

FDA GASTROINTESTINAL DRUGS

ADVISORY COMMITTEE #12538

April 5, 2002

c/o THOMAS H. PEREZ, MPH

Center for Drug Evaluation and Research

Subject: April 23, 2002, meeting on LOTRONEX, GLAXO Smith Kline

Dear Committee Members:

I have IBS-DIARRHEA AND I have been using LOTRONEX CONTINUALLY SINCE MARCH 2000.

Without LOTRONEX, I have constant cramping, Severe ABDOMINAL PAIN, URGENCY, DIARRHEA, INABILITY to Digest FOOD, DANGEROUS weight LOSS AND INSOMNIA. My ANXIETY AND stress, due to the withdrawal of LOTRONEX, HAS EXACERBATED my ROSACEA CONDITION.

Since I started taking LOTRONEX over 2 years ago, I have had IMMEDIATE AND complete Relief FROM this HORRIBLE AND PAINFUL DISEASE, with ABSOLUTELY NO ADVERSE SIDE effects whatsoever. I should therefore NOT be considered AT RISK FOR ANY SERIOUS ADVERSE events.

LOTRONEX IS A MEDICAL NECESSITY FOR ME, IN ORDER THAT I CAN COMBAT this Debilitating AND Life threatening DISEASE.

LOTRONEX PERFORMS AS CLAIMED by GLAXO Smith Kline, thus its EFFICACY should NOT be Questioned.

I AM AN intelligent ADULT, who Along with my Internist AND two(2) gastroenterologists, Are fully

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CAPABLE OF MAKING DECISIONS CONCERNING my health. By making LOTRONEX UNAVAILABLE to me, the FDA has DENIED me my RIGHT to make AN INFORMED DECISION About my OWN health care.

Groups with their own political and monetary agenda's, such as PUBLIC CITIZEN and LAWYERS, should NOT be able to deprive me of my right to receive LOTRONEX. IBS-D IS A VERY SERIOUS DISEASE. TO DISMISS it AS A CASUAL problem IS CRUEL, CALLOUS AND shows A complete LACK OF UNDERSTANDING OF debilitating IBS-D.

My internist and gastroenterologists have ALL ADVISED me that they CAN DO NOTHING to effectively Relieve my debilitating IBS-DIARRHEA, AS there IS NO comparable DRUG to LOTRONEX on the market OR any effective ALTERNATIVE treatment AVAILABLE. They DO NOT UNDERSTAND why LOTRONEX WAS REMOVED FROM the market, AS ALL their patients taking LOTRONEX, have had very good results with NO problems.

I AND THOUSANDS OF people like myself, should NOT be DENIED ACCESS to LOTRONEX because A very few people, who CANNOT manage their own health care, have had A negative Experience.

The FDA has CONDEMNED THOUSANDS OF people, with debilitating IBS-D, to A QUALITY OF LIFE THAT NO one should have to endure, because of the MISTAKES OF A VERY FEW.

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LOISE YUTAN

I strongly URGE AND PRAY that this committee will RECOMMEND to the FDA that LOTRONEX be MADE IMMEDIATELY AVAILABLE to the thousands of Desparate people with IBS-D, who CANNOT Live NORMAL Lives without LOTRONEX. To do otherwise would show AN utter DISREGARD FOR the Lives of thousands of people like myself, who SUFFER EVERY DAY OF their Lives with this DISABLING IBS-DIARRHEA DISEASE.

Sincerely,

Lois E. Yutan

LOISE E. YUTAN