231 Bethesda Avenue, ML 559 Cincinnati, OH 45267-0559 USA	5077US/0001:0015 (204638/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0013:0012	D-B Comp	1.117/1, 1.148/1, 1.306/1	1.398/1	CANDA
	5077IL/0013:0012	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0031:0020	D-B Comp	1.261/333	1.442/273	CANDA
Kerwin, Dr. R. Institute of Psychiatry De Crespigny Park Denmark Hill London SE5 8AF UNITED KINGDOM	204636/0007:0001	D-B Comp	1.217/1 1.348/1	1.415/1	CANDA
Keys, Michael A., MD Older Adult Center for Clinical Research University of Cincinnati College of Medicine 231 Bethesda Avenue, ML 559 Cincinnati, OH 45267-0559 USA	5077IL/0017:0003 <sup>18</sup>	Clin Pharm	1.100/1	1.379/231	CANDA
	5077IL/0017:0003 <sup>18</sup>	O-L E	1.262/1	1.442/274	CT Report
Kidoie, Dr. Yoichi Shin Awaji Hospital 43 Kamikamo Sumoto-shi Hyogo JAPAN	H-15-22:13	O-L	1.282/402	1.442/276	CANDA
	H-15-23 <sup>13</sup>	O-L	1.282/435	1.442.277	NA



NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
King, Dr. D.J. Department of Therapeutics and Pharmacology Queen's University of Belfast 97 Lisburn Road Belfast BT9 7BL UNITED KINGDOM	5077IL/0012:0002	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0002	O-L E	1.262/1	1.442/274	CT Report
Kissling, Dr. W. Psychiatrische Klinik der TU Munchen Ismaninger Strasse 22 81675 Munchen GERMANY	5077IL/0012:0011	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0011	O-L E	1.262/1	1.442/274	CT Report
Klieser, Dr. E. Psychiatrische Klinik der Universitat Dusseldorf Bergische Landstrasse 2 4000 Dusseldorf 12 GERMANY	204636/0008:0025 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Knesevich, John W., MD 109 Ponemah Road, #9, Unit F Amherst, NH 03031 USA	5077IL/0015:0033	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0033	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0048:0006	O-L	1.258/1	1.442/272	CANDA
Knesevich, Mary Ann, MD Terrell State Hospital, Ward L1 1200 East Brin Terrell, TX 75160 USA	5077US/0001:0010 (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0013:0007	D-B Comp	1.117/1, 1.148/1, 1.308/1	1.398/1	CANDA
	5077IL/0013:0007	O-L E	1.262/1	1.442/274	CT Report
St. Paul Medical Center 5959 Harry Hines Boulevard PO Box 1, Suite 924 Dallas, TX 75235 USA	5077IL/0015:0012	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0012	O-L E	1.262/1	1.442/274	CT Report
Kolin, Irving S., MD Psychiatric Unit Sand Lake Hospital 9400 Turkey Lake Road Orlando, FL 32819 USA	5077US/0001:0018 (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	1065 West Morse Boulevard Suite 202 Winter Park, FL 32789 USA				
Koponen, Dr. H. Moision Hospital 50 520 Mikkeli FINLAND	5077IL/0014:0027	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0027	O-L E	1.262/1	1.442/274	CT Report

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Koyama, Prof. Tsukasa Hokkaido University School of Medicine Nishi-5 Kita 14-jo Kita-ku Sapporo-shi Hokkaido JAPAN	H-15-22:1	O-L	1.282/402	1.442/276	CANDA
	H-15-23:1	O-L	1.282/435	1.442/277	NA
Krausz, Dr. M. Psychiatrische und Nervenlinik Poliklinik der Universitat Hamburg Martinistrasse 52 20251 Hamburg GERMANY	5077IL/0012:0052	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0052	O-L E	1.282/1	1.442/274	CT Report
Krystal, John, MD West Haven VAMC Psychiatric Services (116 A) West Haven, CT 06516 USA	5077IL/0031:0023	D-B Comp	1.281/333	1.442/273	CANDA
Kuroda, Prof. Shigetoshi Okayama University Medical School 2-5-1 Sikata-tyo Okayama-shi Okayama JAPAN	H-15-22:97	O-L	1.282/402	1.442/276	CANDA
	H-15-23 <sup>13</sup>	O-L	1.282/435	1.442/277	NA
Kutcher, Dr. S.P. Department of Psychiatry Sunnybrook Health Sciences Center 2075 Bayview Avenue Toronto Ontario M4N 3M5 CANADA	5077IL/0012:0049	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0049	O-L E	1.282/1	1.442/274	CT Report
Labelle, Alain, MD Royal Ottawa Hospital 1145 Carling Avenue Ottawa, Ontario K1Z 7K4 CANADA	5077IL/0015:0027 <sup>28</sup>	D-B Comp	1.171/1, 1.314/1	1.408/1	CANDA
	5077IL/0015:0027	O-L E	1.282/1	1.442/274	CT Report
Laddomada, Dr. P. Primario Servizio Psichiatrico Ospedale Sirai 09013 Carbonia CA ITALY	5077IL/0012:0073	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0073	O-L E	1.282/1	1.442/274	CT Report
Lambert, Dr. T. Sir Charles Gairdner Hospital Perth AUSTRALIA	5077IL/0014:0004	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0004	O-L E	1.282/1	1.442/274	CT Report

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Langstrom, B. Prof., Director Uppsala University PET Centre 5-78185 Uppsala SWEDEN	5077IL/0029	Clin Pharm	1.116/1, 1.129/1	1.382/146	CANDA
	5077IL/0033	Clin Pharm	1.116/358, 1.129/358	1.383/1	CANDA
Lawson, William, MD, PhD John L. McClellan VAMC Department of Psychiatry 2200 For. Roots Drive North Little Rock, AR 72114 USA	5077IL/0031:0008	D-B Comp	1.261/333	1.442/273	CANDA
Lindenmayer, J.P., MD Nathan Kline Institute Rockland Psychiatric Center 140 Old Orangeburg Road Building 37 Orangeburg, NY 10962 USA	5077US/0001:0013 (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0031:0018	D-B Comp	1.261/333	1.442/273	CANDA
Manhattan Psychiatric Center Psychopharmacology Research Unit Dunlop 14A, Ward's Island New York, NY 10035 USA					
Lindqvist, Dr. L. Psyk Kliniken Centrallasarettet 961 85 Boden SWEDEN	5077IL/0014:0059	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0059	O-L E	1.262/1	1.442/274	CT Report
Lindstrom, Prof. L. Psychiatriskaforssknig Senneten Uppsala Universitet Centrallasarettet 72189 Vasteras SWEDEN	5077IL/0014:0081 <sup>1</sup>	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0029	Clin Pharm	1.116/1, 1.129/1	1.382/146	CANDA
	5077IL/0029	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0033:0001	Clin Pharm	1.116/358 1.129/358	1.383/1	CANDA
Uppsala Universitet 5 - 751 85 Uppsala SWEDEN					
Lipinski, J.F., Jr., MD Chief, Clinical Research Section McLean Hospital Mailman Research Center 115 Mill Street Belmont, MA 02178 USA	5077IL/0005: US-0003 (APS 0-848-1)	O-L pilot	1.254/1	1.439/272	CANDA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Lohr, James, MD VA Medical Center Hospital Department of Psychiatry, 116A 3350 La Jolla Village Drive San Diego, CA 92161-2002 USA	5077US/0001:0008 (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0031:0010	D-B Comp	1.261/333	1.442/273	CANDA
	5077IL/0048:0005	O-L	1.258/1	1.442/272	CANDA
Longoni, Dr. R. Unita Operativa Psichiatria Ospedale Civile 20070 Vizzolo Predabissi Milano ITALY	5077IL/0012:0076	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0076	O-L E	1.262/1	1.442/274	CT Report
Lopez-Ibor, Prof. J. Hospital Ramon y Cajal Servicio de Psiquiatria Carreterra de Calenmar KM9100 Madrid SPAIN	204636/0007:0012	D-B Comp	1.217/1 1.348/1	1.415/1	CANDA
	5077IL/0014:0051	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
Lynch, Dr. J. St. Lukes' Hospital Clonmel County Tipperary EIRE	204636/0008:0024 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0012:0006	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0006	O-L E	1.262/1	1.442/274	CT Report
Department of Psychiatry St. Michaels' Hospital Clonmel County Tipperary EIRE					
MacEwan, Gordon W., MD St Vincent's Hospital 749 West 33rd Avenue Vancouver, BC V5Z 2K4 CANADA	5077IL/0013:0020	D-B Comp	1.117/1, 1.148/1, 1.306/1	1.398/1	CANDA
	5077IL/0013:0020	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0031:0028 <sup>27</sup>	D-B Comp	1.261/333	1.442/273	CANDA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
MacFarlane, Dr. D.J. Department of Psychiatry Downshire Hospital Ardglass Road Downpatrick County Down Northern Ireland BT30 6RA UNITED KINGDOM	204636/0007:0024	D-B Comp	1.217/1, 1.348/1	1.415/1	CANDA
Ards Hospital Newtownards County Down Northern Ireland BT23 4AS UNITED KINGDOM	50771L/0012:0008	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	50771L/0012:0008	O-L E	1.262/1	1.442/274	CT Report
Machiyama, Prof. Yukiteru Gunma University School of Medicine 3-39-15 Showa-cho Maebashi-shi Gunma JAPAN	H-15-22:12	O-L	1.282/402	1.442/276	CANDA
	H-15-23 <sup>13</sup>	O-L	1.282/435	1.442/277	NA
Mahapatra, Dr. S.B. Department of Psychiatry The General Hospital Hartlepool Cleveland TS24 9AH UNITED KINGDOM	204636/0008:0020 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	50771L/0012:0007	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	50771L/0012:0007	O-L E	1.262/1	1.442/274	CT Report
Mahurin, Rodenick, PhD San Antonio State Hospital Clinical Research Unit MC-4 6711 South New Braunfels Avenue San Antonio, TX 78223 USA	50771L/0031:0022 <sup>18</sup>	D-B Comp	1.261/333	1.442/273	CANDA
Malanowski, Dr. J. Psychiatric Clinic C.H. 7408 CAZ15 SWITZERLAND	50771L/0012:0048	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
Malinen, Dr. H. Kuopio University Julkula Hospital 70 200 Kuopio FINLAND	50771L/0014:0029	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	50771L/0014:0029	O-L E	1.262/1	1.442/274	CT Report
Malla, Dr. A. Department of Psychiatry Victoria Hospital Corporation 375 South Street London Ontario N6G 4G5 CANADA	50771L/0012:0061	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	50771L/0012:0061	O-L E	1.262/1	1.442/274	CT Report

