SUBJECT NAME/IDENTIFICATION

SUBJECT NO. 6.

CLINICAL REPORT

5,0, 7,0, 1, 0,66

PLEASE PRINT ALL DETAILS AND INDICATE [X] WHERE APPLICABLE

INVESTIGATOR Dr. I. Hindmarch

Date of Visit 7, 3, 83
Day Month Year

[01]

Age 40. year

Date of birth 8, 1, 43

Sex male [ ] 1 female* [X] 2

Height 5'6" cm (167)

Weight 11st. kg (70)

*If female, please state method of contraception. (If not applicable, please state why)

Coil.

Written informed consent obtained Yes [X] 1 Date / /

Smoking: 1 Cigarettes ______ per day
3 Pipe ______ gms per week
4 Cigars ______ per day

Non smoker [X] 2

Alcohol: Regular [ ] 1 None [ ] 2

Infrequent [X] Amount per day ______

IX

PHYSICAL EXAMINATION please comment on any relevant abnormalities normal [X] 0

MEDICAL HISTORY please give any relevant details nothing of significance [X] 0

Has the subject recieved any drug therapy during the past 2 weeks? Yes* [ ] 1

No [X] 0

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*If Yes, please specify

K1391

058 001684

Motus/Pfizer

SUBJECT NAME/IDENTIFICATION ______ SUBJECT NO. ______

LABORATORY DATA

5 0 7 0 1 0 06

PLEASE PRINT ALL DETAILS

INVESTIGATOR Dr. I. Hindmarch

(06)

		Date Sample Taken		SCREEN 7/3/83	BASELINE 10/3/83	DAY 7 16/3/83	DAY 14 -/-/-	-/-/-	-/-/-	-/-/-	-/-/-
HAEMATOLOGY		Hb g/100ml	001	12·4	11·5	11·8					
		RBC's 10^6/cmm	003	4·11	3·82	3·89					
		PCV %	002	362	33·8	340					
		MCV	015	88	88	88					
		MCH	016	30·1	30·2	30·4					
		MCHC %	017	34·2	34·2	34·6					
		Platelets 10^3/cmm	005	219	196	208					
		WBC's 10^3/cmm	007	5·9	3·9	3·3					
		Neutrophils %	008			72					
		Lymphocytes %	011			26					
		Monocytes %	012			2					
		Eosinophils %	009			0					
		Basophils %	010			0					
		Aust. Antigen (HBsAg)	038								
CLINICAL CHEMISTRY		Bilirubin Total	021	5	7	5					
		Protein	024	67	64	66					
		Albumin	025	45	43	46					
		Globulin	026								
		SGOT (AST)	028	20	21	19					
		SGPT (ALT)	030	16	21	17					
		Gamma GT	031	8	9	7					
		LDH	032								
		Alk. Phos.	035	2·8	2·6	2·8					
		Na.	054	140	142	138					
		K.	055	4·4	4·6	4·9					
		Cl.	056	101	103	101					
		Blood Urea	046	4·8	4·4	5·6					
		Creatinine	048	81	67	82					
		Uric Acid	050								
		Glucose	068								
		Cholesterol	063								
		Blood Alcohol	272								
		BICARB.	057	25	27	27					
URINALYSIS		Protein	078								
		Glucose	079								
		RBC's / hpf	081								
		WBC's / hpf	080								
		Bacteria / hpf	082								
		Granular / hpf	088								
		Cellular / hpf	089								
		Hyaline casts / hpf	090								
		Crystals	091								
		Ketones	086								
		Epithelial Cells	092								
		Pregnancy Test	113	0							

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K1233b

SUBJECT NAME/IDENTIFICATION ____________ SUBJECT NO. ____________

STUDY RECORD

5 0 7 0 1 0 06

PLEASE PRINT ALL DETAILS AND INDICATE [X] WHERE APPLICABLE

INVESTIGATOR Dr. I. Hindmarch PERIOD 1

[02] TREATMENT

Day	Date	STUDY DRUG No. of Capsules	STUDY DRUG Time of ingestion	DIAZEPAM Dose (mgs.)	DIAZEPAM Time of ingestion
1	10/3/83		1100		
2	11/3/83		1015		
3	12/3/83		0940		
4	/ /				
5	/ /				
6	/ /				
7	/ /				

