

April 11, 2002

Thomas H. Perez
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Perez:

I am writing on behalf of a close friend who participated in a drug study in South Carolina in October - December 1999. This study tested the drug Lotronex manufactured by Glaxo Smith Kline.

Do not allow this drug to be re-introduced to the market under any circumstances. Participation by my friend in the 1999 study resulted in hospitalization for extremely serious side effects and I have learned that the number of similar cases of side effects, including deaths, in users of the drug is unacceptably high.

The use of the drug, before it was removed from the market after only 292 days, resulted in 5 deaths and about 70 cases of life-threatening side effects requiring hospitalization and/or surgery. This drug is not safe, and, although the disorder for which it is prescribed is itself serious, as long as the manufacturer in pouring resources into getting this drug accepted by FDA and a trusting public, they will not work to find a safe, effective drug to replace it.

One death for every two months on the market? May I ask, if there were a philanthropist who donated personal funds to worthy causes, and helped many people, but lost his temper once every two months and murdered an innocent person, would you expect law enforcement to close its eyes because he had helped others?

Please protect the citizens of this country, as I believe has always been your goal, and ban the unacceptable drug Lotronex (alosetron) forever.

Sincerely,



Elizabeth B. Ovbey