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Mallya, Gopinath, MD McLean Hospital 115 Mill Street Belmont, MA 02178 USA	5077IL/0015:003627	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:003627	O-L E	1.262/1	1.442/274	CT Report
Manchanda, Dr. R. Department of Psychiatry University Hospital 339 Windermere Road London Ontario N6A 5A5 CANADA	5077IL/0012:0060	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0060	O-L E	1.262/1	1.442/274	CT Report
Marbury, C. Thomas, MD Orlando Clinical Research Center 4401 South Orange Avenue, Suite 108 Orlando, FL 32806 USA	5077IL/0019:0001	Clin Pharm	1.99/1	1.379/112	NA
Marie-Cardine, Dr. M. C.H.S. Le Vinatier 95 Boulevard Pinel 69677 Bron Cedex FRANCE	5077IL/0012:0036	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0036	O-L E	1.262/1	1.442/274	CT Report
Martens, Dr. J.M. Sint Lucaskliniek Laar 140 2180 Ekeren BELGIUM	5077IL/0012:0022	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0022	O-L E	1.262/1	1.442/274	CT Report
Martin, Dr. Service de Psychiatrie C.H. Victor Duprey 69 rue de Lieutenant Colonel Prudhon 95107 Argenteuil FRANCE	204636/0007:0029	D-B Comp	1.217/1 1.348/1	1.423/1	CANDA
Matsubara, Dr. Shigenro Tokachi National Medical Hospital 2 Suzuranmotomathi Otofuke-cho Katoh-gun Hokkaido JAPAN	H-15-22:2	O-L	1.282/402	1.442/276	CANDA
	H-15-23 <sup>13</sup>	O-L	1.282/435	1.442/277	NA
Matsumoto, Dr. Sumitaka Koseikai Mitinoe Hospital 2-1 Nijigaoka-tyo Nagasaki-shi Nagasaki JAPAN	H-15-21:21	O-L	1.282/377	1.442/275	CANDA
	H-15-22:69	O-L	1.282/402	1.442/276	CANDA
	H-15-23:69	O-L	1.282/277	1.442/277	NA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Mauas, Dr. L. Department A Shalvata Mental Health Center Hod-Hasharon ISRAEL	50771L/0012:0097	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	50771L/0012:0097	O-L E	1.262/1	1.442/274	CT Report
McEvoy, Joseph, MD John Umstead Hospital 12th Street Butner, NC 27509 USA	50771L/0006:0001 (APS 0-A31-1/0001)	D-B Comp	1.132/1, 1.301/1	1.384/1	CANDA
	50771L/0031:0019	D-B Comp	1.261/333	1.442/273	CANDA
McGrath, Dr. J. Wolston Park Hospital Brisbane AUSTRALIA	50771L/0014:0003	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	50771L/0014:0003	O-L E	1.262/1	1.442/274	CT Report
McManus, Dennis, MD Southern Illinois University School of Medicine Department of Neurology RC402 800 North Rutledge, Room C411 Springfield, IL 62794 USA	50771L/0048:0007	O-L	1.258/1	1.442/272	CANDA
Meats, Dr. P.S. Department of Psychiatry Millbrook Kings Mill Hospital Sutton in Ashfield Notts NG17 4NL UNITED KINGDOM	50771L/0012:0013	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
Mehtonen, Dr. O.P. Pitkaniemen Sairaala PL 2000 33521 Tampere FINLAND	50771L/0014:0028	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	50771L/0014:0028	O-L E	1.262/1	1.442/274	CT Report
Meltzer, H., MD Department of Psychiatry Case Western Reserve University School of Medicine 2040 Abington Road Cleveland, OH 44106 USA	50771L/0005: US-0002 (APS 0-754-1)	O-L pilot	1.254/1	1.439/272	CANDA
Mendlewicz, Prof. J. Hopital Erasme Route de Lennik 808 1070 Bruxelles BELGIUM	50771L/0005: UK-0010	O-L pilot	1.254/1	1.439/272	CANDA
	204636/0007:0010	D-B Comp	1.217/1 1.348/1	1.415/1	CANDA
Merideth, Charles H., MD Affiliated Research Institute 7676 Hazard Center Drive, #1320 San Diego, CA 92108 USA	50771L/0013:0026	D-B Comp	1.117/1, 1.148/1, 1.306/1	1.398/1	CANDA
	50771L/0013:0026	O-L E	1.262/1	1.442/274	CT Report

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Mesotten, Dr. F. - Medisch Centrum St. Jozef Abdijstraat 2 3740 Munsterbilzen BELGIUM	5077IL/0012:0021	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0021	O-L E	1.262/1	1.442/274	CT Report
Michaelis, Prof. R. Krankenhaus Itzehoe Abt. Psychiatrie Robert-Koch Strasse 2 25524 Itzehoe GERMANY	5077IL/0012:0051	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0051	O-L E	1.262/1	1.442/274	CT Report
Miller, Alexander, MD University of Texas Health Science Center at San Antonio San Antonio State Hospital Clinical Pharmacy Programs 7703 Floyd Curl Drive San Antonio, TX 78284-7792 USA	5077US/0001:0009 <sup>11</sup> (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0013:0006 <sup>22</sup>	D-B Comp	1.117/1, 1.148/1, 1.306/1	1.398/1	CANDA
	5077IL/0013:0006 <sup>22</sup>	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0015:0013 <sup>6</sup>	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0013 <sup>6</sup> 5077IL/0031:0022	O-L E D-B Comp	1.262/1 1.261/333	1.442/274 1.442/273	CT Report CANDA
Miller, Marvin J., MD Larue D. Carter Memorial Hospital Department of Psychiatry 1315 West 10th Street Indianapolis, IN 46202 USA	5077IL/0015:0014	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0014	O-L E	1.262/1	1.442/274	CT Report
Millson, D. S., BSc, MB, BChir, PhD, MD, MFPM Clinical Pharmacology Unit ZENECA Pharmaceuticals Mereside, Macclesfield SK10 4TG UNITED KINGDOM	5077IL/0025:000125	Clin Pharm	1.96/1	1.378/208	NA
Minami, Dr. Yoshitake Toyokai Kijima Hospital 892 Mori Kaizuka-shi Osaka JAPAN	H-15-22:49	O-L	1.282/402	1.442/276	CANDA
	H-15-23:49	O-L	1.282/435	1.442/277	NA
Miyano, Dr. Satoru Kuchan Kousei Hospital Higashi 1-2 Kita 4-jo Kuchan Abuta-gun Hokkaido JAPAN	H-15-22:3	O-L	1.282/402	1.442/276	CANDA
	H-15-23 <sup>13</sup>	O-L	1.282/435	1.442/277	NA



NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Mori, Dr. Shigeo Darumakai Higashi Kakogawa Hospital 1197-3 Shinzaike Hiraoka-tyo Kakogawa-shi Hyogo JAPAN	H-15-22:51 H-15-23:51	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Mortimer, Dr. A. St. Lukes Hospital Crosland Moor Huddersfield Yorkshire UNITED KINGDOM	204636/0007:0003	D-B Comp	1.217/1 1.348/1	1.415/1	CANDA
Mukherjee, Sukdeb, MD Creedmoor Psychiatric Center Research Division, Building 74 80-45 Winchester Boulevard Queens Village, NY 11427 USA	50771L/0006:0006 (APS 0-A31-1/006)	D-B Comp	1.132/1, 1.301/1	1.384/1	CANDA
Murakami, Dr. Atsushi Fuyokai Samraku Hospital 76-1 Aza-satomi Yotsuishi Aomori-shi Aomori JAPAN	H-15-22:7 H-15-23:7	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Murasaki, Prof. Mitsukuni Kitasato University East Hospital 2-1-1 Asamizodai Sagamihara-shi Kanagawa JAPAN	H-15-11/12 H-15-13 H-15-21:8 H-15-22 <sup>13</sup> H-15-23 <sup>13</sup>	Clin Pharm Clin Pharm O-L O-L O-L	1.79/1 1.79/34 1.282/377 1.282/402 1.282/435	1.371/205 1.371/207 1.442/275 1.442/276 1.442/277	NA NA CANDA CANDA NA
Murray, G H., MB, Mch, MA Medical Research Department ICI Pharmaceuticals Mereside, Alderley Park Macclesfield, Cheshire SK 10 4TF UNITED KINGDOM	204636/0001	D-B Comp	1.77/1	1.371/1	NA
Murray, Prof. R. Institute of Psychiatry De Crespigny Park Denmark Hill London SE5 8AF UNITED KINGDOM	50771L/0005: UK-0004	O-L pilot	1.254/1	1.439/272	CANDA
Nagao, Dr. Kihachiro Nagaokai Neyagawa Sanatorium 1-24-34 Neya Neyagawa-shi Osaka JAPAN	H-15-21:19 H-15-22:45 H-15-23:45	O-L O-L O-L	1.282/377 1.282/402 1.282/435	1.442/275 1.442/276 1.442/277	CANDA CANDA NA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Nair, Vasavan N:P., DPM, MD Douglas Hospital Research Centre 6875 La Salle Boulevard Verdun, Quebec H4H 1R3 CANADA	5077IL/0013:0021  5077IL/0013:0021 5077IL/0031:0011	D-B Comp  O-L E D-B Comp	1.117/1, 1.148/1, 1.306/1 1.262/1 1.261/333	1.398/1  1.442/274 1.442/273	CANDA  CT Report CANDA
Nakajima, Dr. Akira Fukushimakai-Jobu Hospital 5-6-1 Kojima Honjo-shi Saitama JAPAN	H-15-22:29 H-15-23:29	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Nakajima, Prof. Temo Kyoto Prefectural University of Medicine 466 Kajimati Hirokouji-agaru Kawaramatitoori Jyoukyou-ku Kyoto-shi Kyoto JAPAN	H-15-21:11 H-15-22 <sup>13</sup> H-15-23 <sup>13</sup>	O-L O-L O-L	1.282/377 1.282/402 1.282/435	1.442/275 1.442/276 1.442/277	CANDA CANDA NA
Nakane, Prof. Yoshitomi Nagasaki University School of Medicine 1-7-1 Sakamoto Nagasaki-shi Nagasaki JAPAN	H-15-21:13 H-15-22:68 H-15-23 <sup>13</sup>	O-L O-L O-L	1.282/377 1.282/402 1.282/435	1.442/275 1.442/276 1.442/277	CANDA CANDA NA
Nasrallah, Henry A., MD Department of Psychiatry Ohio State University College of Medicine 473 West 12th Avenue Columbus, OH 43210 USA	5077IL/0008:0012 (APS-0-A31-1/012)	D-B Comp	1.132/1, 1.301/1	1.384/1	CANDA
Nemeroff, Charles, MD Wesley Woods Geriatric Center 1841 Clifton Road Atlanta, GA 30329 USA	5077IL/0048:000628	O-L	1.258/1	1.442/272	CANDA
Newcomer, John W., MD Washington University School of Medicine Department of Psychiatry 4940 Children's Place, Box 8134 St. Louis, MO 63110 USA	5077IL/0013:0013  5077IL/0013:0013	D-B Comp  O-L E	1.117/1, 1.148/1, 1.306/1 1.262/1	1.398/1  1.442/274	CANDA  CT Report

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Nikaido, Dr. Matsumo Takikawa City Hospital 2-2-34 Ohmathi Takikawa-shi Hokkaido JAPAN	H-15-22:4 H-15-23:4	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Nimeus, Dr. A. Psyk Kliniken Box 638 St Lars-omr 2200 06 Lund SWEDEN	5077IL/0014:0056	D-B Comp	1.243/1 1.354/1	1.431/1	CANDA
Nomura, Prof. Junichi Faculty of Medicine, Mie University 2-174 Edohashi Tu-shi Mie JAPAN	H-15-22:35 H-15-23 <sup>13</sup>	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Nordahl, Thomas, MD, PhD University of California Davis Medical Center Department of Psychiatry 4430 V Street Sacramento, CA 95817 USA	5077IL/0015:0015 5077IL/0015:0015	D-B Comp O-L E	1.171/1, 1.314/1 1.262/1	1.406/1 1.442/274	CANDA CT Report
Nugent, Dr. D. Department of Psychiatry Gransha Hospital Clooney Road Londonderry Northern Ireland BT47 1TF UNITED KINGDOM	204636/0007:0021	D-B Comp	1.217/1 1.348/1	1.415/1	CANDA
Nyholm, Dr. R. Tammiharjun Hospital 10 600 Tammissaari FINLAND	5077IL/0014:0026 5077IL/0014:0026	D-B Comp O-L E	1.243/1, 1.354/1 1.262/1	1.431/1 1.442/274	CANDA CT Report
O'Brien, Charles P., MD, PhD VA Medical Center, 116A University and Woodland Avenues Philadelphia, PA 19104 USA	5077US/0001:0003 (204636/0008)	D-B Comp	1.171/1, 1.303/1	1.389/1	CANDA
Ohhara, Dr. Sohichiro Hitachi Nagisakai Ohhara Mental Hospital 1-13-18 Ohmika-cho Hitachi-shi Ibaragi JAPAN	H-15-22:11 H-15-23:11	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA

NAME/ADDRESS	LOCATION IN APPLICATION				
	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Ohno, Dr. Tsuneyuki Rokusankai Osaka Sayama Hospital 3-216-1 Iwamuro Osakasayama-shi Osaka JAPAN	H-15-22:47	O-L	1.282/402	1.442/276	CANDA NA
	H-15-23:47	O-L	1.282/435	1.442/277	
Ohtaka, Dr. Tadashi Tochigi Prefecture Okamoto Hospital 2162 Aza-shimookamoto Kawachi-gun Tothigi JAPAN	H-15-22:10	O-L	1.282/402	1.442/276	CANDA NA
	H-15-23:10	O-L	1.282/435	1.442/277	
Oka, Dr. Saori Keiseikai Hospital Higashi 20 Kita 27-jo Higashi-ku Sapporo-shi Hokkaido JAPAN	H-15-22:5	O-L	1.282/402	1.442/276	CANDA NA
	H-15-23:5	O-L	1.282/435	1.442/277	
Okamura, Dr. Tadabiko Kowakai Uenoshiba Hospital 4-5-16 Uenoshiba-tyo Sakai-shi Osaka JAPAN	H-15-22:48	O-L	1.282/402	1.442/276	CANDA NA
	H-15-23:48	O-L	1.282/435	1.442/277	
Ostorharics, Dr. H.G. Department of Psychiatry Petz A Hospital Gyor, Vas Vari P U 2 H-9002 HUNGARY	5077IL/0012:0093	D-B Comp	1.255/1, 1.350/1	1.423/1	CANDA CT Report
	5077IL/0012:0093	O-L E	1.262/1	1.442/274	
Owen, Richard, MD John L. McClellan VA Medical Center North Little Rock Division 116A/NLR Department of Psychiatry 2200 Fort Roots Drive North Little Rock, AR 72114-1706 USA  Arkansas State Hospital 4313 North Markham Street Little Rock, AR 72205 USA	5077US/0001:0012 <sup>17</sup> (204636/0008)	D-B Comp	1.131/1, 1.303/1	1.389/1	CANDA
	5077IL/0015:0016	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0016	O-L E	1.262/1	1.442/274	CT Report

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Oxenkrug, Gregory F., MD, PhD Psychiatry Services, 116A VA Medical Center 830 Chalkstone Avenue Providence, RI 02908 USA	5077IL/0006:0011 (APS 0-A31-1/011)	D-B Comp	1.132/1, 1.301/1	1.384/1	CANDA
	5077IL/0013:0008	D-B Comp	1.117/1, 1.148/1 1.306/1	1.398/1	CANDA
	5077IL/0013:0008	O-L E	1.262/1	1.442/274	CT Report
St. Elizabeth's Medical Center SEMC/Department of Psychiatry 736 Cambridge Street Boston, MA 02135 USA					
Ozsvath, Prof. Dr. K. Department of Psychiatry University Medical School of Pecs RET utea 2 H-7623 Pecs HUNGARY	204636/0008:0018 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0014:0036	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0036	O-L E	1.262/1	1.442/274	CT Report
Pailes, Verdeau, Dr. Hospital de Santa Maria Clinique de la Cite 12 rue do Jardin Beaumetz BP no 191 1104 Carcassonne Cedex France	204636/0007:0030	D-B Comp	1.217/1 1.348/1	1.415/1	CANDA
Paes de Sousa, Dr. M.J. Servicio de Psiquiatria Avenida Prof. Egas Moniz 1600 Lisboa PORTUGAL	5077IL/0012:0081	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0081	O-L E	1.262/1	1.442/274	CT Report
Palha, Prof. A.P. Casa de Saude de Bom Jesus Nogueiro 4719 Braga PORTUGAL	5077IL/0012:0080	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0080	O-L E	1.262/1	1.442/274	CT Report
Palomo, Dr. T. Servicio de Psiquiatria Hospital 12 de Octubre Ctra Andalucia KM 5400 Madrid SPAIN	5077IL/0012:0085	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0085	O-L E	1.262/1	1.442/274	CT Report
Pancheri, Prof. P. Universita di Roma Viale dell'Universita 30-00185 Roma ITALY	5077IL/0012:0072	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0072	O-L E	1.262/1	1.442/274	CT Report