[03] CONCOMITANT DRUG THERAPY None [ ] 0

DRUG (generic name)	Unit Dose (mg)	Frequency per day	Date Started d/m	Time of first dose	Date Stopped d/m	Reason for Therapy
ASPIRIN 180	1	1	11/3/83	0400	11/3/83	HEADACHE 179

[04] SIDE EFFECTS None [ ] 0

	SIDE EFFECT (please specify)	SEVERITY Mild 1	Moderate 2	Severe 3	Date of Onset	Duration (Days)	DUE TO STUDY TREATMENT Yes 1	No 2	? 3	COURSE Enter code from Key below

Key: 1. Disappeared with continued treatment 2. Tolerated with continued treatment 3. Dose of active treatment reduced 4. Symptomatic treatment given 5. Study treatment stopped 6. Study treatment temporarily stopped

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K1392

SUBJECT NAME/IDENTIFICATION ______________ SUBJECT NO. ______________

PSYCHOMETRIC TESTS

50 70 1 006

PLEASE PRINT ALL DETAILS

INVESTIGATOR Dr. I. Hindmarch

PERIOD 1

(59)

PERFORMANCE TESTS			DAY 1	DAY 2	DAY 3	DAY 4
Date			10/3/83	11/3/83	12/3/83	13/3/83
Critical Flicker Fusion	CFF	525				
Complex Reaction Time	CRT	527				
Mental Arithmetic Test	MAT	521				
Getting to Sleep	SEQ – GTS(a)	528	59	58	93	44
Quality of Sleep	SEQ – QOS	529	62	52	75	45
Awaking from Sleep	SEQ – AFS	530	47	48	27	44
Behaviour on Waking	SEQ – BOW	531	85	48	83	44
How do you feel now SEQ		552				
MOOD TESTS—visual analogue scale						
Anxious	(more – less)	541				
Tired	(less – more)	542				
Happy	(less – more)	543				
Relaxed	(more – less)	544				
Drowsy	(more – less)	545				
Dizzy	(less – more)	546				
Clumsy	(less – more)	547	72	46	46	45
Alert	(more – less)	548				
Energetic	(less – more)	549				
Sad	(more – less)	550				
Depressed	(more – less)	551				
Quality of Sleep	Wakeful Periods	556	63	53	76	44
Getting to sleep SEQ GTS(b)		553	59	58	93	46
Getting to sleep SEQ GTS(c)		554	45	48	74	45
Awaking from sleep SEQ AFS(b)		555	47	48	28	45

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K1393

058 001687

Motus/Pfizer

SUBJECT NAME/IDENTIFICATION ______________ SUBJECT NO. 6

BLOOD PRESSURE, PULSE

5 0 7 0 1 006

PLEASE PRINT ALL DETAILS AND INDICATE [X] WHERE APPLICABLE

INVESTIGATOR Dr. I. Hindmarch

PERIOD 1

[05] BLOOD PRESSURE AND PULSE

Date	DAY1		DAY 5 PRE		DAY 5 (POST)		DAY 7	
	10/3/73		6/3/73		/ /		/ /	
All sitting	~~Lying~~ Sitt	Standing	Lying	Standing	Lying	Standing	Lying	Standing
Actual Time	1030		1053.					
Systolic	120		120					
Diastolic	80		90					
Pulse	96		84					

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K1394

058 001688

Motus/Pfizer

SUBJECT NAME/IDENTIFICATION ____________ SUBJECT NO. ____________

STUDY RECORD

5 0 7 0 1 0 06

PLEASE PRINT ALL DETAILS AND INDICATE [X] WHERE APPLICABLE

INVESTIGATOR Dr. I. Hindmarch

PERIOD 2

[02] TREATMENT

Day	Date	STUDY DRUG No. of Capsules	STUDY DRUG Time of ingestion	DIAZEPAM Dose (mgs.)	DIAZEPAM Time of ingestion
8	/ /				
9	/ /				
10	/ /				
11	/ /				
12	/ /				
13	/ /				
14	/ /				

