



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Corey Miller
Tom R. Bell, Psy.D.
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Coordinators
Lotronex Action Group
4640 Vinings Central Run
Smyrna, GA 30080

Re: Docket No. 01P-0169/CP1

Dear Lotronex Action Group Coordinators:

This letter is in response to your citizen petition dated March 21, 2001, asking the Food and Drug Administration (FDA) to work with GlaxoSmithKline (GSK) to permanently provide access to and safe distribution of Lotronex (alosetron hydrochloride). As you may know, on June 7, 2002, FDA approved a supplemental new drug application that permits marketing of Lotronex with restrictions. Your petition, therefore, is effectively granted.

Under the new marketing restrictions, the labeled indication of Lotronex has been narrowed to treatment of women with severe, diarrhea-predominant irritable bowel syndrome (IBS) who have failed to respond to conventional IBS therapy. In addition, GSK will be implementing a risk management program designed to help ensure that patients and physicians are fully informed of the risks and benefits of Lotronex prior to using it, and that only GSK-enrolled physicians prescribe the drug. The marketing of Lotronex is being restricted because serious and unpredictable gastrointestinal adverse events, including some that resulted in death, were reported in association with its use when it was previously marketed. The risk management program emphasizes the need for doctors, patients, and pharmacists to work together to maximize the benefits and minimize the risks of Lotronex.

The Lotronex Risk Management Program is outlined in the approval letter (attached) that was sent to GSK. It includes the following components:

- Enrollment of qualified physicians in a physician prescribing program.
- Implementation of a plan to educate physicians, pharmacists, and patients about the risks and benefits of Lotronex.
- Implementation of a reporting and collection system for serious adverse events associated with the use of Lotronex.

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- Implementation of a plan to evaluate the effectiveness of the Lotronex Risk Management Program.

Our action follows an April 23, 2002, recommendation by FDA's Gastrointestinal Drugs Advisory Committee and the Drug Safety and Risk Management Subcommittee of the Advisory Committee for Pharmaceutical Science to restore access to Lotronex through a restricted distribution and use program. Additional information on Lotronex, including the revised professional and patient labels and patient-physician agreement documents, can be found on FDA's website at:

<http://www.fda.gov/cder/drug/infopage/lotronex/lotronex.htm>.

We appreciate the valuable input that the Lotronex Action Group has provided throughout this process and we encourage your continued communication with us with regard to the ongoing Lotronex Risk Management Program.

Sincerely,



Steven K. Galson, M.D., M.P.H.

Acting Director

Center for Drug Evaluation and Research

Attachment