NAME/ADDRESS	LOCATION IN APPLICATION				
	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Parashos, Dr. A.- Aristotelian University of Thessaloniki Konstantinoupoleos 36 Stavroupoli 564 29 Thessaloniki GREECE	5077IL/0012:0064	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0064	O-L E	1.262/1	1.442/274	CT Report
Patel, Dr. A.G. Department of Mental Services Fairfield Hospital Stotfold Near Hitchin Hertfordshire SG5 4AA UNITED KINGDOM	204636/0008:0010 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Patris, Prof. M. Hopital Central C.H.U. Clinique Psychiatre 1 Place de L'Hopital BP 426 67091 Strasbourg Cedex FRANCE	204636/0008:0008 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0012:0031	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0031	O-L E	1.262/1	1.442/274	CT Report
Patterson, William M., MD Birmingham Research Group, Inc. 2120 Lyngate Drive Birmingham, AL 35216 USA Hillcrest Hospital 6869 Fifth Avenue South Birmingham, AL 35212 USA	5077US/0001:0016 (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0013:0025 <sup>21</sup>	D-B Comp	1.117/1, 1.148/1, 1.306/1	1.398/1	CANDA
	5077IL/0013:0025 <sup>21</sup>	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0015:0017	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
5077IL/0015:0017	O-L E	1.262/1	1.442/274	CT Report	
Pavan, Prof. L. Universita di Padova Via Giustiniani 2-30538 Padova ITALY	5077IL/0012:0069	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0069	O-L E	1.262/1	1.442/274	CT Report
Pears, J. S., MB, ChB, MRCP, MD Clinical Pharmacology Unit ZENECA Pharmaceuticals Mereside, Adderly Park Macclesfield, Cheshire SK10 4TG UNITED KINGDOM	5077IL/0025:0001 <sup>23</sup>	Clin Pharm	1.96/1	1.378/208	NA
Peters, Prof. U.H. Med Einrichtung der Universitat Koin Fachabteilung Psychiatrie Josef-Stelzmann Strasse 9 50931 Koin GERMANY	5077IL/0012:0055	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0055	O-L E	1.262/1	1.442/274	CT Report

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Peuskens, Prof. J. University Psychiatric Centre St. Jozef Kliniek Leuvensesteenweg 517 3070 Kortenberg BELGIUM	5077IL/0005: UK-0009	O-L pilot	1.254/1	1.439/272	CANDA
	204636/0007:0007	D-B Comp	1.217/1, 1.348/1	1.415/1	CANDA
	5077IL/0014:0008	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0008	O-L E	1.262/1	1.442/274	CT Report
Pfefferbaum, Adolf, MD Stanford VA Mental Health Clinical Research Center, Unit 4C2 and 4B2 DVA Medical Center 3801 Miranda Avenue Palo Alto, CA 94304 USA	5077US/0001:0014 <sup>12</sup> (204636/0008)	D-B Comp	1.137/1 1.303/1	1.389/1	CANDA
Pitts, Wesley M., MD VA Medical Center 1500 East Woodrow Wilson Avenue Jackson, MS 39216-5199 USA  University of Mississippi Medical Center 2500 North State Street Jackson, MS 39216 USA	5077US/0001:0006 <sup>4</sup> (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0013:0002	D-B Comp	1.117/1, 1.148/1, 1.308/1	1.398/1	CANDA
	5077IL/0013:0002	O-L E	1.262/1	1.442/274	CT Report
Poirier, Dr. C.H. Sainte Anne 1 rue Cabanis 75674 Paris Cedex 14 FRANCE	204636/0007:0025	D-B Comp	1.217/1 1.348/1	1.415/1	CANDA
Pomara, Nunzio, MD Nathan Kline Institute 140 Old Orangeburg Road Orangeburg, NY 10962 USA	5077IL/0048:0009	O-L	1.258/1	1.442/272	CANDA
Potkin, Steven G., MD, PhD UCI Medical Center Department of Psychiatry and Human Behavior 101 City Drive South, Route 88 Orange, CA 92688 USA	5077IL/0015:0018	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0018	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0024:0002 (Part A)	Clin Pharm	1.123/1	1.383/2	NA
	5077IL/0024:0002 <sup>13</sup>	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0027:0001	Clin Pharm	1.111/1, 1.126/1	1.381/230	NA
	5077IL/0031:0012	D-B Comp	1.261/333	1.442/273	CANDA
	5077IL/0035:0001	Clin Pharm	1.85/1	1.376/1	CANDA
	5077IL/0035:0001	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0044:0002	Clin Pharm	1.90/1	1.377/1	NA
	5077IL/0046:0001	Clin Pharm	1.114/1	1.382/1	NA
5077IL/0046:0001	O-L E	1.262/1	1.442/274	CT Report	

NAME/ADDRESS	LOCATION IN APPLICATION				
	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Pretorius, Dr. H.W. Department of Psychiatry University of Pretoria PO Box 667 Pretoria 0001 SOUTH AFRICA	5077IL/0014:0049	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0049	O-L E	1.262/1	1.442/274	CT Report
Priest, Prof. R. Department of Psychiatry St. Mary's Hospital Medical School Praed Street London W2 1NY UNITED KINGDOM	5077IL/0012:0020	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0020	O-L E	1.262/1	1.442/274	CT Report
Puystjens, Dr. M. OLV Kliniek Koning Albertiaan 8 8200 Brugge BELGIUM	5077IL/0014:0009	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0009	O-L E	1.262/1	1.442/274	CT Report
Ramirez, Luis F., MD Cleveland VA Medical Center Department of Psychiatry, Room 116A 10000 Brecksville Road Brecksville, OH 44141 USA	5077IL/0015:0037	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0037 <sup>27</sup>	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0031:0013	D-B Comp	1.261/333	1.442/273	CANDA
Rapisarda, Prof. V. Universita di Catania Ospedale Policlin Viale Andrea Doria 6 95125 Catania ITALY	5077IL/0012:0078	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0078	O-L E	1.262/1	1.442/274	CT Report
Ravizza, Prof. L. Universita di Torino Ospedale Molinette Via Cherasco 15-10126 Torino ITALY	5077IL/0012:0066	D-B Comp	1.225/1, 1.350/1,	1.423/1	CANDA
	5077IL/0012:0066	O-L E	1.262/1	1.442/274	CT Report
Reiman, Eric, MD Good Samaritan Regional Medical Center 925 East McDowell Road, 4th Floor Phoenix, AZ 85006 USA	5077IL/0031:0028	D-B Comp	1.261/333	1.442/273	CANDA



NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Remington, Gary J., MD, PhD Clarke Institute of Psychiatry 250 College Street Toronto, Ontario M5T 1R8 CANADA	5077IL/0015:0028	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0028	O-L E	1.262/1	1.442/274	CT Report
Riccio, M., Dr. Consultant Psychiatrist St Mary Abbots Hospital Marloes Road Kensington London W8 5LQ UK	204636/0008:0001 <sup>18</sup> (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Riesenberg, Robert A., MD DeKalb Medical Center 2701 North Decatur Road Decatur, GA 30033 USA  Biobehavioral Research Center 825 DeKalb Industrial Way Decatur, GA 30033 USA	5077US/0001:0017 (204636/0008) <sup>15</sup>	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0015:0019	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0019	O-L E	1.262/1	1.442/274	CT Report
Rinaldi, Prof. F. Universita di Napoli Via Pansini 5 80131 Napoli ITALY	5077IL/0012:0079	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0079	O-L E	1.262/1	1.442/274	CT Report
Robotti, Dr. C.A. Il Servizio di Psichiatria Ospedale Maggiore di Borgotrento Piazzale Stefani 1-37126 Verona ITALY	5077IL/0012:0070	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0070	O-L E	1.262/1	1.442/274	CT Report
Roche-Rabreau, Dr. Hopital de Lagny 31 Avenue de General Leclerc 77405 Lagny Cedex FRANCE	204636/0007:0039	D-B Comp	1.217/1 1.348/1	1.415/1	CANDA
Roland, Dr. A. Psykiatrisk Acedling Sentraljokehuset 1 Moere OG Romsdal 8026 Alesund NORWAY	5077IL/0014:0038	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0038	O-L E	1.262/1	1.442/274	CT Report
Ropert, Dr. Pavillion H. Michaud C.H.S. Sainte Anne 1 rue Cabanis 75674 Paris Cedex 14 FRANCE	204636/0007:0038	D-B Comp	1.217/1 1.348/1	1.415/1	CANDA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Rosenthal, Murray H., DO Behavioral Medicine Resources 9449 Balboa Avenue, Suite 205 San Diego, CA 92123 USA	5077IL/0015:0020	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0020	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0048:0010	O-L	1.258/1	1.442/272	CANDA
Rotrosen, John, MD Department of Veterans Affairs New York VA Medical Center 423 East 23rd Street New York, NY 10010 USA	5077US/0001:0011 (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0013:0015	D-B Comp	1.117/1, 1.148/1, 1.308/1	1.398/1	CANDA
	5077IL/0013:0015	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0015:0021	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0021	O-L E	1.262/1	1.442/274	CT Report
5077IL/0031:0014	D-B Comp	1.261/333	1.442/273	CANDA	
Rudolf, Prof. G.A. Klinik und Poliklinik Fur Psychiatrie der Wilhelms Universitat Muenster Albert Schweizer Strasse 11 48149 Muenster GERMANY	5077IL/0012:0057	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0057	O-L E	1.262/1	1.442/274	CT Report
Rushton, A., MB, ChB, MRCP, DMS Medical Research Department ICI Pharmaceuticals Mereside, Alderley Park Macclesfield, Cheshire SK10 4TF UNITED KINGDOM	5077IL/0025:0001 <sup>25</sup> 204636/0001	Clin Pharm Clin Pharm	1.96/1 1.77/1	1.378/208 1.371/1	NA NA
Ruther, Prof. E. Psychiatrische Klinik der Gottingen Universitat Von Siebold Strasse 5 37075 Gottingen GERMANY	5077IL/0012:0053	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0053	O-L E	1.262/1	1.442/274	CT Report
Ruyer, Dr. F. C.H.S. d'Evereux 62 Rue des Conches 27022 Evereux Cedex FRANCE	5077IL/0012:0034	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0034	O-L E	1.262/1	1.442/274	CT Report
Ryan, William, MD University Hospital Jefferson Towers, North Wing University of Alabama at Birmingham School of Medicine 619 South 18th Street Birmingham, AL 35233 USA  VAB Clinical Research 2nd Floor 920 18th St. South Birmingham, AL 95233 USA	5077IL/0006:0003 <sup>22</sup> (APS-A31-1/003)	D-B Comp	1.132/1, 1.301/1	1.384/1	CANDA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Saarijarvi, Dr. S.: Psykiatrisen Klinikka Kunnallissairaalaantie 20 Rak. 9 20 700 Turku FINLAND	5077IL/0014:0025	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0025	O-L E	1.262/1	1.442/274	CT Report
Saito, Dr. Masaharu Inogashira Hospital 4-14-1 Kamirenjaku Mitaka-shi Tokyo JAPAN	H-15-21:3	O-L	1.282/377	1.442/275	CANDA
	H-15-22:18	O-L	1.282/402	1.442/276	CANDA
	H-15-23:18	O-L	1.282/435	1.442/277	NA
Saitoh, Prof. Masami Kansai Medical University 1 Fomizono-tyo Moriguti-shi Osaka JAPAN	H-15-22:43	O-L	1.282/402	1.442/276	CANDA
	H-15-23:43	O-L	1.282/435	1.442/277	NA
Sakai, Prof. Toshiaki Osaka Medical College 2-7 Daigaku-tyo Takatuki-shi Osaka JAPAN	H-15-22:39	O-L	1.282/402	1.442/276	CANDA
	H-15-23:39	O-L	1.282/435	1.442/277	NA
Sakamura, Dr. Yu National Psychiatric Institute of Shimolusa 578 Hennda-cho Midori-ku Chiba-shi Chiba JAPAN	H-15-22:25	O-L	1.282/402	1.442/276	CANDA
	H-15-23 <sup>13</sup>	O-L	1.282/435	1.442/277	NA
Salorio, Dr. B. Servicio de Psiquiatria Hospital General Intendente Jorge Palacios I Murcia SPAIN	5077IL/0014:0055	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
Salzman, Carl, MD Psychopharmacology Research Corp. 74 Fenwood Road. Boston, MA 02115 USA	5077IL/0048:0012	O-L	1.258/1	1.442/272	CANDA

NAME/ADDRESS	LOCATION IN APPLICATION				
	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Sasaki, Dr. Toshiki Ishigoka Hospital 915 Hamano-cho Chuo-ku Chiba-shi Chiba JAPAN	H-15-22:24 H-15-23:24	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Sasaki, Dr. Yunoshin Keiaikai Fukuma Hospital 2310 Fukuma-tyo Munakata-gun Fukuoka JAPAN	H-15-22:13 H-15-23:13	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Satin, Andrew, MD Director of Geriatrics McLean Hospital 115 Mill Street Belmont, MA 02178 USA	5077IL/0017:0004	Clin Pharm	1.100/1	1.379/231	CANDA
Saton, Dr. Joji Fukukokai Soba Hospital 3-3-1 Ichiba Funabashi-shi Chiba JAPAN	H-15-22:26 H-15-23:13	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Saxena, Bishan, PhD Psychopharmacology Research Training Center Hamilton Psychiatric Hospital 100 West 5th Street Hamilton, Ontario L9C 3N6 CANADA	5077IL/0015:0029 5077IL/0015:0029 5077IL/0031:0007*	D-B Comp O-L E D-B Comp	1.171/1, 1.314/1 1.282/1 1.261/333	1.406/1 1.442/274 1.442/273	CANDA CT Report CANDA
Schaerf, Frederick, MD Medical Studies, Florida 12645 New Brittany Boulevard Building 15 Fort Myers, FL 33907 USA	5077IL/0048:0017	O-L	1.258/1	1.442/272	CANDA
Schneider, Lon, MD 2011 Zonal Avenue Hoffman Building, Room 101 Los Angeles, CA 90033 USA	5077IL/0048:0013	O-L	1.258/1	1.442/272	CANDA

NAME/ADDRESS	LOCATION IN APPLICATION				
	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Schooler, Nina, PhD Western Psychiatric Institute and Clinic 3811 O'Hara Street Pittsburgh, PA 15213 USA  Special Studies Center South 2, Ward 4B 1601 Mayview Road Bridgeville, PA 15107 USA	5077IL/0031:0009 <sup>31</sup>	D-B Comp	1.261/333	1.442/273	CANDA
Schroeder, Dr. Y. Psychiatrische Universitaetklinik Voss Strasse 9 69115 Heidelberg GERMANY	5077IL/0012:0025 5077IL/0012:0025	D-B Comp O-L E	1.225/1, 1.350/1 1.262/1	1.423/1 1.442/274	CANDA CT Report
Schweitzer, Prof. I. Academic Unit Nemps PO Box 101 Bundoora, Victoria 3083 AUSTRALIA	5077IL/0014:0002 5077IL/0014:0002	D-B Comp O-L E	1.243/1, 1.354/1 1.262/1	1.431/1 1.442/274	CANDA CT Report
Seifertova, Mudr. D. Psychocentrum Praha Ustavani 91 CS-181 03 Praha 8-Bohnice CZECH REPUBLIC	204636/0008:0013 (5077US/0001) 5077IL/0014:0014 5077IL/0014:0014	D-B Comp D-B Comp O-L E	1.137/1, 1.303/1 1.243/1, 1.354/1 1.262/1	1.389/1 1.431/1 1.442/274	CANDA CANDA CT Report
Sensky, T., Dr. Department of Psychiatry West Middlesex Hospital Isleworth Middlesex TW7 6AF UK	204636/0008:0001 <sup>18</sup> (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Seva, Dr. A. Servicio de Psiquiatria Hospital Clinico Avenida San Juan Bosco 15 50009 Zaragoza SPAIN	5077IL/0014:0052	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
Sharif, Zafar A., MD Creedmoor Psychiatric Center 80-45 Winchester Boulevard Building 40, 11th Floor, SRU Queens Village, NY 11427 USA	5077IL/0013:0003 <sup>14</sup> 5077IL/0013:0003 <sup>14</sup> 5077IL/0031:0017	D-B Comp O-L E D-B Comp	1.117/1, 1.148/1, 1.306/1 1.262/1 1.261/333	1.398/1 1.442/274 1.442/273	CANDA CT Report CANDA