[03] CONCOMITANT DRUG THERAPY None [ ] 0

DRUG (generic name)	Unit Dose (mg)	Frequency per day	Date Started d/m	Time of first dose	Date Stopped d/m	Reason for Therapy

[04] SIDE EFFECTS None [ ] 0

	SIDE EFFECT (please specify)	SEVERITY Mild 1	SEVERITY Moderate 2	SEVERITY Severe 3	Date of Onset	Duration (Days)	DUE TO STUDY TREATMENT Yes 1	DUE TO STUDY TREATMENT No 2	DUE TO STUDY TREATMENT ? 3	COURSE Enter code from Key below

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Key: 1. Disappeared with continued treatment 2. Tolerated with continued treatment 3. Dose of active treatment reduced 4. Symptomatic treatment given 5. Study treatment stopped 6. Study treatment temporarily stopped

K1392a

INVESTIGATOR'S SIGNATURE

SUBJECT NAME/IDENTIFICATION ______________ SUBJECT NO. ______________

PSYCHOMETRIC TESTS

5 0 7 0 1 0 0 6

PLEASE PRINT ALL DETAILS

INVESTIGATOR Dr. I. Hindmarch

PERIOD 2

[59]

PERFORMANCE TESTS		Date	DAY 12 (PRE) / /	DAY 12 (POST) / /	DAY 14 / /	DAY 15 / /
Critical Flicker Fusion	CFF	525				
Complex Reaction Time	CRT	527				
Mental Arithmetic Test	MAT	521				
Getting to Sleep	SEQ – GTS	528				
Quality of Sleep	SEQ – QOS	529				
Awaking from Sleep	SEQ – AFS	530				
Behaviour on Waking	SEQ – BOW	531				
MOOD TESTS—visual analogue scale						
Anxious	(more – less)	541				
Tired	(less – more)	542				
Happy	(less – more)	543				
Relaxed	(more – less)	544				
Drowsy	(more – less)	545				
Dizzy	(less – more)	546				
Clumsy	(less – more)	547				
Alert	(more – less)	548				
Energetic	(less – more)	549				
Sad	(more – less)	550				
Depressed	(more – less)	551				

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K1393a

SUBJECT NAME/IDENTIFICATION ______________________ SUBJECT NO. __________

BLOOD PRESSURE, PULSE

5 0 7 0 1 9 0 6

PLEASE PRINT ALL DETAILS AND INDICATE [X] WHERE APPLICABLE

INVESTIGATOR Dr. I. Hindmarch

PERIOD 2

[05] BLOOD PRESSURE AND PULSE

	DAY 12 (PRE)		DAY 12 (POST)		DAY 14	
Date	/ /		/ /		/ /	
	Lying	Standing	Lying	Standing	Lying	Standing
Actual Time						
Systolic						
Diastolic						
Pulse						

END OF STUDY

Did the subject complete the full treatment period? Yes [ ] 1 No* [ ] 0

Were all the examinations and tests performed? Yes [ ] 1 No* [ ] 0

*If No, please give reasons why not.

PHYSICAL EXAMINATION (on Day 15)

please comment on any relevant abnormalities Normal [ ] 0

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K1395

INVESTIGATOR'S SIGNATURE ______________

058 001691

Motus/Pfizer

ADVERSE EFFECTS CHECKLIST HPRU 183 OXJW1 (1-5)

050-206-070-006

Patient's study number | 0 | 0 | 6 | (8-10)

Patient's initials

Visit number | | (11)

THURSDAY

Doctor's initials

Date of Visit (day month year) | 1 | 0 | 0 | 3 | 8 | 3 | (13-18)

| 7 | (19-20)

PHYSICIAN'S CHECK LIST OF COMMON SYMPTOMS

	SYMPTOM	SEVERITY *Please underline*				*Please leave blank*	
038	Drowsiness	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(21)
023	Insomnia	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(22)
045	Restlessness	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(23)
013	Apprehension	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(24)
079	Headache	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(25)
056	Fainting or lightheadedness	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(26)
037	Dizziness	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(27)
106	Dry mouth	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(28)
077	Palpitations	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(29)
103	Constipation	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(30)
061	Blurred vision	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(31)
	Sweating	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(32)
176	Flushing	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(33)
152	Rash	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(34)
117	Nausea	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(35)
114	Indigestion	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(36)
032	Weakness	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(37)
059	Tremor	absent$_0$	mild$_1$	moderate$_2$	severe$_3$		(38)

