

**Perez, Thomas**

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**From:** CDER DRUGINFO  
**Sent:** Friday, March 29, 2002 12:56 PM  
**To:**  
**Subject:** RE: Lotronex -Reply

Thanks for writing. It is impossible for us to know why you did not meet the criteria for enrollment. However, if you want to add your comments to the upcoming April public advisory committee meeting please read on:

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 15, 2002.

Contact Person: Thomas H. Perez, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6758, e-mail at PerezT@cdcr.fda.gov

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-----Original Message-----

**From:** Pat Mellitt |  
**Sent:** Thursday, March 28, 2002 8:57 AM  
**To:** DRUGINFO@cdcr.fda.gov  
**Subject:** RE: Lotronex -Reply

**\*\* High Priority \*\***

Thank you for your prompt response to my recent email. I attach for your information a copy of an email which I sent to Dr. Woodcock on November 29, 2000, when Lotronex was withdrawn from the market. I would very much like to be part of any clinical study which you may be doing. I did make a phone call volunteering (I heard an ad on TV asking for participants and am not even sure what the medication was) but was not accepted into the program. Was it because of my age? 64+. Was it because I have had cancer? 3 year survivor. Was it because the diarrheal aspect of the disease only takes over between 25 to 50% of my life? Of course, the tricky part of that is that one never knows when that 25 to 50% will occur. Was it because I am a victim of panic attacks and always carry Xanax with me? Strangely enough, when I was on Lotronex, I don't remember having any panic attacks and therefore didn't need Xanax. I'm not sure if you understand what a luxury it is to have a minimal amount of control over one aspect of your own life - in other words, living in a way which other people take for granted. I would appreciate hearing from you again. Thank you.

This was emailed on 11/29/00.

"Dear Dr. Woodcock:

The year 2000 was a great one for me! Lotronex came on the market and I was lucky enough to be one of the first recipients. My life changed dramatically. For the first time in over ten years I was able to attend family functions,

go out to dinner with friends, go to New York City on the train for the day with my daughter, visit friends at the Cape for a weekend and, in general, enjoy the quality of life that most people take for granted. Now you are taking all of those things away from me.

You know what irritable bowel syndrome is, but you probably do not have any idea of the constrictions which are placed on the person who suffers from this illness.

This person's life must be planned in detail. You must always know where a bathroom is and you must be able to reach it immediately. In planning for a normal social outing, one of several methods may be used. One can either take an anti-diarrheal medication (which sometimes has an adverse effect), or one can fast for a day prior to the event. If one doesn't eat, then there won't be anything in the bowel. Neither of these methods, of course, can be maintained for any length of time.

Irritable bowel syndrome takes over your life.

In 1999 I had breast cancer surgery and radiation treatment. As a result of the radiation and lymph node surgery I developed lymphedema of the arm and underwent physical therapy for this condition. I mention these things only so that you will know that I am a person who has dealt with serious medical problems. Those things, however, did not control my life as completely as the irritable bowel syndrome has done for the past ten years.

I beg of you to reconsider your decision. While this medication is being further tested, I would like to be part of a test or control group. I await your reply.

Sincerely,"