NAME/ADDRESS	LOCATION IN APPLICATION				
	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Shaw, Dr. S.H. Department of Psychiatry Stanley Royd Hospital Aberford Road Wakefield West Yorkshire WF1 4DQ UNITED KINGDOM	204636/0008:0019 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0012:0012	D-B Comp	1.225/1 1.350/1	1.423/1	CANDA
	5077IL/0012:0012	O-L E	1.262/1	1.442/274	CT Report
Sheni, G. Michael, MD Birmingham Research Group, Inc 2120 Lynngate Drive Birmingham, AL 35216 USA	5077IL/0013:0025 <sup>21</sup>	D-B Comp	1.117/1, 1.148/1	1.398/1	CANDA
	5077IL/0013:0025 <sup>21</sup>	O-L E	1.262/1	1.442/274	CT Report
Shinkai, Dr. Noritoshi Narimasu Kousei Hospital 1-19-1 Misono Itabashi-ku Tokyo JAPAN	H-15-22:17	O-L	1.282/402	1.442/276	CANDA
	H-15-23 <sup>13</sup>	O-L	1.282/435	1.442/277	NA
Shriqui, Christian L., MD, MSc Hospital Robert-Giffard 2601 Chemin de la Canardiere Beauport, Quebec G1J 2G3 CANADA	5077IL/0013:0022	D-B Comp	1.117/1, 1.148/1, 1.308/1	1.398/1	CANDA
	5077IL/0013:0022	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0031:0027	D-B Comp	1.261/333	1.442/273	CANDA
Siddiqui, Dr. V.A. Princess Royal Hospital Lewes Road Haywards Heath West Sussex, RH16 4EX UNITED KINGDOM	5077IL/0012:0010 <sup>7</sup>	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
Silver, Dr. H. Mazra Psychiatric Hospital Akko ISRAEL	5077IL/0012:0098	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0098	O-L E	1.262/1	1.442.274	CT Report
Silverstone, Dr. P. Department of Psychiatry University of Alberta Hospital 8440-112 Street Edmonton Alberta T6G 2B7 CANADA	5077IL/0012:0063	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0063	O-L E	1.262/1	1.442/274	CT Report
Simpson, George M., MD Medical College of Pennsylvania (EPPI) Department of Clinical Psychopharmacy 3200 Henry Avenue Philadelphia, PA 19129 USA	5077IL/0015:0032	D-B Comp	1.171/1, 1.314/1	1.408/1	CANDA
	5077IL/0015:0032	O-L E	1.262/1	1.442/274	CT Report

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Sirota, Dr. P. Department 6A Abarbanel Mental Health Center Bat-Yam ISRAEL	5077IL/0012:0083	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0083	O-L E	1.262/1	1.442/274	CT Report
Small, Gary, MD UCLA Neuropsychiatric Institute 760 Westwood Plaza, 37-432 Los Angeles, CA 90033 USA	5077IL/0048:0014 <sup>27</sup>	O-L	1.258/1	1.442/272	CANDA
Small, Joyce, MD Department of Psychiatry Larue D. Carter Memorial Hospital 1315 West 10th Street Indianapolis, IN 46202 USA	5077US/0001:0001 (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0013:0009	D-B Comp	1.117/1, 1.148/1, 1.306/1	1.398/1	CANDA
	5077IL/0013:0009	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0031:0015	D-B Comp	1.261/333	1.442/273	CANDA
Smeraldi, Prof. E. DSNP Ospedale S Raffaele Via Prinetti 29-20127 Milano ITALY	5077IL/0012:0065	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0065	O-L E	1.262/1	1.442/274	CT Report
Smith, Nathan, MD University Hospital Jefferson Towers, North Wing University of Alabama at Birmingham School of Medicine 619 South 19th Street Birmingham, AL 35233 USA  University of Alabama Clinical Research 2nd Floor 920 18th Street South Birmingham, AL 35233 USA	5077IL/0006:0003 <sup>22</sup> (APS 0-031-1/003)	D-B Comp	1.132/1, 1.301/1	1.384/1	CANDA
	5077IL/0006:003 <sup>22</sup> (APS 0-031-1/003)	O-L E	1.262/1	1.442/274	CT Report
Soni, Dr. S. Department of Psychiatry Hope Hospital Eccles Old Road Salford, Manchester M6 8HD UNITED KINGDOM	204636/0007:0002	D-B Comp	1.217/1, 1.348/1	1.415/1	CANDA
Sorita, Dr. Katsuhiko Hamazono Hospital 2968 Wada-cho Kohfu-shi Yamanashi JAPAN	H-15-21:9	O-L	1.282/377	1.442/275	CANDA
	H-15-22:34	O-L	1.282/402	1.442/276	CANDA
	H-15-23:34	O-L	1.282/435	1.442/277	NA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Steinbook, Richard, MD University of Miami Jackson Memorial Medical Center Department of Psychiatry, D-29 Mental Health Institute, Room 112B 1611 NW 12th Avenue Miami, FL 33136 USA	5077US/0001:0004 <sup>10</sup> (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
	5077IL/0013:0010	D-B Comp	1.117/1, 1.148/1, 1.308/1	1.398/1	CANDA
	5077IL/0013:0010	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0015:0022 <sup>4</sup>	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0022 <sup>4</sup> 5077IL/0031:0016	O-L E D-B Comp	1.262/1 1.281/333	1.442/274 1.442/273	CT Report CANDA
Stip, Dr. E. Centre de Recherche Fernard-Seguin 7331 rue Hochelaga Montreal Quebec H1N 3V2 CANADA	5077IL/0012:0059	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0059	O-L E	1.262/1	1.442/274	CT Report
Stoessl, Dr. J. Psychiatrisches Krankenhaus der Stadt Wien VII Psychiatrische Abteilung Baumgartner Hohe 1 1145 Wien AUSTRIA	5077IL/0012:0029	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0029	O-L E	1.262/1	1.442/274	CT Report
Strakowski, Stephen M., MD Biological Psychiatry Program University of Cincinnati College of Medicine 231 Bethesda Avenue, Suite ML-0559 Cincinnati, OH 45267-0559 USA	5077IL/0015:0023	D-B Comp	1.171/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0023	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0047:0001	Clin Pharm	1.106/1	1.380/254	CANDA
	5077IL/0047:0001	O-L E	1.262/1	1.442/274	CT Report
Sumiyoshi, Dr. Akitsugu Tokiwa Hospital 3439-2 Tokiwa-cho Machida-shi Tokyo JAPAN	H-15-21:7	O-L	1.282/377	1.442/275	CANDA
Sundararajan, Dr. K. Department of Psychiatry Halifax General Hospital Halifax West Yorkshire UNITED KINGDOM	204636/0008:0022 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Suzuki, Dr. Toru Seikeika Komakino Hospital 274 Uratakao-chu Hachiohji-shi Tokyo JAPAN	H-15-21:4	O-L	1.282/377	1.442/275	CANDA
	H-15-22:19	O-L	1.282/402	1.442/276	CANDA
	H-15-23 <sup>13</sup>	O-L	1.282/435	1.442/277	NA



NAME/ADDRESS	LOCATION IN APPLICATION				
	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Svetska, Prof. Mudr. J. Psychiatricka Klinika Lekarska Fakulta Masarykovy University 657 15 Brno Bohnice CZECH REPUBLIC	5077IL/0014:0016	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0016	O-L E	1.262/1	1.442/274	CT Report
Szulecka, Dr. T.K. Department of Psychiatry Bassetlaw District General Hospital Blythe Road Worksop Nottingham UNITED KINGDOM	204636/0008:0021 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Doncaster Royal Infirmary Armthorpe Road Doncaster DN2 5LT UNITED KINGDOM	5077IL/0012:0005	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0005	O-L E	1.262/1	1.442/274	CT Report
Takahashi, Dr. Katsuro National Nagasaki Central Hospital 2-1001-1 Hisahara Omura-shi Nagasaki JAPAN	H-15-21:22	O-L	1.282/377	1.442/275	CANDA
	H-15-22:70	O-L	1.282/402	1.442/276	CANDA
	H-15-23:70	O-L	1.282/435	1.442/277	NA
Takahashi, Dr. Yukiniko Seifukai Ibaraki Hospital 1-4-1 Soujiji Ibaraki-shi Osaka JAPAN	H-15-21:15	O-L	1.282/377	1.442/275	CANDA
	H-15-22 <sup>13</sup>	O-L	1.282/402	1.442/276	CANDA
	H-15-23 <sup>13</sup>	O-L	1.282/435	1.442/277	NA
Takamatsu, Dr. Isao Jikokai Wakahisa Hospital 5-3-1 Wakahisa Minami-ku Fukuoka-shi Fukuoka JAPAN	H-15-22:66	O-L	1.282/402	1.442/276	CANDA
	H-15-23:66	O-L	1.282/435	1.442/277	NA
Tammimga, Carol A., MD Maryland Psychiatric Research Center Inpatient Unit, PO Box 21247 White Building Spring Grove Hospital Grounds Baltimore, MD 21228 USA	5077IL/0006:0007 (APS 0-A31-1/0007)	D-B Comp	1.132/1 1.301/1	1.384/1	CANDA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Tandon, Rajiv, MD University of Michigan Medical Center Department of Psychiatry, Unit 8D 1500 East Medical Center Drive Ann Arbor, MI 48109-0116 USA	50771L/0013:0016  50771L/0013:0016 50771L/0015:0025  50771L/0015:0025	D-B Comp  O-L E D-B Comp  O-L E	1.117/1, 1.148/1 1.306/1 1.262/1 1.171/1, 1.314/1 1.262/1	1.398/1  1.442/274 1.406/1  1.442/274	CANDA  CT Report CANDA  CT Report
Targum, Steven D., MD Crozer-Chester Medical Center One Medical Center Boulevard Old Main Upland, PA 19013 USA Delaware Valley Clinical Studies 1015 Chestnut Street Suite 1303 Philadelphia, PA 19107 USA	50771L/0015:0024  50771L/0015:0024 50771L/0048:0018	D-B Comp  O-L E O-L	1.171/1, 1.314/1 1.262/1 1.258/1	1.406/1  1.442/274 1.442/272	CANDA  CT Report CANDA
Tariot, Pierre, MD Monroe Community Hospital Psychiatric Unit 435 East Henrietta Road Rochester, NY 14620 USA	50771L/0048:0015	O-L	1.258/1	1.442/272	CANDA
Tashiro, Prof. Nobutada Faculty of Medicine Kyushu University 3-1-1 Maidashi Higashi-ku Fukuoka-shi Fukuoka JAPAN	H-15-22:65 H-15-23 <sup>13</sup>	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA US
Thienhaus, Ole J., MD Older Adult Center for Clinical Research University of Cincinnati College of Medicine 231 Bethesda Avenue, ML 559 Cincinnati, OH 45267-0559 USA	50771L/0017:0003 <sup>11</sup> 50771L/0017:0003 <sup>18</sup>	Clin Pharm O-L E	1.100/1 1.262/1	1.379/231 1.442/274	NA CT Report
Thomas, Dr. C.S. Department of Psychiatry University Hospital of South Manchester Manchester M20 UNITED KINGDOM	50771L/0012:0019  50771L/0012:0019	D-B Comp  O-L E	1.225/1, 1.350/1 1.262/1	1.423/1  1.442/274	CANDA  CT Report
Tignol, Prof. J. C.H.S. Charles Perrens 121 Rue de la Bechade 33076 Bordeaux Cedex FRANCE	50771L/0012:0035  50771L/0012:0035	D-B Comp  O-L E	1.225/1, 1.350/1 1.262/1	1.423/1  1.442/274	CANDA  CT Report