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ANY OTHER SYMPTOMS *(please specify, and underline severity)*

038 014 decreased concentration	mild$_1$	moderate$_2$	severe$_3$	(39-42)	(43)
	mild$_1$	moderate$_2$	severe$_3$	(44-47)	(48)

058 001692

ADVERSE EFFECTS CHECKLIST HPRU 183 OXJW1 (1-5)

050-206-070-006

Patient's initials ________ Patient's study number 006 (8-10)

Visit number ___ (11)

Doctor's initials ________

FRIDAY

	day	month	year	
Date of Visit	11	03	83	(13-18)

7 (19-20)

PHYSICIAN'S CHECK LIST OF COMMON SYMPTOMS

	SYMPTOM	SEVERITY *Please underline*				*Please leave blank*	
038	Drowsiness	absent₀	mild₁	moderate₂	severe₃		(21)
023	Insomnia	absent₀	mild₁	moderate₂	severe₃		(22)
045	Restlessness	absent₀	mild₁	moderate₂	severe₃		(23)
013	Apprehension	absent₀	mild₁	moderate₂	severe₃		(24)
079	Headache	absent₀	mild₁	moderate₂	severe₃		(25)
056	Fainting or lightheadedness	absent₀	mild₁	moderate₂	severe₃		(26)
037	Dizziness	absent₀	mild₁	moderate₂	severe₃		(27)
106	Dry mouth	absent₀	mild₁	moderate₂	severe₃		(28)
077	Palpitations	absent₀	mild₁	moderate₂	severe₃		(29)
103	Constipation	absent₀	mild₁	moderate₂	severe₃		(30)
061	Blurred vision	absent₀	mild₁	moderate₂	severe₃		(31)
188	Sweating	absent₀	mild₁	moderate₂	severe₃		(32)
176	Flushing	absent₀	mild₁	moderate₂	severe₃		(33)
152	Rash	absent₀	mild₁	moderate₂	severe₃		(34)
117	Nausea	absent₀	mild₁	moderate₂	severe₃		(35)
114	Indigestion	absent₀	mild₁	moderate₂	severe₃		(36)
032	Weakness	absent₀	mild₁	moderate₂	severe₃		(37)
059	Tremor	absent₀	mild₁	moderate₂	severe₃		(38)

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ANY OTHER SYMPTOMS (please specify, and underline severity)

malaise 174, tired 038, decreased concentration 044	mild₁	moderate₂	severe₃	(39-42)	(43)
059 Tremor	mild₁	moderate₂	severe₃	(44-47)	(48)

058 001693

ADVERSE EFFECTS CHECKLIST **HPRU 183** 0XJW1 (1-5)

050-206-070-006

Patient's study number | 006 | (8-10)

Patient's initials 6

Visit number SATURDAY | | (11)

Doctor's initials ______

Date of Visit (day month year) | 1 2 0 3 8 3 | (13-18)

| 7 | (19-20)

PHYSICIAN'S CHECK LIST OF COMMON SYMPTOMS

	SYMPTOM	SEVERITY *Please underline*				*Please leave blank*
038	Drowsiness	absent₀	mild₁	moderate₂	severe₃	(21)
023	Insomnia	absent₀	mild₁	moderate₂	severe₃	(22)
045	Restlessness	absent₀	mild₁	moderate₂	severe₃	(23)
013	Apprehension	absent₀	mild₁	moderate₂	severe₃	(24)
1074	Headache	absent₀	mild₁	moderate₂	severe₃	(25)
056	Fainting or lightheadedness	absent₀	mild₁	moderate₂	severe₃	(26)
037	Dizziness	absent₀	mild₁	moderate₂	severe₃	(27)
106	Dry mouth	absent₀	mild₁	moderate₂	severe₃	(28)
077	Palpitations	absent₀	mild₁	moderate₂	severe₃	(29)
103	Constipation	absent₀	mild₁	moderate₂	severe₃	(30)
061	Blurred vision	absent₀	mild₁	moderate₂	severe₃	(31)
188	Sweating	absent₀	mild₁	moderate₂	severe₃	(32)
176	Flushing	absent₀	mild₁	moderate₂	severe₃	(33)
152	Rash	absent₀	mild₁	moderate₂	severe₃	(34)
117	Nausea	absent₀	mild₁	moderate₂	severe₃	(35)
114	Indigestion	absent₀	mild₁	moderate₂	severe₃	(36)
032	Weakness	absent₀	mild₁	moderate₂	severe₃	(37)
059	Tremor	absent₀	mild₁	moderate₂	severe₃	(38)

