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December 8, 2000

Docket Management Branch  
FDA  
5630 Fishers Lane, Rm. 1061, HFA-305  
Rockville, MD 20852

Dear Sir or Madam:

I am writing in response to the recent withdrawal of the drug *Lotronex* by GlaxoWellcome, Docket 00P-1499. I have been on this medication since March of 2000. After just two days of being on this medication, I started seeing results. I had no side effects from the drug, only relief from an illness that I have suffered from for years. I have suffered from Irritable Bowel Syndrome for approximately 20 years. Throughout this time I have been prescribed different medications with no successful result. I have suffered severe spasms, diarrhea and discomfort for years. I had come to a point that it was debilitating. I didn't want to even leave my house due to the severe pain and diarrhea. I had even resorted to Psychological and Psychiatric treatment due to my suffering from panic attacks if I was in a situation where a bathroom was not easily (and immediately) accessible. I was at the end of my rope when my two-year old brought me one of her "pull ups", due to my having "accidents" from the diarrhea and spasms.

You can understand my relief with the successful treatment with Lotronex. I had been able to take my life back. I was able to function and go places and not worry or panic. You should also understand my horror when I went to my pharmacy to pick up my refill of Lotronex and was given a different drug, due to the unavailability of Lotronex. I took the alternative, which I have taken in the past. (Levbid) and within two days, my IBS symptoms were back in full force. Plus I was experiencing the same side effects that I have experienced in the past with Levsin and Levbid. Nausea and dry mouth. I had no side effects from the Lotronex, only Miraculous Relief!.

I fully understand that there are side effects to any medication. Each time I received my prescription for Lotronex, it had enclosed warnings to contact my doctor immediately if constipation or other symptoms occur. I can see that if the drug causes severe constipation in some patients, that blockages and obstructions can occur. I would also think that someone would be smart enough to contact their doctor if this occurred.

I am requesting that you and GlaxoWellcome come to some agreement perhaps close monitoring by the prescribing doctor. Maybe only allowing doctors who have had close follow-up with their patients and whose patients have had no side effects, be allowed to prescribe, and or dispense Lotronex.

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CC. GlaxoWellcome

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