NAME/ADDRESS	LOCATION IN APPLICATION				
	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Toone, Dr. B.K. Department of Psychiatry King's College Hospital Denmark Hill London SE5 9RS UNITED KINGDOM	50771L/0005: UK-0002	O-L pilot	1.254/1	1.439/272	CANDA
Toru, Prof. Michio Tokyo Medical and Dental University School of Medicine 1-5-45 Yushima Bunkyo-ku Tokyo JAPAN	H-15-22 <sup>13</sup> H-15-23 <sup>13</sup>	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
True, Janet E., MD San Antonio State Hospital Clinical Research Unit-MC-4 6711 South New Braunfels Avenue San Antonio, TX 78223 USA	50771L/0013:0006 <sup>23</sup> 50771L/0013:0006 <sup>23</sup> 50771L/0031:0022 <sup>19</sup>	D-B Comp O-L E D-B Comp	1.117/1, 1.148/1, 1.306/1 1.262/1 1.261/333	1.398/1 1.442/274 1.442/273	CANDA CT Report CANDA
Tsutsumi, Dr. Shigetoshi Osaka Psychiatry Research Institute Shinabuyama Hospital 4-10-1 Usahara Takatuki-shi Osaka JAPAN	H-15-21:16 H-15-22:40 H-15-23:40	O-L O-L O-L	1.282/377 1.282/402 1.282/435	1.442/275 1.442/276 1.442/277	CANDA CANDA NA
Tsutsumi, Dr. Yurichiro Ongata Hospital 105 Nishitarakata-cho Hachiohji-hi Tokyo JAPAN	H-15-22 <sup>13</sup> H-15-23 <sup>13</sup>	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Tune, Larry, MD Wesley Woods Geriatric Center 1841 Clifton Road Atlanta, GA 30329 USA	50771L/0048:0006 <sup>26</sup>	O-L	1.258/1	1.244/272	CANDA
Tuning, Dr. E. Psykiatriska Ingang S2 Allmanna Sjukhuset S 214 01 Malmo SWEDEN	50771L/0014:0068 50771L/0014:0068	D-B Comp O-L E	1.243/1, 1.354/1 1.262/1	1.431/1 1.442/274	CANDA CT Report

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Uchida, Dr. Shigeru Mannari Hospital 1-6-5 Tanimannari Okayama-shi Okayama JAPAN	H-15-22:58 H-15-23:58	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Udelman, Harold D., MD Biomedical Stress Research Foundation, Ltd. 45 East Osborn Road Phoenix, AZ 85012 USA	5077IL/0015:0035 5077IL/0015:0035	D-B Comp O-L E	1.171/1, 1.314/1 1.262/1	1.408/1 1.442/274	CANDA CT Report
Uebelhack, Prof. R. Humboldt-Universitat Berlin Abteilung Psychiatrie Schumannstrasse 20-21 10115 Berlin GERMANY	5077IL/0012:0054 5077IL/0012:0054	D-B Comp O-L E	1.225/1, 1.350/1 1.262/1	1.423/1 1.442/274	CANDA CT Report
Ushijima, Prof. Sadanobu The Jikei University School of Medicine 3-19-18 Nishishinbashi Minato-ku Tokyo JAPAN	H-15-22:14 H-15-23 <sup>13</sup>	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Vaadal, Dr. J.M. Psykiatrisk Avdeling Fylkessjukehuset 1 Molde 6450 Hjelset NORWAY	5077IL/0014:0044 5077IL/0014:0044	D-B Comp O-L E	1.243/1, 1.354/1 1.262/1	1.431/1 1.442/274	CANDA CT Report
Vallejo, Dr. J. Hospital Principes de Espana Servicio de Psiquiatria Feixa Llarga S/N 08709 Hospitalet de Llobregat Barcelona SPAIN	204638/0007:0013 5077IL/0014:0053	D-B Comp D-B Comp	1.217/1, 1.348/1 1.243/1 1.354/1	1.415/1 1.431/1	CANDA CANDA
Van Moffaert, Prof. M. UZ Gent De Pintelaan 185 9000 Gent BELGIUM	5077IL/0014:0012 5077IL/0014:0012	D-B Comp O-L E	1.243/1, 1.354/1 1.262/1	1.431/1 1.442/274	CANDA CT Report
Varenius, Dr. A. S:TA Maria Sjukhus Psykos S 251 88 Helsingborg SWEDEN	5077IL/0014:0069 5077IL/0014:0069	D-B Comp O-L E	1.243/1, 1.354/1 1.262/1	1.431/1 1.442/274	CANDA CT Report