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ANY OTHER SYMPTOMS *(please specify, and underline severity)*

AGGRESSION (022)	mild₁	moderate₂	severe₃	(39-42) (43)
(038) Tired	mild₁	moderate₂	severe₃	(44-47) (48)

058 001694

Motus/Pfizer

ADVERSE EFFECTS CHECKLIST HPRU 183 OXJW1 (1-5)

050-206-070-006

Patient's study number 0 0 6 (8-10)

Patient's initials ____________

Visit number SUNDAY [ ] (11)

Doctor's initials ____________

	day	month	year	
Date of Visit	1 3	0 3	8 3	(13-18)

[7] (19-20)

No tablets taken

PHYSICIAN'S CHECK LIST OF COMMON SYMPTOMS

	SYMPTOM	SEVERITY *Please underline*				*Please leave blank*	
038	Drowsiness	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(21)
	Insomnia	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(22)
045	Restlessness	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(23)
013	Apprehension	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(24)
179	Headache	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(25)
056	Fainting or lightheadedness	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(26)
037	Dizziness	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(27)
106	Dry mouth	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(28)
077	Palpitations	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(29)
103	Constipation	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(30)
061	Blurred vision	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(31)
188	Sweating	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(32)
176	Flushing	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(33)
152	Rash	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(34)
117	Nausea	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(35)
114	Indigestion	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(36)
032	Weakness	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(37)
059	Tremor	absent$_0$	mild$_1$	moderate$_2$	severe$_3$	[ ]	(38)

ANY OTHER SYMPTOMS *(please specify, and underline severity)*

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(117) (022) (179)	mild$_1$	moderate$_2$	severe$_3$	(39-42)	(43)
____________	mild$_1$	moderate$_2$	severe$_3$	(44-47)	(48)

058 001695

Motus/Pfizer

ADVERSE EFFECTS CHECKLIST HPRU 183

OXJW1 (1-5)

050-206-070-006

Patient's initials ________

Patient's study number | 0 | 0 | 6 | (8-10)

Visit number MONDAY [ ] (11)

Doctor's initials ________

Date of Visit (day month year) | 1 | 4 | 0 | 3 | 8 | 3 | (13-18)

| | 7 | (19-20)

PHYSICIAN'S CHECK LIST OF COMMON SYMPTOMS

	SYMPTOM	SEVERITY *Please underline*				*Please leave blank*
038	Drowsiness	absent₀	mild₁	moderate₂	severe₃	(21)
	Insomnia	absent₀	mild₁	moderate₂	severe₃	(22)
045	Restlessness	absent₀	mild₁	moderate₂	severe₃	(23)
013	Apprehension	absent₀	mild₁	moderate₂	severe₃	(24)
079	Headache	absent₀	mild₁	moderate₂	severe₃	(25)
056	Fainting or lightheadedness	absent₀	mild₁	moderate₂	severe₃	(26)
037	Dizziness	absent₀	mild₁	moderate₂	severe₃	(27)
106	Dry mouth	absent₀	mild₁	moderate₂	severe₃	(28)
077	Palpitations	absent₀	mild₁	moderate₂	severe₃	(29)
103	Constipation	absent₀	mild₁	moderate₂	severe₃	(30)
061	Blurred vision	absent₀	mild₁	moderate₂	severe₃	(31)
	Sweating	absent₀	mild₁	moderate₂	severe₃	(32)
176	Flushing	absent₀	mild₁	moderate₂	severe₃	(33)
152	Rash	absent₀	mild₁	moderate₂	severe₃	(34)
117	Nausea	absent₀	mild₁	moderate₂	severe₃	(35)
114	Indigestion	absent₀	mild₁	moderate₂	severe₃	(36)
032	Weakness	absent₀	mild₁	moderate₂	severe₃	(37)
059	Tremor	absent₀	mild₁	moderate₂	severe₃	(38)

