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April 10, 2002

Mr. Thomas Perez
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5600 Fishers Lane
Rockwell, MD 20857

Re: Lotronex Meeting on April 23, 2002

Dear Mr. Perez:

I understand that Glaxo Smith Kline is making efforts to re-introduce Lotronex, a drug to treat Irritable Bowel Syndrome. A hearing is set up for April 23, 2002.

I wish to express my concerns based on my experience with it.

From October 1999 - December 1, 1999 I was in the Glaxo Wellcome study conducted by Coastal Carolina Research. I developed severe pain from constipation, nausea and I was doubled over in pain on the bathroom floor. I was taken to Roper Hospital in Charleston, SC where I spent two days. It left me so weak that it has taken me two years to feel better and I am finally having normal bowel movements.

Lotronex was put on the market February 9, 2000. November 28, 2000 it was pulled due to fatal gastrointestinal surgery due to complications of constipation, reports of eschemic colitis and even death.

I am sure you will review the numerous reports of how dangerous Lotronex is. Please do not give in to Glaxo Smith Kline's request to re-introduce this horrible drug.

Stick with your decision of November 28, 2000 to keep Lotronex off the market.

Thank you.

Sincerely yours,

Anne DuPre Rovall