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Vaz Serra, Prof. A. Hospitais de Universidade de Coimbra, Servicio de Psiquiatria Alameda Dr Armando Goncalves 3000 Coimbra PORTUGAL	5077IL/0012:0089	D-B Comp	1.225/1, 1.350/1	1.423/1	CANDA
	5077IL/0012:0089	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0014:0030	D-B Comp	1.243/1, 1.354/1	1.431/1	CANDA
	5077IL/0014:0030	O-L E	1.262/1	1.442/274	CT Report
Veltigan, Dawn, PhD San Antonio State Hospital Clinical Research Unit-MC-4 6711 South New Braunfels San Antonio, TX 78223 USA	5077IL/0013:0006 <sup>23</sup>	D-B Comp	1.117/1, 1.148/1, 1.306/1	1.398/1	CANDA
	5077IL/0013:0006 <sup>23</sup>	O-L E	1.262/1	1.442/274	CT Report
Verdeau-Pailles, Dr. Clinique de la Cite 12 rue du Jardin Beaumetz BP no 191 11004 Carcassonne Cedex FRANCE	204636/0007:0030	D-B Comp	1.217/1 1.348/1	1.415/1	CANDA
Verecken, Dr. St. Jan Hospital of Psychiatry 9900 Eeklo BELGIUM	204636/0007:0034	D-B Comp	1.217/1 1.348/1	1.415/1	CANDA
Vidon, Dr. Centre C.H.S. Esquirol 57 rue du Mazrechal Leclerc 94229 Saint Maurice Cedex FRANCE	204636/0007:0033	D-B Comp	1.217/1 1.348/1	1.415/1	CANDA
Vinar, Dr. O. Institute of Psychiatric Research Ustavni 91 CS-18103 Praha 8-Bohnice CZECH REPUBLIC	204636/0008:0014 (5077US/0001)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Vinogradov, Sophia, MD San Francisco VA Medical Center 4150 Clement Street, 116C San Francisco, CA 94121 USA	5077IL/0015:0026	D-B Comp	1.117/1, 1.314/1	1.406/1	CANDA
	5077IL/0015:0026	O-L E	1.262/1	1.442/274	CT Report
	5077IL/0048:0016	O-L	1.258/1	1.442/272	CANDA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Wagner, Richard L., MD Institute of Mental Health Louis Pasteur Building, 4th floor Howard Avenue Cranston, RI 02920 USA	5077US/0001:0005 (204636/0008)	D-B Comp	1.137/1, 1.303/1	1.389/1	CANDA
Waki, Dr. Akira Ryofukai Takahashi Hospital 2200 Abe Otiai-tyo Takahashi-shi Okayama JAPAN	H-15-22 <sup>13</sup> H-15-23 <sup>13</sup>	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Watanabe, Prof. Shosuke Kawasaki Medical School 577 Matubara Kurashiki-shi Okayama JAPAN	H-15-22:59 H-15-23:59	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Weizman, Prof. A. Psychiatric Department Geha Psychiatric Hospital PO Box 102 Petach Tikva 49100 ISRAEL	5077IL/0012:0047 5077IL/0012:0047	D-B Comp O-L E	1.225/1, 1.350/1 1.262/1	1.423/1 1.442/274	CANDA CT Report
Wiesel, Prof. F.A. Insitutionen for Psykiatei Ulleraker Akademisuta Sjuthuset 73017 Uppsala SWEDEN	5077IL/0033:0002 <sup>24</sup>	Clin Pharm	1.116/358 1.129/358	1.383/1	CANDA
Williams, A. J., MB, ChB, BSc, PhD, MFPM, FRCP Clinical Pharmacology Unit Medical Research Department ZENECA Pharmaceuticals Mereseide, Alderley Park Macclesfield, Cheshire SK10 4TG UNITED KINGDOM	5077IL/0025:0001 <sup>25</sup>	Clin Pharm	1.98/1	1.378/208	NA
Williams, Richard, MD Calgary General Hospital Department of Psychiatry 841 Centre Avenue East Calgary, Alberta T2E 0A1 CANADA	5077IL/0013:0023 5077IL/0013:0023	D-B Comp O-L E	1.117/1, 1.148/1 1.306/1 1.262/1	1.398/1 1.442/274	CANDA CT Report
Wilmotte, Dr. Hopital Van Gogh Charleroi BELGIUM	204636/0007:0008	D-B Comp	1.217/1 1.348/1	1.415/1	CANDA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Wistedt, Dr. B.L. Psyk Kliniken Danderyds Sjukhus 182 88 Danderyd SWEDEN	5077IL/0014:0062 5077IL/0014:0062 <sup>13</sup>	D-B Comp O-L E	1.243/1, 1.354/1 1.262/1	1.431/1 1.442/274	CANDA CT Report
Yagi, Prof. Gohei School of Medicine, Keio University 35 Shinanomachi Shinjuku-ku Tokyo JAPAN	H-15-22:13 H-15-23:13	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Yamauchi, Prof. Toshiro Saitama Medical School 38 Ohaza-morohongo Moroyama-cho Iruma-gun Saitama JAPAN	H-15-21:1 H-15-22:27 H-15-23 <sup>13</sup>	O-L O-L O-L	1.282/377 1.282/402 1.282/435	1.442/275 1.442/276 1.442/277	CANDA CANDA NA
Yamawaki, Prof. Shigeto Hiroshima University School of Medicine 1-2-3 Kasumi Minami-ku Hiroshima-shi Hiroshima JAPAN	H-15-22 <sup>13</sup> H-15-23:61	O-L O-L	1.282/402 1.282.435	1.442/276 1.442/277	CANDA CANDA NA
Yamazumi, Dr. Shun Yamazumi Hospital 1-6-10 Misaku Kohfu-shi Yamanashi JAPAN	H-15-21:8 H-15-22:33 H-15-23 <sup>13</sup>	O-L O-L O-L	1.282/377 1.282/402 1.282/435	1.442/275 1.442/276 1.442/277	CANDA NA
Yano, Dr. Tetsuo Yoshida Hospital 3666 Yoshida Yoshida-tyo Takada-gun Hiroshima JAPAN	H-15-22:13 H-15-23 <sup>13</sup>	O-L O-L	1.282/402 1.282/435	1.442/276 1.442/277	CANDA NA
Yates, R. A., MA, MB, ChB, PhD, MRCP, MFPM Medical Research Department ICI Pharmaceuticals Mereside, Alderley Park Macclesfield, Cheshire SK10 4TF UNITED KINGDOM	204636/0002:0001 204636/0003:0001 5077IL/0025:0001 <sup>25</sup>	D-B Comp D-B Comp Clin Pharm	1.77/164 1.78/1 1.98/1	1.371/36 1.371/92 1.378/208	NA CANDA NA

NAME/ADDRESS	TRIAL NUMBER/ CENTER	TYPE OF TRIAL	LOCATION IN APPLICATION		
			TRIAL REPORT vol/pg	CRF TABULATION vol/pg	CASE REPORT F- ORMS*
Yoshimasu, Prof. Fumio Wakayama Prefectural Medical University 17 ban-tyo Wakayama-shi Wakayama JAPAN	H-15-21:17	O-L	1.282/377	1.442/275	CANDA
	H-15-22 <sup>13</sup>	O-L	1.282/402	1.442/276	CANDA
	H-15-23 <sup>13</sup>	O-L	1.282/435	1.442/277	NA
Yoshimoto, Dr. Wataru Shinwakai Hatano Hospital 131 Sanya Hatano-shi Kanagawa JAPAN	H-15-21:10	O-L	1.282/377	1.442/275	CANDA
	H-15-22:31	O-L	1.282/402	1.442/276	CANDA
	H-15-23:31	O-L	1.282/435	1.442/277	NA
Yoshiura, Dr. Kazunari Nagasaki Prefecture Ohmura Hospital 1575-2 Nishibe-tyo Omura-shi Nagasaki JAPAN	H-15-22:71	O-L	1.282/402	1.442/276	CANDA
	H-15-23:71	O-L	1.282/435	1.442/277	NA

\*Request for waiver of paper case report form requirement was granted July 25, 1995 (FDA Serial No. 95-127).

CANDA = CRFs on CANDA

NA = No CRFs on CANDA

\*\*Type of trial:

D-B Comp = Double-Blind Comparison

O-L = Open-Label

Clin Pharm = Clinical Pharmacology

O-L E = Open-Label Extension

\*\*\*Trial number/center:

If more than one number exists for a trial, the primary number is listed first followed by the alternate number in parentheses.



- ed drug for trial 50771L/0014, but he is not included in the
- <sup>1</sup> Prof. L. Lindstrom is included in this list because he received trial report because he did not enroll subjects in this trial.
  - <sup>2</sup> Nina Schooler and Robert Baker were coinvestigators on this trial.
  - <sup>3</sup> Bruce Diamond and Richard Borison were coinvestigators on this trial.
  - <sup>4</sup> Richard Steinbook and Ramon Boza were coinvestigators on this trial.
  - <sup>5</sup> Barry Jones, Erhard Busse, and Bishan Saxena were coinvestigators on this trial.
  - <sup>6</sup> Alexander Miller and John Chiles were coinvestigators on this trial.
  - <sup>7</sup> Dr. V.A. Siddiqui was the subject of a fraud investigation and, therefore, his results were not included in the report for Trial 50771L/0012.
  - <sup>8</sup> Wesley Pitts and Brian Crabtree were coinvestigators on this trial.
  - <sup>9</sup> Richard Dubinsky and William Gabrielli were coinvestigators on this trial.
  - <sup>10</sup> Dr. Eichelman did not conduct the trial although drug was sent to his site, and Center 4 was reassigned to Dr. Steinbook.
  - <sup>11</sup> Alexander Miller, Larry Ereshefsky, and Cheryl Anderson were coinvestigators on this trial.
  - <sup>12</sup> Adolf Pfefferbaum and William Faustman were coinvestigators on this trial.
  - <sup>13</sup> This investigator received a drug shipment but had enrolled no subjects as of the primary data cutoff date (1 June 1995). For Japanese sites, center numbers were not assigned until a subject was enrolled.
  - <sup>14</sup> This site was taken over by Dr. Z. A. Sharif upon Dr. Gewirtz's death.
  - <sup>15</sup> Robert Riesenber and Michael Gladson were coinvestigators on this trial.
  - <sup>16</sup> Dr. T.R.E. Barnes, Dr. T. Sensky, Dr. M. Riccio, Dr. S. Franks, Dr. A. Jolley, and Dr. C. Hallstrom were coinvestigators on this trial.
  - <sup>17</sup> Richard Owen and Craig Karson were coinvestigators on this trial.
  - <sup>18</sup> Michael A. Keys, MD began the trial, but it was completed by Ole J. Thienhaus, MD.
  - <sup>19</sup> Janet True and Roderick Mahurin were coinvestigators on this trial.
  - <sup>20</sup> Larry Tune and Charles Nemeroff were coinvestigators on this trial.
  - <sup>21</sup> Michael Shehi and William Patterson were coinvestigators on this trial.
  - <sup>22</sup> Nathan Smith and William Ryan were coinvestigators on this trial.
  - <sup>23</sup> Janet True and Dawn Velligan were coinvestigators on this trial. True and Velligan were replaced by Alexander Miller on 30-Jun-95.
  - <sup>24</sup> Prof. F.A. Wiesel was inadvertently not included in the ongoing trial report for Trial 50771L/0033. He did contribute two subjects to the trial before the data cut-off date of 1 June 1995.
  - <sup>25</sup> Dr. A.J. Williams, Dr. D.S. Millson, Dr. J.S. Pears, Dr. A. Rushton, and Dr. R.A. Yates were coinvestigators on this trial.
  - <sup>26</sup> Barry Jones and Alan LaBelle were coinvestigators on this trial.
  - <sup>27</sup> This investigator received a drug shipment but did not participate in the open-label extension trial; no subjects enrolled.
  - <sup>28</sup> Ruth Dickson replaced Richard Williams as the principal investigator at this center before the secondary data cutoff date (1 March 1996).