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ANY OTHER SYMPTOMS *(please specify, and underline severity)*

________	mild₁	moderate₂	severe₃	(39-42)	(43)
________	mild₁	moderate₂	severe₃	(44-47)	(48)

058 001696

Motus/Pfizer

080-206-070-006

Pfizer

Timesheet

CONFIDENTIAL

Subject No. 6

Week No.	Date	Day	3 Capsules	1 Tablet	LSEQ Completed
Week 1	Thursday 10th March	1	11-00		✓
	Friday 11th March	2	10-15		✓
	Saturday 12th March	3	9-40.		✓
	Sunday 13th March	4	NONE		✓
	Monday 14th March	5			✓
	Tuesday 15th March	6			
	Wednesday 16th March	7			
Week 2	Thursday 17th March	8			
	Friday 18th March	9			
	Saturday 19th March	10			
	Sunday 20th March	11			
	Monday 21st March	12			
	Tuesday 22nd March	13			
	Wednesday 23rd March	14			

Note the time medication was taken in space provided and tick when each LSEQ is completed.

Take 3 capsules at 9.00 am every day from 10th March - 23rd March. Also during two three day periods;

14th - 16th March and 21st - 23rd March, take one tablet at 9.00 am with the capsules.

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Motus/Pfizer

LEEDS SLEEP EVALUATION QUESTIONNAIRE

050-206-070-006

(1-5)

Patients name

Patients study number | 6 | (1-5)

Visit number . . . . | | (12)

| 6 | (14)

day month year

| 1 1 | 0 3 | 8 3 | (16-21)

Each question is answered by placing a vertical mark on the line. If no change was experienced then place the mark in the middle of the line. If a change was experienced then the position of your mark will indicate the nature and extent of the change i.e. large changes near the ends of the line, small changes near the middle.

For example, this would indicate a small change:

How would you compare getting to sleep using the medication with getting to sleep normally, i.e. without medication?

(a) Easier than usual — Harder than usual | 59

(b) Quicker than usual — Slower than usual | 59

(c) Felt more drowsy than usual — Felt less drowsy than usual | 45

How would you compare the quality of sleep using the medication with non-medicated (your usual) sleep?

(a) More restful than usual — More restless than usual | 62

(b) Fewer periods of wakefulness than usual — More periods of wakefulness than usual | 63

How did your awakening after medication compare with your usual pattern of awakening?

(a) Easier than usual — More difficult than usual | 47

(b) Took shorter than usual — Took longer than usual | 47

How did you feel on waking?

CONFIDENTIAL

Alert — Tired | 85

How do you feel now?

Alert — Tired | 85

058 001698

Motus/Pfizer

050-206-070-006

10-3-83. Capsules @ 11.00.

By 1pm slight nausea (117)
" headache (179)
" slowed down feeling (038)
" lack of co-ordination (044)

This continued until 5pm.

Then nausea persisted (117)
headache " (179)

Went to bed @ 10.30pm.
Headache worse (179)
Slight nausea. (117)

Woke @ 4 am. — (11-3-83)
Bad headache (179)
Nausea worse (117)
Took an asprin (180)
Nausea increased (117)

Had trouble getting back to sleep (023)
awakened at the usual time.
Feel exhausted and head felt slightly "headachy" (179)
(174).

Slightly nauseous (117)
Slight tremor (059)

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Motus/Pfizer

LEEDS SLEEP EVALUATION QUESTIONNAIRE

050-206-070-006

(1-5)

Patients name___ Patients study number | | | | 6 | (1-5)

Visit number .... | | (12)

| 6 | (14)

day		month		year	
1	2	0	3	8	3

(16-21)

Each question is answered by placing a vertical mark on the line. If no change was experienced then place the mark in the middle of the line. If a change was experienced then the position of your mark will indicate the nature and extent of the change i.e. large changes near the ends of the line, small changes near the middle.

For example, this would indicate a small change:

How would you compare getting to sleep using the medication with getting to sleep normally, i.e. without medication?

