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By Fax to No. 001-301-827 68 01

F D A

Food and Drug Administration

Med. watch office

Special attention of **Mr. Thomas P e r e z**

5600 Fishers Lane

HFD 200 Rockwell, Maryland MD 20857

April 17, 2002

**Re: L O T R O N E X manufactured by Glaxo Wellcome Co.
public hearing on April 23rd, 2002**

Dear Mr. Perez,

I politely refer to our telephone conference of April 16th and thank you for allowing me to make my statement on this matter although the deadline was already yesterday.

I was borne in 1932 and suffered - starting appr. after my 20th birthday - from so called "Colon irritable" or "irritable intestines". My pain problem was diarrhea together with exhalation and belly-ache.

In 1997 I was operated at may stomach because of reflux esophagus and the surgeon persuaded me to also have my vagus nerve cut which turned out to be a catastrophe. I learnt thereafter - too late - that the vagus/sympathicus nerve has a strong influence on the intestines. So after this operation the complete system collapsed, I had constant diarrhea and extreme exhalation and I lost 10 kilos of weight.

N o medicine whatsoever had any positive impact on my problems.

Then I heard about the new drug LOTRONEX - especially developed for patients with "Colon irritable" a n d diarrhea (n o t for patients with obstipation!). I ordered Lotronex from the USA and took it during three months. This was the first time my problems were relieved and I even regained some weight. You can imagine my feelings when Lotronex from one day to another was taken from the market and nowhere available. My old problems immediately came back and meanwhile my weight has come down from 80 to 68 kilos (1.80 m high) and my suffering is getting unbearable.

Therefore I desperately need to get access again to LOTRONEX and I know that a great number of patients suffering from similar problems are in the same situation.

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As far as I was informed Glaxo withdrew Lotronex from the market because some people had apparently used this medicine in the wrong way i.e. taken it although they had obstipation and not diarrhea. This apparently has led to surgical measures with negative consequences.

Howe ver I must draw your (and Glaxo's) attention to the fact that there are hundreds of drugs and medicines officially licensed for sale in the market which can be abused even to the effect of lethal consequences - this is practically unavoidable.

Howe ver it is - to my opinion - not more than fair that Glaxo and the FDA should have a stronger responsibility for those persons whose quality of life is minimized without access to Lotronex - than for those who may be harmed by using this medicine without consideration of the printed instructions Glaxo delivers with each package of Lotronex.

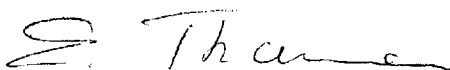
I myself - and I am sure many others concerned - am of course willing to

- a) submit a subscription of a renowned German doctor and specialist in the field of gastrologic diseases and
- b) sign a document in which I take full responsibility for my using Lotronex and declare "expressis verbis" that I will launch no claim whatsoever against the manufacturer in case I should suffer from any negative consequences from using Lotronex.

Dear Mr. Perez, you will have read between the lines of this statement that the non-availability of Lotronex is becoming a real threat to my life.
Please use **all** I have written in the public hearing on 23rd of April.
I would be most grateful if this would lead to a positive result.

Thanking you in advance

yours sincerely



Ernst Thamer