1.17 Duration on Fluoxetine

The Company provided the following breakdown of its total fluoxetine cohort by length of exposure as follows (Vol. 1.76, p. 025):

Table 2

No. of Days	No. of Patients
<14	1173
14-30	1009
31-90	774
91-182	393
183-365	218
>365	74*

*Three dystonia musculorum deformans patients have been on fluoxetine for more than two years, one of them for more than four years.

1.2 Non-Domestic Marketing Experience

Fluoxetine has not been marketed outside the U.S.A. However, the company is presently engaged in studies overseas with the motive of eventual marketing. To date all adverse events occurring overseas have been submitted to IND.

1.3 Catastrophic and Serious Events and Seriously Abnormal Laboratory Findings

In general these adverse events were reported by the Company in the individual safety summaries or in a special section of events "requiring further comment."

In addition, such reactions were discovered by reviewing all the laboratory data and all the early termination summaries of patients participating in late Phase II and Phase III clinical trials. 52 cases were selected where ratory values were egregiously abnormal or reasons for early termination caused concern. These 52 cases were then subjected to review of case reports on microfiche. Certain additional adverse events, not reported by the Company, which were revealed on microfiche, are also included in this tabulation. In most cases, these adverse events involved the onset of an unreported psychotic episode.