(a) Easier than usual |——————|—————| Harder than usual | 58 |

(b) Quicker than usual |——————|—————| Slower than usual | 58 |

(c) Felt more drowsy than usual |——————|—————| Felt less drowsy than usual | 48 |

How would you compare the quality of sleep using the medication with non-medicated (your usual) sleep?

(a) More restful than usual |——————|—————| More restless than usual | 52 |

(b) Fewer periods of wakefulness than usual |——————|—————| More periods of wakefulness than usual | 53 |

How did your awakening after medication compare with your usual pattern of awakening?

(a) Easier than usual |——————|—————| More difficult than usual | 48 |

(b) Took shorter than usual |——————|—————| Took longer than usual | 48 |

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How did you feel on waking?

Alert |——————|—————| Tired | 48 |

How do you feel now?

Alert |——————|—————| Tired | 48 |

058 001700

Motus/Pfizer

050-206-070-006

11-3-83 Med. @ 10.15am (038)

Felt a little tired all day.

Vague feeling of nausea ~~of~~ (117) and headache

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058 001701

Motus/Pfizer

LEEDS SLEEP EVALUATION QUESTIONNAIRE

050-206-070-006

(1-5)

Patients name ______ Patients study number | | | | 6 | (1-5)

Visit number .... [ ] (12)

[6] (14)

day		month		year	
1	3	0	3	8	3

(16-21)

Each question is answered by placing a vertical mark on the line. If no change was experienced then place the mark in the middle of the line. If a change was experienced then the position of your mark will indicate the nature and extent of the change i.e. large changes near the ends of the line, small changes near the middle.

For example, this would indicate a small change:

How would you compare getting to sleep using the medication with getting to sleep normally, i.e. without medication?

(a) Easier than usual |——| Harder than usual [9 3]

(b) Quicker than usual |——| Slower than usual [9 3]

(c) Felt more drowsy than usual |——| Felt less drowsy than usual [7 4]

How would you compare the quality of sleep using the medication with non-medicated (your usual) sleep?

(a) More restful than usual |——| More restless than usual [7 5]

(b) Fewer periods of wakefulness than usual |——| More periods of wakefulness than usual [7 6]

How did your awakening after medication compare with your usual pattern of awakening?

(a) Easier than usual |——| More difficult than usual [2 7]

(b) Took shorter than usual |——| Took longer than usual [2 8]

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How did you feel on waking?

Alert |——| Tired [8 3]

How do you feel now?

Alert |——| Tired [8 2]

058 001702

058-206-070-006

12-3-83 Med. @ 9.40

Vague feeling of nausea (117) & headache (179) at times during the day.

Felt aggressive (022) in relationships and whilst driving.

13-3-83 Felt tired (038) all day.

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Motus/Pfizer

LEEDS SLEEP EVALUATION QUESTIONNAIRE

050-206-070-006

(1-5)

Patients name. ______ Patients study number | | | | 6 | (1-5)

Visit number .... [ ] (12)

[6] (14)

day		month		year	
1	4	0	3	8	3

(16-21)

Each question is answered by placing a vertical mark on the line. If no change was experienced then place the mark in the middle of the line. If a change was experienced then the position of your mark will indicate the nature and extent of the change i.e. large changes near the ends of the line, small changes near the middle.

For example, this would indicate a small change:

How would you compare getting to sleep using the medication with getting to sleep normally, i.e. without medication?

(a) Easier than usual |——|—————| Harder than usual [4 4]

(b) Quicker than usual |——|—————| Slower than usual [4 6]

(c) Felt more drowsy than usual |——|—————| Felt less drowsy than usual [4 5]

How would you compare the quality of sleep using the medication with non-medicated (your usual) sleep?

(a) More restful than usual |——|—————| More restless than usual [4 5]

(b) Fewer periods of wakefulness than usual |——|—————| More periods of wakefulness than usual [4 4]

How did your awakening after medication compare with your usual pattern of awakening?

(a) Easier than usual |——|—————| More difficult than usual [4 4]

(b) Took shorter than usual |——|—————| Took longer than usual [4 5]

How did you feel on waking?

Alert |——|—————| Tired [4 4]

How do you feel now?

Alert |——|—————| Tired [4 5]

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058 001704

Motus/Pfizer