DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021107/S-027

SUPPLEMENT APPROVAL

Prometheus Laboratories, Inc.
Attention: Hector Tamburini
Executive Director, Regulatory Affairs and CMC
9410 Carroll Park Drive
San Diego, California 92121

Dear. Mr. Tamburini:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 17, 2015, and your amendments dated December 15, 2015 and December 22, 2015, submitted under section 505b of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lotronex (alosetron hydrochloride) tablets, 0.5 mg and 1 mg.

This Prior Approval supplemental new drug application provides for the following labeling changes to be in alignment with the risk evaluation and mitigation strategy (REMS) modification for Lotronex:

1. Package Insert: Box Warning, Dosage and Administration (2.3), Contraindications(4.3), Warnings and Precautions (5.3), Patient Counseling Information (17)
2. Medication Guide

Your approved Medication Guide will no longer be part of the risk evaluation and mitigation strategy (REMS), but is now approved under 21 CFR 208.

APPROVAL & LABELING

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

We note that your December 22, 2015, submission includes final printed labeling (FPL) for your Medication Guide. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA

automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 LCDR Cheronda Cherry-France, Regulatory Project Manager, at (301) 796-7245.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
Content of Labeling including MEDGUIDE

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

/s/

JOYCE A KORVICK
01/07/2016