Pages 1-9 inclusive redacted under section 22(1) of the FOI Act (irrelevant information)

SERIOUS ADVERSE EXPERIENCES

(92)

Appendix 3B

Information Required for Telephone Reports

A serious adverse experience is one which is life-threatening, temporarily or permanently disabling or requires in-patient hospitalization or prolongation of hospitalization, as well as any occurrence of cancer, congenital anomaly or overdose. According to the SK&F Protocol and Protocol Administrative Document you have agreed to follow, serious adverse experiences must be reported within 24 hours by telephone to SK&F (see the Protocol Administrative Document for complete details.) To assist you in reporting all the required information, this form may be completed before telephoning.

Protocol No. PAROXETINE 29060/356 Patient or Document No. 92

Patient Initials or Identification [redacted] Date of Birth [redacted] (Day Month Year)

Sex F Race [redacted] Weight [redacted] Height _____

Condition being studied DEPRESSION SK&F Medical Monitor [redacted]

Adverse Experience (AE) Suicide [redacted]

Onset Date: [redacted] (Day Month Year) Cleared Date: _____ (Day Month Year)

Severity: ☐ Mild ☐ Moderate ☐ Severe

Did this AE cause.... (Check box if "Yes")
☐ Immediate risk of death ☐ Hospitalization or prolonged hospitalization
☐ Permanent disability ☑ Death

Study drug name/no. Paroxetine vs Fluoxetine Code/Randomization No. 92

Lot No. _____ Vial/Package description _____

Dates of administration: Start Date [redacted] (Day Month Year) Stop Date [redacted] (Day Month Year)

Unit dose [redacted] Route [redacted] Frequency/ Infusion time [redacted] Total daily dose [redacted]

Was the code broken? ☐ Yes ☐ No

Was study medication changed because of this event? ☐ No ☐ Decreased ☑ Discontinued

- If study medication was decreased or discontinued, did the event resolve? ☐ Yes ☐ No
- If discontinued, was study medication reintroduced? ☐ Yes ☐ No
- If yes, did the AE recur? ☐ Yes ☐ No

Relationship of AE to study medication: ☐ Related ☐ Possibly related ☑ Not related

Probable cause: Depression

Other condition: _____

Was the AE treated? ☑ No ☐ Yes (specify) _____

[redacted]

[redacted]

Person who discovered AE [redacted]

Person reporting AE [redacted]

Address

Investigator name [redacted]

Concomitant Medication

Medication Name	Start Date	Stop Date	Unit Dose	Route	Freq	Total Daily Dose
[redacted]						

Relevant Medical History

Condition	Start Date	End Date
[redacted]		

Relevant Laboratory Values

Parameter	Value	Date or Visit No.	Normal Range	Units
[redacted]				

[redacted]

FAX TO: [redacted] FAX NO [redacted]

FROM: [redacted]

DATE: 6 September 1993 NO. OF PAGES:4

If any pages are omitted or unclear please phone (03) 801-8888

Dear [redacted]

RE:PAROXETINE 356

As discussed on Thursday 2 September I have asked the paroxetine investigators for further details on the patients who have attempted suicide. Attached is a letter from centre [redacted] regarding patient [redacted] who committed suicide.

As more letters are received I will forward them to you.

[redacted]

[redacted]

[redacted]