DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-107/S-013

Prometheus Laboratories Inc.
ATTN: Dr. Wayne Frost
9410 Carroll Park Drive
San Diego, CA 92121

Dear Dr. Frost:

Please refer to your supplemental new drug application dated June 1, 2007, received June 1, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotronex (alosetron hydrochloride), 0.5 and 1 mg tablets.

We acknowledge receipt of your submissions dated July 24, 2007, September 4, 2007, September 21, 2007, and January 14, 2008.

This supplemental new drug application provides for the addition of the following items to the package insert:

1. Changes to the dosing regimen for patients who become constipated while using Lotronex.
2. The addition of clinical study information for 0.5 mg once daily dosing.
3. The addition of clinical pharmacology information for the metabolism of Lotronex.
4. The addition of drug interaction information.
5. The package insert has been reformatted to meet the Physician's Labeling Rule format.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert).

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-107/S-013**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable. We are waiving the pediatric study requirement for this application because there is evidence strongly suggesting that Lotronex would be unsafe in all pediatric age groups due to the risk of ischemic colitis.

Please be reminded that provisions in Title IX, Subtitle A, Section 901 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) codified at 21 U.S.C. 355-1 (section 505-1 of the Federal Food, Drug, and Cosmetic Act (FFDCA)) went into effect March 25, 2008. Your drug, Lotronex (alosetron hydrochloride), 0.5 and 1 mg tablets, is deemed to have in effect an approved risk evaluation and mitigation strategy (REMS) under the Food and Drug Administration Amendments Act of 2007 (FDAAA). Holders of applications deemed to have in effect an approved REMS are required to submit a proposed REMS to FDA by September 21, 2008. FDA is developing guidance on the preferred content and format of a proposed REMS required to be submitted under section 909(b) of FDAAA and will issue it as soon as possible.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Thomas Moreno, Regulatory Project Manager, at (301) 796-2247.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joyce Korvick

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